



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 406, 407, 410, 411, 416, 419, 435, 440, 457, 482 and 485

Office of the Secretary

45 CFR Part 180

[CMS-1809-P]

RIN 0938-AV35

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

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 2025 based on our continuing experience with these systems. In this proposed rule, we 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 system. Also, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality

Reporting Program, Rural Emergency Hospital Quality Reporting Program, Ambulatory Surgical Center Quality Reporting Program, and Hospital Inpatient Quality Reporting Program. This proposed rule would request information on options being considered for future changes to the Overall Hospital Quality Star Rating methodology. The proposed rule would narrow the description of “custody” for purposes of Medicare’s no legal obligation to pay payment exclusion. The proposed rule would revise the eligibility requirements in the special enrollment period (SEP) for formerly incarcerated individuals to tie the eligibility for this SEP to the determination made by the Social Security Administration that they are no longer incarcerated for releases that occur on and after January 1, 2025. This rule also proposes to codify the requirement in the Consolidated Appropriations Act, 2023 (CAA, 2023) to provide 12 months of continuous eligibility to children under the age of 19 in Medicaid and CHIP, with limited exceptions. Further, this proposed rule would provide updates to the Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs) in an effort to advance the health and safety of pregnant, birthing, and postpartum patients. This rule proposes 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 under the authorities used to calculate the AIR starting January 1, 2025. This rule also requests further information related to a Tribal Technical Advisory Group request to apply the Indian Health Service encounter rate to all outpatient tribal clinics. Finally, the proposed rule would provide exceptions to the Medicaid clinic services benefit four walls requirement for Indian Health Service and Tribal clinics, and, at state option, for behavioral health clinics and clinics located in rural areas.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by September 9, 2024.

ADDRESSES: In commenting, please refer to file code CMS-1809-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 <https://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-1809-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-1809-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:

Au'Sha Washington or Elise Barringer at OPPS-ASC-Rulemaking@cms.hhs.gov.

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

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

Ambulatory Surgical Center Quality Reporting (ASCQR) Program measures, contact Marsha Hertzberg via email at Marsha.Hertzberg@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 Au'Sha Washington via email at AuShaWashington@cms.hhs.gov or Josh McFeeters via email at Joshua.McFeeters@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 Chuck Braver via email at Chuck.Braver@cms.hhs.gov.

Medicaid Clinic Services Four Walls Flexibilities, contact Sheri Gaskins via email at Sheri.Gaskins@cms.hhs.gov or Ryan Tisdale via email at Ryan.Tisdale@cms.hhs.gov.

Composite APCs (Multiple Imaging and Mental Health) and Comprehensive APCs (C-APCs), via email at Mitali Dayal via email at Mitali.Dayal2@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.

Domestic Personal Protection Equipment RFI, contact Jesse Hawkins via email at jesse.hawkins@hhs.gov

Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals, contact The Clinical Standards Group, HealthandSafetyInquiries@cms.hhs.gov

Hospital Inpatient Quality Reporting (IQR) Program measures, contact Melissa Hager or Ngozi Uzokwe via email melissa.hager@cms.hhs.gov or ngozi.uzokwe@cms.hhs.gov.

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

Hospital Outpatient Quality Reporting (OQR) Program measures, contact Janis Grady via email Janis.Grady@cms.hhs.gov.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Abby Cesnik via email at Abigail.Cesnik@cms.hhs.gov or Nate Vercauteren via email at Nathan.Vercauteren@cms.hhs.gov.

IHS Outpatient Encounter Rate available to all American Indian and Alaska Native (AI/AN) Outpatient Programs Request for Information, contact Lisa Parker via email at Lisa.Parker1@cms.hhs.gov

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

Medicaid and CHIP Continuous Eligibility Policy, contact Cassie Lagorio via email at Cassandra.Lagorio@cms.hhs.gov.

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

No Legal Obligation to Pay Payment Exclusion, contact Frederick Grabau via email at Frederick.Grabau@cms.hhs.gov.

Non-Opioid Policy or Implementation of Section 4135 of the Consolidated Appropriations Act (CAA), 2023, contact Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov or Cory Duke via email at Cory.Duke@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, or Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov.

OPPS Dental Policy, contact Nicole Marcos via email at Nicole.Marcos@cms.hhs.gov.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov, Gil Ngan via email at Gil.Ngan@cms.hhs.gov, Cory Duke via email at Cory.Duke@cms.hhs.gov, or Au'Sha Washington via email at Ausha.Washington@cms.hhs.gov.

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

OPPS Packaged Items/Services, contact Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov or 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.

Outpatient Department Prior Authorization Process, contact Kelly Wojciechowski via email at Kelly.Wojciechowski@cms.hhs.gov.

Overall Hospital Quality Star Rating Request for Information, 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.

Payment Policy for Devices in Category B Investigational Device Exemption Clinical Trials Policy and Drugs with a Medicare Coverage with Evidence Development (CED) Designation, contact Cory Duke via email at Cory.Duke@cms.hhs.gov.

Remote Services, contact Emily Yoder via email at Emily.Yoder@cms.hhs.gov or Nate Vercauteren via email at Nathan.Vercauteren@cms.hhs.gov.

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

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

Special Enrollment Period for Formerly Incarcerated Individuals, contact Steve Manning via email at Steve.Manning@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/>.

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-notice>.

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-notice>.

Current Procedural Terminology (CPT) Copyright Notice

Throughout this final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2021 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

In this proposed rule, 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, 2025. 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 that 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 and refine the requirements for the Hospital Outpatient

Quality Reporting (OQR) Program, the Rural Emergency Hospital Quality Reporting (REHQR) Program, the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, and the Hospital Inpatient Quality Reporting (IQR) Program. This proposed rule would request information on options being considered for future changes to the Overall Hospital Quality Star Rating methodology. Given that the maternal health crisis in the United States is among the highest in high-income countries and also disproportionately impacts racial and ethnic minorities, we are proposing updates to the CoPs for hospitals and CAHs in an effort to advance the health and safety of pregnant, birthing, and post-partum women.

The proposed rule would narrow the description of “custody” for the purposes of Medicare’s no legal obligation to pay payment exclusion at § 411.4(b), add a definition of “penal authority,” reorganize the regulation, and make certain technical edits. The proposed rule would revise the eligibility requirements in the special enrollment period (SEP) for formerly incarcerated individuals at §§ 406.27(d) (Premium Part A) and 407.23(d) (Part B) to tie the eligibility for this SEP to the determination made by SSA that they are no longer incarcerated for releases beginning on January 1, 2025 and limit the current eligibility criteria for the SEP, with reference to “custody” associated with § 411.4(b) to releases between January 1, 2023 and December 31, 2024.

Finally, this proposed rule includes a proposal to create exceptions to the Medicaid clinic services benefit four walls requirement, to authorize Medicaid payment for services provided outside the four walls of the clinic for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas. Our current regulation at 42 CFR § 440.90(b) includes an exception to the four walls requirement under the Medicaid clinic services benefit only for certain clinic services furnished to individuals who are unhoused. We believe these proposed exceptions would help

maintain and improve access for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas.

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 2025, we propose to increase the payment rates under the OPSS by an Outpatient Department (OPD) fee schedule increase factor of 2.6 percent. This increase factor is based on the proposed inpatient hospital market basket percentage increase of 3.0 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a proposed productivity adjustment of 0.4 percentage point. Based on this update, we estimate that total payments to OPSS providers (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case mix) for calendar year (CY) 2025 would be approximately \$88.2 billion, a proposed increase of approximately \$5.2 billion compared to estimated CY 2024 OPSS 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 OPSS payments and copayments for all applicable services.

- *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 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. Using the hospital market basket methodology, for CY 2025, we propose to increase payment rates under the ASC payment system by 2.6 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 3.0 percent reduced by a productivity adjustment of 0.4 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 2025 will be approximately \$7.4 billion, an increase of approximately \$202 million compared to estimated CY 2024 Medicare payments.

- *Data Used in CY 2025 OPPS/ASC Ratesetting:* To set OPPS and ASC payment rates, we normally use the most updated claims and cost report data available. The best available claims data is the most recent set of data which would be from 2 years prior to the calendar year that is the subject of rulemaking. Cost report data usually lags the claims data by a year, and we believe that using the most updated cost report extract available from the Healthcare Cost Report Information System (HCRIS) is appropriate for CY 2025 OPPS ratesetting. Therefore, we are using our typical data process of using the most updated cost reports and claims data available for CY 2025 OPPS ratesetting.

- *Device Pass-Through Payment Applications:* For CY 2025, we received 14 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 2025 OPPS/ASC final rule with comment period.

- *Changes to the List of ASC Covered Surgical Procedures and Ancillary Services Lists:* For CY 2025, we propose to add 20 medical and dental procedures to the ASC CPL and ancillary services lists based upon existing criteria at § 416.166.

- *Changes to the Inpatient Only (IPO) List:* For CY 2025, we propose to add three services for which codes were newly created by the AMA CPT Editorial Panel for CY 2025 to the IPO list: CPT codes 0894T (Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion), 0895T (Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly

physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary), and 0896T (Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment)).

- *Remote Services*: For CY 2025, we are clarifying our policies for remotely furnished outpatient therapy services, Diabetes Self-Management Training and Medical Nutrition Therapy services and mental health services furnished remotely to beneficiaries in their homes by hospital staff to maintain alignment across payment systems.

- *All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities*: In CY 2024 OPPTS/ASC rulemaking, due to health equity and beneficiary access concerns, we solicited comment from the public on whether Medicare should pay separately for certain high-cost drugs provided by IHS and tribal facilities and, if so, how we might do so. Based on the responses we received, we are proposing, starting January 1, 2025, 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 under the authorities used to calculate the AIR.

- *Clinical Trials Coding and Payment*: We propose technical refinements to our Category B clinical trials coding and payment policy for devices and procedures. We are also proposing to extend our coding and payment policy to drugs and devices that meet CAG's coverage and evidence development (CED) requirement for which there is a control arm. ●

- *Payment for HIV Pre-Exposure Prophylaxis (PrEP) in Hospital Outpatient Departments*: For CY 2025, we are proposing to pay for HIV PrEP drugs covered as an additional preventive service and related services under the OPPTS, if covered by CMS through a National Coverage

Determination. We propose a site neutral policy where products are generally paid similar rates under the OPPS and Physician Fee Schedule.

- *Diagnostic Radiopharmaceuticals Separate Payment:* We propose to pay separately for diagnostic radiopharmaceuticals with per day costs above a threshold of \$630, which is approximately two times the volume weighted average cost amount currently associated with diagnostic radiopharmaceuticals. We also propose to update the \$630 threshold in CY 2026 and subsequent years by the Producer Price Index (PPI) for Pharmaceutical Preparations. Finally, we propose to pay for separately payable diagnostic radiopharmaceuticals based on their Mean Unit Cost (MUC) derived from OPPS claims and seek comment on the use of Average Sales Price (ASP) for payment in future years.

- *Exclusion of Cell and Gene Therapies from Comprehensive Ambulatory Payment Classification (C-APC) Packaging:* We propose to exclude qualifying cell and gene therapies from C-APC packaging and seek comment on whether there are other changes to the C-APC packaging policy we should consider for future years.

- *Add-on Payment for Radiopharmaceutical Technetium-99m (Tc-99m):* For CY 2025, an add-on payment applies radiopharmaceuticals that use Tc-99m produced without use of highly enriched uranium (HEU). We propose for CY 2026 that we would replace the add-on payment for radiopharmaceuticals produced without the use of Tc-99m derived from non-HEU sources with an add-on payment for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99.

- *Changes to the Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process:* We are changing the current review timeframe for prior authorization requests for OPD services from 10-business days to 7-calendar days for standard reviews.

- *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: (1) adopt the Hospital Commitment to Health Equity (HCHE) measure in the Hospital OQR and REHQR Programs and the Facility Commitment to Health Equity (FCHE) measure in the ASCQR Program beginning with the CY 2025 reporting period/CY 2027 payment or program determination; (2) adopt the Screening for Social Drivers of Health (SDOH) measure in all three programs beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination; (3) adopt the Screen Positive Rate for SDOH measure in all three programs beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination; and (4) modify the Immediate Measure Removal policy for adopted Hospital OQR and ASCQR Program measures beginning with CY 2025.

- *Hospital Outpatient Quality Reporting (OQR) Program:* In addition to the cross-program proposals, 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 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination; (2) remove the MRI Lumbar Spine for Low Back Pain measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (3) remove the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (4) require electronic health record (EHR) technology to be certified to all electronic clinical quality measures (eCQMs) available to report beginning with the CY 2025 reporting period/CY 2027 payment determination; and (5) publicly report the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED

Patients measure – Psychiatric/Mental Health Patients stratification on Care Compare beginning with CY 2025.

- *Rural Emergency Hospital Quality Reporting (REHQR) Program*: In addition to the cross-program proposals, we propose to: (1) extend the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure from one year to two years beginning with the CY 2027 program determination; and (2) establish when, after status conversion, REHs would be required to report data under the REHQR Program.

- *Ambulatory Surgical Center Quality Reporting (ASCQR) Program*: In addition to the cross-program proposals, we are requesting public comment on the potential development of frameworks for specialty focused reporting and minimum case number for required reporting under the ASCQR Program.

- *Hospital Inpatient Quality Reporting (IQR) Program*: We propose to continue voluntary reporting of the core clinical data elements (CCDEs) and linking variables for both the Hybrid Hospital-Wide Readmission (HWR) and Hybrid Hospital-Wide Standardized Mortality (HWM) measures, for the performance period of July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination for the Hospital IQR Program.

- *Overall Hospital Quality Star Rating*: We are requesting information on potential modifications to the Safety of Care measure group in the Overall Hospital Quality Star Rating methodology.

- *Medicare FFS No Legal Obligation to Pay Payment Exclusion and Incarceration*: We propose to narrow the description of “custody” for purposes of Medicare’s no legal obligation to pay payment exclusion at § 411.4(b), add a definition of “penal authority,” reorganize the regulation, and make certain technical edits.

- *Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals*: The proposed rule would revise the eligibility requirements in the special enrollment period (SEP) for formerly incarcerated individuals at §§ 406.27(d) and 407.23(d) to

remove the reference to “custody” associated with § 411.4(b) and instead tie the eligibility for this SEP to the determination made by SSA that they are no longer incarcerated.

- *Continuous Eligibility in Medicaid and CHIP:* We propose to revise Medicaid and CHIP regulations to codify the requirement within the CAA, 2023 to require States to provide 12 months of continuous eligibility to children under the age of 19 in Medicaid and CHIP, with limited exceptions. Specifically, we propose to remove the option to provide continuous eligibility to a subgroup of Medicaid and CHIP enrollees and for a time period of less than 12 months. For CHIP, we propose to remove the option to disenroll children from CHIP during a continuous eligibility period for failure to pay premiums.

- *Medicaid Clinic Services Four Walls Exceptions:* Beginning with the effective date of any final rule implementing this proposal, we propose to add three exceptions to the Medicaid clinic services benefit four walls requirement at 42 CFR § 440.90. Our current regulation at 42 CFR § 440.90(b) allows for Medicaid payment for clinic services furnished outside of the four walls of the clinic only to individuals who are unhoused. Our proposal would add a mandatory exception to the four walls requirement for IHS/Tribal clinics at 42 CFR § 440.90(c) and optional exceptions for behavioral health clinics and clinics located in rural areas at 42 CFR § 440.90(d) and (e), respectively.

- *Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access*

Hospitals: CMS is proposing new Conditions of Participation (CoPs) for hospitals and CAHs for obstetrical services, including new requirements for maternal quality assessment and performance improvement (QAPI), maternal health data reporting, baseline standards for the organization, staffing, and delivery of care within obstetrical units, and staff training on evidence-based best practices on an annual basis. CMS is further proposing revisions to the emergency services CoP related to emergency readiness for hospitals and CAHs that provide emergency services. In addition, CMS is proposing revisions to the Discharge Planning CoP for all hospitals and CAHs related to transfer protocols. Lastly, CMS is soliciting comments on whether these proposed requirements should also apply to rural emergency hospitals (REHs).

3. Summary of Costs and Benefits

In section XXVI 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 OPSS Changes

Table 131 in section XXVI.C of this proposed rule displays the distributional impact of all the proposed OPSS changes on various groups of hospitals and CMHCs for CY 2025 compared to all estimated OPSS payments in CY 2024. We estimate that the proposed policies in this proposed rule would result in a 2.3 percent overall increase in OPSS payments to providers. We estimate that total OPSS payments for CY 2025, including beneficiary cost-sharing, to the approximately 3,500 facilities paid under the OPSS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately \$1.8 billion compared to CY 2024 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our proposed OPSS policies on CMHCs because CMHCs have historically only been paid for partial hospitalization services under the OPSS.

Since CY 2024, they have also been paid for new intensive outpatient program (IOP) services under the OPSS. Continuing the provider-specific structure we adopted beginning in CY 2011, and basing payment fully on the type of provider furnishing the service, we estimate a 7.2 percent increase in CY 2025 payments to CMHCs relative to their CY 2024 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the fiscal year (FY) 2025 IPPS final rule wage indexes would result in a 0.1 percent increase for urban hospitals under the OPSS and a 1.0 percent increase for rural hospitals. These wage indexes include the 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 2025, we are continuing 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 OPSS 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 had 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 2024, we finalized a target PCR of 0.88. For CY 2025, we are proposing a target PCR of 0.87 to determine the CY 2025 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 2025 OPPS/ASC, we are proposing an OPD fee schedule increase factor of 2.6 percent and proposing to apply that increase factor to the conversion factor for CY 2025. As a result of the proposed OPD fee schedule increase factor and the proposed budget neutrality adjustments, we estimate that urban hospitals would experience an increase in payments of approximately 2.4 percent and that rural hospitals would experience an increase in payments of 2.8 percent. Classifying hospitals by teaching status, we estimate non-teaching hospitals would experience an increase in payments of 2.5 percent, minor teaching hospitals would experience an increase in payments of 2.6 percent, and major teaching hospitals would experience an increase in payments of 2.1 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would experience an increase of 2.3 percent in payments, while hospitals with government ownership would experience an increase of 2.4 percent in payments. We estimate that hospitals with proprietary ownership would experience an increase of 3.5 percent in payments.

e. Impacts of the Proposed 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 CY 2025 payment rates, compared to estimated CY 2024 payment rates, generally ranges between an increase of 1 percent and an increase of 4 percent, depending on the service, with some exceptions. We estimate the impact of applying the proposed inpatient hospital market basket update to ASC payment rates will increase payments by \$202 million under the ASC payment system in CY 2025.

f. Impacts of Medicaid Clinic Services Four Walls Exceptions

We estimate that the proposed exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas would increase total expenditures by \$1.18 billion from FY 2025 through

2029. Our estimate includes a Federal impact of \$1.15 billion and impact to States of \$30 million. These estimates are discussed in more detail in section XXVI of this proposed rule.

g. Impacts of Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals

We propose maternal health focused revisions to the CoPs for hospitals and critical access hospitals (CAHs), which are estimated to increase burden on hospitals and CAHs by \$446 million annually with total costs estimated at \$4.46 billion over 10 years. We expect an average annual cost of \$70,671 per hospital and CAH. As discussed in detail in section XXVI, we expect the benefits of these proposed policies to include reduced maternal morbidity and mortality, leading to financial benefits for patients, their families, and payors. We also expect that the proposed policies are likely to reduce inequality in maternal health outcomes among pregnant and postpartum women from different groups and lead to overall improvements in patient care.

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 OPSS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPSS 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 OPSS. The following Acts made additional changes to the OPSS: 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 (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 Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-238), enacted December 29, 2022.

Under the OPSS, 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 OPSS includes payment for most hospital outpatient services, except those identified in section I.C of this final rule with comment period. Section 1833(t)(1)(B) of the Act provides for payment under the OPSS 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 OPSS 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 OPSS 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 OPSS 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 OPSS. 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 OPSS 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 OPSS, 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 OPSS, 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-notice>.

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 OPPTS. 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, 2022, 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 21, 2023. 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). CMS is 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 OPPTS.

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 21, 2023, meeting that the subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPTS/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 2024 OPPTS/ASC Final Rule with Comment Period

We received approximately 180 timely pieces of correspondence on the CY 2024 OPPTS/ASC final rule with comment period that appeared in the **Federal Register** on November 22, 2023 (88 FR 81540) and the related correction notice. In-scope comments were related to the interim APC assignments and/or status indicators of new or replacement Level II

HCPCS codes, which are identified with comment indicator “NI” in OPSS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule).

II. Proposed Updates Affecting OPSS 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, OPSS 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 2025 OPSS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2025, and before January 1, 2026 (CY 2025), using the same basic methodology that we described in the CY 2024 OPSS/ASC final rule with comment period (88 FR 81549 through 81552), using CY 2023 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 2025, we began with approximately 145 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, 2023, and before January 1, 2024, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 73 million final action claims to develop the proposed CY 2025 OPSS 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-notice>) includes the proposed list of bypass codes for CY 2025. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2023 and, therefore, includes codes that were in effect in CY 2023 and used for billing. We propose to retain these deleted bypass codes on the proposed CY 2025 bypass list because these codes existed in CY 2023 and were covered OPD services in that period, and CY 2023 claims data were used to calculate proposed CY 2025 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 2025 are identified by asterisks (*) in the fourth column of Addendum N.

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

For CY 2025, 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 2025 APC payment rates are based, we calculated hospital-specific departmental CCRs for each hospital for which we had CY 2023 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2022. For the proposed CY 2025 OPPS payment rates, we used the set of claims processed during CY 2023. 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 2023 (the year of claims data we used to calculate the proposed CY 2025 OPSS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2023 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 2024 OPSS 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 OPSS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPSS 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 them in OPSS ratesetting. For CY 2025, we propose not to include the nonstandard cost centers reported in this way in the OPSS 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 OPSS payment rates for CY 2025. The Hospital OPSS 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 2023 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 2025 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-notice>). 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 OPSS, in the CY 2019 OPSS/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 OPSS and subsequent years. For the CY 2025 OPSS, 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 2025 OPSS/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 OPSS 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 OPSS 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 OPSS 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-notice>) for the proposed CY 2025 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 OPSS proposed rule (69 FR 50524 and 50525) for a more comprehensive discussion of the blood-specific CCR methodology;

- the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66807 through 66810) for a detailed history of the OPPTS payment for blood and blood products; and
- the CY 2015 OPPTS/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 OPPTS payment for brachytherapy sources, we refer readers to prior OPPTS final rules, such as the CY 2012 OPPTS/ASC final rule with comment period (77 FR 68240 and 68241). As we have stated in prior OPPTS updates, we believe that adopting the general OPPTS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPTS 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 OPPTS 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 the vast majority of items and services paid under the OPPTS. We refer readers to the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPTS payment for brachytherapy sources.

For CY 2025, except where otherwise indicated, we propose to continue our policy and use the costs derived from CY 2023 claims data to set the proposed CY 2025 payment rates for brachytherapy sources because CY 2023 is the year of data we propose to use to set the proposed payment rates for most other items and services that would be paid under the CY 2025 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 2025 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 2025 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 2025 and subsequent years, we also propose to continue the policy we first 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, based on 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 2025 payment rates for brachytherapy sources are included on Addendum B to this proposed rule (which is available via the Internet on the CMS website) and identified with status indicator “U.”

For CY 2018, we assigned status indicator “U” (Brachytherapy Sources, Paid under OPPS; separate APC payment) 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 mm² for the brachytherapy source’s APC – APC 2648 (Brachytx planar, p-103). For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at \$4.69 per mm² for APC 2648 (Brachytx planar, p-103). 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 mm². 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 mm² 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 mm² 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, and CY 2024 OPPS/ASC final rules with comment period (85 FR 85879 through 85880, 86 FR 63469, 87 FR 71760-71761, and 88 FR 81553), 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 mm² for HCPCS code C2645 for CYs 2021 through 2024.

There are no CY 2023 claims available that reported HCPCS code C2645 for this CY 2025 OPPTS/ASC 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 2024 payment rate of \$4.69 per mm² for HCPCS code C2645, which is proposed to be assigned to APC 2648 (Brachytx planar, p-103), for CY 2025.

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 OPPTS/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 2025, 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 or by mail to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. 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 2025

(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; and 88 FR 81562).

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 OPSS include services that are not covered OPD services, services that cannot by statute be paid for under the OPSS, 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-notice>). 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 OPSS/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 OPSS/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;”
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);
- 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

¹ Status indicator “J1” denotes Hospital Part B Services Paid Through a Comprehensive APC. Further information can be found in CY 2025 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 2025 Addendum D1.

(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) for further instructions on reporting these services in the context of a C-APC service.

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.³

³ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.

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 “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 OP/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 OPPI/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 2025, 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 complexity adjustments for “J1” and add-on code combinations for CY 2025, 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-notice>).

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) 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).

(3) 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 OPSS 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 OPSS/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 OPSS are considered covered ancillary services for which the OPSS 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, biologicals, and radiopharmaceuticals 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, biological, or radiopharmaceutical described by HCPCS code C9399 from packaging when the drug, biological, or radiopharmaceutical 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 for the CY 2025 C-APC payment policy exclusions.

In the CY 2023 OPSS/ASC final rule with comment period, we finalized the proposal in section XI. “CY 2023 OPSS 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 definition, found in Addendum D1, would ensure the MAC

prices claims for drugs, biologicals, or radiopharmaceuticals billed with HCPCS code C9399 at 95 percent of the drug or biological's AWP and pays separately for the drug, biological, or radiopharmaceutical under the OPPS when it appears on the same claim as a primary C-APC service.

(4) 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 (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.

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).

Our intent has been to make a single prospective payment based on the cost of all individually reported codes that appear on a claim with the primary C-APC service, which we

believe represent the provision of a primary service and all adjunctive services provided to support that delivery of the primary service. However, there are rare instances where the cell and gene therapies listed in Table 1, which are usually separately payable under the OPPTS, 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. The therapies in Table 1 are usually separately paid and priced using the ASP methodology when not on a C-APC claim. 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 C-APCs primary services. The cell therapies described in Table 1 are primarily for the treatment of specific cancers and are administered through an intravenous infusion. The gene therapies listed in Table 1 are generally for the treatment of certain rare ocular or spinal conditions caused by specific genetic mutations and are also either intravenously infused or administered through a subretinal injection. 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. Additionally, the current primary C-APC services describe common surgical procedures, such as breast/lymphatic surgery and musculoskeletal procedures. The cell and gene therapies listed in Table 1 are intended to treat a specific condition and would not be used to support the outcome of any primary C-APC procedure. For example, HCPCS code J3399 (Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5×10^{15} vector genomes) may be used to describe the gene therapy Zolgensma. This product is FDA-approved as an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene. The specified mechanism of onasemnogene abeparvovec is a recombinant AAV9-based gene therapy designed to deliver a copy of the gene encoding the human SMN

protein.⁴ The function of a product such as Zolgensma, is not intended to be integral, ancillary, supportive, dependent, and adjunctive to any C-APC as the gene therapy itself is an independent treatment.

Yescarta (HCPCS code Q2041) is an example of a cell therapy that functions as an independent treatment. Based on its FDA-approved indication,⁵ this product's intended clinical use would not be integral, ancillary, supportive, dependent, or adjunctive to any current C-APC primary service. Yescarta is indicated as a CD19-directed genetically modified autologous T cell immunotherapy for the treatment of Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy and adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. Yescarta is the primary treatment being performed when administered for these FDA-approved indications and should not be packaged as supportive of any C-APC primary service even if the two services appear on the same claim.

We explained in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74868) that intravenous drugs, for example, are OPPS services that are considered adjunctive to the primary procedure because the correct administration of the drug either promotes a beneficial outcome, such as the use of intravenous pain medications, or prevents possible complications, such as the use of intravenous blood pressure medications to temporarily replace oral blood pressure medications and reduce the risk of a sudden rise in blood pressure when a normal daily medication is stopped. In the case of the cell and gene therapies described in Table 1, however, we do not believe the therapies “promote a beneficial outcome” or “prevent possible

⁴ Zolgensma. FDA Package Insert. October 2023. <https://www.fda.gov/media/126109/download?attachment>

⁵ FDA Package Insert. Yescarta. April 2024. <https://www.fda.gov/media/108377/download?attachment>

complications” of any of the procedures currently designated as primary C-APC services. While the cell and gene therapies in Table 1 may “promote a beneficial outcome” for the patient in general, we do not believe the provision of cell and gene therapies are “promoting a beneficial outcome” for any of the primary C-APC services themselves, as the cell and gene therapies are serving as independent therapies. These are distinguishable from the previous examples of intravenous pain medications that are directly related to the primary C-APC service and promote a beneficial outcome for that procedure. Further, in the CY 2014 OPPI/ASC final rule with comment period (78 FR 74865), we stated that we proposed to package into C-APCs all of these integral, ancillary, supportive, dependent, and adjunctive services, hereinafter collectively referred to as “adjunctive services,” provided during the delivery of the comprehensive service. This includes the diagnostic procedures, laboratory tests and other diagnostic tests, and treatments that assist in the delivery of the primary procedure. We do not believe that the cell and gene therapies listed in Table 1 are assisting in the delivery of any primary procedure currently assigned to a C-APC.

Therefore, for CY 2025 only, we propose not to package payment for the cell and gene therapies listed in Table 1 into the payment for the primary C-APC service when they appear on the same claim as primary C-APCs services. We propose this policy for one year only in order to gather more information from interested parties as to whether this proposed policy appropriately captures all of the unique therapies, such as the cell and gene therapies listed in Table 1, that function as primary treatments and do not support C-APC primary services. As discussed later in this section, we welcome comments from readers on this proposal and the potential need for a different, modified, expanded, or supplemental policy for future rulemaking. We will assess whether to continue this policy, or a modified version of this policy, beyond one year in future rulemaking, taking into consideration the comments received.

We are not proposing to include therapies that are on drug pass-through status for all of CY 2025 in Table 1 because pass-through drugs are already excluded from C-APC packaging.

We are proposing that products for which pass-through status is expiring in CY 2025 would be excluded from C-APC packaging after their pass-through status expires. For example, the product described by HCPCS code Q2056 has pass-through status expiring June 30, 2025. Until its pass-through status expires, the product will be excluded from C-APC packaging due to the pass-through C-APC exclusion policy, but after its pass-through status expires, we propose that the therapy would continue to be excluded from C-APC packaging under our proposed exclusion for cell and gene therapies. For more information on drug pass-through status, including expiring and continuing pass-through status, please see section V.A. of this proposed rule.

TABLE 1: Cell and Gene Therapies Proposed for Exclusion from C-APC Packaging

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
Carvytki	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

Trade Name	HCPCS Code	Long Descriptor
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Zolgensma	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5×10^{15} vector genomes

We propose to exclude the therapies listed in Table 1 from C-APC packaging. We seek comment on this proposal, and we seek comment on whether there are any additional cell and gene therapies that may be appropriate to exclude from C-APC packaging for CY 2025. Commenters should explain why any additional cell and gene therapies that they believe should be excluded from C-APC packaging are not integral, ancillary, supportive, dependent, or adjunctive to any C-APC primary service. We seek comment on whether this proposal should be extended beyond 1 year or if a different, expanded, or supplemental policy approach may be warranted in future rulemaking. For example, we are interested in comments on whether there are other classes of drugs, biologicals, or other products that are not clearly integral, ancillary, adjunctive, or supportive of a primary C-APC service but could appear on the same claim as the C-APC for that primary service and for which payment would be packaged into the C-APC payment under our current policy. We would expect clinical evidence supporting commenters' assertion that other identified classes of drugs, biologicals, medical devices, or other products are not clearly supportive of a primary C-APC service but may nonetheless appear on the same claim as a primary C-APC procedure. Similarly, we seek comment on whether interested parties believe it is appropriate for these other classes of drugs, biologicals, or medical devices to be excluded from packaging with all C-APCs or only specific C-APCs, such as the Comprehensive Observation Services C-APC (SI = "J2").

Finally, we seek comment on the following:

(1) Because the cell and gene therapies listed in Table 1 are not integral, ancillary, supportive, dependent, or adjunctive to any current C-APC procedure, how could CMS structure

a new C-APC, or similar packaged payment policy, for the service to administer cell or gene therapies, such by creating as a Chimeric Antigen Receptor (CAR) T-cell therapy administration C-APC, with which the CAR-T or gene therapy would be integral, ancillary, supportive, dependent, or adjunctive to the primary C-APC service?

(2) What integral, ancillary, supportive, dependent, or adjunctive items and services are routinely provided as part of the administration of cell and gene therapies or in conjunction with cell and gene therapies generally?

We recognize that currently, the following HCPCS codes are associated with CAR-T therapy: HCPCS code 0537T (Chimeric antigen receptor t-cell (car-t) therapy; harvesting of blood-derived t lymphocytes for development of genetically modified autologous car-t cells, per day), 0538T (Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (eg, cryopreservation, storage)), 0539T (Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration), and 0540T (Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous) as discussed in previous OPPTS rulemaking, including the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63550 through 63552).

Separately, we also seek comment on whether policy revisions to the C-APC policy may be appropriate in future rulemaking, such as a modified outlier payment policy specific to C-APCs to address related situations in the future. We list all proposed C-APC exclusion categories for CY 2025 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>).

(5) 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, we propose 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. Please see section XIII.F. of this proposed rule for a list of the products that we propose would qualify for payment under the new payment policy for non-opioid drugs, biologicals, and devices for pain relief.

(6) C-APCs for CY 2025

For CY 2025 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 2025; thus, we propose that the number of C-APCs for CY 2025 would be the same as the number for CY 2024, which is 72 C-APCs.

Table 2 lists the proposed C-APCs for CY 2025, all of which were established in past rules. All C-APCs are also displayed in Addendum J to this proposed rule (which is available via the internet on the CMS website). 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 2025 C-APCs

C-APC	CY 2025 APC Group Title	Clinical Family	New C-APC
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	

C-APC	CY 2025 APC Group Title	Clinical Family	New C-APC
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	
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	

C-APC	CY 2025 APC Group Title	Clinical Family	New C-APC
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 more recent background.

(1) Mental Health Services Composite APC

For CY 2025, 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 more recent background.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580, 33581, 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 OPPTS/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 4 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 OPPTS/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 at a hospital represent the most resource intensive of all outpatient mental health services. For CY 2025 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 this 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 below.

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 2025, 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 2025, except where otherwise indicated, we propose to use the costs derived from CY 2023 claims data to set the proposed CY 2025 payment rates. Therefore, for CY 2025, 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 2023 claims available for the CY 2025 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) and are discussed in more detail in section II.A.1.a of this proposed rule.

For this CY 2025 OPPS/ASC proposed rule, we were able to identify approximately 0.95 million “single session” claims out of an estimated 2.1 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 45.0 percent of all eligible claims, to calculate the proposed CY 2025 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 proposed geometric mean costs for CY 2025.

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

Family 1 – Ultrasound	
CY 2025 APC 8004 (Ultrasound Composite)	CY 2025 Approximate APC Geometric Mean Cost = \$305.72
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 1 st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2025 APC 8005 (CT and CTA without Contrast Composite) *	CY 2025 Approximate APC Geometric Mean Cost = \$225.57
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 2025 APC 8006 (CT and CTA with Contrast Composite)	CY 2025 Approximate APC Geometric Mean Cost = \$434.01
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 neck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
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 2025 APC 8007 (MRI and MRA without Contrast Composite) *	CY 2025 Approximate APC Geometric Mean Cost = \$536.10
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 2025 APC 8008 (MRI and MRA with Contrast Composite)	CY 2025 Approximate APC Geometric Mean Cost = \$853.87
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 payment 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. Because packaging encourages efficiency and is an essential component of a prospective payment system, 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 OPSS 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 OPSS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPSS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPSS 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 OPSS to determine which OPSS services can be packaged to further achieve the objective of advancing the OPSS toward a more prospective payment system.

b. Proposal on Packaged Items and Services

For CY 2025, we examined the items and services currently provided under the OPSS, 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 OPSS packaging policies or a logical expansion of those existing OPSS packaging policies.

For CY 2025, we do not propose 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. Proposed 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 radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure is 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 believed 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. Diagnostic radiopharmaceuticals are one specific type of product that is policy packaged under the category described by § 419.2(b)(15). Since we implemented this policy in CY 2008, interested parties have raised concerns regarding policy packaging of diagnostic radiopharmaceuticals. In previous rulemaking (87 FR 71962 and 71963), commenters recommended that CMS always pay separately under the OPPS for

diagnostic radiopharmaceuticals, not just when the products have pass-through payment status. Many of these commenters mentioned that pass-through payment status helps the diffusion of new diagnostic radiopharmaceuticals into the market. However, commenters believe the packaged payment rate is often inadequate after pass-through status expires, especially in cases where the diagnostic radiopharmaceutical is high-cost and has low utilization.

We have heard from interested parties regarding alternative payment methodologies, such as subjecting diagnostic radiopharmaceuticals to the drug packaging threshold and creating separate APC payments for diagnostic radiopharmaceuticals with a per-day cost greater than \$500. Interested parties have also recommended that we analyze our nuclear medicine APC structure and consider establishing additional nuclear medicine APCs to reflect the costs of diagnostic radiopharmaceuticals more accurately. Historically, commenters opposed incorporating the cost of diagnostic radiopharmaceuticals into the associated nuclear medicine APC as the nuclear medicine APCs are sometimes paid at a lower rate than the payment rate for the diagnostic radiopharmaceutical itself when it has pass-through payment status (87 FR 71962 and 71963).

Importantly, commenters historically have also been concerned that packaging payment for precision diagnostic radiopharmaceuticals in the outpatient hospital setting creates barriers to beneficiary access for safety net hospitals serving a high proportion of Medicare beneficiaries and hospitals serving underserved communities (87 FR 71962 and 71963). Commenters specified that certain populations, such as those with Alzheimer's disease, depend on the use of certain high-cost diagnostic radiopharmaceuticals. Commenters discussed difficulties enrolling hospitals in clinical studies due to OPPS packaging policies and suggested that we pay separately under the OPPS specifically for radiopharmaceuticals that are used for Alzheimer's disease. Additionally, commenters have recommended that CMS continue to apply radiolabeled product edits to the nuclear medicine procedures to ensure that all packaged costs are included on nuclear medicine claims to establish appropriate payment rates in the future. Beginning January 1, 2008,

CMS implemented OPSS edits that require hospitals to include a HCPCS code for a radiolabeled product when a separately payable nuclear medicine procedure is present on a claim. This policy to require hospitals to include a HCPCS code for a radiolabeled product for a separately payable nuclear medicine procedure ended in CY 2014 (78 FR 75033 through 75034).

Many of these comments and our responses have been discussed in rulemaking since the policy to package diagnostic radiopharmaceuticals was adopted, and they prompted us to solicit comment on the payment of diagnostic radiopharmaceuticals in the CY 2024 OPSS/ASC proposed rule (88 FR 49577). In that proposed rule, we stated we continue to believe that diagnostic radiopharmaceuticals are an integral component of many nuclear medicine and imaging procedures and charges associated with them should be reported on hospital claims to the extent they are used. Accordingly, we reiterated our belief that the payment for the diagnostic radiopharmaceutical should be reflected within the payment for the primary procedure with which it is used. We noted that ratesetting uses the geometric mean of reported procedure costs, which in the example of nuclear medicine procedures includes the costs of the reported diagnostic radiopharmaceutical, based on data submitted to CMS from all hospitals paid under the OPSS to set the payment rate for the service. The costs that are calculated by Medicare reflect the average costs of items and services that are packaged into a primary procedure and will not necessarily equal the sum of the cost of the primary procedure and the average sales price of the specific items and services used in the procedure in each case. Furthermore, we explained that the costs are based on the reported costs submitted to Medicare by the hospitals and not the list price established by the manufacturer. Claims data that include the diagnostic radiopharmaceutical packaged with the associated procedure should reflect the combined cost of the procedure and the radiopharmaceutical used in the procedure.

As we have reiterated over the years, we believe packaging policies are inherent principles of the OPSS and are essential to a prospective payment system. At the same time, we have explained that we are committed to ensuring beneficiary access to diagnostic

radiopharmaceuticals while also ensuring the availability of new and innovative diagnostic tools for Medicare beneficiaries. Therefore, we sought public comments on potential modifications to our packaging policy for diagnostic radiopharmaceuticals to ensure equitable payment and continued beneficiary access.

As described in the CY 2024 OPPTS/ASC proposed rule (88 FR 49578), we solicited comment on how the OPPTS packaging policy for diagnostic radiopharmaceuticals has impacted beneficiary access, including whether there are specific patient populations or clinical disease states for whom this issue is especially critical.

In addition, we solicited comment on the following potential approaches that would enhance beneficiary access, while also maintaining the principles of the outpatient prospective payment system. These approaches included: (1) paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPTS drug packaging threshold of \$140; (2) establishing a specific per-day cost threshold that may be greater or less than the OPPTS drug packaging threshold; (3) restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals; (4) creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and (5) adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

Finally, we were interested in hearing from stakeholders how the suggested policy modifications might impact our overarching goal of utilizing packaging policies to better align OPPTS policies with those of a prospective payment system rather than a fee schedule. We stated we would also like to know if making any of the suggested policy changes could have negative consequences for beneficiaries, such as unintentionally influencing clinical practice decisions, increasing beneficiary cost-sharing obligations, or inadvertently encouraging the use of higher-cost diagnostic radiopharmaceuticals over lower cost, but equally effective, diagnostic options.

We received a significant number of comments in response to the comment solicitation on potential issues caused by our current payment policy for diagnostic radiopharmaceuticals under the OPSS and on new approaches to payment for these products. Commenters expressed concerns regarding the CMS policy to package diagnostic radiopharmaceuticals and the financial implications this policy has for facilities. Commenters believe that, for newer, more innovative radiopharmaceuticals, the current OPSS packaging policy has led to a lack of patient access to the technologies after the radiopharmaceutical's pass-through status expires, especially if there is no clinical alternative to the radiopharmaceutical. Most commenters requested that CMS provide separate payment for diagnostic radiopharmaceuticals. Some commenters believed paying separately for all diagnostic radiopharmaceuticals regardless of their per-day cost was the best methodology to avoid encouraging price inflation for diagnostic radiopharmaceuticals to reach a certain threshold. Other commenters thought that applying the existing OPSS per-day cost threshold (\$135 for CY 2024) to the payment of diagnostic radiopharmaceuticals would be an adequate solution. Others supported a \$500 threshold, and many cited the Facilitating Innovative Nuclear Diagnostics Act (FIND Act) of 2023 as their rationale for that number and recognized that the \$500 threshold number may be a more targeted approach relative to the OPSS drug packaging threshold as the higher cost diagnostic radiopharmaceuticals are the most disadvantaged by the OPSS packaging policy in their view. For the full discussion on the comment solicitation summarized here, refer to the CY 2024 OPSS/ASC final rule with comment period (88 FR 81573 through 81577).

(2) Proposed Packaging Threshold for Diagnostic Radiopharmaceuticals

As stated in the CY 2024 OPSS final rule with comment period (88 FR 81577), we agree with commenters that payment for diagnostic radiopharmaceuticals is a complex and important issue. We explained that we intended to further consider these points and take them into consideration for future notice and comment rulemaking. After significant consideration and

ongoing engagement from interested parties, we are proposing a change to our current policy that packages diagnostic radiopharmaceuticals regardless of their cost.

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. While we continue to believe that this should be the policy for most diagnostic radiopharmaceuticals, we believe 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 situations where a hospital may have to pay significantly more to purchase a diagnostic radiopharmaceutical than Medicare pays, a hospital may decide not to provide that specific diagnostic radiopharmaceutical imaging agent to Medicare beneficiaries. This could potentially deny access to diagnostic tools for which there is no clinical alternative. To ensure Medicare payment policy is not providing a financial disincentive to using high cost, low utilization diagnostic radiopharmaceuticals, especially when those agents may be the most clinically appropriate, and to ensure appropriate beneficiary access, we believe a subset of diagnostic radiopharmaceuticals with higher per day costs should be paid separately and not packaged into the diagnostic procedure with which the diagnostic radiopharmaceutical is used.

To address these concerns, we propose to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than \$630. Any diagnostic radiopharmaceutical with a per day cost below that threshold would continue to be policy packaged under the current policy at § 419.2(b)(15). We discuss our methodology for determining the proposed per day cost threshold of \$630 in further detail in this section.

To determine an appropriate threshold, we estimated the approximate payment that would typically be attributable to diagnostic radiopharmaceutical payment within each nuclear medicine APC (APCs 5591, 5592, 5593, and 5594). We did this by assessing the offsets associated with these APCs that were directly attributable to “policy packaged” drugs. The offset amounts used are correlated with the approximate portion of APC payment associated with these "policy packaged" drugs. For nuclear medicine APCs, the primary “policy packaged” drugs are diagnostic radiopharmaceuticals. To calculate this threshold, we calculated a volume weighted average of the offset dollar amount of each nuclear medicine APC. This involved taking the offset percentage for “policy packaged” drugs, multiplying it by the APC geometric mean to get an offset dollar amount, and then multiplying that offset amount by the number of single claims to get the total offset amount for each nuclear medicine APC level. We then calculated the sum of the total offset amount for all 4 of the nuclear medicine APCs. We divided this number by the total number of single claims for all 4 nuclear medicine APCs, resulting in \$314.28, which represents the volume weighted average policy packaged offset amount for the nuclear medicine APC series. We then took that number and multiplied it by 2, and rounded it to the nearest \$5 increment, which resulted in \$630. See Table 4 for the values used to calculate this threshold amount. We note that the data values in Table 4 were collected without unpackaging the set of diagnostic radiopharmaceuticals listed in Table 5. If we finalize our proposal and those diagnostic radiopharmaceuticals are unpackaged, it would change the APC geometric mean unit costs (MUCs) as well as the offset percentages. This is why the APC geometric mean cost values listed below are not the same as in the addenda to this rule.

TABLE 4: CY 2025 Costs Statistics for Nuclear Medicine APCs

APC	APC Title	Number of Single Claims	APC Geometric mean Cost	Portion of APC Payment Associated with "Policy Packaged" Drugs / Offset Percent for <u>Packaged Drugs that are Always Packaged</u>
5591	Level 1 Nuclear Medicine and Related Services	155,289	\$416.50	0.152

5592	Level 2 Nuclear Medicine and Related Services	60,334	\$556.84	0.2146
5593	Level 3 Nuclear Medicine and Related Services	496,758	\$1,399.48	0.2387
5594	Level 4 Nuclear Medicine and Related Services	402,439	\$1,738.01	0.2393

The offset percentages used have been updated based on the available data for CY 2025 rulemaking and would be updated for the final rule. However, the file and corresponding offset percentages used are similar to the ones that can be found in the CY 2024 NFRM APC Offset File. These files are available via the internet on the CMS OPSS website.⁶

We propose to multiply by two the volume weighted average amount of the offset to establish the threshold triggering separate payment because this amount would ensure that separate payment would apply only to diagnostic radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product in the nuclear medicine APC payment. This is consistent with the principles of a prospective payment system where some payments are lower than hospitals' costs while other payments are greater than a hospitals' costs. However, diagnostic radiopharmaceuticals with costs more than double the volume weighted average amount of the offset could present a hospital with a significant financial loss. This is why the OPSS has several payment provisions that rely on a multiplier of costs as a threshold for modifying payment.

Our proposed approach to multiply the average offset amount by two is consistent with the two-times rule the OPSS uses to determine Ambulatory Payment Classification (APC) levels, where a significant service that has a cost greater than two times the lowest cost significant service in an APC is generally moved to a higher level APC in the series. The two-times rule requires that the highest calculated cost of an individual procedure categorized to any given APC cannot exceed two times the calculated cost of the lowest cost procedure categorized to that same

⁶ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/annual-policy-files>

APC. We note that the two-times rule does not apply to diagnostic radiopharmaceuticals themselves, but only to the procedures in which they are used, which is why we are proposing a diagnostic radiopharmaceutical packaging threshold utilizing a similar two-times methodology.

Our proposed approach to multiply the average offset amount by two is also generally consistent with the OPSS outlier policy applicable to certain high-cost procedures, where costs greater than 1.75 times the APC payment trigger an additional outlier payment. The OPSS 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. Outlier payments are provided on a service basis when the cost of a service exceeds the APC payment amount multiplier threshold (1.75) as well as the APC payment amount plus a fixed-dollar amount threshold. The proposed diagnostic radiopharmaceutical packaging threshold would serve a similar purpose as the outlier policy, in that it would provide payments to hospitals to help mitigate the financial risk associated with high-cost diagnostic radiopharmaceuticals, where a very costly diagnostic radiopharmaceutical could present a hospital with significant financial loss.

While we are proposing two, and believe two is the most appropriate number for the multiplier for the volume weighted average amount of the offset, for the reasons articulated for the OPSS outlier policy, we seek comment on the alternatives of using 1.75 times the volume weighted average amount of the offset as the threshold amount for triggering separate payment, or another appropriate multiplier amount. For example, an interested party could present data that a financial disincentive to use diagnostic radiopharmaceuticals exists when costs are 1.75 times, or three times or five times, the volume weighted average offset amount. Since the hospital outpatient outlier payment policy is a longstanding policy familiar to most hospitals, we seek comment on utilizing elements of that policy for purposes of our proposed diagnostic radiopharmaceutical packaging policy in order to help hospitals mitigate the financial risk that may be associated with furnishing high-cost and complex diagnostic radiopharmaceuticals. As

previously mentioned, we seek comment on the use of 1.75 times as the multiplier threshold rather than 2. Although the outlier policy uses both a 1.75 multiplier threshold and a fixed-dollar threshold, we are seeking comment regarding the use of 1.75 as the multiplier to set a fixed dollar threshold for the volume weighted average amount of the offset as the goals of the outlier policy and this proposed diagnostic radiopharmaceutical policy are similar.

We also solicit comment on the alternative of using the standard drug packaging threshold, which is proposed to be \$140 for CY 2025 in this rule, as the threshold for separate payment for diagnostic radiopharmaceuticals. We believe that diagnostic radiopharmaceuticals are functioning as supplies to the nuclear medicine procedure in which they are used. Because diagnostic radiopharmaceuticals function as supplies in the diagnostic procedures in which they are used, they are serving as an item that is integral, ancillary, supportive, dependent, or adjunctive to the primary diagnostic service. This is in contrast to therapeutic drugs, biologicals, and therapeutic radiopharmaceuticals that are typically packaged under the standard drug packaging threshold. These products could be the only therapeutic modality provided to a patient during an encounter and may not serve as an item that is integral, ancillary, supportive, dependent, or adjunctive to the primary service. Due to this clinical difference, we do not believe that using the standard drug packaging threshold is appropriate for diagnostic radiopharmaceuticals, and therefore we are proposing a threshold specific to diagnostic radiopharmaceuticals. We would be interested to hear from commenters whether they agree or disagree with this assessment.

(3) Calculating the Per Day Cost of Diagnostic Radiopharmaceuticals

We are proposing to calculate the per day costs for diagnostic radiopharmaceuticals using a methodology similar to the one we use for determining the per day costs of drugs and biologicals for comparison to the OPPS drug packaging threshold, proposed to be \$140 for CY 2025.

We propose to calculate the per day cost based on the methodology described in section V.B.1.b. of this proposed rule, which relies on the methodology in the CY 2006 OPPTS/ASC proposed rule (70 FR 42723 and 42724) and finalized in the CY 2006 OPPTS final rule with comment period (70 FR 68636 through 68638). Though the clinical use of the drugs, biologicals, and therapeutic radiopharmaceuticals differs from diagnostic radiopharmaceuticals, we believe the method of determining how much of that item is used per day should be similar. Therefore, we are proposing to use a similar methodology for determining the per day costs of diagnostic radiopharmaceuticals, as we do drugs, biologicals, and therapeutic radiopharmaceuticals. This methodology consists of nine steps:

Step 1. After application of the CCRs, we aggregated all line-items for a single date of service on a single claim for each product. This resulted in creation of a single line-item with the total number of units and the total cost of a diagnostic radiopharmaceutical given to a patient in a single day.

Step 2. We then created a separate record for each diagnostic radiopharmaceutical by date of service, regardless of the number of lines on which the diagnostic radiopharmaceutical was billed on each claim. For example, “diagnostic radiopharmaceutical X” is billed on a claim with two different dates of service, and for each date of service, the diagnostic radiopharmaceutical is billed on two line-items with a cost of \$10 and 5 units for each line-item. In this case, the computer program would create two records for this diagnostic radiopharmaceutical, and each record would have a total cost of \$20 and 10 units of the product.

Step 3. We trimmed records with unit counts per day greater or less than 3 standard deviations from the geometric mean.

Step 4. For each remaining record for a diagnostic radiopharmaceutical, we calculated the cost per unit of the diagnostic radiopharmaceutical. If the HCPCS descriptor for “diagnostic radiopharmaceutical X” is “per 1 millicurie” and one record was created for a total of 10 millicurie (as indicated by the total number of units for the diagnostic radiopharmaceutical on the

claim for each unique date of service), the computer program divided the total cost for the record by 10 to give a per unit cost. We then weighted this unit cost by the total number of units in the record. We did this by generating a number of line-items equivalent to the number of units in that particular claim. Thus, a claim with 100 units of “diagnostic radiopharmaceutical X” and a total cost of \$200 would be given 100 line-items, each with a cost of \$2, while a claim of 50 units with a cost of \$50 would be given 50 line items, each with a cost of \$1.

Step 5. We trimmed the unit records with cost per unit greater or less than 3 standard deviations from the geometric mean.

Step 6. We aggregated the remaining unit records to determine the mean cost per unit of the diagnostic radiopharmaceutical.

Step 7. Using only the records that remained after records with unit counts per day greater or less than 3 standard deviations from the geometric mean were trimmed (step 3), we determined the total number of units billed for each item and the total number of unique per-day records for each item. We divided the count of the total number of units by the total number of unique per day records for each item to calculate an average number of units per day.

Step 8. We used the payment rate (the mean unit cost (MUC) derived from the CY 2023 hospital claims data) for each diagnostic radiopharmaceutical and multiplied the payment rate by the average number of units per day for each diagnostic radiopharmaceutical to arrive at its per day cost.

Step 9. We packaged the items with per day costs less than or equal to \$630 and designated items with per day costs greater than \$630 as separately payable.

As just described, to determine the proposed CY 2025 packaging status for all nonpass-through diagnostic radiopharmaceuticals, we propose to use the per day cost, calculated on a HCPCS code-specific basis, of each diagnostic radiopharmaceutical that had a HCPCS code in CY 2023 and was paid (via packaged or separate payment) under the OPPI. We used data from CY 2023 claims processed through December 31, 2023, for this calculation.

We propose to continue to package payment for diagnostic radiopharmaceuticals with per day costs less than or equal to \$630 under our existing packaging policy for diagnostic radiopharmaceuticals that function as surgical supplies under § 419.2(b)(15). Similar to our policy for the drug packaging threshold, we propose to use updated claims data to make final determinations of the packaging status of HCPCS codes for diagnostic radiopharmaceuticals for each OPPS/ASC final rule with comment period. We propose to make an annual packaging determination for each diagnostic radiopharmaceutical HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. We propose that only diagnostic radiopharmaceutical HCPCS codes that are identified as separately payable in the final rule with comment period would be subject to quarterly updates.

Consequently, the packaging status of some HCPCS codes for diagnostic radiopharmaceuticals in the OPPS/ASC proposed rule may differ from the same HCPCS codes' packaging status determined based on the data used for the final rule with comment period. Under these circumstances, we propose to follow the established policies for the OPPS drug packaging threshold, which were initially adopted for the CY 2005 OPPS (69 FR 65780), to more equitably pay for those diagnostic radiopharmaceuticals whose costs fluctuate relative to the proposed CY 2025 OPPS diagnostic radiopharmaceutical packaging threshold in a way that affects the product's payment status (packaged or separately payable). Our policy for the OPPS drug packaging threshold has not changed for many years and is the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). We believe these same policies should apply to diagnostic radiopharmaceuticals in order to ensure payment consistency for those diagnostic radiopharmaceuticals whose costs fluctuate relative to the proposed CY 2025 OPPS diagnostic radiopharmaceutical packaging threshold. For CY 2025, similar to our historical practice for the drug packaging threshold, we propose to apply the following policies to those HCPCS codes for diagnostic radiopharmaceuticals whose relationship to the diagnostic radiopharmaceutical packaging threshold changes based on the final updated data: HCPCS codes

for diagnostic radiopharmaceuticals that are proposed for separate payment in CY 2025, and that then have per day costs equal to or less than the CY 2025 final rule diagnostic radiopharmaceutical packaging threshold, based on the updated hospital claims data used for the CY 2025 final rule, would remain packaged in CY 2025. HCPCS codes for diagnostic radiopharmaceuticals for which we proposed packaged payment in CY 2025 but that then have per-day costs greater than the CY 2025 final rule drug packaging threshold, based on updated hospital claims data used for the CY 2025 final rule, would receive separate payment in CY 2025.

(4) Proposal to Update the Diagnostic Radiopharmaceutical Packaging Threshold in CY 2026

Starting in CY 2026 and subsequent years, we propose to update the proposed threshold amount of \$630 by the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI). IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the various price indexes including the Producer Price Index (PPI) Pharmaceuticals for Human Use (Prescription). 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) 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 calendar year. We believe it is appropriate to use the same PPI for Pharmaceuticals for Human Use (Prescription) for the diagnostic radiopharmaceutical packaging threshold, as diagnostic radiopharmaceuticals are also prescription pharmaceuticals for human use. We propose that starting for CY 2026, we would use the most recently available four quarter moving average PPI levels to trend the final CY 2025 threshold forward from the third quarter of CY 2024 to the third quarter of CY 2025 and round the resulting dollar amount to the nearest \$5 increment. This proposal to update the diagnostic radiopharmaceutical packaging threshold maintains consistency with our longstanding methodology for updating the OPPS drug packaging

threshold, which is discussed in more detail in section V.B.1.a. of this rule and also in the CY 2007 OPPTS/ASC final rule with comment period (71 FR 68085 and 68086).

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

Once we determine that the per day cost of a nonpass-through diagnostic radiopharmaceutical exceeds the proposed cost threshold of \$630 per day for CY 2025, we then propose to assign that radiopharmaceutical to an APC, making it a specified covered outpatient drug (SCOD) per section 1833(t)(14)(B) of the Act. Accordingly, we 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 find that the ASP data we have is not usable for payment purposes. As previously mentioned, radiopharmaceuticals are not required to report ASP under 1847A, and as such, there are very few manufacturers reporting ASP for their products currently. Of those few manufacturers reporting ASP, the ASP values that we do have generally do not align with the ASP we would expect based on the cost and MUC data submitted to CMS by hospitals. For example, a frequently used diagnostic radiopharmaceutical has a reported ASP that is over 23,000 percent higher than the MUC derived from claims data. As manufacturers of diagnostic radiopharmaceuticals may be unaware of the correct reporting requirements, we believe it would be inappropriate to propose to pay for separately payable diagnostic radiopharmaceuticals based on their ASPs as currently reported, without giving manufacturers the opportunity to submit, certify, or restate the ASPs of their products. We believe 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.

Under our policy for therapeutic radiopharmaceuticals (74 FR 60520), there are several requirements for reporting ASP. For example, ASP data submitted would need to be provided for a patient-specific dose, or patient-ready form, of the radiopharmaceutical in order to properly

calculate the ASP amount for a given HCPCS code if that HCPCS code dose descriptor was per study dose or similar. ASP data submitted should align with the code's dose descriptor and billing unit. We stated we would expect that the ASP data reported by a manufacturer would be representative of the item(s) sold by the manufacturer. We used the term "patient-ready" in that rule to ensure that ASP data submitted for OPPS payment purposes for separately payable radiopharmaceuticals reflect the costs of all the component materials of the finished radiopharmaceutical product. We expect that the ASP data would represent the sales price of all of the component materials of the finished radiopharmaceutical product sold by the manufacturer in terms that reflect the applicable HCPCS code descriptor such as "per study dose", "per millicurie" and "up to XX millicuries." For the few manufacturers currently reporting ASP data for their diagnostic radiopharmaceuticals, we believe it may be possible that they are not aware of the reporting requirements or are unaware of how to properly report ASP for their product, as CMS has not used ASP as the basis of payment for non-passthrough diagnostic radiopharmaceuticals before. Therefore, we believe a reasonable alternative for separate payment of diagnostic radiopharmaceuticals that exceed the per day cost threshold is the use of their mean unit cost from claims data. This is consistent with our current practice for therapeutic radiopharmaceuticals when ASP data is not available. For diagnostic radiopharmaceuticals, we believe that ASP data is effectively not available for purposes of determining a payment amount and, therefore, payment based on MUC is a reasonable alternative.

We previously acknowledged (74 FR 35335), and continue to acknowledge, the complexities associated with reporting ASP for radiopharmaceuticals. We encourage manufacturers to submit ASP information for diagnostic radiopharmaceuticals, if possible. While CMS is proposing to use MUC to pay for separately payable diagnostic radiopharmaceuticals in CY 2025, manufacturers can begin, or continue, to report ASP data for potential future use in paying for diagnostic radiopharmaceuticals. For CY 2025, 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. If manufacturers choose to report ASP data, the data must meet reporting requirements in order to be used for payment under the OPSS.

Manufacturers that choose to report ASP data for their diagnostic radiopharmaceuticals would need to provide comprehensive data in order for CMS to calculate an ASP amount for a given HCPCS code. In instances where there is more than one manufacturer of a particular diagnostic radiopharmaceutical, we propose that all manufacturers would need to submit ASP information in order for payment to be made based on ASP. This is because it would be inappropriate for Medicare payment for a HCPCS code to be based on the payment information submitted by one manufacturer, if that payment is used for a product made by different manufacturers. This is because the ASP information reported by one manufacturer might not reflect the ASP of the same product made by other manufacturers.

We note that ASP submissions for radiopharmaceutical payment under the OPSS would need to meet all of the existing regulatory and subregulatory requirements of the ASP reporting process under sections 1847A and 1927(b)(3) of the Act.

Specifically, we reiterate our ASP reporting requirements outlined in the CY 2010 OPSS/ASC final rule with comment period (74 FR 60520) for products for which we are encouraging the reporting of ASP, but for which reporting is not statutorily required. The ASP data submitted would need to be provided for a patient-specific dose, or patient-ready form, of the diagnostic radiopharmaceutical in order to properly calculate the ASP amount that aligns with the dose descriptor for a given HCPCS code. When reporting an ASP for a separately payable radiopharmaceutical, we expect that the ASP data reported by a manufacturer would be representative of the item(s) sold by the manufacturer. In the CY 2010 OPSS/ASC final rule with comment period (74 FR 60520), we used the term “patient-ready” to ensure that ASP data submitted for OPSS payment purposes for separately payable radiopharmaceuticals reflect the costs of all the component materials of the finished radiopharmaceutical product. We expect that

the ASP data would represent the sales price of all of the component materials of the finished radiopharmaceutical product sold by the manufacturer in terms that reflect the applicable HCPCS code descriptor, such as “per study dose” or “millicurie.” We defined a “patient-ready” dose for OPPS purposes as including all component materials of the radiopharmaceutical, at a minimum, and any other processing the manufacturer requires to produce the radiopharmaceutical that it sells that are reflected in the sales price, including radiolabeling, as long as any fees paid for such processing done on behalf of the manufacturer meet the definition of “bona fide service fees” under § 414.802 (74 FR 60525).

We understand that manufacturers of separately payable radiopharmaceuticals produce radiopharmaceuticals that require a variety of processing steps in order to prepare the product for administration to a beneficiary. To be used for separate OPPS radiopharmaceutical payment, the ASP data reported by a manufacturer must represent sales of all of the component materials associated with the radiopharmaceutical. For our full policy on which factors to incorporate into ASP pricing, please see the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521).

In order to be used for payment under the OPPS, all radiopharmaceutical ASP submissions should meet the existing regulatory and subregulatory requirements of the ASP submission process under sections 1847A and 1927(b)(3) of the Act. In particular, we believe the “bona fide service fee” test in the ASP regulations is instructive here, and we refer readers to the CY 2010 OPPS/ASC final rule with comment period for our discussion on radiopharmaceutical ASP reporting (74 FR 60521).

To summarize our CY 2010 policy for ASP reporting on radiopharmaceuticals for OPPS payment purposes (74 FR 60521), a patient-specific dose or patient-ready form in the context of OPPS ASP submission for radiopharmaceutical payment means that the ASP reflecting manufacturer sales must represent sales of all of the component materials for the radiopharmaceutical, including a minimum of a cold kit and a radioisotope, and be reported in

terms that reflect the applicable HCPCS code descriptor, such as “treatment dose” or “millicurie.” The ASP would not necessarily take into account the preparation of the final form of the radiopharmaceutical for patient administration, including radiolabeling, which may be conducted by the manufacturer, freestanding radiopharmacy, hospital pharmacy, or other entity. With respect to the latter, fees paid by the manufacturer for these services would be excluded from the ASP calculation (that is, would not be considered price concessions that reduce the ASP) only if they are “bona fide service fees” as defined in the regulations governing ASP. Thus, if the manufacturer pays a “bona fide service fee” for the services of the freestanding radiopharmacy, hospital pharmacy, or other entity, and reflects that fee in its price for the radiopharmaceutical, the amount of the “bona fide service fee” would be taken into account in the reported ASP data. However, manufacturers are not required to pay for the preparation of a radiopharmaceutical (including radiolabeling) in a freestanding radiopharmacy, hospital pharmacy, or other entity after sale of all of the component materials, and in that case, the cost of those services would not be reflected in the ASP data submitted to CMS. Manufacturers should submit ASP data for a separately payable radiopharmaceutical that incorporates prices for sales of all of the component materials by the manufacturer. We seek comment on these ASP reporting requirements outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60521) and previous CMS guidance on the guidelines for the Submission of OPPS ASP Data for Nonpass-Through Separately Payable Therapeutic Radiopharmaceuticals and Radiopharmaceuticals with Pass-Through Status.⁷ We continue to believe that these ASP reporting practices should be applicable to radiopharmaceuticals, including both therapeutic and diagnostic radiopharmaceuticals, but seek comment from interested parties in this space to ensure that these reporting guidelines are clear and reflective of clinical practice today.

⁷ https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/opps_asp_radiopharm_guidance10302009.pdf

We still see the 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 believe that the use of ASP information for OPSS 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 OPSS for other separately payable drugs and biologicals, as well as therapeutic radiopharmaceuticals. Because the per day cost calculations determine whether a diagnostic radiopharmaceutical qualifies for separate payment, using the most accurate pricing information is paramount. The use of ASP information could provide an opportunity to further improve the accuracy of the per day cost calculations and the separate payment amounts for diagnostic radiopharmaceuticals. As previously mentioned, we do not believe that the limited amount of ASP information submitted currently is adequate for the purpose of determining separate payment for those few products that currently do report ASP, which is why we are proposing to pay diagnostic radiopharmaceuticals with per day costs above the proposed \$630 threshold at each diagnostic radiopharmaceutical's mean unit cost. However, we are still interested in the potential to use ASP for the purpose of determining a diagnostic radiopharmaceutical's per day cost and payment amount in the future. Therefore, we want to engage with interested parties to learn about the unique aspects and challenges that may be associated with reporting ASP for diagnostic radiopharmaceuticals, and radiopharmaceuticals in general. We specifically seek comment as to whether interested parties believe CMS should require payment for diagnostic radiopharmaceuticals on ASP in the future, such as in CY 2026 rulemaking, if interested parties are confident in their reporting ability.

We do believe that there could be situations in which it is appropriate to use ASP currently. For example, in section V.A.4. of this proposed rule, we propose to utilize ASP in payment for diagnostic radiopharmaceuticals on OPSS transitional pass-through status. In this situation, we believe the use of ASP is appropriate as the manufacturer of that diagnostic

radiopharmaceutical is actively involved in the radiopharmaceutical's pass-through application, and CMS can ensure that pricing is reported appropriately for purposes of the drug pass-through cost significance tests and for purposes of payment if the pass-through status is approved.

Typically, there is only one manufacturer for a diagnostic radiopharmaceutical applying for pass-through status, 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, as discussed in section V.B.5. (Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but Without OPPS Hospital Claims Data) of this rule, we propose to base the initial payment for new diagnostic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on ASP, and on the WAC for these products if ASP data for these diagnostic radiopharmaceuticals are not available. If the WAC also is unavailable, we propose 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 until a MUC is available. Similar to drugs applying for pass-through status, 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.

We seek comments on additional unique situations in which it still may be appropriate for CMS to use ASP information to assess per day costs and payment amounts for diagnostic radiopharmaceuticals for CY 2025. For example, one such unique situation could be continuing the use of ASP for a particular HCPCS code once its pass-through status has ended, if the HCPCS code was actively being paid based on ASP while on pass-through status. Under our current proposal, payment for a diagnostic radiopharmaceutical would be based on MUC once its pass-through status ends. We seek comment on this potential unique situation, as well as others of which readers may be aware, and we may finalize utilizing ASP in additional situations that commenters bring to our attention in the final rule as policies for CY 2025 depending on comments received.

As discussed, we propose to base the payment rate for diagnostic radiopharmaceuticals on mean unit cost data derived from hospital claims. We are not proposing to use ASP data for determining payment rates of non-passthrough diagnostic radiopharmaceuticals with claims data but are seeking comment on its use for determining the per day cost and setting the payment rate for diagnostic radiopharmaceuticals in the future. Additionally, we are not proposing to use WAC or AWP as a basis for payment for diagnostic radiopharmaceuticals. Similar to our reasoning for payment of therapeutic radiopharmaceuticals in the CY 2012 OPPS/ASC final rule with comment period (77 FR 68390), we believe that paying for diagnostic radiopharmaceuticals using mean unit cost would appropriately pay for the average price of nonpass-through separately payable diagnostic radiopharmaceuticals for the applicable year. We believe 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 average therapeutic radiopharmaceutical acquisition cost and associated handling costs when

manufacturers are not required to submit ASP data because payment based on WAC or AWP for separately payable drugs and biologicals is usually temporary for a calendar quarter until a manufacturer is able to submit the required ASP data in accordance with the quarterly ASP submission timeframes for reporting under section 1847A of the Act. However, WAC and AWP reported to compendia may not be reflective of a patient ready dose. We are additionally concerned about the use of WAC and AWP since ASP reporting for OPSS payment of separately payable diagnostic radiopharmaceuticals would not be required for CY 2025. 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.

Given all of the concerns we currently have with other pricing methodologies for diagnostic radiopharmaceuticals, we propose to rely on CY 2023 mean unit cost data derived from hospital claims data for payment rates for diagnostic radiopharmaceuticals for CY 2025.

Our proposed payment methodology for diagnostic radiopharmaceuticals that have costs above a \$630 threshold would be similar, but not the same as the methodology adopted for therapeutic radiopharmaceuticals as described in the CY 2010 OPSS/ASC final rule with comment period (74 FR 60518). Although therapeutic radiopharmaceuticals are generally targeted at treating a certain disease or condition, and diagnostic radiopharmaceuticals are generally targeted at diagnosing a certain disease or condition, we believe they are clinically very similar products, manufactured in a similar manner, and should generally be paid using a similar payment methodology when paid separately. As such, we believe the same payment method as is used for therapeutic radiopharmaceuticals should apply to diagnostic radiopharmaceuticals above the cost threshold. However, as previously discussed, given our concerns with current ASP reporting patterns, we are proposing to use MUC as the basis of payment for non-passthrough diagnostic radiopharmaceuticals for CY 2025. Therefore, we believe it is

appropriate for the methodology to determine the proposed payment amounts to differ between diagnostic and therapeutic radiopharmaceuticals, at least for CY 2025. We will consider aligning the payment methodologies between therapeutic and diagnostic radiopharmaceuticals, either based on ASP or MUC, in future rulemaking.

We believe mean unit cost data is an appropriate and adequate proxy for the average price for diagnostic radiopharmaceuticals and associated handling costs for these products. Mean unit cost data is reflective of the actual cost data that hospitals submit to CMS. The MUC payment methodology is consistent with our payment policy for therapeutic radiopharmaceuticals as stated in the CY 2010 OPPI/ASC final rule with comment period (74 FR 60523) and is the basis for payment of many therapeutic radiopharmaceuticals when ASP is unavailable currently.

As previously discussed, we find that the ASP data we have is not usable for the purpose of paying for diagnostic radiopharmaceuticals and, therefore, we are proposing to pay for qualifying non-passthrough diagnostic radiopharmaceuticals with claims data based on MUC. However, we are also seeking comment on how we could potentially use our equitable adjustment authority at section 1833(t)(2)(E) of the Act to make an adjustment to the ASP data that has been reported in order to make it usable for the purpose of paying equitably for these products. For example, we seek comment as to whether CMS could use its equitable adjustment authority to adjust payment for diagnostic radiopharmaceuticals based on an adjusted ASP value when the ASP amounts reported to CMS deviate by a given threshold, such as two times the MUC calculated for the diagnostic radiopharmaceutical using claims data. Alternatively, the adjusted payment rate could be an average of the reported ASP and MUC, or other methodologies suggested by commenters. We broadly seek comment on this potential use of equitable adjustment authority to make the limited ASP data reported for diagnostic radiopharmaceuticals usable for purposes of setting payment rates for qualifying products.

We note, if readers do not believe it is appropriate for CMS to base the payment amount for diagnostic radiopharmaceuticals on MUC for CY 2025, we would propose in the alternative to maintain our current policy of unconditionally policy packaging all diagnostic radiopharmaceuticals regardless of their cost until an appropriate payment methodology can be established to determine a separate payment amount for diagnostic radiopharmaceuticals.

HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that meet or exceed the proposed diagnostic radiopharmaceutical packaging threshold would be assigned to a status indicator of “K”, indicating separate payment. An APC and a 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 would continue to be assigned to a status indicator of “N”, indicating packaged payment. We welcome comment on these determinations. The proposed list of diagnostic radiopharmaceuticals that have calculated per day costs that exceed \$630 and their proposed status indicators can be found in table 5.

TABLE 5: Proposed Qualifying Diagnostic Radiopharmaceuticals with Per Day Costs Exceeding \$630

HCPCS Code	Short Descriptor	Proposed CY 2025 Status Indicator Assignment
A9515	Choline c-11	K
A9521	Tc99m exametazime	K
A9542	In111 ibritumomab, dx	K
A9547	In111 oxyquinoline	K
A9548	In111 pentetate	K
A9557	Tc99m bicisate	K
A9568	Technetium tc99m arcitumomab	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**
A9800	Gallium locametz 1 millicuri	K***
C9067	Gallium ga-68 dotatoc	K
Q9982	Flutemetamol f18 diagnostic	K
Q9983	Florbetaben f18 diagnostic	K

*HCPCS code A9596 will be assigned to status indicator “G” until its pass through expiration on 06/30/2025. For the remainder of CY 2025, we would propose to assign it to status indicator “K.”

**HCPCS code A9602 will be assigned to status indicator “G” until its pass through expiration on 09/30/2025. For the remainder of CY 2025, we would propose to assign it to status indicator “K.”

***HCPCS code A9800 will be assigned to status indicator “G” until its pass through expiration on 09/30/2025. For the remainder of CY 2025, we would propose to assign it to status indicator “K.”

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.

We propose corresponding regulation text edits at § 419.2(b)(15) to only package diagnostic radiopharmaceuticals when their per day cost is at or below the per day diagnostic radiopharmaceutical packaging threshold for the applicable year. This is achieved by adding the text “at or below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year” to qualify the packaging of diagnostic radiopharmaceuticals. We also propose corresponding regulation text edits at § 419.41 (Calculation of national beneficiary copayment amounts and national Medicare program payment amounts) to codify our proposed payment policy for diagnostic radiopharmaceuticals and our existing policy for therapeutic radiopharmaceuticals.

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

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.

As the additional payments are required to begin on January 1, 2025, we propose to implement the CAA, 2023 section 4135 amendments in this proposed rule. Our proposal to implement section 4135 of CAA, 2023 can be found in section XIII.E of this proposed rule.

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 2024 OPPS/ASC final rule with comment period (88 FR 81577 through 81578), we applied this policy and calculated the relative payment weights for each APC for CY 2024 that were shown in Addenda A and B of the CY 2024 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 2024 OPPS/ASC final rule with comment period (88 FR 81549 through 81572). For CY 2025, as we did for CY 2024, we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2025 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 OPSS 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 OPSS (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 2025, as we did for CY 2024, we propose to continue to standardize all of 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 OPSS services. For CY 2025, as we did for CY 2024, 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 OPSS 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 OPSS for CY 2025 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 proposed to compare the estimated aggregate weight using the CY 2024 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2025 unscaled relative payment weights.

For CY 2024, we multiplied the CY 2024 scaled APC relative payment weight applicable to a service paid under the OPSS by the volume of that service from CY 2023 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 in order to calculate an estimated aggregate weight for the year. For CY 2025, we propose to apply the same process using the estimated CY 2025 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2024 estimated aggregate weight by the unscaled CY 2025 estimated aggregate weight.

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

<https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>. Click on the link labeled “Hospital Outpatient Prospective Payment- Notice of Proposed Rulemaking with Comment Period (NPRM)” for 2025, which can be found under the heading “Hospital Outpatient Regulations and Notices” and open the claims accounting document link, which is labeled “2025 NPRM OPSS Claims Accounting (PDF).”

We propose to compare the estimated unscaled relative payment weights in CY 2025 to the estimated total relative payment weights in CY 2024 using CY 2023 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 2025 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2025 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4405 to ensure that the proposed CY 2025 relative payment weights are scaled to be budget neutral. The proposed CY 2025 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website) 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 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 2025 OPSS.

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 OPSS 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 under section 1886(b)(3)(B)(iii) of the Act. In the FY 2025 IPPS/Long Term Care Hospital (LTCH) PPS proposed rule (89 FR 36204), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2023 forecast, the proposed FY 2025 IPPS market basket percentage increase was 3.0 percent. We note that under our regular process for the CY 2025 OPSS/ASC final rule with comment period, we would use the market basket update for the FY 2025 IPPS/LTCH PPS final rule. If that forecast is different than the IPPS market basket percentage increase used for this proposed rule, the CY 2025 OPSS/ASC final rule with comment period OPD fee schedule increase factor would reflect that updated forecast of the market basket percentage increase.

For CY 2025, we propose to use the estimate of the hospital inpatient market basket percentage increase of 3.0 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 2025 IPPS/LTCH PPS proposed rule (89 FR 36204), the proposed productivity adjustment for FY 2025 was 0.4 percentage point.

Therefore, we propose that the productivity adjustment for the CY 2025 OPPS/ASC would be 0.4 percentage point. We also propose that if more recent data subsequently became

available after the publication of the CY 2025 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 updated data, if appropriate, to determine the CY 2025 hospital inpatient market basket update and the productivity adjustment, 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 propose for CY 2025 an OPD fee schedule increase factor of 2.6 percent for the CY 2025 OPPS/ASC (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.0 percent, less the proposed 0.4 percentage point productivity adjustment).

3. Other Conversion Factor Adjustments

To set the OPPS conversion factor for 2025, we propose to increase the CY 2024 conversion factor of \$87.382 by 2.6 percent. In accordance with section 1833(t)(9)(B) of the Act, we propose further to adjust the conversion factor for CY 2025 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We propose to calculate an overall budget neutrality factor of 1.0026 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2025 IPPS wage indexes to those payments using the FY 2024 IPPS wage indexes, as adopted on a calendar year basis for the OPPS. We further propose to calculate an additional budget neutrality factor of 0.9982 to account for our proposed policy to cap wage index reductions for hospitals at 5 percent on an annual basis.

For CY 2025, we propose to maintain the current rural adjustment policy, as discussed in section II.E of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

We propose to calculate a CY 2025 budget neutrality adjustment factor for the cancer hospital payment adjustment by transitioning from the target PCR of 0.89 we finalized 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. Therefore, we propose to apply a budget neutrality adjustment factor of 1.0006 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act (Pub. L. 114-255), we reduce the target PCR by 0.01, which brings the proposed target PCR to 0.87. This is 0.02 less than the target PCR of 0.89 from CY 2021 through CY 2023, which was held at the pre-PHE target.

For this proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2025 would equal approximately \$625 million, which represents 0.71 percent of total projected CY 2025 OPPS spending. Therefore, we stated that the proposed conversion factor would be adjusted by the difference between the 0.27 percent estimate of pass-through spending for CY 2024 and the 0.71 percent estimate of proposed pass-through spending for CY 2025, resulting in a proposed decrease to the conversion factor for CY 2025 of 0.44 percent.

We propose that estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2025. We estimated for this proposed rule that outlier payments would be approximately 0.85 percent of total OPPS payments in CY 2024; the 1.00 percent for proposed outlier payments in CY 2025 would constitute a 0.15 percent increase in payment in CY 2025 relative to CY 2024.

For 2025, we propose to use a conversion factor of \$87.382 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 2.6 percent for CY 2025, the required proposed wage index budget neutrality adjustment of approximately 1.0026, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9982, the proposed cancer hospital payment adjustment of 1.0006, and the proposed adjustment of a decrease of 0.44 percentage point of projected OPPS spending for the difference in pass-through spending, which resulted in a proposed conversion factor for CY 2025 of \$89.379.

For CY 2025, 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, but use a reduced OPD fee schedule update factor of 0.6 percent (that is, the proposed OPD fee schedule increase factor of 2.6 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2025 of \$87.636 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.743 in the conversion factor relative to hospitals that met the requirements). For further discussion of the Hospital OQR Program, we refer readers to section XV of this proposed rule. For 2025, we propose to use a reduced conversion factor of \$87.636 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.743 in the conversion factor relative to hospitals that met the requirements).

The calculations we performed to determine the CY 2025 proposed conversion factor are shown in Table 6.

TABLE 6: CALCULATION OF CY 2025 PROPOSED OPPS CONVERSION FACTOR

<i>Start:</i> CY 2024 Final OPPS Conversion Factor = \$87.382
<i>Step 1a:</i> Adjust the conversion factor to temporarily account for additional drug and device pass-through spending and outlier spending in CY 2024. This action causes an increase in the conversion factor. So, the amount of both drug and device pass-through spending (0.0027) 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 2024.

➤ $1.0000 - (0.0027 + 0.01) = 0.9873$

Step 1b: Divide \$87.382 by 0.9873

➤ $\$87.382 / 0.9873 = \mathbf{\$88.506}$

Step 2: Adjust the conversion factor by the required wage index budget neutrality adjustment of approximately 1.0026. This adjustment increases the amount of OPPS outpatient hospital spending and is multiplied with \$88.506.

➤ $\$88.506 * 1.0026 = \mathbf{\$88.736}$

Step 3: Adjust the conversion factor by the 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9982. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with \$88.736.

➤ $\$88.736 * 0.9982 = \mathbf{\$88.576}$

Step 4: Adjust the conversion factor by the cancer hospital payment adjustment of 1.0006. Because the PCR for cancer hospitals is declining between CY 2024 and CY 2025, it increases the amount of OPPS outpatient hospital spending for providers that are not cancer hospitals and is multiplied with \$88.576.

➤ $\$88.576 * 1.0006 = \mathbf{\$88.630}$

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

➤ $\$88.630 * 1.0000 = \mathbf{\$88.630}$

Step 6a: Adjust the conversion factor by the OPD fee schedule increase factor of 0.026 for CY 2025. The OPD fee schedule increase factor increases outpatient hospital spending in CY 2025 over CY 2024 and is added to 1.0000 which represents total outpatient hospital OPSS spending in CY 2024.

➤ $1.0000 + 0.026 = 1.0260$

Step 6b: Multiply \$88.630 by 1.0260.

➤ $\$88.630 * 1.0260 = \mathbf{\$90.934}$

Step 7a: Adjust the conversion factor to remove additional drug and device pass-through spending and outlier spending for CY 2025. This action causes a decrease in the conversion factor. So, the amount of both drug and device pass-through spending (0.0071) and the percentage of outlier spending (0.01) as a share of total OPSS outpatient hospital spending is subtracted from 1.0000, which represents total OPSS outpatient hospital spending for CY 2025.

$$\text{➤ } 1.0000 - (0.0071 + 0.01) = 0.9829$$

Step 7b: Multiply \$90.934 by 0.9829 to get the CY 2025 final OPPS conversion factor.

$$\$90.934 * 0.9829 = \mathbf{\$89.379}$$

Finish: **CY 2025 OPPS Conversion Factor = \$89.379**

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 2025 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 2025 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 42 CFR 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 2025 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 2024 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; and for FY 2024, 88 FR 58977.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2025 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 also propose to continue the low wage index hospital policy, under which we increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We refer readers to the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36181 through 36186) for a detailed discussion of all proposed changes to the FY 2025 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 2025 would not be less than 95 percent of its final wage index for FY 2024. 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).

We delineate hospital labor market areas based on Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget (OMB). As discussed in the FY 2025 IPPS/ LTCH PPS proposed rule (89 FR 36139 through 36174), OMB issued revisions to the current labor market area delineations on July 21, 2023, that included a number of significant changes such as new CBSAs, urban counties that become rural, rural counties that become urban, and existing CBSAs that are split apart (OMB Bulletin 23-01). This bulletin can be found at: <https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf>. The proposed changes to the IPPS wage index based on the newest CBSA delineations are available in the FY 2025 IPPS/ LTCH PPS proposed rule. We propose that corresponding changes would be adopted in the OPSS, which uses the IPPS wage index, based on the new OMB delineations in this CY 2025 OPSS/ASC proposed rule, consistent with any proposals in the FY 2025 IPPS/ LTCH PPS proposed rule. We believe that using the revised delineations based on OMB Bulletin No. 23-01 will increase the integrity of the OPSS wage index system by creating a more accurate representation of current geographic variations in wage levels. We refer readers to

proposed changes based on the new OMB delineations in the FY 2025 IPPS/LTCH proposed rule at 89 FR 36139 through 36174, which includes a discussion of the effects of implementation of the proposal to adopt the revised OMB labor market area delineations on reclassified hospitals.

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 OPSS 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 from 2020. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: <https://www.census.gov/geo/reference/county-changes.html> (which, as of May 6, 2019, migrated to: <https://www.census.gov/programs-surveys/geography.html>). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of cross walking 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 cross walking counties to CBSAs for the OPSS wage index, in the CY 2018 OPSS/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 2025, under the OPSS, we are continuing to use only the FIPS county codes for purposes of cross walking counties to CBSAs.

We propose to use the FY 2025 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPSS to determine the wage adjustments for both the OPSS payment rate and the copayment rate for CY 2025. We note that the proposed FY 2025 IPPS

wage indexes reflect several proposed changes as a result of the revised OMB delineations, including proposed policies to accommodate changes in rural or urban status for existing counties, as well as addition or removal of certain individual CBSAs compared to the previous delineations. Therefore, any policies and adjustments that are finalized for the FY 2025 IPPS post-reclassified wage index would be reflected in the final CY 2025 OPSS wage index beginning on January 1, 2025, if appropriate. We refer readers to the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36181 through 36186) and the proposed FY 2025 hospital wage index files posted on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipp-pps-proposed-rule-home-page>. Regarding budget neutrality for the CY 2025 OPSS 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 OPSS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPSS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPSS, 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 2025. We refer readers to the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36181 through 36186) for a detailed discussion of the proposed changes to the FY 2025 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPSS 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 OPSS. 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 2025, we propose to continue our policy of allowing non-IPPS hospitals paid under the OPSS 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 2025 to non-IPPS hospitals paid under the OPSS would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, we propose that the wage index that would apply to non-IPPS hospitals paid under the OPSS would include the 5-percent cap on wage index decreases.

For CMHCs, for CY 2025, 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 2025 would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. 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 2025 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-2025-ipp-pps-proposed-rule-home-page>) identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2025 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 2025. We are including the outmigration adjustment information from Table 2 associated with the FY 2025 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 OPSS at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>. At this link, readers will find a link to the proposed FY 2025 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 OPSS 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 OPSS/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 CY 2025 OPSS/ASC proposed rule, which is posted on our website. We propose to calculate the default ratios for CY 2025 using the most recent cost report data.

We no longer publish a table in the **Federal Register** containing the statewide average CCRs in the annual OPPTS proposed rule and final rule with comment period. These CCRs with the upper limit will be available for download with each OPPTS CY proposed rule and final rule on the CMS website. We refer readers to our website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>; 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 limit 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 2025

In the CY 2006 OPPTS 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 OPPTS, 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 OPPTS 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 OPPTS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPTS, 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 OPPTS/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 2024.

For CY 2025, 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 2025

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), 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 OPSS 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 OPSS than the payment amount they would have received before implementation of the OPSS, 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 OPSS, 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 7 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2024.

TABLE 7: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT-TO-COST RATIOS (PCRS), CY 2012 THROUGH CY 2024

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

2. Proposed Policy for CY 2025

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 target PCR adjustment be reduced by 1.0 percentage point less than what would otherwise apply. Section 16002(b) 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, 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, and adjusted by the proposed post-Public Health Emergency (PHE)

transition as described later in this section. 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 2025.

To calculate the proposed CY 2025 target PCR, we would use the same extract of cost report data from HCRIS used to estimate costs for the CY 2025 OPSS 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 2023 claims data that we used to model the impact of the proposed CY 2025 APC relative payment weights (3,448 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2025 OPSS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2019 to 2023; however, the cost reporting periods were predominantly from fiscal years ending in 2022 and 2023. 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 OPSS, and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 16 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPSS 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 3,421 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPSS payments to other hospitals furnishing services under the OPSS were approximately 87 percent of reasonable cost (weighted average PCR of 0.87). 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 0.86 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 for the CY 2025 OPPS/ASC proposed rule, since the target PCR that would otherwise apply under our standard process would be a target PCR of 0.86, we propose to reduce the CY 2024 target PCR of 0.88 by 1 percentage point and propose a cancer hospital target PCR of 0.87 for CY 2025.

Table 8 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2025, due to the cancer hospital payment adjustment policy. The actual, final amount of the CY 2025 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2025 payments and costs from the settled CY 2025 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 8: ESTIMATED CY 2025 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 2025 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	51.5%
050660	USC Norris Cancer Hospital	44.3%
100079	Sylvester Comprehensive Cancer Center	32.4%
100271	H. Lee Moffitt Cancer Center & Research Institute	23.9%
220162	Dana-Farber Cancer Institute	46.6%
330154	Memorial Sloan-Kettering Cancer Center	56.3%
330354	Roswell Park Cancer Institute	21.3%
360242	James Cancer Hospital & Solove Research Institute	16.0%
390196	Fox Chase Cancer Center	30.0%
450076	M.D. Anderson Cancer Center	45.1%
500138	Seattle Cancer Care Alliance	47.7%

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPSS 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 OPSS/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 OPSS 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 2024, 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 \$7,750 (the fixed-dollar amount threshold) (88 FR 81589 through 81591). 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 OPSS/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 OPSS. Our estimate of total outlier payments as a percent of total CY 2023 OPSS payments, using CY 2023 claims available for this CY 2025 OPSS proposed rule, is approximately 0.68 percent. Therefore, for CY 2023, we estimate that we did not meet the outlier target by 0.32 percent of total aggregated OPSS payments.

For this proposed rule, using CY 2023 claims data and CY 2024 payment rates, we estimate that the aggregate outlier payments for CY 2024 would be approximately 0.85 percent of the total CY 2024 OPSS payments. We provide estimated CY 2025 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. Outlier Calculation for CY 2025

For CY 2025, we propose to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPSS. 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 OPSS 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 OPSS 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 2025 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPSS, 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 calculated the proposed fixed-dollar threshold using the standard methodology most recently used for CY 2024 (88 FR 81589 through 81591). For purposes of estimating outlier payments for CY 2025, we use the hospital-specific overall ancillary CCRs available in the April 2024 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 OPSS Pricer to pay claims. The claims that we generally use to model each OPSS update lag by 2 years.

In order to estimate the CY 2025 hospital outlier payments, we inflate the charges on the CY 2023 claims using the same proposed charge inflation factor of 1.084555 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572). We used an inflation factor of 1.04142 to estimate CY 2024 charges from the CY 2023 charges reported on CY 2023 claims before applying CY 2024 CCRs to estimate the percent of outliers paid in CY 2024. The proposed methodology for determining these charge inflation factors is discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572). As

we stated in the CY 2005 OPSS 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 OPSS 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 OPSS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPSS 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 2025 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2025 OPSS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2025, we propose to apply an adjustment factor of 1.03331 to the CCRs that were in the April 2024 OPSF to trend them forward from CY 2024 to CY 2025. The methodology for calculating the proposed CCR adjustment factor is discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572 through 36573).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2024 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 1.03331 to approximate CY 2025 CCRs) to charges on CY 2023 claims that were adjusted (using the proposed charge inflation factor of 1.084555 to approximate CY 2025 charges). We simulated aggregated CY 2023 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 2025 OPSS payments. We estimated that a proposed fixed-dollar threshold of \$8,000, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPSS payments to outlier payments. 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 proposed 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 OPSS 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 OPSS 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 via the CMS website "[Hospital Outpatient Regulations and Notices](#)") and for most

HCPCS codes to which separate payment under the OPSS has been assigned in Addendum B to this proposed rule (which is available on the CMS website link above) is calculated by multiplying the proposed CY 2025 scaled weight for the APC by the CY 2025 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 OPSS 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 0.9805 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/ASC 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.

$X = .60 * (\text{national unadjusted payment rate}).$

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 2025 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. We are continuing to apply for the CY 2025 OPSS wage index any adjustments for the FY 2025 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment, a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010, and an adjustment to the wage index for certain low wage index hospitals. For further discussion of the wage index we are applying for the CY 2025 OPSS, 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 2025 IPPS wage index, which are listed in Table 3 associated with the FY 2025 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 2025 IPPS Proposed Rule Home Page” and select “FY 2025 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).

$X_a = \text{labor-portion of the national unadjusted payment rate} * \text{applicable wage index.}$

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.

$Y = 0.40 * (\text{national unadjusted payment rate}).$

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.

$\text{Adjusted Medicare Payment (SCH or EACH)} = \text{Adjusted Medicare Payment} * 1.071.$

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.

$$\text{Adjusted Medicare Payment} = X_a + Y$$

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 2025 full national unadjusted payment rate for APC 5071 is \$700.10. The proposed reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is \$686.45. 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 \$420.06 ($0.60 * \700.10). The labor-related portion of the proposed reduced national adjusted payment is approximately \$411.87 ($0.60 * \686.45).

Step 2 & 3. The FY 2025 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of the proposed IPPS 2025 wage index policies, is 1.2867.

Step 4. The wage adjusted labor-related portion of the proposed full national unadjusted payment is approximately \$540.49 ($\$420.06 * 1.2867$). The wage adjusted labor-related portion of the proposed reduced national adjusted payment is approximately \$529.95 ($\$411.87 * 1.2867$).

Step 5. The nonlabor-related portion of the proposed full national unadjusted payment is approximately \$280.04 ($0.40 * \700.10). The nonlabor-related portion of the proposed reduced national adjusted payment is approximately \$274.58 ($0.40 * \686.45).

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 \$820.53 ($\$540.49 + \280.04). The sum of the

portions of the proposed reduced national adjusted payment is approximately \$804.53 (\$529.95 + \$274.58) as shown in Table 9.

TABLE 9: 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
\$820.53	\$804.53

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 OPDS 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 OPPTS/ASC final rule with comment period (75 FR 72013).

Section 122 of the Consolidated Appropriations Act (CAA) of 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 OPPTS/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 thus far have primarily been implemented through program instruction, as permitted under section 1847A(c)(5)(C) of the Act. As such, we issued guidance for 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 on

February 9, 2023.^{8,9} 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, 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 OPSS 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 OPSS, 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 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

⁸ <https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf>

⁹ 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>

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 OPSS, 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.

In the CY 2024 OPSS/ASC final rule with comment period (88 FR 81594), we codified the OPSS program payment and cost sharing amounts for Part B rebatable drugs as required by section 1833(t)(8)(F) 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 Medicare PFS proposed rule, CMS proposes to adopt 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. This proposed new provision includes references to the existing provisions at §§ 410.152(m), 419.41(e), and 489.30(b)(6) of this title. CMS further proposes at § 427.201(c) 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.

Additionally, CMS proposes at § 427.201(b) that CMS will use the published payment amount in quarterly pricing files^{10, 11, 12} to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance equal to 20 percent of the inflation-adjusted payment amount as described in section 1847A(i)(3)(C) for a calendar quarter. This proposed approach deviates from the rebate calculation approach proposed 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. The approach proposed at § 427.201(b) would be used only to determine whether there should be a coinsurance adjustment and would not impact the applicability or calculation of inflation rebates. CMS believes this approach is consistent with

¹⁰ See: <https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files>.

¹¹ See: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates>.

¹² See: <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda>.

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 CY 2025 Medicare PFS proposed rule for a detailed discussion of proposals related to the Part B inflation rebates, including inflation-adjusted beneficiary coinsurance and Medicare payment for Medicare Part B rebatable drugs.

2. Proposed OPPS Copayment Policy

For CY 2025, 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 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, 2025, 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 2025, 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 OPSS 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 OPSS cost modeling process. However, as described in the CY 2004 OPSS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPSS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPSS 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 OPSS 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 OPSS 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 OPSS payment rate for all OPSS 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, \$140.02 is approximately 20 percent of the full national unadjusted payment rate of \$700.10.

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.

$B = \text{National unadjusted copayment for APC} / \text{national unadjusted payment rate for APC}.$

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 with comment period. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H of this final rule with comment period.

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.

$\text{Wage-adjusted copayment amount for the APC} = \text{Adjusted Medicare Payment} * B.$

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

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 OPSS that would be effective January 1, 2025, are shown in Addenda A and B to 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 proposed CY 2025 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, HCPCS codes, that are reported on 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 OPSS are published through the annual rulemaking cycle and through the OPSS 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 OPSS 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 OPSS/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 OPSS, 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 OPSS 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 2025 Payment Status and Comment Indicators” of this proposed rule, we discuss the various status indicators and comment indicators used under the OPSS. We also provide a complete list of the proposed status indicators and their definitions in Addendum D1 to this proposed rule.

1. April 2024 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2024 update, 73 new HCPCS codes were established and made effective on April 1, 2024. Through the April 2024 OPSS quarterly update CR (Transmittal 12552, Change Request 13568, dated March 21, 2024), we recognized several new HCPCS codes for payment under the OPSS. 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 April 1, 2024). 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, 2024, 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 OPSS 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 OPSS Addendum B (OPSS payment file by HCPCS code), Addendum D1 (OPSS Status Indicators), and Addendum D2 (OPSS Comment Indicators) are available via the CMS website.

TABLE 10: NEW HCPCS CODES EFFECTIVE APRIL 1, 2024

CY 2025 HCPCS Code	CY 2024 Long Descriptor
A2026	Restrata minimatrix, 5 mg
A4271	Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per month
A4438	Adhesive clip applied to the skin to secure external electrical nerve stimulator controller, each
A4564	Pessary, disposable, any type
A4593	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, controller
A4594	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, mouthpiece each
A9293	Fertility cycle (contraception & conception) tracking software application, FDA cleared, per month, includes accessories (e.g., thermometer)
C9166	Injection, secukinumab, intravenous, 1 mg
C9167	Injection, adamts13, recombinant-krhn, 10 iu
C9168	Injection, mirikizumab-mrkz, 1 mg

C9796	Repair of enterocutaneous fistula small intestine or colon (excluding anorectal fistula) with plug (e.g., porcine small intestine submucosa [SIS])
C9797	Vascular embolization or occlusion procedure 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 intervention; for tumors, organ ischemia, or infarction
E0152	Walker, battery powered, wheeled, folding, adjustable or fixed height
E0468	Home ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions
E0736	Transcutaneous tibial nerve stimulator
E0738	Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories
E0739	Rehab system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors
E2104	Home blood glucose monitor for use with integrated lancing/blood sample testing cartridge
E2298	Complex rehabilitative power wheelchair accessory, power seat elevation system, any type
G0138	Intravenous infusion of cipaglucosidase alfa-atga, including provider/supplier acquisition and clinical supervision of oral administration of miglustat in preparation of receipt of cipaglucosidase alfa-atga
H0051	Traditional healing service
J0177	Injection, aflibercept hd, 1 mg
J0209	Injection, sodium thiosulfate (hope), 100 mg
J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy
J0578	Injection, buprenorphine extended-release (brixadi), greater than 7 days of therapy and up to 28 days of therapy
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit
J0650	Injection, levothyroxine sodium, not otherwise specified, 10 mcg
J0651	Injection, levothyroxine sodium (fresenius kabi), not therapeutically equivalent to J0650, 10 mcg
J0652	Injection, levothyroxine sodium (hikma), not therapeutically equivalent to J0650, 10mcg
J1010	Injection, methylprednisolone acetate, 1 mg
J1202	Miglustat, oral, 65 mg
J1203	Injection, cipaglucosidase alfa-atga, 5 mg
J1323	Injection, elranatamab-bcmm, 1 mg
J1434	Injection, fosaprepitant (focinvez), 1 mg
J2277	Injection, motixafortide, 0.25 mg
J2782	Injection, avacincaptad pegol, 0.1 mg
J2801	Injection, risperidone (rykindo), 0.5 mg
J2919	Injection, methylprednisolone sodium succinate, 5 mg
J3055	Injection, talquetamab-tgvs, 0.25 mg
J3424	Injection, hydroxocobalamin, intravenous, 25 mg
J7165	Injection, prothrombin complex concentrate, human-lans, per i.u. of factor ix activity
J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)
J9073	Injection, cyclophosphamide (ingenus), 5 mg
J9074	Injection, cyclophosphamide (sandoz), 5 mg
J9075	Injection, cyclophosphamide, not otherwise specified, 5 mg
J9248	Injection, melphalan (hepzato), 1 mg
J9249	Injection, melphalan (apotex), 1 mg
J9376	Injection, pozelimab-bbfg, 1 mg

K1037	Docking station for use with oral device/appliance used to reduce upper airway collapsibility
L1320	Thoracic, pectus carinatum orthosis, sternal compression, rigid circumferential frame with anterior and posterior rigid pads, custom fabricated
L5783	Addition to lower extremity, user adjustable, mechanical, residual limb volume management system
L5841	Addition, endoskeletal knee-shin system, polycentric, pneumatic swing, and stance phase control
Q4305	American amnion ac tri-layer, per square centimeter
Q4306	American amnion ac, per square centimeter
Q4307	American amnion, per square centimeter
Q4308	Sanopellis, per square centimeter
Q4309	Via matrix, per square centimeter
Q4310	Procenta, per 100 mg
Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Q5134	Injection, natalizumab-sztn (tyruko), biosimilar, 1 mg
S4988	Penile contracture device, manual, greater than 3 lbs traction force
S9002	Intra-vaginal motion sensor system, provides biofeedback for pelvic floor muscle rehabilitation device
0439U	Cardiology (coronary heart disease [CHD]), DNA, analysis of 5 single-nucleotide polymorphisms (SNPs) (rs11716050 [LOC105376934], rs6560711 [WDR37], rs3735222 [SCIN/LOC107986769], rs6820447 [intergenic], and rs9638144 [ESYT2]) and 3 DNA methylation markers (cg00300879 [transcription start site {TSS200} of CNKSR1], cg09552548 [intergenic], and cg14789911 [body of SPATC1L]), qPCR and digital PCR, whole blood, algorithm reported as a 4-tiered risk score for a 3-year risk of symptomatic CHD
0440U	Cardiology (coronary heart disease [CHD]), DNA, analysis of 10 single-nucleotide polymorphisms (SNPs) (rs710987 [LINC010019], rs1333048 [CDKN2B-AS1], rs12129789 [KCND3], rs942317 [KTN1-AS1], rs1441433 [PPP3CA], rs2869675 [PREX1], rs4639796 [ZBTB41], rs4376434 [LINC00972], rs12714414 [TMEM18], and rs7585056 [TMEM18]) and 6 DNA methylation markers (cg03725309 [SARS1], cg12586707 [CXCL1], cg04988978 [MPO], cg17901584 [DHCR24-DT], cg21161138 [AHRN], and cg12655112 [EHD4]), qPCR and digital PCR, whole blood, algorithm reported as detected or not detected for CHD
0441U	Infectious disease (bacterial, fungal, or viral infection), semiquantitative biomechanical assessment (via deformability cytometry), whole blood, with algorithmic analysis and result reported as an index
0442U	Infectious disease (respiratory infection), Myxovirus resistance protein A (MxA) and C-reactive protein (CRP), fingerstick whole blood specimen, each biomarker reported as present or absent
0443U	Neurofilament light chain (NfL), ultra-sensitive immunoassay, serum or cerebrospinal fluid
0444U	Oncology (solid organ neoplasia), targeted genomic sequence analysis panel of 361 genes, interrogation for gene fusions, translocations, or other rearrangements, using DNA from formalin-fixed paraffin-embedded (FFPE) tumor tissue, report of clinically significant variant(s)
0445U	β -amyloid (A β 42) and phospho tau (181P) (pTau181), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology
0446U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic risk score for current disease activity
0447U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 11 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic prognostic risk score for developing a clinical flare

0448U	Oncology (lung and colon cancer), DNA, qualitative, nextgeneration sequencing detection of single-nucleotide variants and deletions in EGFR and KRAS genes, formalin-fixed paraffinembedded (FFPE) solid tumor samples, reported as presence or absence of targeted mutation(s), with recommended therapeutic options
0449U	Carrier screening for severe inherited conditions (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia), regardless of race or self-identified ancestry, genomic sequence analysis panel, must include analysis of 5 genes (CFTR, SMN1, HBB, HBA1, HBA2)

2. July 2024 HCPCS Codes Proposed Rule Comment Solicitation

For the July 2024 update, 127 new codes were established and made effective July 1, 2024. Through the July 2024 OPSS quarterly update CR (Transmittal 12665, Change Request 13632, dated May 31, 2024), we recognized several new codes for payment and assigned them to appropriate interim OPSS 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 11 (New HCPCS Codes Effective July 1, 2024). 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 OPSS 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 OPSS can be found in Addendum D2 to this proposed rule. We note that OPSS Addendum B (OPSS payment file by HCPCS code), Addendum D1 (OPSS Status Indicators), and Addendum D2 (OPSS Comment Indicators) are available via the internet on the CMS website.

TABLE 11: NEW HCPCS CODES EFFECTIVE JULY 1, 2024

CY 2025 HCPCS Code	CY 2025 Long Descriptor
90637	Influenza virus vaccine, quadrivalent (qIRV), mRNA; 30 mcg/0.5 mL dosage, for intramuscular use

90638	Influenza virus vaccine, quadrivalent (qIRV), mRNA; 60 mcg/0.5 mL dosage, for intramuscular use
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
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation
C1606	Adapter, single-use (i.e. disposable), for attaching ultrasound system to upper gastrointestinal endoscope
G0519	Management of new patient-caregiver dyad with dementia, low complexity, for use in CMMI Model
G0520	Management of new patient-caregiver dyad with dementia, moderate complexity, for use in CMMI Model
G0521	Management of new patient-caregiver dyad with dementia, high complexity, for use in CMMI Model
G0522	Management of a new patient with dementia, low complexity, for use in CMMI Model
G0523	Management of a new patient with dementia, moderate to high complexity, for use in CMMI Model
G0524	Management of established patient-caregiver dyad with dementia, low complexity, for use in CMMI Model
G0525	Management of established patient-caregiver dyad with dementia, moderate complexity, for use in CMMI Model
G0526	Management of established patient-caregiver dyad with dementia, high complexity, for use in CMMI Model
G0527	Management of established patient with dementia, low complexity, for use in CMMI Model
G0528	Management of established patient with dementia, moderate to high complexity, for use in CMMI Model
G0529	In-home respite care, 4-hour unit, for use in CMMI Model
G0530	Adult day center, 8-hour unit, for use in CMMI Model
G0531	Facility-based respite, 24-hour unit, for use in CMMI Model
G9037	Interprofessional telephone/Internet/electronic health record clinical question/request for specialty recommendations by a treating/requesting physician or other qualified health care professional for the care of the patient (i.e. not for professional education or scheduling) and may include subsequent follow up on the specialist's recommendations; 30 minutes
G9038	Co-management services with the following elements: New diagnosis OR acute exacerbation and stabilization of existing condition; Condition which may benefit from joint care planning; Condition for which specialist is taking a co-management role; Condition expected to last at least 3 months; Comprehensive care plan established, implemented, revised or monitored in partnership with co-managing clinicians; Ongoing communication and care coordination between co-managing clinicians furnishing care
J0211	Injection, sodium nitrite 3 mg and sodium thiosulfate 125 mg (nithiodote)
J0687	Injection, cefazolin sodium (wg critical care), not therapeutically equivalent to j0690, 500 mg

J0872	Injection, daptomycin (xellia), unrefrigerated, not therapeutically equivalent to j0878 or j0873, 1 mg
J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)
J1597	Injection, glycopyrrolate (glyrx-pf), 0.1 mg
J1598	Injection, glycopyrrolate (fresenius kabi), not therapeutically equivalent to J1596, 0.1 mg
J2183	Injection, meropenem (wg critical care), not therapeutically equivalent to j2185, 100 mg
J2246	Injection, micafungin in sodium (baxter), not therapeutically equivalent to j2248, 1 mg
J2267	Injection, mirikizumab-mrkz, 1 mg
J2373	Injection, phenylephrine hydrochloride (immphentiv), 20 micrograms
J2468	Injection, palonosetron hydrochloride (avyxa), not therapeutically equivalent to J2469, 25 micrograms
J2470	Injection, pantoprazole sodium, 40 mg
J2471	Injection, pantoprazole (hikma), not therapeutically equivalent to J2470, 40 mg
J3247	Injection, secukinumab, intravenous, 1 mg
J3263	Injection, toripalimab-tpzi, 1 mg
J3393	Injection, betibeglogene autotemcel, per treatment
J3394	Injection, lovotibeglogene autotemcel, per treatment
J7171	Injection, adams13, recombinant-krhn, 10 iu
J7355	Injection, travoprost, intracameral implant, 1 microgram
J8611	Methotrexate (jylamvo), oral, 2.5 mg
J8612	Methotrexate (xatmep), oral, 2.5 mg
J9361	Injection, efbemalenograstim alfa-vuxw, 0.5 mg
Q4311	Acesso, per square centimeter
Q4312	Acesso ac, per square centimeter
Q4313	Dermabind fm, per square centimeter
Q4314	Reeva ft, per square centimeter
Q4315	Regenelink amniotic membrane allograft, per square centimeter
Q4316	Amchoplast, per square centimeter
Q4317	Vitograft, per square centimeter
Q4318	E-graft, per square centimeter
Q4319	Sanograft, per square centimeter
Q4320	Pellograft, per square centimeter
Q4321	Renograft, per square centimeter

Q4322	Caregraft, per square centimeter
Q4323	Alloply, per square centimeter
Q4324	Amniotx, per square centimeter
Q4325	Acapatch, per square centimeter
Q4326	Woundplus, per square centimeter
Q4327	Duoamnion, per square centimeter
Q4328	Most, per square centimeter
Q4329	Singlay, per square centimeter
Q4330	Total, per square centimeter
Q4331	Axolotl graft, per square centimeter
Q4332	Axolotl dualgraft, per square centimeter
Q4333	Ardeograft, per square centimeter
Q5136	Injection, infliximab-dyyb (zymfentra), biosimilar, 10 mg
Q5137	Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg
Q5138	Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater than or equal to 50 mL
0868T	High-resolution gastric electrophysiology mapping with simultaneous patient symptom profiling, with interpretation and report
0869T	Injection(s), bone-substitute material for bone and/or soft tissue hardware fixation augmentation, including intraoperative imaging guidance, when performed
0870T	Implantation of subcutaneous peritoneal ascites pump system, percutaneous, including pump-pocket creation, insertion of tunneled indwelling bladder and peritoneal catheters with pump connections, including all imaging and initial programming, when performed
0871T	Replacement of a subcutaneous peritoneal ascites pump, including reconnection between pump and indwelling bladder and peritoneal catheters, including initial programming and imaging, when performed
0872T	Replacement of indwelling bladder and peritoneal catheters, including tunneling of catheter(s) and connection with previously implanted peritoneal ascites pump, including imaging and programming, when performed
0873T	Revision of a subcutaneously implanted peritoneal ascites pump system, any component (ascites pump, associated peritoneal catheter, associated bladder catheter), including imaging and programming, when performed
0874T	Removal of a peritoneal ascites pump system, including implanted peritoneal ascites pump and indwelling bladder and peritoneal catheters
0875T	Programming of subcutaneously implanted peritoneal ascites pump system by physician or other qualified health care professional
0876T	Duplex scan of hemodialysis fistula, computer-aided, limited (volume flow, diameter, and depth, including only body of fistula)

0877T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging
0878T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained with concurrent CT examination of the same structure
0879T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; radiological data preparation and transmission
0880T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; physician or other qualified health care professional interpretation and report
0881T	Cryotherapy of the oral cavity using temperature regulated fluid cooling system, including placement of an oral device, monitoring of patient tolerance to treatment, and removal of the oral device
0882T	Intraoperative therapeutic electrical stimulation of peripheral nerve to promote nerve regeneration, including lead placement and removal, upper extremity, minimum of 10 minutes; initial nerve (List separately in addition to code for primary procedure)
0883T	Intraoperative therapeutic electrical stimulation of peripheral nerve to promote nerve regeneration, including lead placement and removal, upper extremity, minimum of 10 minutes; each additional nerve (List separately in addition to code for primary procedure)
0884T	Esophagoscopy, flexible, transoral, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for esophageal stricture, including fluoroscopic guidance, when performed
0885T	Colonoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed
0886T	Sigmoidoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed
0887T	End-tidal control of inhaled anesthetic agents and oxygen to assist anesthesia care delivery (List separately in addition to code for primary procedure)
0888T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including imaging guidance
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
0893T	Noninvasive assessment of blood oxygenation, gas exchange efficiency, and cardiorespiratory status, with physician or other qualified health care professional interpretation and report
0894T	Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion
0895T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment)
0896T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)
0897T	Noninvasive augmentative arrhythmia analysis derived from quantitative computational cardiac arrhythmia simulations, based on selected intervals of interest from 12-lead electrocardiogram and uploaded clinical parameters, including uploading clinical parameters with interpretation and report
0898T	Noninvasive prostate cancer estimation map, derived from augmentative analysis of image-guided fusion biopsy and pathology, including visualization of margin volume and location, with margin determination and physician interpretation and report
0899T	Noninvasive determination of absolute quantitation of myocardial blood flow (AQMBF), derived from augmentative algorithmic analysis of the dataset acquired via contrast cardiac magnetic resonance (CMR), pharmacologic stress, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)
0900T	Noninvasive estimate of absolute quantitation of myocardial blood flow (AQMBF), derived from assistive algorithmic analysis of the dataset acquired via contrast cardiac magnetic resonance (CMR), pharmacologic stress, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)
0450U	Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LCMS/MS), monoclonal paraprotein sequencing analysis, serum, results reported as baseline presence or absence of detectable clonotypic peptides

0451U	Oncology (multiple myeloma), LCMS/MS, peptide ion quantification, serum, results compared with baseline to determine monoclonal paraprotein abundance
0452U	Oncology (bladder), methylated PENK DNA detection by linear target enrichment-quantitative methylation-specific real-time PCR (LTE-qMSP), urine, reported as likelihood of bladder cancer
0453U	Oncology (colorectal cancer), cellfree DNA (cfDNA), methylationbased quantitative PCR assay (SEPTIN9, IKZF1, BCAT1, Septin9-2, VAV3, BCAN), plasma, reported as presence or absence of circulating tumor DNA (ctDNA)
0454U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping
0455U	Infectious agents (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis, multiplex amplified probe technique, vaginal, endocervical, gynecological specimens, oropharyngeal swabs, rectal swabs, female or male urine, each pathogen reported as detected or not detected
0456U	Autoimmune (rheumatoid arthritis), next-generation sequencing (NGS), gene expression testing of 19 genes, whole blood, with analysis of anticyclic citrullinated peptides (CCP) levels, combined with sex, patient global assessment, and body mass index (BMI), algorithm reported as a score that predicts nonresponse to tumor necrosis factor inhibitor (TNFi) therapy
0457U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 9 PFAS compounds by LC-MS/MS, plasma or serum, quantitative
0458U	Oncology (breast cancer), S100A8 and S100A9, by enzymelinked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score
0459U	β -amyloid (Abeta42) and total tau (tTau), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology
0460U	Oncology, whole blood or buccal, DNA single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, with variant analysis and reported phenotypes
0461U	Oncology, pharmacogenomic analysis of single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, whole blood or buccal swab, with variant analysis, including impacted gene-drug interactions and reported phenotypes
0462U	Melatonin levels test, sleep study, 7 or 9 sample melatonin profile (cortisol optional), enzyme-linked immunosorbent assay (ELISA), saliva, screening/preliminary
0463U	Oncology (cervix), mRNA gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk human papillomavirus [HPV] types 16, 18, 31, 33, 45, 52, 58), by real-time nucleic acid sequence-based amplification (NASBA), exo- or endocervical epithelial cells, algorithm reported as positive or negative for increased risk of cervical dysplasia or cancer for each biomarker
0464U	Oncology (colorectal) screening, quantitative real-time target and signal amplification, methylated DNA markers, including LASS4, LRRC4 and

	PPP2R5C, a reference marker ZDHHC1, and a protein marker (fecal hemoglobin), utilizing stool, algorithm reported as a positive or negative result
0465U	Oncology (urothelial carcinoma), DNA, quantitative methylationspecific PCR of 2 genes (ONECUT2, VIM), algorithmic analysis reported as positive or negative
0466U	Cardiology (coronary artery disease [CAD]), DNA, genomewide association studies (564856 single-nucleotide polymorphisms [SNPs], targeted variant genotyping), patient lifestyle and clinical data, buccal swab, algorithm reported as polygenic risk to acquired heart disease
0467U	Oncology (bladder), DNA, nextgeneration sequencing (NGS) of 60 genes and whole genome aneuploidy, urine, algorithms reported as minimal residual disease (MRD) status positive or negative and quantitative disease burden
0468U	Hepatology (nonalcoholic steatohepatitis [NASH]), miR-34a5p, alpha 2-macroglobulin, YKL40, HbA1c, serum and whole blood, algorithm reported as a single score for NASH activity and fibrosis
0469U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis for chromosomal abnormalities, copy number variants, duplications/deletions, inversions, unbalanced translocations, regions of homozygosity (ROH), inheritance pattern that indicate uniparental disomy (UPD), and aneuploidy, fetal sample (amniotic fluid, chorionic villus sample, or products of conception), identification and categorization of genetic variants, diagnostic report of fetal results based on phenotype with maternal sample and paternal sample, if performed, as comparators and/or maternal cell contamination
0470U	Oncology (oropharyngeal), detection of minimal residual disease by next-generation sequencing (NGS) based quantitative evaluation of 8 DNA targets, cell-free HPV 16 and 18 DNA from plasma
0471U	Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of KRAS and NRAS genes (exons 2, 3, 4), formalin-fixed paraffin-embedded (FFPE), predictive, identification of detected mutations
0472U	Carbonic anhydrase VI (CA VI), parotid specific/secretory protein (PSP) and salivary protein (SPI) IgG, IgM, and IgA antibodies, enzyme-linked immunosorbent assay (ELISA), semiquantitative, blood, reported as predictive evidence of early Sjögren syndrome
0473U	Oncology (solid tumor), nextgeneration sequencing (NGS) of DNA from formalin-fixed paraffinembedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden
0474U	Hereditary pan-cancer (eg, hereditary sarcomas, hereditary endocrine tumors, hereditary neuroendocrine tumors, hereditary cutaneous melanoma), genomic sequence analysis panel of 88 genes with 20 duplications/deletions using nextgeneration sequencing (NGS), Sanger sequencing, blood or saliva, reported as positive or negative for germline variants, each gene
0475U	Hereditary prostate cancer-related disorders, genomic sequence analysis panel using next-generation sequencing (NGS), Sanger sequencing,

	multiplex ligation-dependent probe amplification (MLPA), and array comparative genomic hybridization (CGH), evaluation of 23 genes and duplications/deletions when indicated, pathologic mutations reported with a genetic risk score for prostate cancer
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3. October 2024 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, 2024, in the CY 2025 OPSS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2025 OPSS/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2024 OPSS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2025, we propose to continue our established policy of assigning comment indicator “NI” in Addendum B to the OPSS/ASC final rule with comment period to those new HCPCS codes that will be effective October 1, 2024, 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 2025 OPSS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2026 OPSS/ASC final rule with comment period.

4. January 2025 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, 2025, in the CY 2025 OPSS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2026 OPSS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPSS/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 2025, we propose to include the new Level II HCPCS codes effective January 1, 2025, in Addendum B to the CY 2025 OPPS/ASC final rule with comment period, which would be incorporated in the January 2025 OPPS quarterly update CR. Specifically, for CY 2025, we propose to continue our established policy of assigning comment indicator “NI” in Addendum B to the OPPS/ASC final rule with comment period to the new HCPCS codes that will be effective January 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 2025 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2026 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 final rule.

For the CY 2025 OPPS update, we received the CPT codes that will be effective January 1, 2025, 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 2025 CPT codes in Addendum O, specifically under the column labeled "CY 2025 OPPS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code." The final HCPCS code numbers will be included in the CY 2025 OPPS/ASC final rule with comment period. In summary, we solicit public comments on the proposed CY 2025 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2025. 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 2025 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 12 (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 12: 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 2024	HCPCS (CPT and Level II codes)	April 1, 2024	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
July 2024	HCPCS (CPT and Level II codes)	July 1, 2024	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
October 2024	HCPCS (CPT and Level II codes)	October 1, 2024	CY 2025 OPPS/ASC final rule with comment period	CY 2026 OPPS/ASC final rule with comment period
January 2025	CPT Codes	January 1, 2025	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
			CY 2025	CY 2026

	Level II HCPCS Codes	January 1, 2025	OPPS/ASC final rule with comment period	OPPS/ASC final rule with comment period
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B. Proposed 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 OPPTS, 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 2025, 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.

2. 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 paragraph (2) 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 2025 OPPTS update will be discussed in the relevant specific sections throughout the CY 2025 OPPTS/ 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 2025, 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 2025 OPPTS 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-notice> 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 2025 included in this

proposed rule are related to changes in costs of services that were observed in the CY 2023 claims data available for CY 2025 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, 2024, OPSS 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-updates>

3. Proposed APC Exceptions to the 2 Times Rule

While considering the APC changes that we propose for CY 2025, 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 2023 claims data available for this proposed rule, we found 23 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 2025 and found that all of the 23 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2023 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 13 below. 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 13 of this proposed rule lists the 23 APCs for which we propose to make an exception under the 2 times rule for CY 2025 based on the criteria cited above and claims data submitted between January 1, 2023, and December 31, 2023, and processed on or before December 31, 2023, 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-notice>.

TABLE 13: PROPOSED CY 2025 APC EXCEPTIONS TO THE 2 TIMES RULE

APC	APC Group Title
5012	Clinic Visits and Related Services
5053	Level 3 Skin Procedures
5071	Level 1 Excision/Biopsy/Incision and Drainage
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
5593	Level 3 Nuclear Medicine and Related Services
5611	Level 1 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration

5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5733	Level 3 Minor Procedures
5734	Level 4 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5743	Level 3 Electronic Analysis of Devices
5791	Pulmonary Treatment
5811	Manipulation Therapy
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. Proposed 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/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc> on the CMS website and then follow the instructions to access the MEARIS™ system for OPSS New Technology APC applications.¹³

In the CY 2004 OPSS 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 OPSS; separate APC payment) and the other set with a status indicator of “T” (Significant Procedure, Multiple Reduction Applies. Paid under OPSS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2024, 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 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 OPSS. Payment for each APC is made at the mid-point of the APC’s assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level 7 (\$501–\$600)) is made at \$550.50.

¹³ Currently approved under OMB control number 0938-0860; expires 07/31/2024.

Under the OPSS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPSS, 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 OPSS, 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 OPSS/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 to 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 OPPTS/ 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 OPPTS/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 OPPTS/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 OPPTS/ASC final rule with comment period (86 FR 63529) for further discussion regarding this policy.

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 OPPTS 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 OPPTS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2025, 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/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>)

2. Proposal to Exempt Services with Very Low Claims Volume 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 very low claims volume of fewer than 10 claims in the 4-year lookback period used under the universal low volume APC policy. Historically, we have used our equitable adjustment authority at section 1833(t)(2)(E) of the Act to exempt a number of services with very low claims volume from the universal low volume APC policy in instances where application of the universal low volume policy would lead to significant fluctuations in payment. Given the frequency with which we have needed to utilize our equitable adjustment authority to address significant fluctuations in payment for very low volume services, we believe that refinements to our universal low volume policy for services assigned to New Technology APCs may be necessary. We also recognize that determining initial cost estimates for these services may be particularly challenging, given the lack of cost information for new and innovative technologies.

To allow time for us to consider these issues, we propose for CY 2025 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 propose that we would maintain the New Technology APC assignment for each service from the prior year, which in this case would be the New Technology APC assignment for CY 2024. We believe it is appropriate to apply this policy to New Technology APCs because services assigned to New Technology APCs represent new technologies for which it may be more challenging to determine an appropriate cost than for other, more established services. We believe 10 claims is an appropriate ceiling for exempting

services from reassignment based on the universal low volume policy because we believe that at 10 claims a rough standard distribution begins to appear. We also 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 our proposal to exempt services with fewer than 10 claims in the 4-year lookback period from the universal low volume APC policy and maintain their CY 2024 New Technology APC assignment. We will update the APC placement as needed in the final rule.

3. Procedures Assigned to New Technology APCs for CY 2025

As we described in the CY 2002 OPPTS 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 2025, 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.¹⁴ 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.”

¹⁴Luxturna. FDA Package Insert. Available: <https://www.fda.gov/media/109906/download>.

Interested parties, including the manufacturer of Luxturna[®], recommended CPT code 67036 (Vitreotomy, mechanical, pars plana approach) for the administration of the gene therapy.¹⁵ However, the manufacturer previously contended the administration was not accurately described by any existing codes as CPT code 67036 (Vitreotomy, 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 OPPTS/ASC proposed rule (85 FR 48832), we proposed to establish a new HCPCS code, C97X1 (Vitreotomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process. We stated that we believed this new HCPCS code accurately described the unique service associated with intraocular administration of HCPCS code J3398. We recognized that CPT code 67036 represents a clinically similar procedure and process that approximates similar resource utilization to C97X1. However, we also recognized that it is not prudent for the code that describes the administration of this unique gene therapy, C97X1, to be assigned to the same C-APC to which CPT code 67036 is assigned, as this would package the primary therapy, HCPCS code J3398, into the code that represents the process to administer the gene therapy.

Therefore, for CY 2021, we proposed to assign the services described by C97X1 to a New Technology APC with a cost band that contains the geometric mean cost for CPT code 67036. The placeholder code C97X1 was replaced by HCPCS code C9770. For CY 2021, we finalized our proposal to create HCPCS code C9770 (Vitreotomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent), and we assigned this code 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 code C9770 to APC 1561 (New Technology – Level 24 (\$3001-\$3500)) using the geometric mean cost of CPT code 67036.

¹⁵ 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>

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 OPPI/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 New Technology 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).

Since CMS recognized CPT code 0810T starting January 1, 2024, we do not have claims data for CPT code 0810T available for CY 2025 rulemaking. However, as HCPCS code C9770 was still in use until December 31, 2023, we propose to determine the payment rate for CPT

code 0810T using the claims data for HCPCS code C9770. This is similar to the policy we finalized for CY 2024. For CY 2025, we propose to designate CPT code 0810T as a low volume procedure under our universal low volume APC policy, given that there are only 34 claims available for HCPCS code C9770 and none for CPT code 0810T. 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 for HCPCS code C9770 to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC.

Using all available claims from the 4-year lookback period, based on 34 claims, we determined the geometric mean cost to be \$3,934, the arithmetic mean cost to be \$4,173, and the median cost to be \$4,103. 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 \$4,173 falls within the cost band for New Technology APC 1563 (New Technology - Level 26 (\$4001-\$4500)). Therefore, we propose to assign CPT code 0810T to APC 1563 for CY 2025. 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 2025 OPPS/ASC final rule with comment period and update the APC assignment as needed.

Please refer to Table 14 below for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0810T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 14: FINAL CY 2024 AND PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0810T

HCPCS Code	Long Descriptor	Final CY 2024 OPPTS SI	Final CY 2024 OPPTS APC	Proposed CY 2025 OPPTS SI	Proposed CY 2025 OPPTS APC
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	T	1563	T	1563

b. BgRT (APC 1521)

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, the proposed OPPTS payment rates are based on available CY 2023 claims data. As HCPCS codes C9794 and C9795 were effective January 1, 2024, we do not have any claims data for the service. Therefore, for CY 2025, we propose to continue 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.

Please refer to Table 15 below for the proposed OPSS New Technology APC and status indicator assignment for HCPCS codes C9794 and C9795 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 15: PROPOSED CY 2025 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BIOLOGY GUIDED RADIATION THERAPY

HCPCS	Long Descriptor	Proposed CY 2025 OPSS SI	Proposed CY 2025 OPSS APC
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)	S	1521
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	S	1525

c. Blinded procedure for NYHA class III/IV heart failure (APC 1590)

A randomized, double-blinded, controlled IDE study is currently in progress 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 New Technology 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 New Technology 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.

For CY 2022, we used the same claims data from CY 2019 that we did for the CY 2021 OPPS/ASC final rule with comment period. Because there were no claims reporting HCPCS code C9758, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of \$17,500.50 for CY 2022. For CY 2023 we used claims data from CY 2019 through CY 2022. Because there were no claims reporting HCPCS code C9758 in CY 2023 or CY 2024, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of \$17,500.50 for CY 2023 and 2024.

For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. There were only three claims for HCPCS code C9758 within this time period. As

this is below the threshold of 100 claims for a service within a year, we would designate C9758 as a low volume service and apply our universal low volume APC policy. Under this policy, 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 HCPCS code C9758 to the appropriate New Technology APC. Given 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 applicable for the universal low-volume APC policy, we propose to continue assigning HCPCS code C9758 to New Technology New Technology APC 1590 with a proposed payment rate of \$17,500.50.

Please refer to Table 16 below for the proposed OPSS New Technology APC and status indicator assignments for HCPCS code C9758 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 16: PROPOSED CY 2025 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS	Long Descriptor	Proposed CY 2025 OPSS SI	Proposed CY 2025 OPSS 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	T	1590

d. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy (APC 1562)

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 New Technology 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. We found the geometric mean cost for the service to be approximately \$2,693, the arithmetic mean cost to be approximately \$3,086, and the median cost to be approximately \$3,708. 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 New Technology APC 1562 (New Technology—Level 25 (\$3501–\$4000)). Therefore, we assigned HCPCS code C9751 to APC 1562 for CY 2021.

In CY 2022, we again used the claims data from CY 2019 for HCPCS code C9751. Because the claims data was unchanged from when it was used in CY 2021, the values for the geometric mean cost (\$2,693), the arithmetic mean cost (\$3,086), and the median cost (\$3,708) for the service described by HCPCS code C9751 remained the same. The highest cost metric using these methodologies was again the median and within the cost band for New Technology APC 1562 (New Technology—Level 25 (\$3,501–\$4,000)). Therefore, we continued to assign

HCPCS code C9751 to APC 1562 (New Technology—Level 25 (\$3,501– \$4,000)), with a payment rate of \$3,750.50 for CY 2022.

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

For CY 2025, there are no new claims for HCPCS code C9751.

Given 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 applicable for the universal low-volume APC policy, we propose for CY 2025 to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 (\$3501–\$4000)), with a payment rate of \$3,750.50.

Please refer to Table 17 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9751 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 17: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9751

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 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])	T	1562

e. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1520 and 1522)

For CY 2025, the OPPS payment rates for the service described by CPT codes 78431, 78432, and 78433 are proposed to be based on available CY 2023 claims data. CPT code 78431 had over 26,000 single frequency claims in CY 2023. The geometric mean for CPT code 78431 is approximately \$2,350. 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 2025, 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 19 single frequency claims in CY 2023 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 \$1,762, the arithmetic mean cost of the service is approximately \$1,923, and the median cost of the service is approximately \$1,544. The arithmetic mean is the statistical methodology that estimates the highest cost for the service. The arithmetic mean cost of \$1,923, is an amount that is above the cost band for APC 1520 (New Technology—Level 20 (\$1801–\$1900)), where the procedure is currently assigned. Therefore, we propose, for CY 2025, to assign CPT code 78432 to APC 1521 (New Technology—Level 21 (\$1901–\$2000)) with a payment rate of \$1950.50.

There were over 1,400 single frequency claims for CPT code 78433 in CY 2023. The geometric mean for CPT code 78433 is approximately \$2,010, 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 2025, we propose to reassign CPT code

78433 to APC 1522 (New Technology—Level 22 (\$2001–\$2500)) with a payment rate of \$2,250.50.

Please refer to Table 18 below for the proposed OPSS New Technology APC and status indicator assignments for CPT codes 78431, 78432, and 78433 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPSS/ASC proposed rule via the Internet on the CMS website.

TABLE 18: FINAL CY 2024 AND PROPOSED CY 2025 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Final CY 2024 OPSS SI	Final CY 2024 OPSS APC	Proposed CY 2025 OPSS SI	Proposed CY 2025 OPSS 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	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	1520	S	1521
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	1521	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 Trial¹⁶ and the CardiAMP Cell Therapy Heart Failure Trial.¹⁷ 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 are proposed to be based on available CY 2023 claims data. We have identified three single frequency paid claims for C9782 for ratesetting for

¹⁶ 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>.

¹⁷ 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>.

CY 2025. As this is below the threshold of 100 claims for a service within a year, we would designate C9782 as a low volume service and apply our universal low volume APC policy. Under this policy, 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 codes C9782 to the appropriate New Technology APC. Our analysis of the data found the geometric mean cost of the service is approximately \$18,045, the arithmetic mean cost of the service is approximately \$18,332, and the median cost of the service is approximately \$20,394. The median was the statistical methodology that estimated the highest cost for the service. However, because there are only three claims for HCPCS code C9782 from the CY 2023 claims data, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service. Given 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 applicable for the universal low-volume APC policy, we therefore propose to continue to assign HCPCS code C9782 to New Technology APC 1590 with a payment rate of \$17,050.50.

Please refer to Table 19 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9782 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 19: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE CARDIAMP CELL THERAPY IDE STUDIES

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 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),	T	1590

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPI SI	Proposed CY 2025 OPPI APC
	performed in an approved Investigational Device Exemption (IDE) study		

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 OPSS 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 OPSS payment rates were proposed to be 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 OPSS in October 2022, and, therefore, the claims available only reflect two months of data, we were concerned that we do 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 adopted as final our proposal to maintain CPT code 0625T’s current assignment to APC 1511 (New Technology - Level 11 (\$901 - \$1000)) with a payment rate of \$950.50.

For setting CY 2025 payment rates, there were only three separately payable claims in the CY 2023 data reported for CPT code 0625T that have a geometric mean of approximately \$180, which is substantially lower than the current payment rate of \$950.50. In CY 2022 and CY 2023, there are a total of 40 separately payable claims reported for CPT code 0625T, but it is unlikely that a service with a current payment rate of \$950.50 would have a geometric mean of \$4.20, an arithmetic mean of \$6.60, and a median of \$3.52. These findings lead to uncertainty about the appropriate payment rate for the service described by CPT code 0625T. A review of the evidence submitted by the developer of the procedure when this procedure was originally assigned to a New Technology APC before any claims data were available indicated the procedure had a cost between \$901 and \$1,000. Claims assigned to CPT code 0625T from CY 2021 and CY 2022, indicate that the cost of the procedure is less than \$10, which would not appear to cover basic cost of this procedure including computing time, generating a report, and having medical personnel interpret the report. For CY 2023, the geometric mean cost of approximately \$180 based on three 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. Therefore, we propose to use 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 based on the data currently available to us, which we believe best reflects the cost of the service as described by the New Technology APC application.

Refer to Table 20 below for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0625T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule via the Internet on the CMS website.

**TABLE 20: PROPOSED CY 2025 NEW TECHNOLOGY APC AND STATUS
INDICATOR ASSIGNMENTS FOR ATHEROSCLEROSIS IMAGING-
QUANTITATIVE COMPUTER TOMOGRAPHY (AI-QCT)
HCPCS CODE 0625T**

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPI SI	Proposed CY 2025 OPPI 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	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, 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, 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 OPPI 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 New Technology 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. In CY 2022, we generally used the same claims data as was used in the CY 2021 OPPI final rule to set the payment rates for that year. Accordingly, because there were no claims for this service in CY 2019, we continued to assign HCPCS code C9760 to New Technology APC 1592 in

CY 2022. There continued to be no claims data for this service in CYs 2021 or 2022, so we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2023 and CY 2024, the years for which we used CY 2021 and CY 2022 data, respectively, for ratesetting.

For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. There were no claims for HCPCS code C9760 in CY 2023. Therefore, we propose to continue assigning HCPCS code C9760 to New Technology APC 1592.

Refer to Table 21 below for the proposed OPPS New Technology APC and status indicator assignments for CPT code C9760. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 21: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NON-BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
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 (for example, ultrasound, fluoroscopy) performed in an approved investigational device exemption (ide) study	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. For CY 2022, we assigned CPT code 0693T to New Technology APC 1505 (New Technology—Level 5 (\$301–\$400)). For CY 2023, the OPPS payment rates were based on claims submitted between January 1, 2021, and December 31, 2021, processed through June 30, 2022. Due to its effective date of January 1, 2022, there were no claims available for CPT code 0693T for rate setting in CY 2023. Therefore, in CY 2023, we continued to assign CPT code 0693T to New Technology APC 1505. For CY 2024, there were no claims available, so we again continued to assign CPT code 0693T to New Technology APC 1505.

For CY 2025, the OPPS payment rates are proposed based on available CY 2023 claims data. Although CPT code 0693T was effective January 1, 2022, we have no claims data at this time. Because we have no claims data, for CY 2025, we propose to continue to assign CPT code 0693T to APC 1505 with a proposed payment rate of \$350.50.

Please refer to Table 22 below for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0693T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 22: PROPOSED CY 2024 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPSS SI	Proposed CY 2025 OPSS 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 1558)

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 New Technology

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)¹⁸.

Because we created HCPCS code C9789 effective October 1, 2023, we have limited claims data from CY 2023 available for CY 2025 rulemaking. Specifically, we only have 6 claims available. Given 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 applicable for the universal low-volume APC policy, we therefore propose to continue to assign HCPCS code C9789 to New Technology APC 1559 (New Technology - Level 22 (\$2001-\$2500)).

Please refer to Table 23 below for the proposed OPSS New Technology APC and status indicator assignments for CPT code C9789 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 23: FINAL CY 2024 AND PROPOSED CY 2025 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9789

HCPCS Code	Long Descriptor	Final CY 2024 OPSS SI	Final CY 2024 OPSS APC	Proposed CY 2025 OPSS SI	Proposed CY 2025 OPSS APC
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance,	T	1559	T	1559

¹⁸ Jelmyto Package Insert. 01/14/2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211728s002lbl.pdf

HCPCS Code	Long Descriptor	Final CY 2024 OPPI SI	Final CY 2024 OPPI APC	Proposed CY 2025 OPPI SI	Proposed CY 2025 OPPI APC
	including volumetric measurement if performed				

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 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. To determine the appropriate New Technology APC assignment for CY 2024, we looked at the available cost information. There were only 15 claims for the procedure for CY 2021 and CY 2022, so the LimFlow TADV procedure was subject to our new technology procedure low volume APC policy. An analysis of the median, arithmetic mean, and geometric mean of CPT code 0620T for CY 2024 rulemaking found that the median was approximately \$25,800, the arithmetic mean was approximately \$28,600, and the geometric mean was

approximately \$26,700. Because the arithmetic mean had the highest value of the three cost statistics, for CY 2024, we assigned CPT code 0620T to New Technology APC 1578 (New Technology—Level 41 (\$25,001-\$30,000)) with a payment rate of \$27,500.50.

For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. There are only six 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 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 HCPCS code 0620T to the appropriate New Technology APC. Considering the available claims data for HCPCS code 0620T, the arithmetic mean is approximately \$35,000; the median is approximately \$36,000; and the geometric mean cost is approximately \$33,000. Of these, the median is the statistical methodology that estimates the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for New Technology APC 1579 (New Technology—Level 42 (\$30,001– \$40,000)) with a payment rate of \$35,000.50. Therefore, for CY 2024, we propose to assign HCPCS code 0620T to New Technology APC 1579.

Please refer to Table 24 for the proposed New Technology APC and status indicator assignments for CPT code 0620T. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

**TABLE 24: PROPOSED CY 2025 OPPTS APC STATUS INDICATOR ASSIGNMENTS
FOR CPT CODE 0620T**

CPT Code	Long Descriptor	Proposed CY 2025 OPPTS SI	Proposed CY 2025 OPPTS 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

1. Liver Histotripsy Service (APC 1576)

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.¹⁹ 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 reflects payment for both the service that is performed

¹⁹ 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>.

and the device used each time it is reported on a claim. For CY 2024, we assigned CPT code 0686T to New Technology APC 1576 (New Technology – Level 39 (\$15,001 - \$20,000)) with a payment rate of \$17,500.50.

For CY 2025, OPSS payment rates are proposed to be based on available CY 2023 claims data. We have identified one claim for CPT code 0686T within the CY 2023 claims data. As the available claims data is below the threshold of 100 claims for a service within a year, we would propose to designate CPT code 0686T as a low volume service under our universal low volume APC policy, and use the highest of the geometric mean cost, arithmetic mean cost, or median cost to assign CPT code 0686T to the appropriate New Technology APC. However, because there is only a single claim in the CY 2023 data, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service.

Given 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 applicable for the universal low-volume APC policy, and based on the fact that there have only been 3 claims for CPT code 0686T in the prior 4-year period, we propose to continue to assign CPT code 0686T to APC 1576 (New Technology – Level 39 (\$15,001 - \$20,000)) with a payment rate of \$17,500.50 as shown in Table 25.

Please refer to Table 25 below for the proposed OPSS New Technology APC and status indicator assignments for CPT code 0686T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule.

TABLE 25: PROPOSED CY 2025 OPPTS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Proposed CY 2025 OPPTS SI	Proposed CY 2025 OPPTS APC
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1576

m. LiverMultiScan Service (APC 1511)

Effective July 1, 2021, 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)) 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, we assigned CPT codes 0648T and 0649T to New Technology APC 1511 (New Technology – Level 11 (\$901 - \$1,000) with a payment rate of \$950.50.

For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. We identified 71 claims for CPT code 0648T and 72 claims CPT code 0649T for CY 2023. As this is below the threshold of 100 claims for each code 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 codes 0648T and 0649T to the appropriate New Technology APC. There are available claims data from CY 2021 and CY 2022 for CPT codes 0648T and 0649T. Our analysis of the combined data, 114 claims for CPT code 0648T and 115 claims for CPT code 0649T, yielded a geometric mean cost of approximately \$180, an arithmetic mean cost of approximately \$234, and a median cost of approximately \$197. We believe it is appropriate to utilize our universal low volume APC policy to assign the LiverMultiScan service to a New Technology APC because we believe that the combined claims data from CY 2021 to CY 2023 provide sufficient claims to capture the cost of the service. The arithmetic mean was the statistical methodology that estimated the highest cost for CPT codes 0648T and 0649T. Therefore, we propose to reassign CPT codes 0648T and 0649T to New Technology APC 1504 (New Technology - Level 4 (\$201 - \$300)) with a payment rate of \$250.50 as shown in Table 26.

TABLE 26: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER MULTISCAN SERVICE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 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	1504
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	1504

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 are proposed to be based on available CY 2023 claims data. We identified three claims for CPT codes 0721T and 0722T for ratesetting for CY 2025. As this is below the threshold of 100 claims for a service within a year, we would usually 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 codes 0721T and 0722T to the appropriate New Technology APC. There are available claims data only from CY 2023 for CPT codes 0721T and 0722T. Our analysis of the data for CPT code 0721T found the geometric mean cost of the service is approximately \$84, the arithmetic mean cost of the service is approximately \$98, and the median cost of the service is approximately \$130. We did not identify any reported claims for CPT code 0722T. However, because there are only three claims for the Optellum LCP service and these claims show a much lower cost than would be expected based on the current APC assignment of this service, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service. We believe it is appropriate to continue assigning the Optellum LCP service to its current APC assignment determined from the New Technology APC application review due to insufficient claims data to capture the cost of this service at this time. Given 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 applicable for the universal low-volume APC policy, we propose to continue to assign CPT codes 0721T and 0722T to New Technology APC 1508 (New Technology - Level 8 (\$601-\$700)) with a proposed payment rate of \$650.50.

Please refer to Table 27 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS codes 0721T and 0722T for CY 2025. The proposed CY 2025

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

TABLE 27: PROPOSED CY 2025 OPPTS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPTS SI	Proposed CY 2025 OPPTS 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 1511)

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. 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 is be assigned to the identical APC and status indicator as CPT code 0697T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0697T and 0698T to New Technology APC 1511 (New Technology - Level 11 (\$900-\$1,000)).

For CY 2025, the OPSS payment rates are proposed to be based on available CY 2023 claims data. We identified 46 claims for CPT code 0698T and no claims for CPT code 0697T in CY 2023. 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 codes 0697T and 0698T to the appropriate New Technology APC. There are available claims data from CY 2022 and CY 2023 for CPT code 0697T and 0698T. Our analysis of the combined data, zero claims for CPT code 0697T and 46 claims for CPT code 0698T, yielded a geometric mean cost of approximately \$444, an arithmetic mean cost of approximately \$622, and a median cost of approximately \$786. The median cost is the statistical methodology that estimates the highest cost for CPT codes 0697T and 0698T. Therefore, we propose, for CY 2025, to reassign CPT codes 0697T and 0698T to APC 1509 (New Technology - Level 9 (\$701 - \$800)) with a payment rate of \$750.50.

Refer to Table 28 below for the proposed OPSS New Technology APC and status indicator assignments for CPT codes 0697T and 0698T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 28: PROPOSED CY 2025 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPI SI	Proposed CY 2025 OPPI 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	1509
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	1509

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 New Technology APC 1511 (New Technology - Level 11 (\$900-\$1,000)).

For CY 2025, the OPSS payment rates are proposed to be based on available CY 2023 claims data. We identified 3 claims for CPT code 0724T and no claims for CPT code 0723T in CY 2023. As this is below the threshold of 100 claims for a service within a year, we would usually 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 codes 0723T and 0724T to the appropriate New Technology APC. There is only a single claim from CY 2022 for CPT code 0724T and no claims for CPT code 0723T. For CY 2023, we received 3 claims for CPT code for CPT 0724T and no claims for CPT code 0723T. Our analysis of the combined CY 2022 and CY 2023 data for CPT code 0723T and 0724T found the geometric mean cost of the service is approximately \$26, the arithmetic mean cost of the service is approximately \$26, and the median cost of the service is approximately \$27. However, because there are only three claims for CPT codes 0723T and 0724T and these claims show costs far below what would be expected for these services given their current APC assignments, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service. Given 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 applicable for the universal low-volume APC policy, we propose to continue to assign the CPT codes 0723T and 0724T to New Technology APC 1511 (New Technology – Level 11 (\$901 - \$1,000)) with a payment rate of \$950.50.

Refer to Table 29 below for the proposed OPSS New Technology APC and status indicator assignments for CPT codes 0723T and 0724T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 29: PROPOSED CY 2025 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPSS SI	Proposed CY 2025 OPSS 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 1514)

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 OPSS; 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. 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 OPSS payment rates are proposed to be based on available CY 2023 claims data. The Scalp Cooling service became effective in the OPSS in CY 2022, and we have identified 38 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 propose to designate CPT code 0662T as a low volume service under our universal low volume APC policy and to 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, the geometric mean cost for CPT code 0662T is approximately \$841; the median is approximately \$1,351; and the arithmetic mean is approximately \$1,361. Therefore, for CY 2025, we propose to designate this service as a low volume service under our universal low volume APC policy and to reassign CPT code 0662T to APC 1515 (New Technology—Level 15 (\$1301 - \$1400)) with a payment rate of \$1,350.50 for CY 2025 based on the arithmetic mean of approximately \$1,361.

Refer to Table 30 below for the current and proposed OPSS New Technology APC and status indicator assignments for CPT code 0662T. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 30: FINAL CY 2024 AND PROPOSED CY 2025 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR SCALP COOLING

HCPCS	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1514	S	1515

r. Supervised Visits for Esketamine Self-Administration (APCs 1513 and 1518)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, 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 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. For CY 2020, HCPCS code G2082 was assigned to New Technology APC 1508 (New Technology—Level 8 (\$601–\$700)) with a payment rate of \$650.50. HCPCS code G2083 describes a similar service to HCPCS code G2082 but involves the administration of more than 56 mg of esketamine. For CY 2020, HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology—Level 11 (\$901–\$1000)) with a payment rate of \$950.50. Updates to the APC assignments for G2082 and G2083 have been made in past rules. See the CY 2021 OPSS/ASC final rule with comment period (85 FR 85948), CY 2022 OPSS/ASC final rule with comment period (86 FR 63538), CY 2023 OPSS/ASC final rule with comment period (87 FR 71816–71817), and CY 2024 OPSS/ASC final rule with comment period (88 FR 81628 – 81630) for these updates.

For CY 2025, the OPSS payment rates are proposed based on available CY 2023 claims data as the available single frequency claims exceed the 100 claims threshold generally used for our universal low volume policy. Therefore, for CY 2025, we propose to assign HCPCS codes G2082 and G2083 to New Technology APCs based on the codes' geometric mean costs. Specifically, we propose to assign HCPCS code G2082 to New Technology APC 1512 (New

Technology—Level 12 (\$1001–\$1100)) with a payment rate of \$1,050.50 based on its geometric mean cost of \$1,087, which was calculated using the available 424 single frequency claims from CY 2023 claims data. We also propose to assign HCPCS code G2083 to New Technology APC 1518 (New Technology—Level 18 (\$1601–\$1700)) with a payment rate of \$1,650.50 based on its geometric mean cost of \$1,643, which was calculated using the available 2,482 single frequency claims from CY 2023 claims data. We note, as we have begun to gather adequate claims data on these codes, we are considering placing HCPCS codes G2082 and G2083 in clinical APCs through future rulemaking.

The proposed New Technology APC and status indicator assignments for HCPCS codes G2082 and G2083 are shown in Table 31. The proposed CY 2025 payment rates for these HCPCS codes can be found in Addendum B to this proposed rule.

**TABLE 31: FINAL CY 2024 AND PROPOSED CY 2025
NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS
FOR HCPCS CODES G2082 AND G2083**

HCPCS Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 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	1513	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	S	1520	S	1518

	hours post-administration observation				
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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 New Technology APC 1534 (New Technology - Level 34 (\$8001-\$8500)).

For CY 2025, there were only 3 single frequency claims in CY 2023 for HCPCS code C9780. There were no available claims from CY 2021 or CY 2022. Given 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 applicable for the universal low-volume APC policy, we propose to continue to assign HCPCS code C9780 to APC 1534 (New Technology - Level 34 (\$8001-\$8500)) with a payment rate of \$8,250.50. Refer to Table 32 for the proposed New Technology APC and status indicator assignments for HCPCS code C9780.

TABLE 32: PROPOSED CY 2025 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR SURFACER® INSIDE-OUT® ACCESS CATHETER SYSTEM PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 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. 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 is currently in a Category B IDE clinical trial. 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.

For CY 2025, the proposed OPPS payment rates are based on available CY 2023 claims data. Due to the effective date of the code of October 1, 2023, there were no claims available for HCPCS code C9792 for rate setting in CY 2024. Therefore, in CY 2025, we propose to continue to assign HCPCS code C9792 to APC 1537.

Please refer to Table 33 below for the current and proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9792. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 33: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR TRANSCATHETER ATRIAL SHUNT SYSTEM

HCPCS	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 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	S	1537

	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		
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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 New Technology APC 1551 (New Technology - Level 14 (\$1201- \$1300)). For CY 2024, the OPSS payment rates were based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. 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 New Technology APC 1551.

For CY 2025, the proposed OPSS payment rates are generally based on available CY 2023 claims data. Although HCPCS code C9791 was effective October 1, 2023, we do not have any claims data for the service. Therefore, for CY 2025, we propose to continue to assign HCPCS code C9791 to APC 1551 with a proposed payment rate of \$1,250.50.

Refer to Table 34 for the proposed OPSS New Technology APC and status indicator assignment for HCPCS code C9791 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 34: PROPOSED CY 2025 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR MAGNETIC RESONANCE IMAGING WITH INHALED HYPERPOLARIZED XENON-129 CONTRAST AGENT PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPSS SI	Proposed CY 2025 OPSS APC
C9791	Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent	T	1551

D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs

In the CY 2022 OPSS/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 2025 OPSS/ASC proposed rule, CY 2023 claims are generally the claims used for ratesetting; and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2023 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 OPSS/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 the CY 2025 OPSS/ASC proposed rule, we proposed 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 2023 for the CY 2025 OPPS/ASC proposed rule). Nine of the 11 APCs were designated as low volume APCs in CY 2024. Based on data for the CY 2025 OPPS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, gold-198) and APC 5881 (Ancillary Outpatient Services When Patient Dies) now meet our criteria to be designated a Low Volume APCs; and we proposed to designate those APCs as such for CY 2025.

Table 35 includes the CY 2023 claims available for ratesetting for each of the APCs we are proposing to be designated as low volume APCs for CY 2025. The cost statistics for our proposed 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 web page.

TABLE 35: PROPOSED LOW VOLUME APCS USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2025

APC	APC Description	CY 2023 Claims Available for Ratesetting
2632	Iodine I-125 sodium iodide	0
2635	Brachytx, non-str, HA, p-103	13
2636	Brachy linear, non-str, p-103	1
2642	Brachytx, stranded, c-131	90
2645	Brachytx, non-str, gold-198	86
2647	Brachytx, NS, Non-HDRIr-192	2
5244	Level 4 Blood Product Exchanges and Related Services	47
5494	Level 4 Intraocular Procedures	81
5495	Level 5 Intraocular Procedures	57
5496	Level 6 Intraocular Procedures	26
5881	Ancillary Outpatient Services When Patient Dies	55

* For this proposed rule, there are no CY 2023 claims that contain the HCPCS code assigned to APC 2632 that are available for CY 2025 OPPS/ASC ratesetting.

E. APC-Specific Policies

1. Request for Information on Cardiac CT Services

For the 2006 coding update, the AMA's CPT Editorial Panel established six Category III CPT codes to describe cardiac computed tomography angiography (cardiac CT services) with contrast materials effective January 1, 2006. The codes were active and separately payable under the OPSS between January 1, 2006 and December 31, 2009. The CPT Editorial Panel deleted the Category III CPT codes and replaced them with Category I CPT codes 75572 through 75574 effective January 1, 2010. With the deletion of the Category III CPT codes on December 31, 2009, we crosswalked the APC assignments from the Category III CPT codes (predecessor codes) to the new Category I CPT codes effective January 1, 2010. Since 2010, the Category I CPT codes describing cardiac computed tomography angiography with contrast materials are CPT codes 75572, 75573, and 75574. The codes and their long descriptors are listed below.

- 75572: Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
- 75573: Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of left ventricular (LV) cardiac function, right ventricular (RV) structure and function and evaluation of vascular structures, if performed)
- 75574: Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)

The cardiac CT codes that are described by CPT codes 75572, 75573, and 75574 have been paid separately under the OPSS since 2010. From CY 2015 through CY 2024, the OPSS

payment rate, based on the geometric mean cost (GMC) for the cardiac CT codes, has ranged between \$175 and \$265 for these codes, as listed in Table 36 below.

TABLE 36: CY 2015 – CY 2024 OPPTS PAYMENT RATES FOR CPT CODES 75572 – 75574

CPT Codes	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
75572-75574	\$216.05	\$236.86	\$265.02	\$252.74	\$201.74	\$182.22	\$178.55	\$182.43	\$180.34	\$175.06

We note that the OPPTS payment rate applies only to the hospital outpatient facility and does not include the physician service payment. Physician services are paid under Medicare’s Physician Fee Schedule (PFS).

As we have stated in every OPPTS/ASC proposed and final rule, we update the OPPTS payment rates on an annual basis consistent with the requirements set forth in section 1833(t)(9)(A) of the Act, which requires the HHS Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments 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. Because of the annual updates, OPPTS payment rates for services may fluctuate from year to year. We note that we generally use the latest claims data available to set the annual payment rates. Payment rates for the CY 2025 OPPTS/ASC final rule will be based on claims with dates of service between January 1, 2023, and December 31, 2023, processed through June 30, 2024.

Over the years we have received comments noting that the payment for these codes has declined since 2017. Commenters have indicated that the payment amount is insufficient to cover the cost of providing the service and have stated that the payment amount does not

consider the hospital resources required to perform these services, including the use of the equipment, medication administration, staff time, and scanner time. We have maintained over the years that an analysis of our claims data for these three (3) codes have shown geometric mean costs consistent with the geometric mean cost for APC 5571 (Level 1 Imaging with Contrast).

We have also received comments in the past urging CMS to allow hospitals the flexibility to submit charges for cardiac CT services with a revenue code other than CT scan (035X) and Radiology Diagnostic (032X) revenue codes, implying that MACs had applied edits to the cardiac CT codes that prevented hospitals from reporting a cardiology (048X) revenue code when appropriate. It is longstanding CMS policy that hospital outpatient facilities are responsible for reporting the appropriate cost centers and revenue codes on claims. As stated in section 20.5 in Chapter 4 (Part B Hospital) of the Medicare Claims Processing Manual, CMS “does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPSS since hospitals’ assignment of cost vary. Where explicit instructions are not provided, HOPDs should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.” We have consistently stated that hospital outpatient facilities must determine the most appropriate cost center and revenue code for the cardiac CT codes (87 FR 71849, 88 FR 81664).

After we issued the CY 2024 OPSS/ASC final rule, interested parties notified CMS of a specific claims edit that may have affected the revenue codes reported with the cardiac CT codes in prior years’ claims data. CMS confirmed the existence of the revenue code edit and removed the revenue code edit in early December 2023. We informed the public of our findings and the changes that we made in the January 2024 OPSS Update (Transmittal 12421, Change Request 13488), dated December 21, 2023. Specifically, we stated the following: “We recently identified an outdated return-to-provider (RTP) Healthcare Common Procedure Coding System-to-revenue

code edit that resulted in certain claims submissions being limited to specific revenue codes for CPT codes 75572, 75573, and 75574. These claims were returned to the providers for resubmission. The outdated edit has been removed; and providers, when appropriate, may begin billing these codes with any appropriate revenue code.”

We believe the edit may have prevented some providers from reporting the cardiology revenue code (048X), which maps to the cardiology cost center (03140), when billing for cardiac CT services. In the past, commenters have indicated that the cardiology cost center has a higher cost-to-charge ratio (CCR) than the imaging cost centers, and they believe the inability to report the cardiology revenue code has resulted in a lower payment rate for cardiac CT services. Since the OPSS 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 OPSS payment compared to utilizing cost centers with higher CCRs. With the edit no longer in place, hospitals may bill for cardiac CT services with whichever revenue code they believe appropriate for CY 2024, and the CY 2026 OPSS payment rates (which most likely will be based on CY 2024 claims) will reflect those updated revenue code billing patterns.

We note that for CY 2025, based on our standard ratesetting methodology using claims submitted during CY 2023, our analysis reveals that the angiocardiology and CT scan revenue codes were reported with CPT codes 75572 – 75574, which were mapped to cost centers angiocardiology and CT scan, as shown in Table 37.

TABLE 37: STANDARD OPSS RATESETTING METHODOLOGY – REVENUE CODES AND COST CENTERS REPORTED WITH THE CARDIAC COMPUTED TOMOGRAPHY (CT) CPT CODES 75572, 75573, AND 75574

2023 Revenue Code	Revenue Code Description (applicable to CY 2023 claims)	Used in 2025 OPSS (2023 claims)	Primary Cost Center	Primary Cost Center Description
0321	Radiology - Diagnostic: Angiocardiology	Y	03030	Angiocardiology
0350	Computed tomographic (CT scan) - general	Y	05700	CT Scan

0351	Computed tomographic (CT scan) - head scan	Y	05700	CT Scan
0352	Computed tomographic (CT scan) - body scan	Y	05700	CT Scan
0359	Computed tomographic (CT scan) - other CT scans	Y	05700	CT Scan

Because we wanted to determine the extent to which the revenue edit may have affected the GMC for CPT codes 75572 – 75574, we conducted a study to calculate HCPCS geometric mean costs for these codes based on a simulation that assumed that differing numbers of HOPDs (specifically 25 percent, 50 percent, and 75 percent of the total number of HOPDs billing for these services) would have assigned these services to the cardiology revenue code (048X) and cardiology cost center (03140). Based upon the results of the study, we found that if 50 percent or more of HOPDs had billed these services with the cardiology revenue code (048X) and cardiology cost center (03140), the GMC for these codes would have increased and would have resulted in a revised APC assignment from APC 5571 (Level 1 Imaging with Contrast) to APC 5572 (Level 2 Imaging with Contrast). Specifically, as noted in Table 38, under our standard ratesetting methodology, the GMC for the cardiac CT codes would be approximately \$182, which maps to APC 5571, while an assumption that 50 percent of HOPDs billed with the cardiology revenue code (048X) and cardiology cost center (03140) on CY 2023 claims would result in a GMC of about \$386, which maps to APC 5572.

TABLE 38: STANDARD OPPTS RATESETTING METHODOLOGY VS. SIMULATED 50 percent OF HOPDs UTILIZING THE CARDIOLOGY REVENUE CODE AND CARDIOLOGY COST CENTER

Code	Number of Claims Used for Ratesetting	Standard OPPTS Methodology GMC	Standard OPPTS Methodology Ambulatory APC	50% HOPD GMC	50% HOPD Methodology APC
75572	26,819	\$148.88	APC 5571	\$240.70	APC 5572
75573	647	\$182.26	GMC \$181.72	\$278.20	GMC \$386.46

75574	69,377	\$185.98		\$299.80	
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Because the RTP edit associated with the cardiac CT codes may have affected the CY 2023 data we have available to establish the CY 2025 OPSS payment rates for these services, in this CY 2025 OPSS/ASC proposed rule, we are requesting information on the following topics regarding hospitals' billing practices for cardiac CT services:

- 1) Where are cardiac CT services performed in a hospital? Are cardiac CT services performed in a dedicated cardiology department, radiology department, or some other hospital outpatient department?
- 2) What factors determine the revenue code assignment for cardiac CT services (i.e., the department in which the service is performed, the type of service that is performed, or some other factor)?
- 3) What revenue codes are HOPDs reporting for these services in CY 2024? Are HOPDs using the cardiology revenue code on claims for cardiac CT services now that they are no longer restricted from using this revenue code?

In addition to reviewing comments received, we will review the limited CY 2024 claims data for Cardiac CT services to ascertain the percentage of HOPDs that are utilizing the cardiology revenue code (048X) and cardiology cost center (03140) with the understanding that many HOPDs may still be updating their current billing practices. The comments received and the information we glean from the CY 2024 claims data will help us identify whether the current OPSS payment is appropriate for the cardiac CT codes, or whether we should consider revising the payment methodology for the CY 2025 OPSS. If these comments indicate a number of HOPDs sufficient to affect the geometric mean and APC assignment for these codes (i.e., 50 percent or more of HOPDs) are now billing these codes with the cardiology revenue code and cardiology cost center, we would change the payment methodology for these codes to simulate the GMC these codes would have had for CY 2025 ratesetting, with the assumption that 50

percent or more of HOPDs would have billed in CY 2023 using the cardiology revenue code (048X) and cardiology cost center (03140) if not for the revenue code edit. We would assign these services to the APC that corresponds to the simulated GMC, which we currently project to be APC 5572 (Level 2 Imaging with Contrast). We note that if a revision in payment methodology is implemented for CY 2025 for the cardiac CT codes, specifically, CPT codes 75572, 75573, and 75574, for CY 2025, such a change would not involve reprocessing of claims with dates prior to January 1, 2025. If, after comments are received and the limited CY 2024 claims data for cardiac CT services is reviewed, we are not persuaded that 50 percent or more of HOPDs would have billed using the cardiology revenue codes (048X) and cardiology cost center (03140) in CY 2023 if not for the revenue code edit, we would maintain our standard ratesetting for these services as proposed in this proposed rule.

2. Neurostimulator and Related Procedures (APCs 5461 Through 5465)

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66807 through 66808), we finalized a restructuring of what were previously several neurostimulator procedure-related APCs into a four-level series. In addition to that restructuring, in the CY 2015 OPPS/ASC final rule with comment period, we also made the Levels 2 through 4 APCs comprehensive APCs (79 FR 66807 through 66808). Later, in the CY 2020 OPPS/ASC final rule with comment period, we also made the Level 1 Neurostimulator and Related Procedure APC (APC 5461) a comprehensive APC (84 FR 61162 through 61166).

In reviewing the claims data available for the CY 2021 OPPS/ASC proposed rule, we believed that it was appropriate to create an additional Neurostimulator and Related Procedures level, between what were then the Levels 2 and 3 APCs. Creating this APC allowed for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Therefore, for the CY 2021 OPPS, we finalized a five-level APC structure for the Neurostimulator and Related Procedures series (85 FR 85968 through 85970). In addition to creating the new level, we also assigned CPT code 0398T (Magnetic resonance

image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to the new Level 3 APC (85 FR 85970).

Some interested parties requested for the CY 2023 OPSS/ASC proposed rule 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. Based on our review of the data available for the CY 2023 OPSS/ASC proposed rule, we believed that the five-level structure for the Neurostimulator and Related Procedures APC series remained appropriate. The proposed geometric mean cost for the Level 5 Neurostimulator and Related Procedures was \$30,198.36 with the geometric means of cost significant codes in Level 5 ranging from approximately \$28,000 to \$36,000, which was well within the range of the 2 times rule. In addition, a review of the clinical characteristics of the services in the APC suggested that the current structure was appropriate. Finally, as discussed in the CY 2021 OPSS/ASC final rule with comment period, we reiterated that the OPSS 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 OPSS 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 did not propose any changes in the CY 2023 OPSS/ASC proposed rule to the 5-level structure of the Neurostimulator and Related Procedures APC series, we recognized the interested parties' concerns regarding the granularity of the current APC levels and their request to create an additional level to address such concerns. Accordingly, we solicited comments on the potential creation of a new Level 6 APC. After consideration of those comments, we

finalized a five level APC structure for the series and reassigned HCPCS code 0424T to New Tech APC 1581 (87 FR 71869).

In the CY 2024 OPPTS/ASC final rule with comment period, we did not make any changes to the 5 level APC structure for the Neurostimulator and Related Procedures series. However, we made temporary changes to services previously assigned to the neurostimulator APCs: reassigning HCPCS codes 0424T and 33276 from New Tech APC 1581 to New Tech APC 1580 (88 FR 81645 through 81647) and assigning HCPCS code 0266T to New Tech APC 1580 (88 FR 81658).

For this CY 2025 OPPTS/ASC proposed rule, we believe that the 5 level APC structure for the series remains appropriate. We note that while we have claims data available for HCPCS codes 0424T, 0266T, and several other codes in the APC series that are no longer active, there will be cost and coding changes associated with the new CPT codes as their claims data become available. For example, CPT codes 33276 (Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed) and 33287 (Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator) both became newly active in CY 2024. With the changes associated with those codes we believe that it is appropriate to reassign HCPCS codes 0266T and 33276 to the clinical APCs, specifically to the level 5 APC in the series. We will continue to monitor as more claims data become available for the new codes.

While we continue to believe that a five-level structure for the Neurostimulator and Related Procedures APC series remains appropriate, we continue to solicit comments 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 APC.

In summary, for the CY 2025 OPSS, we propose to maintain the current 5-level structure for the Neurostimulator and Related Procedure APC series and assign HCPCS codes 0424T, 0266T, and 33276 to the level 5 APC. However, we are also soliciting comment on potentially creating an additional Level 6 APC in the series from the current Level 5 APC that would include HCPCS codes 33276, 0266T, 64568, 0424T, 0427T, and 0431T.

See Table 39 for the services that will be reassigned to the Level 5 APC and Table 40 below for the proposed CY 2025 Neurostimulator and Related Procedures APCs.

TABLE 39: FINAL CY 2024 AND PROPOSED CY 2025 APC AND STATUS INDICATOR ASSIGNMENTS

HCPCS Code	HCPCS Long Descriptor	Final CY 2024 OPSS SI	Final CY 2024 OPSS APC	Proposed CY 2025 OPSS SI	Proposed CY 2025 OPSS APC
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	S	1580	J1	5465
0424T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)	D	N/A	D	N/A
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed	S	1580	J1	5465

TABLE 40: PROPOSED CY 2025 NEUROSTIMULATOR AND RELATED PROCEDURES APCS

APC	Group Title	SI	Proposed CY 2025 APC Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	\$3,653.12
5462	Level 2 Neurostimulator and Related Procedures	J1	\$6,779.89
5463	Level 3 Neurostimulator and Related Procedures	J1	\$13,472.02
5464	Level 4 Neurostimulator and Related Procedures	J1	\$21,777.61
5465	Level 5 Neurostimulator and Related Procedures	J1	\$31,222.52

3. Focal Laser Ablation (APC 5374)

Focal laser ablation is an MRI directed and image guided, minimally invasive procedure that targets prostate cancer tissue. The focal laser ablation procedure, represented by CPT code 0655T (Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with mr-fused images or other enhanced ultrasound imaging), became effective July 1, 2021, and describes the destruction of localized prostate cancer tissue with the high energy source of focal laser radiation. The procedure utilizes real-time intraoperative prostate ultrasound fused with MRI guidance to allow the surgeon to precisely plan the ablation and guide the laser targeting as well as providing real-time feedback to minimize changes to the tissues outside of the targeted ablation zone. This procedure offers another therapy option for select patients with localized intermediate risk prostate cancer.

For CY 2024, we assigned CPT code 0655T to APC 5374 (Level 4 Urology and Related Services) with a payment rate of \$3,321.58 based on its geometric mean cost of approximately \$10,323, which was calculated using the available 16 single frequency claims from the CY 2022 claims data.

For this CY 2025 OPPS/ASC proposed rule, we reviewed the CY 2023 claims submitted between January 1, 2023, through December 31, 2023, that were processed on or before December 31, 2023, for CPT code 0655T and found seven single frequency claims available for ratesetting, with a resulting geometric mean cost of \$12,777. Additionally, for this CY 2025 OPPS/ASC proposed rule, we examined the procedures assigned to the Urology Procedures APCs. Based on our examination of the procedures assigned to Urology and Related Procedures APCs and the available CY 2023 claims data, we believe it is appropriate to move CPT code 0655T to APC 5375 (Level 5 Urology and Related Services) from APC 5374 (Level 4 Urology and Related Services) because 0655T shares more resource cost and clinical homogeneity with procedures in APC 5375. Specifically, we believe CPT code 0655T shares resource and clinical homogeneity with CPT code 0714T (Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance), and CPT code 52648 (Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)). We note that the seven available CY 2023 single frequency claims for CPT code 0655T would not significantly impact the geometric mean cost calculations for APC 5374 and APC 5375. Therefore, for CY 2025, we propose to reassign CPT code 0655T from APC 5374 (Level 4 Urology and Related Services) to APC 5375 (Level 5 Urology and Related Services).

4. Bone Mass Measurement: Biomechanical Computed Tomography (BCT) Analysis with Vertebral Fracture Assessment (APCs 5521, 5523, and 5731)

CPT code 0743T (Bone strength and fracture risk using finite element analysis of functional data and bone mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture-risk assessment, interpretation and report) became effective January 1, 2023.

This code describes the service associated with BCT analysis with concurrent vertebral fracture assessment (VFA).

In the CY 2023 OPSS/ASC final rule (87 FR 71844 through 71846), we stated that, based on our review and understanding of the service, BCT analysis does not meet Medicare's definition of bone mass measurement, as specified in §410.31(a), which specifies the coverage of, and payment for, bone mass measurements for Medicare beneficiaries. Therefore, we assigned the BCT codes (CPT codes 0554T–0558T) and CPT code 0743T to status indicator “E1” to indicate that these codes are not covered by Medicare, and not paid by Medicare when submitted on outpatient claims (any outpatient bill type). The complete long descriptors for the codes can be found in Table 41 below.

In the CY 2024 OPSS/ASC proposed rule, we proposed to continue to assign the codes to status indicator “E1” to indicate non-coverage and non-payment for the services. (See Addendum B for CY 2024/ASC proposed rule via the internet on the CMS website.) However, as discussed in the CY 2024 OPSS/ASC final rule (88 FR 81660 through 81661), based on comments received and further review of the issue, we did not finalize our proposal. We instead assigned CPT code 0555T to APC 5731 (Level 1 Minor Procedures) and SI of “S,” (Procedure or Service, Not Discounted When Multiple; Paid under OPSS; separate APC payment.), CPT code 0556T to APC 5523 (Level 3 Imaging without Contrast) and SI of “S,” and CPT code 0558T to APC 5521 (Level 1 Imaging without Contrast) with SI of “S,” which were the same APC assignments for the codes between CY 2019 and CY 2022. In addition, we assigned CPT codes 0554T, 0557T, and 0743T to SI of “M” (Items and Services Not Billable to the MAC. Not paid under OPSS.) to indicate that these codes are not payable under the OPSS because they describe physician-only services. The final payment rates for these codes were listed in the OPSS Addendum B that was released with the CY 2024 OPSS/ASC final rule via the internet on the CMS website.

For CY 2025, we propose to continue to assign CPT codes 0554T and 0557T to status indicator of “M” as the codes include or describe a professional component of the service that is provided by a physician as evidenced by “interpretation and report” in the descriptor. It is important to note that CPT code 0554T is a comprehensive code (or “parent code”) that includes both technical and professional components. Because there are additional CPT codes (“child codes”) that facilities can use to describe the technical components of BCT analysis, it is appropriate for the comprehensive code that includes the professional component to be assigned a SI of “M”. In addition, we propose to continue to assign CPT code 0555T to APC 5731 (Level 1 Minor Procedures) and a SI of “S,” CPT code 0556T to APC 5523 (Level 3 Imaging without Contrast) and a SI of “S,” and CPT code 0558T to APC 5521 (Level 1 Imaging without Contrast) with a SI of “S.” However, for CY 2025, based on input from our medical advisors, we now believe the service described by CPT code 0743T is a comprehensive code and involves both a technical component and a professional component that are performed by hospital outpatient facilities. Unlike CPT 0554T, there are no additional codes to describe the technical component(s) of this service (BCT analysis and VFA) and there is a parenthetical note instructing facilities to not report the BCT analysis codes (0554T – 0557T) with CPT code 0743T. Consequently, we propose to assign CPT code 0743T to APC 5523 (Level 3 Imaging without Contrast) and we propose to change the status indicator for 0743T from a “M” in CY 2024 to a “S” (Procedure or Service, Not Discounted When Multiple; Paid under OPSS; separate APC payment) for CY 2025. As a reminder, Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Accordingly, we emphasize that HOPDs would only receive payment for these services when the appropriate MAC determines that the service meets the relevant conditions for coverage and payment. As we have consistently stated in past OPSS/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 OPSS

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).

Please refer to Table 41 below for the proposed APCs and status indicator assignment for CPT codes 0554T–0558T and CPT code 0743T for CY 2025. The proposed CY 2025 payment rates, where applicable, can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 41—PROPOSED CY 2025 APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 0554T-0558T AND CPT CODE 0743T

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0554T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone-mineral density, interpretation and report	M	
0555T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data	S	5731
0556T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone-mineral density	S	5523
0557T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; interpretation and report	M	
0558T	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis	S	5521
0743T	Bone strength and fracture risk using finite element analysis of functional data and bone mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with	S	5523

	overall fracture-risk assessment, interpretation and report		
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IV. Proposed OPSS Payment for Devices

A. Proposed 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 OPSS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at § 419.66(g) provided that this pass-through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPSS/ASC final rule with comment period (81 FR 79654), 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 OPSS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the dates for expiration of pass-through status for device categories as part of the OPSS annual update. This means that device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through payments had been made, regardless of the quarter in which the device

was approved. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices. We also have an established 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.²⁰

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 13 device categories eligible for pass-through payment. These devices are listed in Table 42 of this proposed rule where we detail the expiration dates of

²⁰ 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.

pass-through payment status for each of the 13 devices currently receiving device pass-through payment.

TABLE 42: DEVICES WITH PASS-THROUGH STATUS EXPIRING IN 2024, IN 2025, IN 2026, OR IN 2027

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1831	Personalized, anterior and lateral interbody cage (implantable)	10/01/2021	09/30/2024
C1832	Autograft suspension, including cell processing and application, and all system components	01/01/2022	12/31/2024
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	01/01/2022	12/31/2024
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

As discussed in section IV.A.2. New Device Pass-Through Applications for CY 2024 of the CY 2024 OPPS/ASC final rule with comment period, we approved HCPCS code C1601 (Endoscope, single-use (i.e. disposable), pulmonary, imaging/illumination device (insertable)), as a new device category for pass-through status under the OPPS, with an effective date of January 1, 2024. For the full discussion of the criteria used to evaluate device pass-through applications, refer to the CY 2024 OPPS/ASC final rule with comment period, which was published in the Federal Register on November 22, 2023 (88 FR 81729 through 81743). We note that HCPCS code C1601 was established for a bronchoscope that can only be used for a single procedure and cannot be reprocessed. As such, HCPCS code C1601 only describes devices that cannot be reprocessed.

In addition, 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.

2. New Device Pass-Through Applications for CY 2025

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 OPPTS, 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.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory 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 annual rulemaking process, 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.

b. Applications Received for Device Pass-Through Status for CY 2025

We received 14 complete applications by the March 1, 2024 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 two applications in the second quarter of 2023, two application in the third quarter of 2023, three applications in the fourth quarter of 2023, and seven applications in the first quarter of 2024. Three of the applications were approved for device pass-through payment during the quarterly review process: The DETOUR™ System, which received was preliminarily approved upon quarterly review under the alternative pathway effective January 1, 2024, and the AVEIR™ DR Dual Chamber Leadless Pacemaker System and the EndoSound Vision System® (EVS) which both were preliminarily approved upon quarterly review under the alternative pathway effective July 1, 2024. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically

be included in the next applicable OPPTS annual rulemaking cycle. Therefore, the DETOUR™ System, the AVEIR™ DR Dual Chamber Leadless Pacemaker System, and the EndoSound Vision System® (EVS) are discussed in the following section IV.2.b.1.

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 1, 2024 deadline are included in this proposed rule.

(1) Alternative Pathway Device Pass-Through Applications

We received 10 device pass-through applications by the March 2024 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) AGENT™ Paclitaxel-Coated Balloon Catheter

Boston Scientific Corporation submitted an application for a new device category for transitional pass-through payment status for AGENT™ Paclitaxel-Coated Balloon Catheter for CY 2025. Per the applicant, AGENT™ Paclitaxel-Coated Balloon Catheter is a device/drug combination product consisting of a semi-compliant intracoronary balloon catheter with a paclitaxel/acetyl tributyl citrate drug coating on the balloon component. The applicant asserted that AGENT™ Paclitaxel-Coated Balloon Catheter delivers paclitaxel, an antiproliferative drug, directly to the arterial tissue which inhibits the proliferation of neointimal smooth muscle cells without introducing an additional stent layer, thereby reducing the rate of restenosis. According to the applicant, AGENT™ Paclitaxel-Coated Balloon Catheter is intended for use in adult patients, after appropriate vessel preparation, undergoing percutaneous coronary intervention

(PCI) in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating in-stent restenosis (ISR) and the management of atherosclerotic coronary artery disease.

Please refer to the online application posting for the AGENT™ Paclitaxel-Coated Balloon Catheter, available at <https://mearis.cms.gov/public/publications/device-ftp/DEP2402295H2TU> , for additional detail describing this device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPTS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), AGENT™ Paclitaxel-Coated Balloon Catheter received FDA Breakthrough Device designation effective January 22, 2021, as a combination product indicated for percutaneous transluminal coronary angioplasty in coronary arteries 2.0 mm to 4.0 mm in diameter to treat ISR, up to 26 mm in length, for the purpose of improving myocardial perfusion. FDA approved the premarket approval application (PMA) for AGENT™ Paclitaxel-Coated Balloon Catheter on February 29, 2024, as indicated for use after appropriate vessel preparation in adult patients undergoing PCI in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating ISR. We note that while the indication for the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we believe that FDA premarket approval indication is the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for AGENT™ Paclitaxel-Coated Balloon Catheter on February 29, 2024, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether AGENT™ Paclitaxel-Coated Balloon Catheter meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished, 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. The applicant did not explicitly indicate whether the AGENT™ Paclitaxel-Coated Balloon Catheter is integral to the service provided. The applicant stated that the AGENT™ Paclitaxel-Coated Balloon Catheter is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted as required by § 419.66(b)(3).

We are inviting public comments on whether AGENT™ Paclitaxel-Coated Balloon Catheter meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant did not indicate whether AGENT™ Paclitaxel-Coated Balloon Catheter is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if AGENT™ Paclitaxel-Coated Balloon Catheter is a supply or material furnished incident to a service.

We are inviting public comments on whether AGENT™ Paclitaxel-Coated Balloon 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. According to the applicant, no previous or

existing device categories for pass-through payment appropriately describe the AGENT™ Paclitaxel-Coated Balloon Catheter. Per the applicant, while device category C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) describes related or similar products to the AGENT™ Paclitaxel-Coated Balloon Catheter, the AGENT™ Paclitaxel-Coated Balloon Catheter is not appropriately described by C2623 because the devices in this category differ from AGENT™ Paclitaxel-Coated Balloon Catheter in both size and indicated use, and therefore, the device is not appropriately described by C2623. The applicant further claimed that the devices described by C2623 are approved for use in the femoral or popliteal arteries in vessels with a diameter of at least 4.0 mm, whereas AGENT™ Paclitaxel-Coated Balloon Catheter is indicated for use in coronary arteries that are between 2.0 mm to 4.0 mm in diameter. In addition, the applicant also noted that the length of the lesions (up to 180 mm) treated with devices in this device category greatly exceeds the maximum lesion size of 26 mm for AGENT™ Paclitaxel-Coated Balloon Catheter. Moreover, the applicant asserted that the devices described by C2623 are used to treat peripheral arterial disease and are contraindicated for use in coronary arteries. Per the applicant, the AGENT™ Paclitaxel-Coated Balloon Catheter is used in conjunction with transluminal PCIs which are described by different procedure codes than the percutaneous transluminal angioplasty services used for the devices in C2623. Lastly, the applicant stated that an analysis of claims found that the devices described by C2623 are typically reported with femoral or popliteal revascularization procedures (CPT® codes from 37224 to 37227).

We note that, based on the description the applicant provided, the AGENT™ Paclitaxel-Coated Balloon Catheter is a device/drug combination product consisting of a semi-compliant intracoronary balloon catheter with a paclitaxel/acetyl tributyl citrate drug coating on the balloon component and thus could be appropriately described by C2623. Specifically, we believe that C2623 may appropriately describe the AGENT™ Paclitaxel-Coated Balloon Catheter because it is a non-laser, drug-coated catheter used for transluminal angioplasty procedures. In this context, we believe the AGENT™ Paclitaxel-Coated Balloon Catheter may be similar to the devices

described by C2623, and therefore, the AGENT™ Paclitaxel-Coated Balloon Catheter may also be appropriately described by C2623.

In addition, while we acknowledge that when C2623 was established as a device category code effective April 1, 2015, the procedure codes with which C2623 could be reported (CPT® 37224 and CPT® 37226) were limited to use in the femoral or popliteal arteries. However, based on the subsequent changes that were made to the procedure codes with which C2623 could be reported, we do not agree that C2623 is limited to use with femoral or popliteal revascularization procedures. First, we note that effective August 25, 2017, while C2623 was in device pass-through payment status, CMS added two procedure codes with which C2623 could be reported that were for procedures other than femoral popliteal revascularization procedures. Specifically, based on the FDA approval of a new indication for an existing device (a drug-coated balloon catheter for use with dialysis circuit procedures for the treatment of patients with dysfunctional arteriovenous fistulae²¹), CMS added two procedure codes, CPT® codes 36902 and 36903 (transluminal balloon angioplasty procedures in peripheral dialysis segments), with which C2623 could be reported effective August 25, 2017. The devices used with these two added CPT® codes, 36902 and 36903, which are also described by C2623, are drug-coated balloon catheters used for dialysis circuit procedures in the upper extremities. We believe that the inclusion of these additional reportable procedure codes illustrates our belief that devices that may be described by C2623 were neither intended to be restricted to the treatment of vascular lesions of a specified dimension nor anatomically limited to femoral or popliteal revascularization procedures and is inconsistent with the applicant's assertion that AGENT™ Paclitaxel-Coated Balloon Catheter is not appropriately described by C2623 because the

²¹Centers for Medicare & Medicaid Services (2017). Pub 100-04 Medicare Claims Processing (Transmittal 3941) in CMS Manual System. Accessed at <https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2017downloads/r3941cp.pdf>

category is only applicable for devices used in femoral or popliteal arteries with a diameter of at least 4.0 mm, and not smaller coronary arteries.

Further, beginning January 1, 2018, upon the expiration of device pass-through payment status for C2623, CMS packaged the payment for the costs of each of the devices described by C2623 into the payment for the costs related to the procedure with which each device is reported in the hospital claims data (FR 82 59321 through 59323). We further note that upon becoming packaged for payment, C2623 effectively became reportable with other transluminal angioplasty procedure codes, including procedure codes for percutaneous coronary transluminal angioplasty services. Finally, we note that while, per the applicant, the devices described by C2623 are typically reported with femoral or popliteal revascularization procedures, other procedure codes, including procedure codes for other percutaneous transluminal angioplasty services and other related coronary procedure codes can and have been performed with devices described by C2623. As such, we believe that the procedures with which AGENT™ Paclitaxel-Coated Balloon Catheter is utilized could be reported with C2623.

In this context, based on the description the applicant provided, we believe the AGENT™ Paclitaxel-Coated Balloon Catheter may be similar to the devices described by C2623, and therefore, the AGENT™ Paclitaxel-Coated Balloon Catheter may also be appropriately described by C2623.

We are inviting public comment on whether AGENT™ Paclitaxel-Coated Balloon 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: (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. AGENT™ Paclitaxel-Coated Balloon Catheter has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether AGENT™ Paclitaxel-Coated Balloon Catheter meets the device category criterion at § 419.66(c)(2)(ii).

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 provided the following information in support of the cost significance requirements. The applicant stated that AGENT™ Paclitaxel-Coated Balloon Catheter would be reported with the HCPCS codes as shown in Table 43.

Table 43: HCPCS CODES REPORTED WITH AGENT™ PACLITAXEL-COATED BALLOON CATHETER

HCPCS Code	Long Descriptor	SI	APC
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	J1	5192
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch	J1	5193
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J1	5193
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	J1	5194
C9600	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J1	5193
C9602	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	J1	5194

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 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5192, which had a CY 2024 payment rate of \$5,445.84 at the time the application was received. HCPCS code 92920 in APC 5192 had a device offset amount of \$1,662.61 at the time the application was received. According to the applicant, the cost of AGENT™ Paclitaxel-Coated Balloon Catheter is \$5,500.00.

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 \$5,500.00 for AGENT™ Paclitaxel-Coated Balloon Catheter is 101.00 percent of the applicable APC payment amount for the service related to the category of devices of \$5,445.84 ($(\$5,500.00/\$5,445.84) \times 100 = 101.00$ percent). Therefore, we believe AGENT™ Paclitaxel-Coated Balloon 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 \$5,500.00 for AGENT™ Paclitaxel-Coated Balloon Catheter is 330.81 percent of the cost of the device-related portion of the APC payment amount for the related service of \$1,662.61

$((\$5,500.00/\$1,662.61) \times 100 = 330.81 \text{ percent})$. Therefore, we believe that AGENT™

Paclitaxel-Coated Balloon 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 \$5,500.00 for AGENT™ Paclitaxel-Coated Balloon Catheter and the portion of the APC payment amount for the device of \$1,662.61 is 70.46 percent of the APC payment amount for the related service of \$5,445.84 ($((\$5,500.00 - \$1,662.61)/\$ 5,445.84) \times 100 = 70.46 \text{ percent}$). Therefore, we believe that AGENT™ Paclitaxel-Coated Balloon Catheter meets the third cost significance requirement.

We are inviting public comment on whether the AGENT™ Paclitaxel-Coated Balloon Catheter meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(b) Aveir™ DR Dual Chamber Leadless Pacemaker System

Abbott Laboratories submitted an application for a new device category for transitional pass-through payment status for the Aveir™ DR Dual Chamber Leadless Pacemaker System (Aveir™ DR System) for CY 2025. Per the applicant, the Aveir™ DR System is comprised of two leadless pacemakers, one atrial and one ventricular with each containing a generator and electrodes, that provide dual-chamber pacing therapy after being placed within the heart's myocardium through a minimally invasive catheter-based procedure. According to the applicant, the Aveir™ DR System is a programmable system equipped with bidirectional implant-to-implant communication without the need for traditional wire electrodes and can provide beat-to-beat communication and synchrony between the two pacemakers for the treatment of arrhythmia/bradycardia. Per the applicant, patients with indication for dual-chamber pacing would benefit from a dual-chamber leadless pacemaker system that provides atrial and

ventricular bradycardia therapy, while eliminating the complications associated with conventional pacing systems.

Please refer to the online application posting for the Aveir™ DR System, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP230831B8DX0> , for additional detail describing the device and the disease treated by the device.

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 Aveir™ DR System received FDA Breakthrough Device designation effective March 27, 2020, as a pacemaker implantation indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of these symptoms. FDA approved the premarket approval application (PMA) for the Aveir™ DR System on June 29, 2023, for the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the Aveir™ DR System on March 23, 2023, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the Aveir™ DR 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, 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. The applicant did not indicate whether the Aveir™ DR System is integral to the service furnished. The applicant also did not explicitly state that the Aveir™ DR System is single-use; however, the applicant stated that one Aveir™ DR System is required per patient per procedure. While the applicant did not explicitly state whether the Aveir™ DR System comes in contact with human tissue or is surgically inserted or implanted, the applicant noted that the two Aveir™ Delivery

Catheters are inserted into the peripheral vasculature and the cardiovascular system to deliver and implant the Aveir™ AR Atrial Leadless Pacemaker and the Aveir™ VR Ventricular Leadless Pacemaker into the right atrium and right ventricle of the heart, respectively.

We are inviting public comments on whether the Aveir™ DR System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant did not indicate whether the Aveir™ DR System is equipment, an instrument, apparatus, implement, or item of this type for which depreciating and financing expenses are recovered, or if the Aveir™ DR System is a supply or material furnished incident to a service.

We are inviting public comments on whether the Aveir™ DR 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. The applicant asserted that the Aveir™ DR System is the only dual-chamber leadless pacemaker authorized by FDA and indicated for implantation in patients with one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those conditions. Per the applicant, the Aveir™ DR System is a modular dual-chamber leadless

pacemaker system with bidirectional implant-to-implant communication that can accommodate all pacing indications. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the Aveir™ DR System. The applicant stated that device categories C1785 (Pacemaker, dual-chamber, rate-responsive (implantable)) and C1889 (Insertable/implantable device, not otherwise classified) do not appropriately describe the Aveir™ DR System because the Aveir™ DR System received Breakthrough Device designation from FDA and has specific functionality and capabilities that are new to the market. The applicant also asserted that the Aveir™ DR system is modular, such that a single device can be implanted in a heart chamber initially, and the second pacemaker added to the other heart chamber in the future should the clinical need arise; and therefore, it is not appropriately described by either C1785 or C1889.

We have not identified an existing pass-through payment category that describes the Aveir™ DR System. We are inviting public comment on whether the Aveir™ DR 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 Aveir™ DR 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 discussion of the newness criterion), and therefore, is not evaluated for substantial clinical improvement.

We are inviting public comment on whether Aveir™ DR System meets the device category criterion at § 419.66(c)(2)(ii).

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 provided the following information in support of the cost significance requirements. The applicant stated that the Aveir™ DR System would be reported with HCPCS codes as shown in Table 44.

Table 44: HCPCS CODES REPORTED WITH THE AVEIR™ DR SYSTEM

HCPCS Code	Long Descriptor	SI	APC
0801T**	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)	J1	5224
0795T**	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	J1	5224

**Denotes a HCPCS code that was not included in Addendum P to the CY 2023 OPSS/ASC final rule with comment period, with no CY 2023 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. Since neither of the HCPCS/CPT codes provided by the applicant had a CY 2023 HCPCS/CPT code level device offset amount available at the time the application was received, we used the CY 2023 APC level device offset amount 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 OPSS 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 2023 payment rates for the three tests of the

cost criterion. For our calculations, we used APC 5224, which had a CY 2023 payment rate of \$18,672.01 at the time the application was received. We used the CY 2023 APC level device offset amount of \$11,739.09 for APC 5224, as HCPCS codes 0795T and 0801T provided by the applicant were not included in Addendum P to the CY 2023 OPSS/ASC final rule with comment period and no CY 2023 HCPCS/CPT code level device offset amount was available at the time the application was received.²² According to the applicant, the cost of the Aveir™ DR System is \$24,000.00.

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 \$24,000.00 for the Aveir™ DR System is 128.54 percent of the applicable APC payment amount for the service related to the category of devices of \$18,672.01 ($(\$24,000.00/\$18,672.01) \times 100 = 128.54$ percent). Therefore, we believe the Aveir™ DR 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 \$24,000.00 for the Aveir™ DR System is 204.45 percent of the cost of the device-related portion

²²We note that the applicant originally utilized APC 5231 (Level 1 ICD and Similar Procedures) for the three tests of the cost criteria in the application. However, the applicant provided supplemental information indicating that, HCPCS codes 0795T and 0801T were assigned to APC 5224 (Level 4 Pacemaker and Similar Procedures) in the corrected Addendum B to the CY 2024 OPSS/ASC final rule with comment period and they believed that APC 5224 is currently the appropriate APC for the purposes of performing the cost significance calculations. We agree with the applicant and selected APC 5224 for our calculation, which we believe is a more appropriate APC to use based on the assignment of HCPCS codes 0795T and 0801T to APC 5224 and the clinical similarity to other pacemaker insertion codes in APC 5224.

of the APC payment amount for the related service of \$11,739.09 ($(\$24,000.00/\$11,739.09) \times 100 = 204.45$ percent). Therefore, we believe that the Aveir™ DR 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 \$24,000.00 for the Aveir™ DR System and the portion of the APC payment amount for the device of \$11,739.09 is 65.66 percent of the APC payment amount for the related service of \$18,672.01 ($((\$24,000.00 - \$11,739.09)/\$18,672.01) \times 100 = 65.66$ percent). Therefore, we believe that the Aveir™ DR System meets the third cost significance requirement.

We are inviting public comment on whether the Aveir™ DR System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(c) CANTURIO™ Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) System

Canary Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for the CTE with CHIRP® System for CY 2025. The applicant is only seeking a new device category for transitional pass-through payment status for the CTE component (hereinafter referred to as “CTE”) of the CTE with CHIRP® System. According to the applicant, the CTE implant is a physical implant that is attached to the tibial baseplate as part of a total knee arthroplasty (TKA) to form the patient’s knee prosthesis and provide additional stability to the replacement knee joint. Per the applicant the software and electronics within the CTE implant with CHIRP® system collects unprocessed 3-D accelerometer and 3-D gyroscopic sensor data using its Inertial Measurement Unit on the patient’s functional movement and gait parameter post-surgery and transmits the encrypted data via the Home Base Station to the cloud

platform. According to the applicant, the CTE implant with CHIRP® System is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension.

Please refer to the online application posting for the CTE implant with CHIRP® System, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP240229Q7CYC> , for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPTS, 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 CTE implant with CHIRP® System received FDA Breakthrough Device designation effective October 24, 2019, as indicated for use with the Zimmer Persona® Personalized Knee System (K113369) for TKA in patients with severe knee pain and disabilities, including: (1) rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis; (2) collagen disorders, and/or avascular necrosis of the femoral condyle; (3) post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy; (4) moderate valgus, varus, or flexion deformities; and (5) the salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery. The CTE implant with CHIRP® System is indicated to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care. FDA noted that the kinematic data are an adjunct to standard of care and physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery. FDA granted De Novo classification for the CTE implant with CHIRP® System on August 27, 2021, with the following indications for use: (1) to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care. The kinematic data are an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery; (2) for use in patients undergoing a cemented TKA procedure that

are normally indicated for at least a 58 mm sized tibial stem extension; (3) the objective kinematic data generated by the CTE implant with CHIRP® System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit; and (4) the CTE implant with CHIRP® System is compatible with Zimmer Persona® Personalized Knee System. We note that while the indication for the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we believe that FDA premarket approval indication is the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the CTE implant with CHIRP® System on February 29, 2024, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the CTE implant with CHIRP® System meets the newness criterion at § 419.66(b)(1).

Regarding the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished, 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. The applicant did not indicate whether the CTE implant is integral to the service furnished. We note that in CY 2014 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. Per the applicant, the CTE implant is a physical implant that is attached to the tibial baseplate as part of a TKA to form the patient’s knee prosthesis and provide additional stability to the replacement knee joint. We question whether the CTE implant is integral to the service furnished because utilization of the CTE implant during the primary procedure, TKA, appears to be purely additive in nature and not necessary to furnish or deliver the TKA consistent with our previous interpretation of integral. Further, we note that the indications for use of the CTE implant with CHIRP® System listed in the FDA DeNovo review letter states that the objective

kinematic data generated by the CTE implant with CHIRP® System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit. Moreover, a warning included in the device IFU for the CTE implant with CHIRP® System provides that the kinematic data obtained from this device have not been demonstrated to have clinical benefit. It is not intended to be utilized for clinical decision-making, and no data have been evaluated by FDA regarding clinical benefits. We note that the inclusion of the CTE implant does not appear to be necessary to furnish or deliver a TKA, nor does it appear that the data generated from the CTE implant post-procedure is necessary to furnish or deliver the primary service. In this context, we question whether the CTE implant can be considered integral in accordance with eligibility criteria at § 419.66(b)(3).

The applicant stated that the CTE implant was single-use, intended to be used with one patient only, comes into contact with human tissue, and is implanted into the patient's knee prosthesis.

We are inviting public comments on whether the CTE implant meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant did not indicate whether the CTE implant is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if the CTE implant is a supply or material furnished incident to a service.

We are inviting public comments on whether the CTE implant 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. The applicant asserted that the CTE implant with CHIRP® System is the only device authorized by FDA with an indication to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the CTE implant. Per the applicant, the device category code C1776 (Joint device (implantable)) does not appropriately describe the CTE implant because C1776 was created for older technology that performs the function of the joint and does not describe a device that captures activity and kinematic data but is not a substitute for the natural knee.

We have not identified an existing pass-through payment category that describes the CTE implant. We are inviting public comment on whether the CTE implant 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 CTE implant with CHIRP® system has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the

Breakthrough Device designation (as explained in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the CTE implant meets the device category criterion at § 419.66(c)(2)(ii).

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 provided the following information in support of the cost significance requirements. The applicant stated that the CTE implant would be reported with the HCPCS code as shown in Table 45.

Table 45: HCPCS CODES REPORTED WITH CTE IMPLANT

HCPCS Code	Long Descriptor	SI	APC
27447	Arthroplasty, knee, condyle, and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	J1	5115

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 OPFS 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 2024 payment rates for the three cost criterion tests. For our calculations, we used APC 5115, which had a CY 2024 payment rate of \$12,539.82 at the time the application was received. HCPCS code 27447 had a device offset amount of \$5,659.22 at the time the application was received. According to the applicant, the cost of the CTE implant part of the CTE implant with CHIRP® System is \$7,250.00.

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 \$7,250.00 for the CTE implant is 57.82 percent of the applicable APC payment amount for the service related to the category of devices of \$12,539.82 ($(\$7,250.00/\$12,539.82) \times 100 = 57.82$ percent). Therefore, we believe the CTE implant 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 \$7,250.00 for the CTE implant is 128.11 percent of the cost of the device-related portion of the APC payment amount for the related service of \$5,659.22 ($(\$7,250.00/\$5,659.22) \times 100 = 128.11$ percent). Therefore, we believe that the CTE implant 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 \$7,250 for the CTE implant and the portion of the APC payment amount for the device of \$5,659.22 is 12.69 percent of the APC payment amount for the related service of \$12,539.82 ($((\$7,250 - \$5,659.22)/\$12,539.82) \times 100 = 12.69$ percent). Therefore, we believe that the CTE implant meets the third cost significance requirement.

We are inviting public comment on whether the CTE implant meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(d) The DETOUR™ System

Endologix, LLC submitted an application for a new device category for transitional pass-through payment status for the DETOUR™ System for CY 2025. According to the

applicant, the DETOUR™ System is an implantable component, used to create a femoropopliteal bypass routed through the femoral vein. The DETOUR™ System is comprised of two main components: (1) the TORUS™ Stent Graft System, which is comprised of the TORUS™ Stent Graft and the TORUS™ Stent Graft Delivery System, and (2) the ENDOCROSS™ Device. Per the applicant, the DETOUR™ System is used to treat patients with advanced peripheral vascular disease, specifically those with long complex femoropopliteal artery stenoses and occlusions resulting in lifestyle limiting claudication or severe lower limb threatening ischemia. According to the applicant, the DETOUR™ System can restore arterial blood flow to the lower limb around the blocked femoral artery and allows for venous blood flow around the conduit for normal venous return, to reduce signs and symptoms of lower limb ischemia and prevent amputation.

Please refer to the online application posting for the DETOUR™ System, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP23090164QL2> , for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPTS, 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 DETOUR™ System received FDA Breakthrough Device designation effective September 2, 2020, under the name the PQ Bypass System, as a device intended for percutaneous revascularization of symptomatic femoropopliteal lesions 200mm to 460mm with a chronic total occlusion 100mm to 425mm, and/or moderate-to-severe calcification, and/or in-stent-restenosis in patients with severe peripheral arterial disease. FDA approved the premarket approval application (PMA) for the DETOUR™ System on June 7, 2023, indicated for use for percutaneous revascularization in patients with symptomatic femoropopliteal lesions from 200 mm to 460 mm in length with chronic total occlusions (100 mm to 425 mm) or diffuse stenosis >70 percent who may be considered suboptimal candidates for surgical or alternative endovascular treatments. The DETOUR™ System, or any of its components, is not for use in the coronary and cerebral vasculature. We note that while the

indication for the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we believe that FDA premarket approval indication is the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the DETOUR™ System on September 1, 2023, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the DETOUR™ 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, 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 DETOUR™ System is integral to the service provided and is used for one patient only. While the applicant did not indicate whether the DETOUR™ System comes in contact with human tissue, the applicant did specify that both components of the DETOUR™ System, the TORUS™ Stent Graft System and the ENDOCROSS™ Device, are inserted or implanted during the percutaneous transmural femoropopliteal bypass procedure, as required by § 419.66(b)(3).

We are inviting public comments on whether the DETOUR™ System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant asserted that the DETOUR™ System meets the device eligibility

requirements because it is not an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

We are inviting public comments on whether the DETOUR™ 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. The applicant described that the DETOUR™ System is a minimally invasive, single-use device with an implantable component, used to create a femoropopliteal bypass routed through the femoral vein. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the DETOUR™ System. The applicant provided a list of existing and previous device categories for pass-through payment for other stents and explained why they do not believe any of the categories describe the DETOUR™ System. In summary, the applicant asserted that the referenced device categories do not adequately describe the DETOUR™ System because, in contrast to the DETOUR™ System, the referenced device categories do not have: (1) a crossing device with long needle for transmural access, (2) a crossing device with high pressure needle delivery for heavily calcified and atherosclerotic arteries, (3) a high radial strength transmural stent graft capable of self-support and sustaining blood flow through conduit bridging artery to vein and back to artery, (4) a percutaneous stent graft delivery catheter, (5) a covered stent graft to allow for arterial blood flow within the conduit as venous blood flows around it in the vein, or (6) a permanent implant to maintain arterial and venous blood flow. The reasons the applicant asserted for why the DETOUR™ System is not adequately described by each of the device categories are shown in Table 46.

TABLE 46: POTENTIAL EXISTING/PREVIOUS DEVICE CATEGORIES

HCPCS Code	Device Category Description	Applicant Assertion: The DETOUR™ System Is Not Appropriately Described by Existing/Previous Device Category
C1874	Stent, coated/covered, with delivery system	(1) No crossing device with long needle for transmural access; (2) No crossing device with high pressure needle delivery for heavily calcific and atherosclerotic arteries; (3) No high radial strength transmural stent graft capable of self-support and sustaining blood flow through conduit bridging artery to vein and back to artery
C1875	Stent, coated/covered, without delivery system	Reasons (1); (2); (3); and (4) No percutaneous stent graft delivery catheter
C1876	Stent, non-coated/non-covered, with delivery system	Reasons (1); (2); (3); and (5) No covered stent graft to allow for arterial blood flow within the conduit as venous blood flows around it in the vein
C1877	Stent, non-coated/non-covered, without delivery system	Reasons (1); (2); (3); (4); and (5)
C2625	Stent, non-coronary, temporary, with delivery system	Reasons (1); (2); (3); (5) and (6) No permanent implant to maintain arterial and venous blood flow
C2617	Stent, non-coronary, temporary, without delivery system	Reasons (1); (2); (3); (4); (5); and (6)
C1768	Graft, vascular	Reasons (1); (2); (3); and (5)
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser	Reasons (1); (2); (3); and (5)
C2629	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, laser	Reasons (1); (2); (3); and (5)

We have not identified an existing pass-through payment category that describes the DETOUR™ System. We are inviting public comment on whether the DETOUR™ 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 DETOUR™ 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 discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the DETOUR™ System meets the device category criterion at § 419.66(c)(2)(i).

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 provided the following information in support of the cost significance requirements. The applicant stated that the DETOUR™ System would be reported with HCPCS code as shown in Table 47.

Table 47: HCPCS CODE REPORTED WITH THE DETOUR™ SYSTEM

HCPCS Code	Long Descriptor	SI	APC
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 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.	J1	5193

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 2023 payment rates for the three tests of the cost criterion. For our calculations, like the applicant, we used APC 5193, which had a CY 2023 payment rate of \$10,615.31 at the time the application was received. HCPCS code 0505T in APC 5193 had a CY 2023 device offset amount of \$5,229.10 at the time the application was received. According to the applicant, the cost of the DETOUR™ System is \$25,000.00.

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 \$25,000.00 for the DETOUR™ System is 235.51 percent of the applicable APC payment amount for the service related to the category of devices of \$10,615.31 ($(\$25,000.00/\$10,615.31) \times 100 = 235.51$ percent). Therefore, we believe the DETOUR™ 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 \$25,000.00 for the DETOUR™ System is 478.09 percent of the cost of the device-related portion of the APC payment amount for the related service of \$5,229.10 ($(\$25,000.00/\$5,229.10) \times 100 = 478.09$ percent). Therefore, we believe that the DETOUR™ 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 \$25,000.00

for the DETOUR™ System and the portion of the APC payment amount for the device of \$5,229.10 is 186.25 percent of the APC payment amount for the related service of \$10,615.31 $((\$25,000.00 - \$5,229.10)/\$10,615.31) \times 100 = 186.25$ percent). Therefore, we believe that the DETOUR™ System meets the third cost significance requirement.

We are inviting public comment on whether the DETOUR™ System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(e) EndoSound Vision System™ (EVS™)

EndoSound, Inc. submitted an application for a new device category for transitional pass-through payment status for the EVS™ for CY 2025. The applicant is only seeking a new device category for transitional pass-through payment status for the Ultrasound Disposable Kit - Diagnostic/Therapeutic (UDK-T) component (hereinafter referred to as “UDK-T”) of the EVS™. According to the applicant, the EVS™ is an ultrasound system designed to externally attach to an upper gastrointestinal (GI) endoscope (gastroscope/upper (EGD) endoscope). Per the applicant, the EVS™ is a device that, once attached to an EGD endoscope, temporarily converts the EGD endoscope to a fully capable endoscopic ultrasound (EUS) endoscope. The applicant asserted that the EVS™ can be coupled with an upper GI endoscope device to enable real-time ultrasound imaging, ultrasound guided needle aspiration, and other EUS guided procedures within the upper GI tract and surrounding organs. According to the applicant, the EVS™ consists of: (1) the EVSScanner, a beamformer/scanner that performs ultrasound signal processing; (2) the Ultrasound Transducer Module (UTM), a reusable transducer assembly that converts the electrical signals from the scanner into ultrasound energy; (3) the Transducer Extension Cable (TEC), a cable/connector to interface the UTM to the EVSScanner; and (4) the UDK-T, a disposable mounting kit with an operator control mechanism used to externally affix the EVS™ to a standard EGD endoscope and to provide needle and transducer angulation while maintaining the native gastroscope controls.

Please refer to the online application posting for the EVS™, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP240228GJT0X> , for additional detail describing this device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPTS, 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 EVS™, which includes the UDK-T, received FDA Breakthrough Device designation effective July 29, 2021, as a device intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the upper GI tract including but not restricted to the organs, tissues, and subsystems: esophagus, stomach, duodenum, and underlying areas. The instrument is introduced “per orally” when indications consistent with the requirement for procedure are observed in adult patient populations. FDA granted the applicant 510(k) clearance for the EVS™ on December 27, 2023, indicated for use such that when affixed to an endoscope, is intended to provide ultrasonic visualization of, and ultrasound guided therapeutic access to the upper GI tract including but not restricted to the organs, tissues, and subsystems: esophagus, stomach, duodenum, and underlying areas. The EVS™, mounted on an endoscope, is introduced orally when indications consistent with the requirement for a GI procedure are met. The EVS™ is a prescription-only device to be used by a qualified physician. The clinical environments where the system can be used include clinics, hospitals, and ambulatory surgery centers. We note that while the indication for the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we believe that FDA premarket approval indication is 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 EVS™ on February 28, 2024, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the EVS™, inclusive of the UDK-T component, meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished, 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. The applicant did not indicate whether the UDK-T component of the EVS™ is integral to the service furnished; however, the applicant did indicate that the UDK-T is single-use, comes in contact with human tissue, and is inserted as part of an endoscopy procedure. We preliminarily approved the EndoSound Vision System® (EVS) HCPCS code C1606 (Adapter, single-use (i.e. disposable), for attaching ultrasound system to upper gastrointestinal endoscope) upon quarterly review under the alternative pathway with an effective of July 1, 2024. We note that HCPCS code C1606 was established for an adapter for attaching an ultrasound system to an upper gastrointestinal endoscope that can only be used for a single procedure and cannot be reprocessed. As such, HCPCS code C1606 only describes devices that cannot be reprocessed.

We are inviting public comments on whether the UDK-T component of the EVS™ meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant claimed that the UDK-T meets the device eligibility requirements because it is not equipment or an item for which depreciation and financing expenses are recovered. In addition, the applicant asserted that the UDK-T is not a supply or material.

We are inviting public comments on whether the UDK-T component of the EVS™ 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, the EVS™ is an ultrasound system designed to externally attach to an upper gastrointestinal (GI) endoscope (gastroscope/upper (EGD) endoscope). According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the UDK-T. Per the applicant, device category C1748 (Endoscope, single-use (i.e., disposable), Upper GI, imaging/illumination device (insertable)) does not appropriately describe the EVS™, inclusive of the UDK-T, because: (1) the EVS™, inclusive of the UDK-T, enables an endoscope that a hospital has to have added functionalities such as the ability to perform an EUS procedure, but is not an endoscope like the devices in C1748; (2) the EVS™, inclusive of the UDK-T, when used with an endoscope allows EUS procedures to be done without an elevator, unlike the other devices described in C1748; and (3) the EVS™, inclusive of the UDK-T, and the devices described in C1748 are used in different procedures. The applicant explained that CMS indicated that C1748 should always be billed with a CPT code in the ranges of 43260-43265 and 43274-43278, but there is no overlap between those CPT codes billed with C1748 and the CPT codes the applicant stated that the EVS™ would be reported with as shown in Table 48.

We have not identified an existing pass-through payment category that describes the UDK-T component of the EVS™.

We are inviting public comment on whether the UDK-T component of the EVS™ 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 EVS™, inclusive of the UDK-T, 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 discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the EVS™, inclusive of the UDK-T component, meets the device category criterion at § 419.66(c)(2)(ii).

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 provided the following information in support of the cost significance requirements. The applicant stated that the EVS™ would be reported with HCPCS codes as shown in Table 48.

Table 48: HCPCS CODES REPORTED WITH THE EVS™

HCPCS Code	Long Descriptor	SI	APC
43231	Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination	J1	5302
43232	Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)	J1	5302
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures	J1	5302
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	J1	5302
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes	J1	5302

	endoscopic ultrasound examination limited to the esophagus, stomach and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)		
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis	J1	5302

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 5302, which had a CY 2024 payment rate of \$1,812.99 at the time the application was received. HCPCS code 43232 in APC 5302 had a CY 2024 device offset amount of \$14.50 at the time the application was received.²³ According to the applicant, the cost of the disposable, single-use UDK-T component of the EVS™ is \$500.00.

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

²³ We note that the applicant selected the APC payment rate of \$1,814.88 and the APC level device offset amount of \$178.95 for APC 5302. However, the values selected are inconsistent with the APC payment rate and the APC level device offset amount found in CY 2024 OPPS APC Offset File, which were corrected as described in the CY 2024 OPPS/ASC final rule with comment period correction (89 FR 9002). The HCPCS/CPT code level device offset amounts for the HCPCS/CPT codes provided by the applicant are available in the corrected Addendum P to the CY 2024 OPPS/ASC final rule with comment period. For our calculation, we selected the APC payment rate of \$1,812.99 and the HCPCS/CPT code level device offset amount of \$14.50 related to HCPCS 43232 in APC 5302 found in the corrected Addendum P, which are the accurate values for these codes. Based on our initial assessment for this proposed rule, using the APC payment rate of \$1,812.99 and the device offset amount of \$14.50 would result in the EVS™ meeting the cost significance requirement.

of \$500.00 for the UDK-T is 27.59 percent of the applicable APC payment amount for the service related to the category of devices of \$1,812.99 ($(\$500.00/\$1,812.99) \times 100 = 27.59$ percent). Therefore, we believe the UDK-T component of the EVS™ 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 \$500.00 for the UDK-T is 3,448.28 percent of the cost of the device-related portion of the APC payment amount for the related service of \$14.50 ($(\$500.00/\$14.50) \times 100 = 3,448.28$ percent). Therefore, we believe that the UDK-T component of the EVS™ 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 \$500.00 for the UDK-T and the portion of the APC payment amount for the device of \$14.50 is 26.78 percent of the APC payment amount for the related service of \$1,812.99 ($((\$500.00 - \$14.50)/\$1,812.99) \times 100 = 26.78$ percent). Therefore, we believe that the UDK-T component of the EVS™ meets the third cost significance requirement.

We are inviting public comment on whether the UDK-T component of the EVS™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(f) iFuse Bedrock Granite™ Implant System

SI-BONE submitted an application for a new device category for transitional pass-through payment status for the iFuse Bedrock Granite™ Implant System for CY 2025. According to the applicant, the iFuse Bedrock Granite™ Implant System consists of iFuse Granite™ implants of various lengths and diameters and associated instruments sets. The titanium (Ti-6Al-4V ELI) iFuse Granite™ implant consists of a porous fusion sleeve with threaded length attached to a solid post that has connection and implant placement features of a typical pedicle fixation screw. The iFuse Granite™ implant is intended to provide sacropelvic fusion of the sacroiliac joint (when placed in the sacral-alar-iliac (SAI) trajectory) and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion only when performing both a lumbar and a sacroiliac joint (SIJ) fusion procedure in the same operative session. The applicant asserted that joint fusion occurs as a result of the device's porous surface and interstices and fixation occurs through the device's helical threaded design and traditional posterior fixation rod connection.

Per the applicant, the device can be placed into the pelvis in two trajectories: the SAI trajectory (i.e., into the sacrum, across the SIJ and into the ilium), or directly into the ilium. The applicant explained that the iFuse Granite™ implant is typically placed in the SAI trajectory, bilaterally, and oftentimes stacked to achieve two points of fusion and fixation/stabilization across each SIJ. According to the applicant, the iFuse Granite™ implant may also be used in a single, but bilateral, configuration, where only two implants may be required when replacing traditional pedicle screws in either a SAI trajectory or iliac trajectory. The applicant asserted that the iFuse Bedrock Granite™ Implant System is always used in addition to lumbar fusion instrumentation when used to perform lumbar and SIJ fusion at the same time.

Please refer to the online application posting for the iFuse Bedrock Granite™ Implant System, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP240220LPFNM>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPTS, 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 iFuse Bedrock Granite™ Implant System received FDA Breakthrough Device designation effective November 23, 2021, as a treatment of the acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including: (1) degenerative disc disease (DDD), as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies; (2) severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra; (3) skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion; (4) spondylolisthesis; (5) trauma (i.e., fracture or dislocation); (6) spinal stenosis; (7) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); (8) spinal tumor; and (9) pseudarthrosis, and/or failed previous fusion. Subsequently, FDA also granted the applicant 510(k) clearance for the iFuse Bedrock Granite™ Implant System on May 26, 2022 and December 22, 2022, for the indication covered by the Breakthrough Device designation with one additional indication for use: SIJ dysfunction that is a direct result of SIJ disruption and degenerative sacroiliitis, including conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. We note that the 510(k) clearance dated December 22, 2022, expanded the previously cleared indication of the iFuse Bedrock Granite™ Implant System to include general compatibility with certain compatible pedicle screw systems, whereas the indications under the May 26, 2022, 510(k) clearance only addressed compatibility of the iFuse Bedrock Granite™ Implant System with the SeaSpine Mariner Pedicle Screw System. Each 510(k) clearance, the May 26, 2022, and the December 22, 2022, are covered by the November 23, 2021 Breakthrough Device designation for the iFuse Bedrock Granite™ Implant System. We received the application for a new device category for transitional pass-through payment status for the iFuse Bedrock Granite™ Implant System on February 20, 2024,

which is within three years of the dates of the May 26, 2022 and December 22, 2022 FDA marketing authorizations for the iFuse Bedrock Granite™ Implant System.

We are inviting public comments on whether the iFuse Bedrock Granite™ Implant System meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished, 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. The applicant did not indicate if the iFuse Bedrock Granite™ Implant System is integral to the service furnished. The applicant provided that the iFuse Bedrock Granite™ Implant is single-use, permanently implanted, and surgically inserted into the patient. However, we note that we do not have sufficient information to determine if the associated instruments sets included in the iFuse Bedrock Granite™ Implant System meet the eligibility criterion at § 419.66(b)(3).

We are inviting public comments on whether the iFuse Bedrock Granite™ Implant System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant did not indicate whether the iFuse Bedrock Granite™ Implant System is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if the iFuse Bedrock Granite™ Implant System is a supply or material furnished incident to a service.

We are inviting public comments on whether the iFuse Bedrock Granite™ Implant 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. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the iFuse Bedrock Granite™ Implant System. Per the applicant, the device category C1821 (Interspinous process distraction device) does not appropriately describe the iFuse Bedrock Granite™ Implant System because the iFuse Bedrock Granite™ Implant System is used to fixate and fuse, while the devices described in C1821 are interspinous spacers which, after implantation, are opened or expanded to distract the neural foramina and decompress the nerves. The applicant asserted that device category C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) also does not appropriately describe the iFuse Bedrock Granite™ Implant System because the iFuse Bedrock Granite™ Implant System allows for simultaneous fusion of the SIJ and fixation of the pelvis by connecting via Tulip Connector to the base of the stabilizing rods within the lumbosacral spinal construct, while C1713 includes implantable pins and/or screws that are used to oppose soft tissue-to-bone, tendon-to-bone, or bone-to-bone. Per the applicant, the device category C1889 (Implantable/insertable device, not otherwise classified) also does not appropriately describe the iFuse Bedrock Granite™ Implant System because it does not describe any specific device category, and therefore does not uniquely describe the device category proposed for the iFuse Bedrock Granite™ Implant System.

We note that, according to the applicant, the iFuse Bedrock Granite™ implant is intended to provide sacropelvic fusion of the sacroiliac joint (when placed in the sacral-alar-iliac (SAI) trajectory) and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion only when performing both a lumbar and sacroiliac joint (SIJ) fusion procedure in the same operative

session. The applicant asserted that joint fusion occurs as a result of the device's porous surface and interstices and fixation occurs through the device's helical threaded design and traditional posterior fixation rod connection. We believe that the device category C1713 may appropriately describe the iFuse Bedrock Granite™ Implant System and question whether a transfixing device utilizing the Tulip Connector is sufficiently distinguishable from traditional implantable pins or screws that it is meant to replace. In this context, based on the description the applicant provided, we believe the iFuse Bedrock Granite™ Implant System may be similar to the devices described by C1713, and therefore, the iFuse Bedrock Granite™ Implant System may also be appropriately described by C1713.

In addition, we believe that the device category C1889 may appropriately describe the iFuse Bedrock Granite™ Implant System because C1889 may be used to describe any implantable/insertable device that is not otherwise described by a more specific device category and is, therefore, sufficiently broad to include implantable devices that allow for simultaneous fusion of the SIJ and fixation of the pelvis. We note that in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79562), CMS created C1889 with the specific intent to recognize devices furnished during a device intensive procedure that are not described by a specific Level II HCPCS Category C-code. In this context, we believe the iFuse Bedrock Granite™ Implant System may be appropriately described by either C1713 or C1889.

We are inviting public comment on whether the iFuse Bedrock Granite™ Implant 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 iFuse Bedrock Granite™ Implant System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the iFuse Bedrock Granite™ Implant System meets the device category criterion at § 419.66(c)(2)(ii).

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 provided the following information in support of the cost significance requirements. The applicant stated that the iFuse Bedrock Granite™ Implant System would be reported with HCPCS codes shown in Table 49.

Table 49: HCPCS CODES REPORTED WITH THE IFUSE BEDROCK GRANITE™ IMPLANT SYSTEM

HCPCS Code	Long Descriptor	SI	APC
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	J1	5116
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)	J1	5116
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar	J1	5116
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	J1	5116

According to the applicant, the iFuse Bedrock Granite™ Implant System is only used when both a SIJ fusion procedure and a lumbar fusion procedure are performed in the same

operative session. The applicant stated that the iFuse Bedrock Granite™ Implant System is not utilized when only a SIJ fusion procedure is performed (HCPCS code 27279) or when only a lumbar fusion procedure is performed (HCPCS code 22612, 22630 or 22633). Rather, per the applicant, the appropriate coding of the procedure where the iFuse Bedrock Granite™ Implant System is used should include the CPT code for SIJ fusion (HCPCS code 27279) *and* a CPT code for lumbar fusion (HCPCS code 22612, 22630 or 22633). Per the applicant, the selection of the primary lumbar fusion CPT code (HCPCS code 22612, 22630 or 22633) is dependent on the procedure performed.

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 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5116, which had a CY 2024 payment rate of \$17,756.28 at the time the application was received. The applicant stated the iFuse Bedrock Granite™ Implant System device should be reported with the SIJ fusion procedure HCPCS code 27279 along with one of the three lumbar fusion procedures (HCPCS code 22612, 22630 or 22633). While the applicant utilized HCPCS code 22612 for the device offset amount for test two of the cost criterion, we believe that HCPCS code 27279 is the appropriate HCPCS code for the offset and subsequent calculation. Specifically, it is our understanding that code 27279 is always reported when the iFuse device is used along with only one of the three specified lumbar fusion codes. That is to say, the SIJ fusion procedure described by code 27279 is always performed when the iFuse device is used along with just one of three possible lumbar procedures, depending on the specific surgical approach used. Therefore, we believe that neither

HCPCS code 22612, 22630, nor 22633 is appropriate to use for the cost criterion calculation. As such, we used HCPCS 27279, the code that should always be reported with the iFuse device, for our calculations.

HCPCS code 27279 in APC 5116 had a CY 2024 device offset amount of \$12,264.26 at the time the application was received. According to the applicant, the cost of the iFuse Bedrock Granite™ Implant System is \$11,689.00. 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 \$11,689.00 for the iFuse Bedrock Granite™ Implant System is 65.83 percent of the applicable APC payment amount for the service related to the category of devices of \$17,756.28 ($(\$11,689.00/\$17,756.28) \times 100 = 65.83$ percent). Therefore, we believe the iFuse Bedrock Granite™ Implant 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 \$11,689.00 for the iFuse Bedrock Granite™ Implant System is 95.31 percent of the cost of the device-related portion of the APC payment amount for the related service of \$12,264.26 ($(\$11,689.00/\$12,264.26) \times 100 = 95.31$ percent). Therefore, we believe that the iFuse Bedrock Granite™ Implant System does not meet 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 \$11,689.00

for the iFuse Bedrock Granite™ Implant System and the portion of the APC payment amount for the device of \$12,264.26 is negative 3.24 percent of the APC payment amount for the related service of \$17,756.28 ($((\$11,689.00 - \$12,264.26)/\$17,756.28) \times 100 = -3.24$ percent).

Therefore, we believe that the iFuse Bedrock Granite™ Implant System does not meet the third cost significance requirement.

We are inviting public comment on whether the iFuse Bedrock Granite™ Implant System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(g) Paradise® Ultrasound Renal Denervation (RDN) System

ReCor Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for the Paradise® Ultrasound RDN System for CY 2025. Per the applicant, the Paradise® Ultrasound RDN System is a catheter-based system that delivers ultrasound energy in the location of sympathetic nerves surrounding the renal arteries. The applicant explained that the Paradise® Ultrasound RDN System is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. According to the applicant, the Paradise® Catheter, when used with the other Paradise® Ultrasound RDN System components, provides complete 360-degree energy delivery and targeted ablation depth with each energy emission with the goal of disrupting the nerves and consequently achieving a reduction in systemic arterial blood pressure. The applicant asserted that the Paradise® Catheter protects the artery walls using a cooling system during periods of ultrasound energy emission (also called sonications).

Per the applicant's instructions for use, the Paradise® Ultrasound RDN System includes the following components: (1) Paradise® Generator, which circulates coolant fluid and electrical energy to the Paradise® Catheter via the Paradise® Cable and Paradise® Cartridge;

(2) Paradise® Catheter, which connects with the Paradise® Generator and has a distal balloon

(available in six different diameters that correspond to varying artery diameter ranges) that is pressurized using coolant fluid; (3) Paradise® Cartridge, which controls the fluid flow into and out of the Paradise® Catheter when used in conjunction with the Paradise® Generator;

(4) Paradise® Connection Cable, which transfers electrical energy from the Paradise® Generator to the Paradise® Catheter; (5) Paradise® Remote, included with the Paradise® Generator for optional use; and (6) Paradise® Cart, an optional wheeled cart to which the Paradise® Generator can be mounted to stabilize the Paradise® Generator during a procedure and to transport the Paradise® Generator from one location to another. Per the applicant, additional items required for the procedure include: (1) a bag of coolant fluid for inflation and cooling of balloon; (2) a 0.014 inch guidewire to track the Paradise® Catheter into position for delivery of ultrasound energy; (3) a Push/Pull style hemostasis valve; (4) a 6 French (Fr) or larger guide sheath; and (5) a 7 Fr or larger guide catheter. According to the applicant, the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable are single-patient, one-time use components of the system. According to the applicant, key steps for operating the Paradise® Ultrasound RDN System include: (1) gaining access to the femoral artery using standard interventional techniques and placing a 7 Fr (or larger) guide catheter; (2) advancing the 7 Fr guide catheter into the left or right renal artery under fluoroscopic guidance; (3) performing an angiogram to verify the patency of the left or right renal artery; (4) measuring the distal, mid, and proximal artery diameters and selecting the appropriate Paradise® Catheter balloon size; (5) preparing and attaching the Paradise® Cartridge, Paradise® Connection Cable, and sterile water supply, and connecting the Paradise® Cartridge extension tubing to the Paradise® Catheter; (6) preparing and flushing the Paradise® Catheter; removing access devices from the lumen of the guide catheter and inserting a 0.014 inch guidewire; (7) verifying the balloon on the Paradise® Catheter is deflated; (8) tracking the Paradise® Catheter over the guidewire and gently inserting the Paradise® Catheter into the push/pull style hemostasis valve and guide catheter; (9) advancing and positioning the Paradise® Catheter in desired locations within the renal arteries;

(10) inflating the balloon via the Paradise® Generator; (11) verifying the position of the balloon and catheter transducer via fluoroscopy and contrast injection; (12) performing denervation of the left and/or right renal artery by delivery of ultrasound energy; (13) verifying balloon deflation via fluoroscopy before moving to the next location; (14) withdrawing the Paradise® Catheter back into the guide catheter prior to moving the device into an alternate artery or accessory vessel, continuing to another position and exchanging the balloon catheter, as needed; (15) removing the Paradise® Catheter, ensuring that Paradise® Catheter balloon is in a deflated state prior to removal, by slowly withdrawing the Paradise® Catheter through the guide catheter, until completely withdrawn, and removing the guidewire and guide catheter; and (16) closing the wound per standard of practice.

Please refer to the online application posting for the Paradise® RDN System, available at <https://mearis.cms.gov/public/publications/device-ntp/DEP231128137E1> , for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPTS, 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 Paradise® Ultrasound RDN System received FDA Breakthrough Device designation effective December 4, 2020, as a device with the indicated use to reduce blood pressure in adult (≥ 22 years of age) patients with uncontrolled hypertension, who may be inadequately responsive to, or who are intolerant to anti-hypertensive medications. FDA approved the premarket approval application (PMA) for the Paradise® Ultrasound RDN System on November 7, 2023 for the indicated use to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. We note that while the indication for the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we believe that FDA premarket approval indication is 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 Paradise® Ultrasound RDN System on November 28, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the Paradise® Ultrasound RDN 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. The applicant did not explicitly state whether the Paradise® Ultrasound RDN System is integral to the service furnished. With respect to whether the Paradise® Ultrasound RDN System is used for one patient only, the applicant asserted that the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable are single patient use. However, the Paradise® Generator, Paradise® Remote, and Paradise® Cart are reusable and are capital equipment. While the applicant did not explicitly state whether the Paradise® Ultrasound RDN System comes into contact with human tissue, the applicant provided that the Paradise® Catheter is placed within the renal artery. According to the applicant, the Paradise® Ultrasound RDN System is an implantable device. We note that the Paradise® Generator, Paradise® Remote, and Paradise® Cart are reusable, do not come in contact with the patient's tissue, are not surgically implanted or inserted, or applied in or on a wound or other skin lesion, as required by § 419.66(b)(3).

We are inviting public comments on whether the Paradise® Ultrasound RDN System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). While the applicant did not explicitly state whether the Paradise® Ultrasound RDN System, or select components, is equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, per the applicant, the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable are single-use only. The applicant further explained that the Paradise® Generator, Paradise® Cart, and Paradise® Remote are capital equipment; as such, they are excluded from device pass-through payment eligibility under § 419.66(b)(4). The applicant did not explicitly state whether the Paradise® Ultrasound RDN System is a supply or material furnished incident to a service.

The applicant requested pass-through payment for the Paradise® Ultrasound RDN System, but we question whether only the Paradise® Catheter component of the Paradise® Ultrasound RDN System, as opposed to the whole system, is eligible for pass-through payments under § 419.66(b)(3) or at § 419.66(b)(4). We do not believe that the Paradise® Generator, Paradise® Cable, Paradise® Cartridge, Paradise® Connection Cable, Paradise® Remote, or Paradise® Cart meet the eligibility requirements under § 419.66(b)(3) or at § 419.66(b)(4), and, as such, are not eligible for pass-through payments.

We are inviting public comments on whether the Paradise® Ultrasound RDN 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 Paradise® Ultrasound RDN System is a catheter-based system that delivers ultrasound energy in the location of sympathetic nerves surrounding the renal arteries. According to the applicant, no previous or existing device categories for pass-through payment have encompassed the Paradise® Ultrasound RDN System. Per the applicant, device categories C1753 (Catheter, intravascular ultrasound)

and C1888 (Catheter, ablation, noncardiac, endovascular (implantable)) do not appropriately describe the Paradise® Ultrasound RDN System. The applicant asserted that C1753 does not appropriately describe the Paradise® Ultrasound RDN System because the Paradise® Ultrasound RDN System is used to treat a disease and denervates renal nerves, whereas C1753 was created to describe ultrasound catheter devices that are not used to treat a disease and are used for imaging of the vessel. According to the applicant, C1888 does not appropriately describe the Paradise® Ultrasound RDN System because the Paradise® Ultrasound RDN System is intended to denervate renal nerves by using ultrasound energy that does not otherwise affect the blood vessel tissue, whereas C1888 was created to describe devices that use radiofrequency or laser technologies to occlude or obliterate blood vessels.²⁴

We have not identified an existing pass-through payment category that describes the Paradise® Ultrasound RDN System. We are inviting public comment on whether the Paradise® Ultrasound RDN System meets the device category criterion at § 419.66(c)(1).

We note that the applicant indicated the Paradise® Ultrasound RDN System is the only device authorized by FDA with an indication for renal denervation using ultrasound energy to achieve reductions in blood pressure. However, we note that the Symplicity Spyral™ Catheter (Symplicity Spyral™ RDN System) device, for which we also received an application for transitional pass-through payments for CY 2025 as discussed in this proposed rule, is authorized by FDA with an indication for renal denervation using a radiofrequency modality to achieve reductions in blood pressure. Accordingly, we note that while the Paradise® Ultrasound RDN System device may have a different modality (i.e., ultrasound compared to radiofrequency) to that of the Symplicity Spyral™ Catheter device, the Paradise® Ultrasound RDN System device may have a similar mechanism of action to that of the Symplicity Spyral™ Catheter device. We

²⁴ The applicant referenced the Medicare Claims Processing Manual, Chapter 4 to support these assertions.

question whether the device descriptions provided in the respective applications support establishing two modality specific pass-through payment device categories or a single device category that would encompass both RDN device modalities. We address this question in detail immediately following the full discussion of all other applicable eligibility criteria for both the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System applications.

We are inviting public comment on whether Paradise® Ultrasound RDN 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. As previously stated, the Paradise® Ultrasound RDN System has Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the Paradise® Ultrasound RDN System meets the device category criterion at § 419.66(c)(2)(ii).

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 provided the following information in support of the cost significance requirements. The applicant stated

that Paradise® Ultrasound RDN System would be reported with HCPCS codes shown in

Table 50.

Table 50: HCPCS CODES REPORTED WITH PARADISE® ULTRASOUND RDN SYSTEM

HCPCS Code	Long Descriptor	SI	APC
0338T**	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral	J1	5192
0339T**	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral	J1	5192

**Denotes a HCPCS code that was not included in Addendum P to the CY 2023 OPSS/ASC final rule with comment period, with no CY 2023 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. Since neither of the HCPCS/CPT codes provided by the applicant had a CY 2023 HCPCS/CPT code level device offset amount available at the time the application was received, we used the CY 2023 APC level device offset amount 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 OPSS 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 2023 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5192, which had a CY 2023 payment rate of

\$5,215.40 at the time the application was received. We used the CY 2023 APC level device offset amount of \$1,491.08 for APC 5192, since HCPCS codes 0338T and 0339T were not included in Addendum P to the CY 2023 OPPI/ASC final rule with comment period and no CY 2023 HCPCS/CPT code level device offset amount was available at the time the application was received.²⁵ According to the applicant, the operating cost²⁶ of the Paradise® Ultrasound RDN System is \$23,000.00.

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 \$23,000.00 for the Paradise® Ultrasound RDN System is 441.00 percent of the applicable APC payment amount for the service related to the category of devices of \$5,215.40 ($(\$23,000.00/\$5,215.40) \times 100 = 441.00$ percent). Therefore, we believe the Paradise® Ultrasound RDN 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 \$23,000.00 for the Paradise® Ultrasound RDN System is 1,542.51 percent of the cost of the

²⁵ The applicant stated as neither HCPCS code 0338T nor 0339T had a device offset amount listed in Addendum P to the CY 2023 OPPI/ASC final rule with comment period, it selected a device offset amount of \$0.00. However, for our calculation, we selected the CY 2023 APC level device offset amount of \$1,491.08 for APC 5192 found in CY 2023 NFRM OPPI APC Offset File, as no CY 2023 HCPCS/CPT code level device offset amount was available at the time the application was received. Based on our initial assessment for this proposed rule, using the device offset amount of \$1,491.08 would result in Paradise® RDN meeting the cost significance requirement.

²⁶ According to the applicant, the current total cost of the Paradise® Ultrasound RDN System device is \$23,235.00. For the cost criteria estimates, the applicant submitted an operating cost of \$23,000.00 for the Paradise® Ultrasound RDN System device. Per the applicant, the individual component costs are as follows: Paradise® Remote (capital equipment) is \$5.00; Paradise® Cart (capital equipment) is \$5.00; Paradise® Generator (capital equipment) is \$225.00; Paradise® RDN Catheter Kit (one time use) is \$22,000.00; Paradise RDN Cable (one time use) is \$250.00; and the Paradise® RDN Cartridge (one time use) is \$750.00.

device-related portion of the APC payment amount for the related service of \$1,491.08 (($\$23,000.00/\$1,491.08$) x 100 = 1,542.51 percent). Therefore, we believe that the Paradise® Ultrasound RDN 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 \$23,000.00 for the Paradise® Ultrasound RDN System and the portion of the APC payment amount for the device of \$1,491.08 is 412.41 percent of the APC payment amount for the related service of \$5,215.40 ((($\$23,000.00 - \$1,491.08$)/ $\$5,215.40$) x 100 = 412.41 percent). Therefore, we believe that the Paradise® Ultrasound RDN System meets the third cost significance requirement.

We are inviting public comment on whether the Paradise® Ultrasound RDN System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(h) Precision GI

Limaca Medical submitted an application for a new device category for transitional pass-through payment status for Precision GI for CY 2025. According to the applicant, Precision GI is a motorized, battery operated, single-use, fully disposable endoscopic ultrasound-guided (EUS) fine needle biopsy device used to obtain biopsies of tissue for definitive diagnosis of pancreatic cancer and other life-threatening GI abnormalities. Per the applicant, Precision GI is untethered and battery operated with an internally powered and controlled motor, featuring a long flexible shaft transferring the proximal force of the motor through the inserted endoscope to the needle circumferential cutting tip. The device is controlled by a physician, who inserts the device into the patient's gastrointestinal (GI) tract via the ultrasound endoscope. Upon reaching the designated biopsy site, the physician operates the device's motorized mechanism that automatically rotates the needle (which is included in the device's package) to cut and extract

tissue. The biopsy site is accessed through the instrument channel of an ultrasound imaging endoscope that detects the device's echogenic needle tip.

Please refer to the online application posting for Precision GI, available at <https://mearis.cms.gov/public/publications/device-ntp/DEP23113023REE>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPTS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), Precision GI received FDA Breakthrough Device designation effective March 24, 2022, as a device used with an ultrasound endoscope for fine needle biopsy of submucosal lesions, mediastinal masses, lymph nodes, and intraperitoneal masses within or adjacent to the GI tract. FDA granted the applicant 510(k) clearance for Precision GI on August 28, 2023, for the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for Precision GI on November 30, 2023, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether Precision GI 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 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. The applicant did not indicate whether Precision GI is an integral part of the service furnished. The applicant stated that the device is intended for single-use. While the applicant did not explicitly state whether Precision GI comes in contact with human tissue and is surgically inserted or implanted, the applicant noted that Precision GI is used to sample targeted submucosal lesions, mediastinal masses, lymph nodes, and intraperitoneal masses within or adjacent to the GI tract and this is achieved by a physician who inserts Precision GI into the patient's GI tract using an ultrasound

endoscope. However, we note that, while the needle (which is a component of the device and is included in the device's package) does come into contact with human tissue and is surgically inserted, the motorized mechanism of the Precision GI device itself may not come in contact with human tissue and may not be surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion, as required at § 419.66(b)(3).

We are inviting public comments on whether Precision GI meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant indicated that Precision GI is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, the applicant noted that Precision GI is a motorized, single-use, fully disposable EUS fine needle biopsy device that functions with no related capital component. The applicant stated that Precision GI is not a material or supply furnished incident. However, based on the description of the device as a biopsy device, we question whether Precision GI 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).

Specifically, in the CY 2001 OPPS interim final rule with comment period (65 FR 67804 through 67805), we explained how we interpreted § 419.43(e)(4)(iv). We stated that we consider a device to be surgically implanted or inserted if it is introduced into the human body through a surgically created incision. We also stated that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We

consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment not eligible for transitional pass-through payments. We stated that we believe the function of these items is different and distinct from that of devices that are used for surgical implantation or insertion. Finally, we stated that, generally, we would expect that surgical implantation or insertion of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for implanting the device. Further, in the CY 2006 OPPI final rule with comment period (70 FR, 68629 through 68630), we adopted as final our interpretation that the surgical insertion or implantation criterion can be met by devices that are surgically inserted or implanted via a natural or surgically created orifice, as well as those devices that are inserted or implanted via a surgically created incision. We reiterated that we maintain all of the other criteria in § 419.66 of the regulations, namely, that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We reiterated this interpretation in the CY 2024 OPPI final rule (88 FR 81543, 81743).

We note that Precision GI, is inserted into the patient's GI tract via the ultrasound endoscope to reach the designated biopsy site where the device's motorized mechanism is then used for cutting and extraction of tissue endoscopically from within or adjacent to the patient's GI tract. However, we question whether Precision GI, which is described as a biopsy device, may be considered a supply or material furnished incident to a service consistent with our previous interpretation of § 419.43(e)(4)(iv) and therefore excluded from device pass-through payment eligibility under § 419.66(b)(4).

We welcome additional evidence regarding whether Precision GI should be considered a material or supply incident to a service based on our previous interpretation of § 419.43(e)(4)(iv) as it has been applied to biopsy devices and we invite public comments on whether Precision GI 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. The applicant asserted that Precision GI is authorized by FDA with an indication to sample targeted submucosal lesions, mediastinal masses, lymph nodes, and intraperitoneal masses within or adjacent to the gastrointestinal tract. Per the applicant, the device category C1830 (Powered bone marrow biopsy needle) does not appropriately describe Precision GI because Precision GI is not targeting the bone marrow and instead is targeting sub-mucosal and extramural gastrointestinal lesions. According to the applicant, another device category C1782 (Morcellator) does not appropriately describe Precision GI because that device category, per Medicare Claims Processing Manual, Ch. 4, § 60.4.3, is only for laparoscopic procedures. The applicant added that Precision GI cuts and extracts tissue endoscopically, not laparoscopically.

We have not identified an existing pass-through payment category that describes Precision GI. We are inviting public comment on whether Precision GI 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. Precision GI 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 discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the Precision GI meets the device category criterion at § 419.66(c)(2)(ii). 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 provided the following information in support of the cost significance requirements. The applicant stated that Precision GI would be reported with HCPCS codes as shown in Table 51.

Table 51: HCPCS CODES REPORTED WITH PRECISION GI

HCPCS Code	Long Descriptor	SI	APC
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	J1	5302
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	J1	5302

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 OPSS 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 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5302, which had a CY 2024 payment rate

of \$1,812.99 at the time the application was received. HCPCS code 43242 in APC 5302 had a CY 2024 device offset amount of \$23.75 at the time the application was received.²⁷ According to the applicant, the cost of Precision GI is \$1,400.00.

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 \$1,400.00 for Precision GI is 77.22 percent of the applicable APC payment amount for the service related to the category of devices of \$1,812.99 ($(\$1,400.00/\$1,812.99) \times 100 = 77.22$ percent). Therefore, we believe Precision GI 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 estimated average reasonable cost of \$1,400.00 for Precision GI is 5894.74 percent of the cost of the device-related portion of the APC payment amount for the related service of \$23.75 ($(\$1,400.00/\$23.75) \times 100 = 5894.74$ percent). Therefore, we believe that Precision GI 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

²⁷ We note that the applicant selected the APC payment rate of \$1,814.88 and the APC level device offset amount of \$178.95 for APC 5302. However, the values selected are inconsistent with the APC payment rate and the APC level device offset amount found in CY 2024 OPSS APC Offset File, which were corrected as described in the CY 2024 OPSS/ASC final rule with comment period correction (89 FR 9002). The HCPCS/CPT code level device offset amounts for the HCPCS/CPT codes provided by the applicant are available in the corrected Addendum P to the CY 2024 OPSS/ASC final rule with comment period. For our calculation, we selected the APC payment rate of \$1,812.99 and the HCPCS/CPT code level device offset amount of \$23.75 related to HCPCS 43242 in APC 5302 found in the corrected Addendum P, which are the accurate values for these codes. Based on our initial assessment for this proposed rule, using the APC payment rate of \$1,812.99 and the device offset amount of \$23.75 would result in Precision GI meeting the cost significance requirement.

the related service. The difference between the estimated average reasonable cost of \$1,400.00 for Precision GI and the portion of the APC payment amount for the device of \$23.75 is 75.91 percent of the APC payment amount for the related service of \$1,812.99 ($((\$1,400 - \$23.75)/\$1,812.99) \times 100 = 75.91$ percent). Therefore, we believe that Precision GI meets the third cost significance requirement.

We are inviting public comment on whether Precision GI meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(i) PulseSelect™ Pulsed Field Ablation (PFA) System

Medtronic, Inc. submitted an application for a new device category for transitional pass-through payment status for the PulseSelect™ PFA System for CY 2025. Per the applicant, the PulseSelect™ PFA System is used to perform pulmonary vein isolation (PVI) via cardiac catheter ablation to treat atrial fibrillation. According to the applicant, unlike existing methods that rely on thermal energy (either radiofrequency or cryoablation), the PulseSelect™ PFA System uses non-thermal irreversible electroporation (IRE) to induce cardiac tissue cell death. The pulsed field ablation, or IRE for PVI during cardiac catheter ablation, is performed as a percutaneous, transvenous procedure under imaging guidance. The applicant stated the PulseSelect™ PFA System consists of three elements: (1) the PulseSelect™ PFA Loop Catheter (Loop Catheter), a one-time use, steerable, multi-electrode loop catheter used to deliver IRE in pulmonary vein isolation as a treatment for atrial fibrillation; (2) the PulseSelect™ PFA Catheter Interface Cable (Catheter Interface Cable), a one-time use interface cable used to connect the Loop Catheter to the PulseSelect™ PFA Generator system; and (3) the PulseSelect™ PFA Generator system (Generator system) used to deliver IRE in pulmonary vein isolation as a treatment for atrial fibrillation..

Please refer to the online application posting for the PulseSelect™ PFA System, available at <https://mearis.cms.gov/public/publications/device-ntp/DEP240228J1461>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPTS, 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 PulseSelect™ PFA System received FDA Breakthrough Device designation effective September 27, 2018, for the treatment of drug refractory recurrent symptomatic atrial fibrillation. The Medtronic multi-electrode cardiac ablation catheter (which is now known as PulseSelect™) is also intended to be used for cardiac electrophysiological (EP) mapping and measuring of intracardiac electrograms, delivery of diagnostic pacing stimuli, and verifying electrical isolation post-treatment. FDA approved the premarket approval application (PMA) for the PulseSelect™ PFA System on December 13, 2023, for the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the PulseSelect™ PFA System on February 28, 2024, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the PulseSelect™ PFA System meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished, 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. The applicant did not indicate whether the PulseSelect™ PFA System is integral to the service furnished. Per the applicant, the Loop Catheter and Catheter Interface Cable components are single-use. While the applicant did not explicitly state whether any of the device components come in contact with human tissue, based on the device description, the procedure with which the PulseSelect™ PFA System Loop Catheter is used is performed percutaneously (i.e., passing

through the skin) and transvenously (i.e., through or across a vein) using the Loop Catheter to achieve ablation in the targeted areas. However, neither the Generator system nor the Catheter Interface Cable which is used to connect the Loop Catheter to the Generator system appear to come in contact with the patient's tissue, be surgically implanted or inserted, or applied in or on a wound or other skin lesion, as required by § 419.66(b)(3) and therefore, we do not believe that either component is eligible for device pass-through payments. We discuss the Catheter Interface Cable in more detail in the following criteria discussions.

We are inviting public comments on whether the PulseSelect™ PFA System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant did not indicate whether the Loop Catheter and the Catheter Interface Cable are equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered or a material or supply furnished incident to a service. However, we note that in the application for a new device category for transitional pass-through payment status for CY 2025, the applicant stated that the Catheter Interface Cable is a one-time use cable that cannot be reprocessed. This assertion appears contrary to the information provided to CMS by the applicant in their application submission for FY 2025 IPPS new technology add-on payment under the name "PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter" (<https://mearis.cms.gov/public/publications/ntap/NTP231017BMQKQ>). Specifically, in the FY 2025 IPPS/LTCH PPS proposed rule, CMS noted that the applicant stated that the PulseSelect™ PFA Interface Cable is a component of the PulseSelect™ PFA Generator

Reusable Accessories. Further, CMS explained that the new technology add-on payment application is for the PulseSelect™ PFA Loop Catheter (as opposed to the PulseSelect™ PFA System) and that the applicant had specified in its application that the PulseSelect™ PFA Generator System is not the subject of this new technology add-on payment application (89 FR 36124). Therefore, we stated that we believe the total cost should be based only on the cost of the PulseSelect™ PFA Loop Catheter.

In contrast to the new technology add-on payment application, the application for a new device category for transitional pass-through payment status is for the PulseSelect™ PFA System, which includes the PulseSelect™ PFA Generator system. The PulseSelect™ PFA Interface Cable is listed as a component of the PulseSelect™ PFA Generator System, which the applicant described as capital equipment in its new technology add-on payment application. We therefore believe the PulseSelect™ PFA Generator System, including the Catheter Interface Cable, is an item for which depreciation and financing expenses are recovered as depreciation assets and thus, is ineligible for device pass-through payment under § 419.66(b)(4).

We are inviting public comments on whether the PulseSelect™ PFA 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. The applicant asserted that the PulseSelect™ PFA System is the only device authorized by FDA with an indication for cardiac electrophysiological mapping (stimulation and recording) and for treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation or persistent atrial fibrillation (episode duration less than 1 year) through the use of IRE. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the PulseSelect™

PFA System. Per the applicant, device categories C2630 (Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, cool-tip) and C1733 (Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, other than cool-tip) do not appropriately describe the PulseSelect™ PFA System because, unlike cardiac catheter ablation technologies using thermal energy where options are either heat (radiofrequency) or cold (cryoablation), the PulseSelect™ PFA System uses non-thermal IRE to elicit targeted cardiac tissue cell death. The applicant stated that the PulseSelect™ PFA System's non-thermal IRE mechanism of action avoids many risks present in thermal cardiac catheter ablation technologies.

We note that, based on the description the applicant provided, the PulseSelect™ PFA System is used to achieve catheter ablation to treat atrial fibrillation, and thus could be appropriately described by C1733. Specifically, we believe that C1733 may appropriately describe the PulseSelect™ PFA System because it includes a catheter used for ablation of tissue without a cool-tip. Further, C1733 does not specify the modality needed to deliver the ablation, whether thermal or by electroporation. In this context, we believe the PulseSelect™ PFA System may be similar to the devices described by C1733, and therefore, the PulseSelect™ PFA System may also be appropriately described by C1733.

We are inviting public comment on whether the PulseSelect™ PFA 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 PulseSelect™ PFA System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the PulseSelect™ PFA System meets the device category criterion at § 419.66(c)(2)(ii).

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 provided the following information in support of the cost significance requirements. The applicant stated that the PulseSelect™ PFA System would be reported with the HCPCS code shown in Table 52.

Table 52: HCPCS CODES REPORTED WITH PULSESELECT™ FA SYSTEM

HCPCS Code	Long Descriptor	SI	APC
93656	Comprehensive electrophysiologic evaluation including transeptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, 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 CY 2024 device offset amount of \$11,251.23 at the time the application was received.

According to the applicant, the cost of the one-time use Loop Catheter is \$9,750.00. We note the applicant included the cost of the Loop Catheter (\$9,750.00) and the cost of the Catheter Interface Cable (\$800.00) in the cost significance tests, totaling the cost of the device as \$10,550.00. However, as previously discussed, we believe that the PulseSelect™ PFA Generator System, including the PulseSelect™ PFA Catheter Interface Cable, is capital equipment and therefore not eligible for device pass-through status payment. As such we removed the cost of Catheter Interface Cable in our calculations and only included the cost of the Loop Catheter, which changed the total device cost from \$10,550.00 to \$9,750.00; we have used \$9,750.00 to perform the cost significance tests. We further note that the decision to exclude the cost of the Catheter Interface Cable (\$800.00) in the cost significance tests did not change the outcome of the cost significance criterion determinations.

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 \$9,750.00 for the PulseSelect™ PFA System is 43.09 percent of the applicable APC payment amount for the service related to the category of devices of \$22,629.19 ($(\$9,750.00/\$22,629.19) \times 100 = 43.09$ percent). Therefore, we believe the PulseSelect™ PFA 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 \$9,750.00

for the PulseSelect™ PFA System is 86.66 percent of the cost of the device-related portion of the APC payment amount for the related service of \$11,251.23 ($(\$9,750.00/\$11,251.23) \times 100 = 86.66$ percent). Therefore, we believe that the PulseSelect™ PFA System does not meet 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 \$9,750.00 for the PulseSelect™ PFA System and the portion of the APC payment amount for the device of \$11,251.23 is negative 6.63 percent of the APC payment amount for the related service of \$22,629.19 ($((\$9,750.00 - \$11,251.23)/\$22,629.19) \times 100 = -6.63$ percent). Therefore, we believe that the PulseSelect™ PFA System does not meet the third cost significance requirement.

We are inviting public comment on whether the PulseSelect™ PFA System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(j) Symplicity Spyral™ Renal Denervation (RDN) System

Medtronic submitted an application for a new device category for transitional pass-through payment status for the Symplicity Spyral™ RDN System, for CY 2025. The applicant is only seeking a new device category for transitional pass-through payment status for the Symplicity Spyral™ Multi-Electrode RDN Catheter (hereinafter Symplicity Spyral™ Catheter) the Symplicity Spyral™ RDN System. According to the applicant, the Symplicity Spyral™ RDN System consists of the Symplicity Spyral™ Catheter and the Symplicity G3™ generator; the applicant requested device pass-through status for the catheter component of the system only. The applicant further explained that the Symplicity Spyral™ RDN System is indicated to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. Per

the applicant, the Symplicity Spyral™ Catheter, when used with the Symplicity G3™ generator, delivers radiofrequency (RF) energy through the wall of the renal artery to disrupt the surrounding renal nerves with the aim of modulating or suppressing sympathetic nerve hyperactivity. According to the applicant, the Symplicity Spyral™ Catheter is a single-use catheter used to deliver multiple ablations in both kidneys, in the renal main, accessory, and branch arteries, based on a patient's artery anatomy and size.

Per the applicant, the Symplicity Spyral™ Catheter is designed to be used with the Symplicity G3™ generator and includes the following components: (1) 4 gold radiopaque electrodes at the spiral (helical) distal end that are deployed into a spiral (helical) shape by partially retracting the guidewire proximal to the spiral section of the catheter; (2) self-expanding electrode array assembly which radially spaces the four gold electrodes for quadratic ablation; (3) rapid exchange port; (4) straightening tool intended to facilitate safe insertion of the guidewire into the catheter; (5) cable connector attached to the catheter handle that connects the catheter to the generator; (6) catheter handle; and (7) femoral marker. Per the applicant, additional components of the Symplicity Spyral™ RDN System include the: (1) Symplicity G3™ generator, which is only compatible with the Symplicity Spyral™ Catheter, which includes a remote control, power cable, and output for the Symplicity Spyral™ Catheter; (2) Symplicity G3™ generator cart, an optional mobile cart; and (3) foot switch, an optional component. Per the applicant, additional items required for the procedure include: (1) a 0.36 mm (0.014 in) guidewire, preferably without hydrophilic coating; (2) a dispersive electrode; (3) a sterile bag to cover the remote control if used in the sterile field; (4) a 6 French (Fr) guide-catheter; (5) an introducer sheath; (6) a stopcock sidearm; (7) a Tuohy-Borst adapter; and (8) other standard items used to aid percutaneous transluminal catheterization in renal arteries.

According to information submitted by the applicant, key steps for operating the Symplicity Spyral™ Catheter include: (1) connecting the Symplicity Spyral™ Catheter to the Symplicity G3™ generator; (2) inserting the Symplicity Spyral™ Catheter through a small

femoral incision and guiding it to the renal artery via the abdominal aorta; (3) advancing the Symplicity Spyral™ Catheter until the distal electrode is located in the desired position within the renal artery; (4) retracting the guidewire, allowing the self-expanding catheter to expand and fit the renal arterial vessel walls; (5) delivering the treatment of RF energy to ablate the renal nerves through the activation of the catheter electrodes, which is controlled using the generator; (6) if treating another vessel, repositioning the guide catheter within the next vessel and repeating the procedure for positioning the catheter and delivering treatments; (7) upon completion of all treatments, straightening the distal end by advancing the guidewire and withdrawing both the guidewire and the straightened catheter from the guide catheter; (8) retracting the guide catheter from the sheath and removing the introducer sheath from the artery; (9) using standard of care procedures to achieve hemostasis at the puncture site; and (10) disposing of the devices.

Please refer to the online application posting for the Symplicity Spyral™ RDN System, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP231130WPU4J> , for additional detail describing the device and the disease treated by the device.

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 Symplicity Spyral™ RDN System received FDA Breakthrough Device designation effective March 27, 2020, as a device with the following indicated use: the Symplicity Spyral multi-electrode renal denervation catheter and the Symplicity G3 RF Generator are indicated for the reduction of blood pressure in patients with uncontrolled hypertension despite the use of anti-hypertensive medications or in patients who may have documented intolerance to anti-hypertensive medications. FDA approved the premarket approval application (PMA) for the Symplicity Spyral™ RDN System on November 17, 2023, for the indicated use to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not

adequately control blood pressure. We received the application for a new device category for transitional pass-through payment status for the Symplicity Spyral™ Catheter on November 30, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the Symplicity Spyral™ Catheter 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, 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. The applicant did not indicate whether the Symplicity Spyral™ Catheter is integral to the service furnished. Per the applicant, the Symplicity Spyral™ Catheter is intended for single patient use only. While the applicant did not explicitly state whether the Symplicity Spyral™ Catheter comes into contact with human tissue, the applicant asserted that the Symplicity™ Catheter ablates renal nerve tissue by positioning the catheter within the renal artery, which expands and fits the renal arterial vessel walls. While the applicant did not explicitly state if the Symplicity Spyral™ Catheter is surgically inserted or implanted, per the device description, the Symplicity Spyral™ Catheter is inserted through a small femoral incision, after which it is inserted into the renal arterial vessel.

We are inviting public comments on whether the Symplicity Spyral™ Catheter meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant did not state whether the Symplicity Spyral™ Catheter is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered whether the Symplicity Spyral™ Catheter is a supply or material furnished incident to a service.

We are inviting public comments on whether the Symplicity Spyral™ 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. According to the applicant, the Symplicity Spyral™ Catheter is a single-use catheter used to deliver multiple ablations in both kidneys, in the renal main, accessory, and branch arteries, based on a patient's artery anatomy and size. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the Symplicity Spyral™ Catheter. The applicant asserted that two categories, C1886 (Catheter, extravascular tissue ablation, any modality (insertable)) and C1888 (Catheter, ablation, noncardiac, endovascular (implantable)), do not appropriately describe the Symplicity Spyral™ Catheter. Per the applicant, C1886 does not appropriately describe the Symplicity Spyral™ Catheter because the Symplicity Spyral™ Catheter ablates renal nerve tissue via an endovascular approach by positioning the catheter within the renal artery and was created to describe devices that ablate extravascular tissue (via an extravascular approach).²⁸ According to the applicant, C1888 does not appropriately describe the Symplicity Spyral™ Catheter because the Symplicity Spyral™ Catheter does not ablate or otherwise affect the blood

²⁸ The applicant referenced CY 2013 OPPS FR (77 FR 68352) and Transmittal 2386, Change Request 7672 (Jan 13, 2012) to support these assertions.

vessel tissue and was created to describe devices designed to occlude or obliterate blood vessels.²⁹

We have not identified an existing pass-through payment category that describes the Symplicity Spyral™ Catheter. We are inviting public comment on whether the Symplicity Spyral™ Catheter meets the device category criterion at § 419.66(c)(1).

We note that the applicant indicated the Symplicity Spyral™ Catheter is not the only device authorized by FDA with an indication for renal denervation to achieve reductions in blood pressure. Paradise® Ultrasound RDN System, for which we also received an application for transitional pass-through payments for CY 2025 as discussed in more detail in this proposed rule, is also authorized by FDA with an indication for renal denervation using ultrasound energy to achieve reductions in blood pressure. Per the applicant, the Paradise® Ultrasound RDN System would also be described by the applicant's proposed pass-through payment category: Ablation catheter, renal nerve, via endovascular approach, any modality. Accordingly, we note that while the Symplicity Spyral™ Catheter device may have a different modality (i.e., radiofrequency compared to ultrasound), the Symplicity Spyral™ Catheter device may have a similar mechanism of action to that of the Paradise® Ultrasound RDN System device. We question whether the device descriptions provided in the respective applications support establishing two modality specific pass-through payment device categories or a single device category that would encompass both RDN device modalities. We will address this question in detail immediately following the full discussion of all other applicable eligibility criteria for the Symplicity Spyral™ RDN System application.

We are inviting public comment on whether Symplicity Spyral™ Catheter meets the device category criterion at § 419.66(c)(1).

²⁹ The applicant referenced the Medicare Claims Processing Manual, Chapter 4, section 60.4.3 to support these assertions.

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. As previously stated, the Symplicity Spyr™ Catheter has Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the Symplicity Spyr™ Catheter meets the device category criterion at § 419.66(c)(2)(ii).

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 provided the following information in support of the cost significance requirements. The applicant stated that the Symplicity Spyr™ Catheter would be reported with HCPCS codes shown in Table 53.

Table 53: HCPCS CODES REPORTED WITH THE SYMPLICITY SPYRAL™ CATHETER

HCPCS Code	Long Descriptor	SI	APC
0338T**	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral	J1	5192
0339T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter	J1	5192

HCPCS Code	Long Descriptor	SI	APC
	placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral		

**Denotes a HCPCS code that was not included in the corrected Addendum P to the CY 2024 OPPS/ASC final rule with comment period, with no CY 2024 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2024 payment rates for the three tests of the cost criterion. We used the CY 2024 HCPCS/CPT code level device offset amount for the HCPCS/CPT code included in the corrected Addendum P 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 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5192, which had a CY 2024 payment rate of \$5,445.84 at the time the application was received. HCPCS code 0339T in APC 5192 had a CY 2024 device offset amount of \$3,362.26 at the time the application was received.³⁰ According to the applicant, the cost of the Symplicity Spyral™ Catheter is \$16,000.00.

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

³⁰ We note that the applicant selected the APC payment rate of \$5,451.51 and the HCPCS/CPT code level device offset amount of \$3,365.76 for HCPCS 0339T in APC 5192. However, the values selected are inconsistent with the APC payment rate and the device offset amount found in the corrected Addendum P to the CY 2024 OPPS/ASC final rule with comment period. For our calculation, we selected the APC payment rate of \$5,445.84 and the HCPCS/CPT code level device offset amount of \$3,362.26 for HCPCS 0339T in APC 5192 found in the corrected Addendum P, which are the accurate values for these codes. Based on our initial assessment for this proposed rule, using the APC payment rate of \$5,445.84 and the HCPCS/CPT code level device offset amount of \$3,362.26 would result in Symplicity Spyral™ Catheter meeting the cost significance requirement.

of \$16,000.00 for the Symplicity Spyral™ Catheter is 293.80 percent of the applicable APC payment amount for the service related to the category of devices of \$5,445.84 ($(\$16,000.00/\$5,445.84) \times 100 = 293.80$ percent). Therefore, we believe the Symplicity Spyral™ 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 \$16,000.00 for the Symplicity Spyral™ Catheter is 475.87 percent of the cost of the device-related portion of the APC payment amount for the related service of \$3,362.26 ($(\$16,000.00/\$3,362.26) \times 100 = 475.87$ percent). Therefore, we believe that the Symplicity Spyral™ 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 \$16,000.00 for the Symplicity Spyral™ Catheter and the portion of the APC payment amount for the device of \$3,362.26 is 232.06 percent of the APC payment amount for the related service of \$5,445.84 ($((\$16,000.00 - \$3,362.26)/\$5,445.84) \times 100 = 232.06$ percent). Therefore, we believe that the Symplicity Spyral™ Catheter meets the third cost significance requirement.

We are inviting public comment on whether the Symplicity Spyral™ Catheter meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(k) Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System Device
Category Code Establishment

As previously discussed, we received two applications, the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System (Symplicity Spyral™ Catheter) for transitional device pass-through payments for CY 2025 that, per the applicants, are RDN devices that use an endovascular approach to enter the renal arteries and ablate renal sympathetic nerves to achieve reductions in blood pressure. We question whether the information provided for each respective nominated device supports establishing two modality specific device pass-through payment device categories or establishing a single device category that would encompass both RDN devices.

We note that the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System are both authorized by FDA for the indicated use to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. In addition, based on the information provided in the respective applications, it appears that the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System use the same procedure (renal sympathetic denervation, also called renal sympathetic nerve ablation), treat the same disease (hypertension) in the same patient population (patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure), and aim to achieve the same therapeutic outcome (to reduce blood pressure), using the same or similar mechanism of action (thermal ablation). We note that in addition to having the same indicated use, per the applicants, both the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System may be used with the same HCPCS procedure codes: 0338T³¹ or 0339T³². In addition,

³¹ HCPCS procedure code 0338T (Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral).

³² HCPCS procedure code 0339T (Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral).

the applicant for the Symplicity Spyral™ RDN System asserted that the Paradise® Ultrasound RDN System similarly generates heat to ablate the same renal sympathetic nerves to achieve reductions in blood pressure and this similarity supports establishing a single device category that would encompass RDN devices regardless of the specified modality.

Despite these similarities, the applicants have proposed different device category descriptions. Based on the information submitted, it appears that the device category proposed for the Paradise® Ultrasound RDN System does not appropriately describe the Symplicity Spyral™ RDN System, however, we believe the device category proposed for the Symplicity Spyral™ RDN System would appropriately describe the Paradise® Ultrasound RDN System. Specifically, the applicant for the Paradise® Ultrasound RDN System proposed the following device category: Catheter, intravascular renal denervation, ultrasound, with balloon cooling;³³ while the applicant for the Symplicity Spyral™ RDN System proposed the following device category: Ablation catheter, renal nerve, via endovascular approach, any modality. The device category descriptor the applicant proposed for the Paradise® Ultrasound RDN System specifies the device's treatment or procedure (catheter renal denervation), the ablation modality (i.e., ultrasound), and an attribute of the catheter (i.e., the cooling balloon). We note that while the device category descriptor the applicant proposed for the Symplicity Spyral™ RDN System device also specifies the device's treatment or procedure (catheter ablation of the renal nerves), it does not specify an ablation modality or any additional attributes of the catheter; rather, the proposed device category for the Symplicity Spyral™ RDN System device more broadly describes any ablation modality (e.g., radiofrequency or ultrasound).

³³The Paradise® Ultrasound RDN System device category does not explicitly describe using an endovascular approach; however, it does describe renal nerve ablation via a catheter. We believe that the device category describes the intravascular sonication (ultrasound treatment) delivered by the catheter. We note that this proposed device description does not preclude an endovascular approach, and that, per the applicant, the Paradise® Ultrasound RDN system is a catheter-based endovascular based system.

We note several differences in procedural technique with use of the Paradise® Ultrasound RDN System device compared to the Symplicity Spyral™ RDN System device. Per the applicants, the Paradise® Ultrasound RDN System delivers ablation while positioned in the main renal arteries only, whereas the Symplicity Spyral™ RDN System may deliver ablation while positioned in the main renal, accessory and branch arteries and therefore may require advancing the catheter beyond the main renal arteries. According to the applicants, the Paradise® Ultrasound RDN System procedural technique requires the measurement of the main renal artery diameter to select the appropriate size cooling balloon catheter, whereas the Symplicity Spyral™ RDN System's one size catheter does not require this measurement. Similarly, per the applicants, the Paradise® Catheter's cooling balloon requires specific procedural techniques to ensure the balloon is appropriately inflated and deflated during the procedure, but the Symplicity Spyral™ Catheter does not have this requirement.

Both the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System received FDA Breakthrough Device designation and marketing authorization from FDA for the indications covered by the Breakthrough Device designation, and therefore, are not evaluated for substantial clinical improvement. However, we note that per the applicant of the Paradise® Ultrasound RDN System, a separate device category associated with ultrasound denervation is supported by possible differences in clinical efficacy between RDN devices using ultrasound and RDN devices using radiofrequency ablation. Specifically, the applicant of the Paradise® Ultrasound RDN System asserted that, when compared to radiofrequency RDN, on average ultrasound RDN requires fewer ablations per patient (5.4 compared to 46.9), less time per ablation (7 seconds compared to 60 seconds), less time for the total procedure (72 minutes compared to 100 minutes), and less ablation depth (1 to 6 mm compared to 2 to 3 mm). The applicant of the Paradise® Ultrasound RDN System further stated that the Paradise® Ultrasound RDN System circumferential (360 degrees) emission per individual ablation and the lack of a requirement for distal renal artery branch ablation to deliver the treatment are technological

features not shared by the radiofrequency RDN device.³⁴ However, we note that we did not evaluate the validity or generalizability of these claims nor is it clear if the two different ablation modalities (i.e., ultrasound and radiofrequency) would render different clinical results in larger studies or in the long term.^{35,36} We further note that we discuss these claims here solely for the purpose of determining whether the information provided supports establishing two modality-specific pass-through payment device categories or establishing a single device category that may encompass both RDN devices.

In seeking comment, we note that in accordance with section 1833(t)(6)(B)(ii)(II) of the Act, new categories must be established in such a way that no medical device is described by more than one category. We further 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. However, there are examples in which CMS has defined specific ablation modalities such as high intensity ultrasound, microwave, and cryoablation in HCPCS codes for use with the OPPIs. In addition, we note the existence of several modality specific tissue ablation procedure codes in the Current Procedural Terminology (CPT®) 2024.. However, there are examples where CMS has established device categories with additional granularity to differentiate similar devices with special characteristics (e.g., implantable neurostimulators). In addition, there are examples where CMS has created HCPCS codes specifying the modality of ablation (e.g., ultrasound, microwave). Finally, we note as previously mentioned, 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

³⁴ See Application's Device Info tab, attachment, Procedural Comparison Ultrasound RDN_11.21.2023.

³⁵ Fengler K, Rommel K-P, Kriese W, et al. Research Correspondence: 6- and 12-Month Follow-Up From a Randomized Clinical Trial of Ultrasound vs Radiofrequency Renal Denervation (RADIO SOUND-HTN). JACC: CARDIOVASCULAR INTERVENTIONS VOL. 16, NO. 3, 2023 Letters FEBRUARY 13, 2023:367 – 369.

³⁶ Fengler K, Rommel K-P, Blazek S, et al. A three-arm randomized trial of different renal denervation devices and techniques in patients with resistant hypertension (RADIO SOUND-HTN). Circulation. 2019;139:590–600.

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). We question whether two modality-specific device category codes may facilitate the collection of more accurate data for incorporating the costs of these two devices into the procedure APC rate as well as foster the tracking of efficacy data for these two ablation modalities.

As such, we are inviting public comment on whether the device descriptions provided in the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System applications support establishing two modality specific pass-through payment device categories or a single device category that would encompass both RDN device modalities.

(2) Traditional Device Pass-Through Applications

(a) Ambu® aScope™ Gastro

Ambu Inc. submitted an application for a new device category for transitional pass-through payment status for the Ambu® aScope™ Gastro for CY 2025. Per the applicant, the Ambu® aScope™ Gastro is a sterile, single-use, flexible gastroscope intended to be used for: (1) endoscopic access to and examination of the upper gastrointestinal (GI) anatomy; and (2) upper GI endoscopy or esophagogastroduodenoscopy (EGD) to diagnose and treat problems in the upper GI tract, including dysphagia, gastroesophageal reflux disease, narrowing or blockages, esophageal varices, inflammation, ulcers, tumors, hiatal hernia, Celiac disease, Crohn's disease, and infections of the upper GI tract in adult patients.

According to the applicant, the Ambu® aScope™ Gastro works with the Ambu® aBox™ 2, a compatible, reusable displaying unit. The Ambu® aScope™ Gastro endoscope is inserted into the upper GI anatomy airway through the mouth, while the Ambu® aBox™ 2 is a non-sterile digital monitor intended to display live imaging data from Ambu visualization devices. The applicant is only seeking a new device category for transitional pass-through payment status for the Ambu® aScope™ Gastro.

Please refer to the online application posting for the Ambu® aScope™ Gastro, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP2305305795M> , for additional detail describing this device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPTS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on February 3, 2022, the applicant received 510(k) clearance from FDA for the Ambu® aScope™ Gastro, Ambu® aBox™ 2, as a sterile, single-use, flexible gastroscope intended to be used for endoscopic access to and examination of the upper gastrointestinal anatomy. The Ambu® aScope™ Gastro is intended to provide visualization via a compatible Ambu displaying unit and to be used with endotherapy accessories and other ancillary equipment. We received the application for a new device category for transitional pass-through payment status for the Ambu® aScope™ Gastro on May 30, 2023, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether Ambu® aScope™ Gastro 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, 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. The applicant did not indicate whether the Ambu® aScope™ Gastro is integral to the service furnished. The applicant stated that the device was single-use and is intended to be used with one patient only. We note that the Ambu® aScope™ Gastro, based on the device description provided by the applicant and the evidence provided in support of the substantial clinical improvement as discussed in detail in the § 419.66(c)(2) analysis in this application summary write-up, explicitly provides that the nominated device is intended to be used on one patient, for a single procedure and then disposed of. As such, we note that our evaluation and final decision as it relates to this potential category of devices (goscopes) will be based on the

understanding that devices included in this device category (gastrosopes) can only be used for a single procedure, on a single patient, and cannot be reprocessed. While the applicant did not explicitly state whether the device comes in contact with human tissue or is surgically inserted, per the device description, Ambu® aScope™ Gastro is a flexible gastroscope intended to be used for endoscopic access to and examination of the upper GI anatomy.

We are inviting public comments on whether Ambu® aScope™ Gastro meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant indicated that the Ambu® aScope™ Gastro is single-use equipment, not intended for use in multiple patients, for which depreciation and financing expenses are not recovered. The applicant explained that the Ambu® aScope™ Gastro is purely an operating cost and is not subject to capitalization or a depreciation schedule.

We note that the applicant stated in the application that the Ambu® aScope™ Gastro is a supply furnished incident to a service rendered, as described, Ambu® aScope™ Gastro would 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 Ambu® aScope™ Gastro 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 Ambu® aScope™ Gastro is a sterile, single-use, flexible, imaging/illumination gastroscopy device that uses an integrated camera module and built-in dual light-emitting diode (LED) illumination to provide access to, illumination, and imaging of the upper GI anatomy for diagnostic and therapeutic purposes for a GI patient. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the Ambu® aScope™ Gastro. Per the applicant, the two device categories, C1747 (Endoscope, single-use (i.e., disposable), urinary tract, imaging/illumination device (insertable)) and C1748 (Endoscope, single-use (i.e., disposable), upper gastrointestinal tract (GI), imaging/illumination device, (insertable)), do not appropriately describe the Ambu® aScope™ Gastro. Specifically, the applicant asserted that the urinary tract scopes described in C1747 are not indicated for use in the GI system and therefore, do not appropriately describe Ambu® aScope™ Gastro. The applicant further asserted that while C1748 describes a single-use endoscopic device, C1748 is only appropriate for single-use duodenoscopes and endoscopic retrograde cholangiopancreatography (ERCP) services. While the long descriptor of C1748 describes disposable endoscopes with imaging and illumination capabilities intended for use in the upper GI and the applicant describes the Ambu® aScope™ Gastro as a single-use, gastroscopy with illumination and imaging intended for use in the upper GI anatomy, we note that C1748 only describes single-use duodenoscopes and ERCP services. As such, Ambu® aScope™ Gastro is not described by C1748.

We have not identified an existing pass-through payment category that describes Ambu® aScope™ Gastro. We are inviting public comment on whether the Ambu® aScope™ Gastro 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 applicant claimed that Ambu® aScope™ Gastro represents a substantial clinical improvement over existing technologies in the diagnosis and management of endoscopic procedures and examination within the upper GI anatomy. The applicant outlined the following areas in which it claimed the Ambu® aScope™ Gastro would provide a substantial clinical improvement: (1) elimination of the risk of cross-contamination between patients and scopes, (2) elimination of the risk of cross-contamination for reusable gastroscopes, (3) elimination of the risk of resistant infections that originate from reusable gastroscopes, (4) avoidance of scope damage and debris after reprocessing, (5) avoidance of damaged and contaminated scopes from being used on patients, (6) elimination of the risk of patient-to-patient infections associated with contaminated scopes, and (7) avoidance of infection and death associated with reusable gastroscope contamination.

The applicant provided seven background articles about reusable GI endoscopes to support its claims. Table 54 summarizes the applicant’s assertions regarding the substantial clinical improvement criterion. Please see the online posting for Ambu® aScope™ Gastro for the applicant’s complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Table 54: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	Supporting evidence provided by the applicant	Reference title*
The aScope Gastro	The literature highlights six studies that show the	Goyal, H., Larsen, S., Perisetti, A., Larsen, N. B., Ockert, L. K.,

<p>eliminates the risk of cross-contamination between patients and scopes between patients and scopes</p>	<p>contamination rate of gastroscopes to be 28.2 percent. Given the aScope Gastro’s disposable design, the contamination rate is eliminated since there is no reuse of the same scope. These positive cultures are a result of normally reprocessing standards being unable to fully sterilize a scope once it has been used.</p>	<p>Adamsen, S., Tharian, B., & Thosani, N. (2022). Gastrointestinal endoscope contamination rates – elevators are not only to blame: a systematic review and meta-analysis. <i>Endoscopy international open</i>, 10(6), E840–E853. https://doi.org/10.1055/a-1795-8883 *</p>
<p>The aScope Gastro would eliminate the contamination MAUDE reports submitted for reusable gastroscopes</p>	<p>More adverse event reports involving potentially contaminated gastroscopes were submitted to the FDA from 2014 -2021 than any other flexible endoscope. 1,135 MAUDE reports were submitted to the FDA for gastroscopes in 2021. Some cases involve patients infected with CRE or a related superbug.</p>	<p>Muscarella, L. F. (2022). Contamination of Flexible Endoscopes and Associated Infections: A Comprehensive Review and Analysis of FDA Adverse Event Reports. https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/</p>
<p>The aScope Gastro would eliminate the risk of superbug related infections that originate from reusable gastroscopes</p>	<p>There have been multiple cases linking a reprocessed gastroscope to infections of resistant bacteria. In some cases, this has lead to patient death. The aScope Gastro would have eliminated the risk of these infections since the scope would not be used on multiple patients.</p>	<p>Muscarella, L. F. (2023). Gastroscopes Have Been Linked to A Cluster of Resistant E. coli Infections — Is the Risk Sufficiently Recognized? https://lfm-hcs.com/2023/01/gastroscopes-have-been-linked-to-a-cluster-of-resistant-e-coli-infections-is-the-risk-sufficiently-recognized/</p>
<p>The aScope Gastro would avoid damage and debris after reprocessing since it is not reused</p>	<p>Visible damage and debris/residue was found in all gastroscopes observed after reprocessing. After visual inspection, all gastroscopes needed to be either repaired or refurbished due to damage and/or debris. Additional issue observed after reprocessing were gapping of distal adhesive bands, leftover fluid, channel shredding, and droplet. All of these introduce issues to patients that may results in readmissions, infections, or deaths. The aScope Gastro avoids all of these issues.</p>	<p>Ofstead, C. L., Smart, A. G., Hopkins, K. M., & Wetzler, H. P. (2023). The utility of lighted magnification and borescopes for visual inspection of flexible endoscopes. <i>American journal of infection control</i>, 51(1), 2–10.</p>
<p>The aScope Gastro avoids damaged and contaminated</p>	<p>27 percent of gastroscopes were found to have positive microbial samples after reprocessing. Additional issues found were fluid</p>	<p>Wallace, M. M., Keck, T., Dixon, H., & Yassin, M. (2023). Borescope examination and microbial culture results of</p>

scopes from being used on patients	retention, channel shredding, scratches, and debris after reprocessing. These issues pose several threats to patient safety. The aScope Gastro bypasses these issues since the scope is never reused.	endoscopes in a tertiary care hospital led to changes in storage protocols to improve patient safety. American journal of infection control, 51(4), 361–366.
The aScope Gastro eliminates the risk of patient-to-patient infections associated with contaminated scopes	The all-cause infection rate for EGDs with reusable gastroscopes was found to be 3.0 per 1000 procedures. The aScope Gastro can eliminate the risk of infection associated with reusable gastroscopes since the design is single-use and will be thrown out after each use.	Wang, P., Xu, T., Ngamruengphong, S., Makary, M. A., Kalloo, A., & Hutfless, S. (2018). Rates of infection after colonoscopy and esophagogastroduodenoscopy in ambulatory surgery centres in the USA. Gut, 67(9), 1626–1636.
The aScope Gastro's single-use design avoids the issues associated with reusable gastroscope contamination such as infection and even death	3 died after testing positive (+) for antibiotic-resistant E coli after undergoing an EGD. 4 patients tested + for E coli after the gastroscope was used on them-one died. 6 patients became infected with the same superbug from the same scope—three died. 2 patients treated with the same gastroscope tested + for CRE-NDM and E coli-84 additional patients had procedures with the scope. A reusable gastroscope was used on a patient with Creutzfeldt-Jakob disease. A superbug remained after reprocessing.	The applicant provided FDA MAUDE Adverse Event Reports

*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.

After review of the information provided by the applicant, we have the following concerns regarding whether Ambu® aScope™ Gastro meets the substantial clinical improvement criterion.

First, we note that the applicant identified 11 other devices that it believed are most like the Ambu® aScope™ Gastro: (1) Olympus GIF-HQ 190; (2) Olympus GIF-1TH190; (3) Olympus GIF-H190; (4) Olympus GIF-CP190N; (5) Fujifilm EG-760R; (6) Fujifilm EG-760CT; (7) Fujifilm EG-760Z; (8) Fujifilm EG-740N; (9) Pentax HD Video Gastroscope EG34 i10; (10) Pentax MagniView EG 2990Zi; and (11) Pentax G EYE. According to the applicant,

these devices are used during the same specific procedure(s) and/or services with which the nominated device is used. The applicant stated that the nominated device's single-use feature is unique among the comparators because its single-use feature eliminates gastroscopereprocessing. The applicant also indicated that there are no HCPCS Level I and/or Level II code(s) used to identify these existing devices. While the evidence provided demonstrates that the Ambu® aScope™ Gastro may be different than the other 11 closely related devices, it does not provide any comparative data that demonstrates that the Ambu® aScope™ Gastro offers a substantial clinical improvement when compared to the other 11 devices.

Second, we note that the nominated device was determined to be substantially equivalent to a predicate device: OLYMPUS EVIS EXERA II Gastrointestinal Videoscope GIF H180 (K100584). The FDA 510(k) summary indicated that both devices share the same technological characteristics such as insertion portion length, working channel diameter, direction of view and bending angles. We note that the 510(k) summary indicated that, unlike the predicate device, the Ambu® aScope™ Gastro is a sterile, single-use device and not intended to be reprocessed. Again, while this demonstrates that the Ambu® aScope™ Gastro may be different than the predicate device, it is unclear whether this difference demonstrates substantial clinical improvement. No comparative data demonstrating that the Ambu® aScope™ Gastro provides a substantial clinical improvement when compared to the OLYMPUS EVIS EXERA II Gastrointestinal Videoscope GIF H180 was provided. We would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical benefit in comparison to other existing devices.

Further, the applicant indicated that while other single-use endoscopes are available, there are no known competitive devices on the market that are single-use, transoral, and marketed in the U.S. The applicant compared the Ambu® aScope™ Gastro to the following two existing devices: (1) EndoFresh Single-Use Gastroscopere; and (2) EvoEndo Model LE Single-Use Gastroscopere. Specifically, the applicant noted that although EndoFresh Single-Use Gastroscopere

is FDA-cleared and a similar device that could also become eligible for transitional pass-through payment under the proposed additional category, it has no commercial activity in the U.S. According to the applicant, while EvoEndo Model LE Single-Use Gastroscope is used during the same specific procedure(s) and/or services as the Ambu® aScope™ Gastro, the Ambu® aScope™ Gastro is different from EvoEndo Model LE Single-Use Gastroscope because the Ambu® aScope™ Gastro is a transoral scope, not transnasal. The applicant also indicated that there are no HCPCS Level I and/or Level II code(s) used to identify EvoEndo Model LE Single-Use Gastroscope. However, we note that EvoEndo Model LE Single-Use Gastroscope is both transoral and transnasal, which is indicated on the EvoEndo's Website³⁷ and on its FDA 510(k)³⁸ clearance letter. We also note that the applicant did not compare the Ambu® aScope™ Gastro to another single-use, FDA-cleared endoscope available on the market—EXALT™ Model D, Single-Use Duodenoscope³⁹—which we believe may be similar. We would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical improvement in comparison to similar single-use competitive devices such as the EvoEndo Model LE Single-Use Gastroscope and the EXALT™ Model D, Single-Use Duodenoscope.

³⁷ EvoEndo® Model LE Single-Use Gastroscope and EvoEndo Controller

³⁸ EvoEndo® Model LE Single-use Gastroscope is FDA cleared and marketed under 510(k) since 2022 (FDA 510(k)) letter: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K213606.pdf. The EvoEndo Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb in patients over the age of five years. The gastroscope is a sterile single-use device and can be inserted orally or transnasally.

³⁹ EXALT™ Model D, Single-Use Duodenoscope is FDA cleared and marketed under 510(k) since 2019 (FDA 510(k)) letter: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193202.pdf. The EXALT™ Model D, Single-Use Duodenoscope is intended for use with a Boston Scientific endoscopic video imaging system, for endoscopy and endoscopic surgery within the duodenum.

In addition, we note that the applicant's self-sponsored studies, which are background articles by Muscarella, L. F. (2022)⁴⁰, Muscarella, L.F. (2023)⁴¹, and Ofstead, et. al. (2022),⁴² lack direct comparison of the nominated device to other 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 treatments, we consider 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 compared to the standard of care. Additional supporting evidence, preferably published peer-reviewed clinical trials, that shows these improved clinical outcomes would help inform our assessment of whether the Ambu[®] aScope[™] Gastro demonstrates substantial clinical improvement over existing technologies.

Moreover, while the details provided in the application and all the articles submitted as evidence of substantial clinical improvement discuss potential adverse events from reusable gastroscopy procedures, they do not appear to directly show any clinical improvement that results from the use of the Ambu[®] aScope[™] Gastro. Rather, the applicant provided evidence which seems to rely on indirect inferences from other sources of data. Specifically, the applicant included an FDA Manufacturer and User Facility Device Experience (MAUDE) report⁴³ which provides the details of multiple adverse event reports associated with the contamination or

⁴⁰ Muscarella, L. F. (2022). Contamination of Flexible Endoscopes and Associated Infections: A Comprehensive Review and Analysis of FDA Adverse Event Reports. <https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/>

⁴¹ Muscarella, L. F. (2023). Gastroscopes Have Been Linked to A Cluster of Resistant E. coli Infections — Is the Risk Sufficiently Recognized? <https://lfm-hcs.com/2023/01/gastroscopes-have-been-linked-to-a-cluster-of-resistant-e-coli-infections-is-the-risk-sufficiently-recognized/>

⁴² Ofstead, C. L., Smart, A. G., Hopkins, K. M., & Wetzler, H. P. (2023). The utility of lighted magnification and borescopes for visual inspection of flexible endoscopes. *American Journal of Infection Control*, 51(1), 2-10.

⁴³ MAUDE Adverse Event Report: AIZU OLYMPUS CO., LTD. EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE (fda.gov)

suspected contamination of reusable gastroscopes but does not directly show any clinical improvement that results from the use of the Ambu® aScope™ Gastro.

While the applicant claims that the Ambu® aScope™ Gastro eliminates cross-contamination associated with reusable gastroscopes and eliminates the risk of infections that originate from reusable gastroscopes, we do not believe that we have sufficient information on the prevalence of infection to evaluate the applicant's substantial clinical improvement claims for the Ambu® aScope™ Gastro. We note the analyses^{44,45} on adverse event reports and the FDA MAUDE report⁴⁶ appear to apply to flexible, reprocessed gastroscopes or endoscopes, broadly, but not to disposable, single-use devices comparable to the nominated device. Therefore, we question the direct relevance of these background articles to the nominated device and the applicant's substantial clinical improvement claims. Further, we note that many of the applicant's substantial clinical improvement claims rely on an assumption that inadequate reprocessing of reusable endoscopes is positively correlated with heightened risk of infection. We note that the applicant's self-sponsored analyses of FDA adverse event reports and studies^{47,48,49} and the FDA MAUDE report⁵⁰ do not provide evidence on the prevalence of infection, establish a clear relationship between infection risk and reprocessing procedures, or substantiate that single-use disposable scopes, or the nominated device specifically, would be a

⁴⁴ Muscarella, L. F. (2022). Contamination of Flexible Endoscopes and Associated Infections: A Comprehensive Review and Analysis of FDA Adverse Event Reports. <https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/>

⁴⁵ Muscarella, L. F. (2023). Gastroscopes Have Been Linked to A Cluster of Resistant E. coli Infections — Is the Risk Sufficiently Recognized? <https://lfm-hcs.com/2023/01/gastroscopes-have-been-linked-to-a-cluster-of-resistant-e-coli-infections-is-the-risk-sufficiently-recognized/>

⁴⁶ MAUDE Adverse Event Report: AIZU OLYMPUS CO., LTD. EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE (fda.gov)

⁴⁷ Muscarella, L. F. (2022). Contamination of Flexible Endoscopes and Associated Infections: A Comprehensive Review and Analysis of FDA Adverse Event Reports. <https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/>

⁴⁸ Muscarella, L. F. (2023). Gastroscopes Have Been Linked to A Cluster of Resistant E. coli Infections — Is the Risk Sufficiently Recognized? <https://lfm-hcs.com/2023/01/gastroscopes-have-been-linked-to-a-cluster-of-resistant-e-coli-infections-is-the-risk-sufficiently-recognized/>

⁴⁹ Ofstead, C. L., Smart, A. G., Hopkins, K. M., & Wetzler, H. P. (2023). The utility of lighted magnification and borescopes for visual inspection of flexible endoscopes. *American Journal of Infection Control*, 51(1), 2-10.

⁵⁰ MAUDE Adverse Event Report: AIZU OLYMPUS CO., LTD. EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE (fda.gov)

substantial clinical improvement over currently available devices. We would be interested in more information on the prevalence of infection due to incomplete/inadequate processing for gastroscopes in the U.S. and whether single-use gastroscopes reduce the infection rate in patients to identify the extent of the problem with existing technologies.

We are inviting public comment on whether Ambu® aScope™ Gastro 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 provided the following information in support of the cost significance requirements. The applicant stated that Ambu® aScope™ Gastro would be reported with HCPCS codes shown in Table 55.

Table 55: HCPCS CODES REPORTED WITH AMBU® ASCOPE™ GASTRO

HCPCS Code	Long Descriptor	SI	APC
43192	Esophagoscopy, rigid, transoral; with biopsy, single or multiple	J1	5302
43193	Esophagoscopy, flexible, transoral; with biopsy, single or multiple	J1	5302
43194	Esophagoscopy, rigid, transoral; with removal of foreign body(s)	J1	5302
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance	J1	5302
43205	Esophagoscopy, flexible, transoral; with band ligation of esophageal varices	J1	5302
43211	Esophagoscopy, flexible, transoral; with endoscopic mucosal resection	J1	5302
43215	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	J1	5302
43216	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	J1	5302
43217	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	J1	5302
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	J1	5303
43233	Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)	J1	5302

HCPCS Code	Long Descriptor	SI	APC
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed	T	5301
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance	T	5301
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures	J1	5302
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	J1	5302
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple	T	5301
43240	Esophagogastroduodenoscopy, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter[s]/stent[s], when performed, and endoscopic ultrasound, when performed)	J1	5331
43241	Esophagogastroduodenoscopy, flexible, transoral; insertion of intraluminal tube or catheter	J1	5302
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	J1	5302
43243	Esophagogastroduodenoscopy, flexible, transoral; injection sclerosis of esophageal/gastric	J1	5302
43244	Esophagogastroduodenoscopy, flexible, transoral; with band ligation of esophageal/gastric varices	J1	5302
43245	Esophagogastroduodenoscopy, flexible, transoral; with dilation of gastric/duodenal stricture(s) (e.g., balloon, bougie)	J1	5302
43246	Esophagogastroduodenoscopy, flexible, transoral; with directed placement of percutaneous gastrostomy tube	J1	5302
43247	Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body(s)	T	5301
43248	Esophagogastroduodenoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) through esophagus over guide wire	T	5301
43249	Esophagogastroduodenoscopy, flexible, transoral; transendoscopic balloon dilation of esophagus (<30 mm)	J1	5302
43250	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	J1	5302
43251	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	J1	5302

HCPCS Code	Long Descriptor	SI	APC
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection	J1	5302
43255	Esophagogastroduodenoscopy, flexible, transoral; with control of bleeding, any method	J1	5302
43266	Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent	J1	5331
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	J1	5302

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 2023 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5301, which had a CY 2023 payment rate of \$825.51 at the time the application was received. HCPCS code 43239 in APC 5301 had a CY 2023 device offset amount of \$2.64 at the time the application was received.⁵¹ According to the applicant, the cost of Ambu® aScope™ Gastro is \$799.00.

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 \$799.00 for Ambu® aScope™ Gastro is 96.79 percent of the applicable APC payment amount

⁵¹ We note that the applicant selected a device offset amount of \$21.55 for APC 5301 without selecting a specific HCPCS/CPT code. However, for the HCPCS/CPT codes provided by the applicant, we note the HCPCS/CPT code level device offset amounts are available in Addendum P to the CY 2023 OPPS/ASC final rule with comment period. For our calculation, we selected the HCPCS/CPT code level device offset amount of \$2.64 related to HCPCS 43239 in APC 5301 found in Addendum P to the CY 2023 OPPS/ASC final rule with comment period. Based on our initial assessment for this proposed rule, using the device offset amount of \$2.64 would result in Ambu® aScope™ Gastro meeting the cost significance requirement.

for the service related to the category of devices of \$825.51 ($(\$799.00/\$825.51) \times 100 = 96.79$ percent). Therefore, we believe Ambu® aScope™ Gastro 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 \$799.00 for Ambu® aScope™ Gastro is 30,265.15 percent of the cost of the device-related portion of the APC payment amount for the related service of \$2.64 ($(\$799.00/\$2.64) \times 100 = 30,265.15$ percent). Therefore, we believe that the Ambu® aScope™ Gastro 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 \$799.00 for Ambu® aScope™ Gastro and the portion of the APC payment amount for the device of \$2.64 is 96.47 percent of the APC payment amount for the related service of \$825.51 ($((\$799.00 - \$2.64)/\$825.51) \times 100 = 96.47$ percent). Therefore, we believe that Ambu® aScope™ Gastro meets the third cost significance requirement.

We are inviting public comment on whether the Ambu® aScope™ Gastro meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(b) OMEZA Wound Care Matrix (OCM™)

OMEZA LLC submitted an application for a new device category for transitional pass-through payment status for OCM™ for CY 2025. According to the applicant, OCM™ is an

amorphous, solid, malleable sheet comprised of hydrolyzed fish peptides infused with cod liver oil, which acts as an anhydrous skin protectant. Per the applicant, OCM™ is indicated for the management of wounds. The applicant asserted that, when applied to a clean wound surface, OCM™ is naturally incorporated into the wound over time. Per the applicant, OCM™'s cold water fish peptides provide building blocks for tissue regeneration and cell signaling molecules stimulate tissue growth. Additionally, OCM™'s matrix-like device also contains active pharmaceutical ingredient(s) (API) and nutrients that continuously reduce biofilm impact, reduce inflammation, increase tissue proliferation, and support remodeling of tissue.

Please refer to the online application posting for the OCM™, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP2403016HWP6>, for additional detail describing the device and the disease treated by the device.

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), on September 1, 2021, the applicant received 510(k) clearance from FDA for OCM™ as a device to be used for the management of wounds including: (1) partial and full-thickness wounds, (2) pressure ulcers, (3) venous ulcers, (4) diabetic ulcers, (5) chronic vascular ulcers, (6) tunneled/undermined wounds, (7) surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), (8) trauma wounds (abrasions, lacerations, superficial partial thickness burns, skin tears), and (9) draining wounds. We received the application for a new device category for transitional pass-through payment status for OCM™ on March 1, 2024, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether OCM™ 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, 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. The applicant did not indicate whether OCM™ is integral to the service furnished. We note that in the CY 2014 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. OCM™ does not appear to be necessary to furnish or deliver the primary procedure with which it is used, specifically debridement. Rather, the use of OCM™ following the debridement procedure, including the duration of treatment and the reapplication frequency, seems to be based entirely on provider discretion. As such, we do not believe that OCM™ is integral to the service furnished as required by § 419.66(b)(3). The applicant stated that OCM™ is classified for one-time use and is designed for intimate contact with both regular and irregular wound beds, and as such, it is applied in or on a wound.

We are inviting public comments on whether OCM™ meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant did not indicate whether OCM™ is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if OCM™ is a supply or material furnished incident to a service. However, in the CY 2014 final rule, we described skin substitutes as a type of supply used in a surgical procedure (78 FR 74929 through 74930). As explained the CY 2014 final rule, supplies are a large category of items that typically are either for single patient use or have a shorter life span in use 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 the hospital outpatient setting, including certain implantable medical devices, which we have considered supplies since the inception of the OPPI (78 FR 74929 through 74930). We clarified that we believe skin substitutes are supplies used in a surgical procedure because, as a part of a surgical repair procedure, they reinforce and aid the healing of tissue like implantable biologicals, but with skin substitutes, the tissue is skin instead of internal connective tissues. (78 FR 74931). As such, we question whether OCM™ would be considered a supply, and as such it would be excluded from device pass-through payments under § 419.66(b)(4).

We are inviting public comments on whether OCM™ 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. The applicant asserted that OCM™ is indicated for the comprehensive treatment of advanced wounds and provides continuous delivery of pharmaceutical grade products through an amorphous, anhydrous solid, which reduces biofilm while simultaneously promoting tissue proliferation and remodeling. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe OCM™.

We have not identified an existing pass-through payment category that describes OCM™. We are inviting public comment on whether OCM™ 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 applicant claimed that OCM™ represents a substantial clinical improvement over existing technologies in the treatment of hard to heal or chronic wounds which require advanced wound care procedures such as venous leg ulcers, diabetic foot ulcers, pressure ulcers, and wound dehiscence where proper wound preparation, product application, and proper secondary dressings are a requirement. Specifically, the applicant claimed that OCM™ demonstrates: (1) superior clinical outcomes and healing for Diabetic Foot Ulcers (DFU) compared to standard of care; (2) faster healing rates than standard of care for Venous Leg Ulcers (VLUs); (3) superior clinical outcomes for patients who could not qualify for clinical trials due to comorbidities; (4) improved results when compared to results with standard of care for patients who failed prior treatment; (5) in vitro/in vivo antimicrobial properties and patient safety; and (6) improved patient safety.

The applicant provided the following clinical trial data and case studies to support these claims: (1) two randomized controlled trials (a single-site trial of patients with DFUs to evaluate percent area reduction, and a randomized, multicenter, open label study for a patient group with VLUs); (2) two real-world trials comprised of two separate case studies of patients receiving follow-up care at two different wound treatment centers; (3) one in vitro study; (4) one in vivo porcine study; and (5) one consumer research study assessing the safety of OCM™ using the skin prick method. Table 56 summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Note that there are multiple variations in poster presentations for the same study; these posters are identified by study number and presentation number in

parentheses. Please see the online posting for OCM™ for the applicant’s complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

TABLE 56: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	Supporting Evidence Provided by the Applicant	Reference Title
Superior clinical outcomes and healing for DFU compared to standard of care	OCM arm shows 55 percent improvement in wound size over standard of care after 12 weeks of treatment. 68 percent of patients treated with OCM had wounds present for over 3 months. 5 wounds were unhealed for over a year with 1 wound present more than 3 years. OCM healed 3 of these wounds in less than 12 weeks. One year-old wound reduced by 85 percent in size and a 72-month-old wound reduced by 73percent in 12 weeks. Every wound treated with OCM reduced by more than 70 percent in 12 weeks. All wounds previously failed treatments.	Simman, R., MD, FACS, FACCWS, Cheney, M., APRN, CNP, CWS, COCN, Shuman, S, BSN, RN, Bakewell, S., PhD, Bell, D.P., DPM, CWS, FFPM RCPS. (submitted 2023). A Clinical Study Using Combination Therapy with Standard of Care for the Treatment of Diabetic Foot Ulcers: Final Analysis. ProMedica Jobst Wound Care.
	These results show encouraging healing rates (60 percent 4-week PAR and 93 percent 12-week PAR) of DFUs managed with the combination therapy and SOC. Clinical trials evaluating the combination therapy in VLU (NCT05291169) and multiple wound types (NCT05921292) are underway.	Bell, D.P. DPM, CWS, FFPM RCPS, Shuman, S., BSN, RN, Cheney, M., APRN, CNP, CWS, COCN, Richard Simman, R., MD, FACS, FACCWS. (submitted 2023). A Clinical Study Using Combination Therapy with Standard of Care for the Treatment of Diabetic Foot Ulcers: Interim Analysis. ProMedica Jobst Wound Care.

	<p>OCM arm shows 55 percent improvement in wound size over standard of care after 12 weeks of treatment. 68 percent of patients treated with OCM had wounds present for over 3 months. 5 wounds were unhealed for over a year with 1 wound present more than 3 years. OCM healed 3 of these wounds in less than 12 weeks. One year-old wound reduced by 85 percent in size and a 72-month-old wound reduced by 73 percent in 12 weeks. Every wound treated with OCM reduced by more than 70percent in 12 weeks. All wounds previously failed treatments.</p>	<p>Black, G., DPM, Bakewell, S., PhD., Bell, D.P., DPM, CWS, FFPM RCPS A (presented 2023). Novel Combination Therapy Technology: Case Studies of Complete Closure of a Diabetic Foot Ulcer and a Charcot Foot Ulcer.</p>
	<p>OCM arm shows 55 percent improvement in wound size over standard of care after 12 weeks of treatment. 68 percent of patients treated with OCM had wounds present for over 3 months. 5 wounds were unhealed for over a year with 1 wound present more than 3 years. OCM healed 3 of these wounds in less than 12 weeks. One year-old wound reduced by 85 percent in size and a 72-month-old wound reduced by 73 percent in 12 weeks. Every wound treated with OCM reduced by more than 70 percent in 12 weeks. All wounds previously failed treatments.</p>	<p>Barrett, C.L., DPM, CWS, Bakewell, S.J., PhD, Bell, D.P., DPM, CWS, FFPM RCPS. (presented 2023). A Novel Combination Therapy Technology: Case Studies of Complete Closure of Diabetic Foot Ulcers.</p>
<p>Faster healing rates than standard of care for VLU</p>	<p>OCM was compared to a standard of care treated group with Venous Leg Ulcers (NCT05291169). The average percent area reduction at 12 weeks was 66 percent. The same percent of patients (77 percent) responded in both cohorts, but OCM treatment increased the rate of healing by 22 percent.</p>	<p>Randomized Controlled Trial in Venous Leg Ulcers (NCT05291169) (no author or publication date given).</p> <p>Demographics for RCT in VLU (no author or publication date given).</p>

<p>Superior clinical outcomes for patients who could not qualify for clinical trials, due to comorbidities</p>	<p>OCM treatment of Multiple Etiologies (NCT05921292) enrolled 78 patients who would not have qualified for clinical trials, because of comorbidities, wound size, tobacco use, BMI, etc. Results show average reduction in wound size at 12 weeks by 73 percent, with 45 percent seeing full closure by 12 weeks. Pain score, exudate, demographics, comorbidities, and medications were collected. Wounds treated include diabetic foot, venous leg ulcers, pressure injuries, arterial, pyoderma, hematomas, surgical, and trauma.</p>	<p>Bettle III, G., Bell, D.P., Bakewell, S.J. (submitted 2023). A Novel Comprehensive Therapeutic Approach to the Challenges of Chronic Wounds: A Brief Review and Clinical Experience.</p>
<p>Improved results when compared to results with standard of care for patients who failed prior treatment</p>	<p>OCM was used by 16 independent investigators treating 65 patients who failed prior treatment. These case studies showed 77 percent of wounds were closed by 12 weeks and average area reduction was 90 percent. Patients were not subjected to inclusion or exclusion criteria. Six patients failed cellular tissue product therapies. The age of wounds healed ranged from 12 weeks to 15 years. Wounds treated include diabetic foot, venous leg ulcers, pressure injuries, arterial, pyoderma, hematomas, surgical, and trauma.</p>	<p>Bettle III, G., Bell, D.P., Bakewell, S.J. (submitted 2023). A Novel Comprehensive Therapeutic Approach to the Challenges of Chronic Wounds: A Brief Review and Clinical Experience</p>
		<p>OCM treating Multiple Etiologies Final Trial Data (no author or publication date given).</p>

Demonstrated antimicrobial properties and patient safety for in vitro/in vivo studies	In vitro study showed OCM significantly inhibiting Methicillin-resistant Staphylococcus aureus (MRSA) and Pseudomonas aeruginosa compared to negative controls. OCM addresses an unmet medical need; no other product demonstrates antimicrobial properties and leads to complete wound healing.	Davis, S.C., Gil, J., Solis, M. MBA, Bell, D.P., DPM, CWS, FFPM RCPS, Bakewell, S.J., PhD., Frost, P. (2023). University of Miami Miller School of Medicine Department of Dermatology & Cutaneous Surgery. In Vitro Study Evaluating Antimicrobial Effects of a Novel Combination Therapy Technology Against Methicillin-Resistant Staphylococcus aureus and Pseudomonas aeruginosa.
	In vivo porcine study showed OCM significantly reducing MRSA and Pseudomonas counts in infected wound, with significant reductions over positive (Silver dressing treatment) and negative results (untreated wounds). OCM addresses an unmet medical need; no other product demonstrates antimicrobial properties and leads to complete wound healing.	Stephen C. Davis. S.C., Jozic, I., PhD., Gil, J., Solis, M., Abdo Abujamra, B. (2023). University of Miami Miller School of Medicine Department of Dermatology & Cutaneous Surgery. Antimicrobial Effects of a Novel Combination Therapy Against Methicillin-Resistant Staphylococcus aureus and Pseudomonas aeruginosa in a Porcine Wound Model.
Demonstrated patient safety	Data show patient safety	Princeton Consumer Research Corp. (2019). Final Report. A safety study to assess the allergy potential of OMEZA collagen matrix in human subjects using the skin prick method.

After review of the information provided by the applicant, we identified the following concerns regarding whether the applicant presents clinical data to suggest that OCM™ provides a substantial clinical improvement over other similar skin protectant and wound healing products to meet the criterion at § 419.66(c)(2)(i). Based on the evidence submitted in the application, we note the following concerns: (1) lack of direct comparison between the nominated device and the predicate or reference devices for skin substitutes, particularly with respect to treatment of deep or persistent chronic wounds in people with DFU and VLU; (2) reliance on non-peer-reviewed studies, such as unpublished abstracts or conference posters, the results of which are only presented in a final data table; and (3) reliance on studies which were sponsored by the device manufacturer rather than independent research. At this time, we note that the unpublished

abstract for OCM™ lacked a detailed discussion of study limitations, patient population, and assurances that studies have been thoroughly peer-reviewed, and free from implicit bias. The abstract furthermore did not state if or how standard of care treatment was administered within the same time period to control groups, and therefore we are not clear if there was a direct comparison between OCM™ and its predicate or reference devices. Furthermore, the two randomized controlled trials^{52,53} and two real world studies^{54,55} submitted by the applicant to support its claims had relatively small sample sizes, some investigating only two patients total, which potentially limits the statistical significance of the results.

We note that the applicant did not provide a comparison of OCM™ to other devices it identified are closely related or similar to OCM™. Specifically, the FDA authorization letter dated September 1, 2021, FDA identified one predicate device, SweetBio Apis (K182725), and three reference devices, INTEGRA™ Flowable Wound Matrix (K072113), Kerecis MariGen Wound Dressing (K132343), and Southwest Technologies Stimulen Collagen (K030774) to which OCM™ may be compared. We note that we did not approve transitional device pass-through payment for Kerecis MariGen Wound Dressing (K132343) for CY 2018 after determining that the clinical data provided by the applicant did not support the claim that Kerecis Omega3 Wound Dressing provides a substantial clinical improvement over other similar skin substitute products (82 FR 59330 through 59332). The FDA authorization letter noted that

⁵² Desmond P. Bell, DPM, CWS, FFPM RCPS, et al. A Clinical Study Using Combination Therapy with Standard of Care for the Treatment of Diabetic Foot Ulcers: Interim Analysis. ProMedica Jobst Wound Care, Toledo, OH, US; ProMedica Jobst Vascular Institute, Sylvania, OH, US; University of Toledo College of Medicine, Toledo, OH, US, Omeza, LLC, Sarasota, FL, US (poster presented at the 20th Annual Desert Foot Conference, December 6-9, 2023, Phoenix, AZ, USA).

⁵³ Randomized Controlled Trial in Venous Leg Ulcers (NCT05291169) (no author or publication date given)

⁵⁴ A Novel Combination Therapy Technology: Case Studies of Complete Closure of a Diabetic Foot Ulcer and a Charcot Foot Ulcer Greg Black, DPM; Suzanne Bakewell, PhD; Desmond Bell, DPM, CWS, FFPM RCPS 1Sylvania Podiatry, Sylvania, OH; Omeza, LLC, Sarasota, FL (poster presented resented at the 2023 Diabetic Foot Conference, September 28-30, 2023, Anaheim, CA).

⁵⁵ A Novel Combination Therapy Technology: Case Studies of Complete Closure of Diabetic Foot Ulcers Christopher L. Barrett, DPM, CWS; Suzanne J. Bakewell, PhD; Desmond Bell, DPM, CWS, FFPM RCPS 1Wound Care Specialist, Downingtown, PA, USA; 2Omeza, Sarasota, FL, USA Presented at the 2023 Diabetic Foot Conference, September 28-30, 2023, Anaheim, CA

OCM™ and the predicate device SweetBio Apis have similar indications and the same intended use, namely, to manage wounds by providing an animal-derived collagen product that is biodegradable and incorporates into the surrounding tissue during the body's natural wound healing processes. Both products supplement the collagen constituent with additional biocompatible materials to achieve a final product that covers and protects the wound, assists in managing wound exudate, and maintains a moist wound environment. Further, the substantial equivalence table included in the FDA authorization letter indicated that OCM™ raised no new questions of safety or effectiveness when compared to the predicate and reference devices.

In the first claim, the applicant asserted OCM™ has superior clinical outcomes and healing for DFU compared to the standard of care. Based on the evidence submitted by the applicant, we note the following concerns: (1) lack of a direct comparison to the predicate or reference devices in the two randomized controlled trials and the two real world clinical studies; (2) reliance on unpublished studies; (3) reliance on manufacturer sponsored studies; and (4) small sample sizes. First, Simman, et al. (2023) describes the results of a single-site trial in patients with DFUs to evaluate percent area reduction in wound healing. The stated goal of this study was to demonstrate that a combination therapy, using OCM™ plus standard of care treatment, moves chronic DFUs from a stalled state to a healing state in a 4-week period. The study enrolled 25 patients, five of whom did not complete the study, and one of whom died during the study from comorbidities related to their underlying condition. Study group DFUs were managed with combination therapy from 4-12 weeks, and control group DFUs (comprised of six total study participants) were managed with standard of care treatment involving cleaning and debridement only.

Interim analyses presented as a poster (Bell, et al., 2023) as evidence to support the first claim was limited to 12 total study participants. The interim analysis concluded that healing rates showed an average of 63 percent area reduction for the remaining participants at 4 weeks following standard of care treatment, and an average of 91 percent area reduction at 12 weeks

following the treatment in patients with DFUs managed with the combination therapy. The interim analysis study further showed that one patient with a 12-week percent area reduction of 73 percent continued to improve through week 14 while three patients' wounds had not healed at the time of analysis for those receiving combination therapy.

In the final results presented in Simman et al. (2023), the average 4-week percent area reduction was 60 percent, with three patients experiencing 100 percent closure with combination therapy. At 12 weeks, the median wound size was 0.0 cm² (range, 0-2.59), and the average percent area reduction was 93 percent, with five additional patients experiencing 100 percent closure with combination therapy. Average 4- and 12-week percent area reductions with standard of care alone were 42 percent and 45 percent, respectively. According to the final analysis study abstract, every wound treated with OCMTM combination therapy was reduced by more than 70 percent in 12 weeks and all wounds previously failed treatments.

We note that the Simman et al. (2023) study abstract and the interim analysis do not provide any direct comparison to standard of care treatment with another collagen-based wound matrix or device that is otherwise similar to the indications for use of OCMTM in nonhealing wounds. In addition, it is unclear if any of the control group patients received collagen-based treatments including the predicate or reference devices to draw comparisons to collagen-based skin protectants that perform similarly to OCMTM. While we recognize, given the number of skin substitute products on the U.S. market, it is not possible to compare OCMTM to each product, we believe that studies comparing the product against other powder, liquid, or gel skin substitute products could provide more evidence demonstrating the clinical superiority of OCMTM. In addition to the lack of comparison to other collagen-based wound matrix devices, the standard of care treatment in this study was limited to cleaning and debridement, which, based on the applicant's description for methods for administering OCMTM, is a step prior to administering OCMTM.

In reference to the applicant's statements that debridement combined with application of OCM™ is more effective in the removal of biofilm compared to the standard of care of debridement alone, we note that neither the abstract nor the interim analysis for this study analyzed results on removal or prevention of biofilm in isolation from the overall metric on wound percent area reduction. We note that FDA recommends sharp debridement alone as an effective method to remove the biofilm and necrotic tissue in a chronic wound (Bettle, et al., 2023). We question whether the results describing the average percent area reduction in wounds transitioning from a nonhealing state to a healing state are sufficient to show substantial clinical improvement in removal or prevention of biofilm. We further question whether the results in percent area reduction can be attributed to debridement combined with application of OCM™ as opposed to debridement alone because it is unclear if debridement was performed on all participants in the retrospective control group.

Furthermore, we note that only the effects of historic standard of care treatments administered prior to the start of the study to patients in the control group were included for analysis. While one of the selection criteria for study participants was having failed prior treatment, neither the abstract nor interim analysis discussed how other variables, such as age and comorbidities, may have contributed to treatment failure, or which specific treatments failed in each of the six control group participants. We note that not all patients in the control group received, or were eligible to receive, the same standard of care treatments prior to the study and did not receive any skin substitute or wound dressing treatments during the study as a comparison to the test group patients that were treated with OCM™. Due to the stated limitations in the study as previously described, we do not believe that the applicant has demonstrated that OCM™ offers a substantial clinical improvement over existing treatments.

Finally, the sample size of 19 individuals (six of whom were assigned to the control group) in the Simman et al. (2023) study limits the generalizability of the findings. Therefore, we question whether OCM™ has superior clinical outcomes and healing for DFUs compared to

the standard of care or the predicate or reference devices. Additionally, we note that the Simman et al. (2023) study abstract and interim analysis were sponsored by the manufacturer and have not been published, and therefore are not based on independent and peer-reviewed findings.

In addition to the Simman et al. (2023) study (including the abstract and interim results), in support of its first claim, the applicant submitted two posters presenting results from limited case studies investigating two patients who received treatment using OCM™ combination therapy at the point of care. The first poster (Black, et al., 2023) discussed the treatment of two patients seeking treatment for DFUs at a wound care clinic: (1) a 75-year-old female patient who developed a DFU on her right third toe whose DFU wound progressed from nonhealing to healing after one application of the combination OCM™ therapy; and (2) a 65-year-old female patient with a history of diabetes and a blister of 3-month duration that progressed from nonhealing (after treatment with collagen powder, a gauze covering, an absorbent dressing, and a protective bandage) to completely closed after nine applications of the combination OCM™ therapy over 63 days. The study authors concluded that these case studies demonstrated: (1) rapid and durable healing of chronic/nonhealing wounds in two patients with diabetes who received the combination therapy for their chronic wounds; (2) significantly faster closure of a DFU within 1 week using OCM™ combination therapy than the average healing rate of 84 days for a 1-3 cm² plantar ulcer managed using standard care practices; and (3) that early treatment of chronic/nonhealing wounds with OCM™ combination therapy improves outcomes and can lead to complete closure.

Similarly, the second poster (Barrett et al. (2023) presented results from a case study of two patients who received follow-up care at an outpatient wound center: (1) a 58-year-old male patient with a distal plantar lateral ulceration with infection, which required hospitalization; and (2) a 56-year-old male patient with leg trauma that had obliterated the patient's anterior tibial and peroneal arteries, leaving him with single vessel runoff to the left foot via the posterior tibial artery. In the first patient, after 5 weeks of initial negative pressure wound therapy following

surgery, the percentage area reduction of the wound was 19 percent. In comparison, after three weekly follow-up applications of OCM™ combination therapy, the patient's percentage area reduction was 95 percent. In the second patient, the amputation site was noted as completely necrotic, and therefore not a candidate for standard of care negative pressure wound therapy due to poor skin condition, ischemia, and hyperalgesia. It was noted that after three applications of OCM™ combination therapy, there was a significant improvement in the wound depth and tissue color, with visible epithelialization at the wound edges despite the patient's obvious ischemia. It was noted that the wound size improved and completely healed between the fourth and fifth application of OCM™ combination therapy and after the seventh application of OCM™ combination therapy. The researchers concluded that the case studies demonstrate complete and rapid healing of refractory DFUs in two patients with diabetes who had previously undergone lower extremity amputations and that early use of OCM™ combination therapy has the potential to reduce the rate of amputations and improve patients' quality of life.

We note that both case studies (Barrett et al. (2023) and (Black, et al., 2023), were sponsored by the manufacturer and only had two study participants treated with OCM™ combination therapy, which limits the generalizability of the findings. Although the studies suggest that the two participants treated with OCM™ combination therapy showed transition to a healing state subsequent to the application of OCM™, the results varied widely in terms of number of applications needed to achieve positive results and treatment duration. Further, these case studies provide no direct comparison to the standard of care treatment or the predicate or reference devices. We note that eligibility for standard of care treatments also varied across patients and resulted in varying degrees of percent area reduction or wound closure from prior treatments before application of OCM™ combination therapy. While in one patient, the study showed an improved clinical outcome in percentage area reduction (19 percent to 95 percent) with treatment utilizing OCM™ combination therapy, we note that the treatment including OCM™ was not only completed subsequent to standard of care treatment with a collagen wound

protectant, but also delivered to the same individual rather than as a comparison to standard of care treatments in a control group.

We question whether the submitted evidence adequately supports the claim that OCM™ has superior clinical outcomes and healing for DFU compared to the standard of care. We would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical improvement in comparison to similar collagen-based matrix devices.

In the second claim, the applicant asserted that OCM™ provides faster healing rates than standard of care for VLUs. However, based on the evidence submitted, we note the following concerns: (1) reliance on unpublished studies; and (2) a lack of any documentation indicating the study authors, study description, methods, limitations, information on standard of care treatment for the comparison or control groups, analysis, or discussion. The only data provided were in the form of two tables. One table⁵⁶ provided demographic information for the study participants such as race, age, gender, presence of VLUs, comorbidities, wound area, and wound age; however, there is no indication of how many initial study participants were included in the final results or how many were assigned to either the treatment or control group receiving the standard of care. The other table⁵⁷ presented one row of data from the final results of a randomized controlled trial on VLUs showing an average percent area reduction of 66 percent at 12 weeks in OCM™ treatment group (there was no comparison to the standard of care treatment group) and an average percent area reduction of 34 percent at 4 weeks in the OCM™ treatment group compared to an average percent area reduction of 31 percent at 4 weeks in the standard of care group. Due to the lack of a study report, we have insufficient information to adequately assess

⁵⁶ Demographics for RCT in VLU (no author or publication date given).

⁵⁷ Randomized Controlled Trial in Venous Leg Ulcers (NCT05291169) (no author or publication date given).

this study or make a determination as to whether the study supports the claim that OCM™ provides faster healing rates than standard of care for VLU.

In order to demonstrate substantial clinical improvement over currently available treatments, we consider 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 compared to the standard of care. Additional supporting evidence, preferably published peer-reviewed clinical trials, that shows these improved clinical outcomes would help inform our assessment of whether OCM™ demonstrates substantial clinical improvement over existing technologies.

In the third claim, the applicant asserted that OCM™ provides superior clinical outcomes for patients who could not qualify for clinical trials due to comorbidities, and in the fourth claim, the applicant stated that OCM™ improved results when compared to results with standard of care for patients who failed prior treatment. The applicant used the same pair of documents as supporting evidence for both the third and fourth claims: (1) a case study by 16 independent investigators (Bettle, et al., 2023), and (2) a final summary table⁵⁸ of the results of that case study. In the case study by the 16 independent investigators, OCM™ combination therapy was administered to 65 patients with wound ages ranging from 12 weeks to 15 years who failed prior treatment, including six patients with prior failed cellular tissue product therapies. Patients were not otherwise subjected to inclusion or exclusion criteria. According to the applicant, the findings by the 16 independent investigators showed 77 percent of wounds were closed by 12 weeks and the average area reduction was 90 percent. Wounds treated included DFUs, VLUs, pressure injuries, arterial, pyoderma, hematomas, surgical, and trauma. We note that the study lacked direct comparison to a standard of care treatment. Rather, the study compared patient data

⁵⁸ OCM treating Multiple Etiologies Final Trial Data (no author or publication date given).

to standardized data on wound closure and mean time to total wound closure by wound type based on standardized data from the U.S. Wound Registry.

We question whether the submitted evidence adequately supports the claims that OCM™ provides superior clinical outcomes for patients who could not qualify for clinical trials, due to comorbidities, or that OCM™ improved results when compared to results with standard of care for patients who failed prior treatment. We would welcome further investigation with comparators to help determine whether the device demonstrates substantial clinical improvement over currently available treatments in the clinical setting where it is most likely to be used.

In its fifth claim, the applicant asserted that in vitro (Davis, et al., 2023) and in vivo (Davis, Jozic, et al., 2023) study results demonstrate antimicrobial properties and patient safety. The applicant further asserted that OCM™ addresses an unmet medical need, stating that no other product demonstrates antimicrobial properties and leads to complete wound healing. In the in vivo study (Davis, Jozic, et al., 2023), researchers made 31 deep reticular wounds across the paravertebral and thoracic areas on each of specific pathogen-free pigs. Pathogenic strains of Methicillin-Resistant *Staphylococcus Aureus* (USA300) or *Pseudomonas Aeruginosa* (ATCC 27312), prepared as 10⁶ CFU/ml inoculum suspensions, were used to inoculate all wounds within 20 minutes after wounding followed by application of polyurethane dressings (Tegaderm, 3M, USA) for 72 hours before being treated. Subsequent treatment consisted of OCM™ alone in one test group, OCM™ plus a skin protectant in another test group, Aquacel Ag Advantage in the positive control group, or the wounds were left untreated in the negative control group. We note that the only in vivo study (Davis, Jozic, et al., 2023) with direct comparison to a skin protectant was conducted on non-human subjects (pigs). We question whether these data can be extrapolated to demonstrate significant clinical improvement in humans. In addition, according to the applicant, the in vitro study (Davis, et al., 2023) showed OCM™ significantly inhibiting Methicillin-resistant *Staphylococcus aureus* and *Pseudomonas aeruginosa* compared to negative controls. We note that the in vitro study (Davis, Jozic, et al., 2023) lacked a direct comparison to

performance of other similar skin protectant products or wound therapies besides infection control methods such as silver sulfadiazine or Mupirocin antibiotic. We further note that both the in vitro and in vivo studies were submitted as poster presentations and that the studies have not been published and peer-reviewed in full.

We question whether the submitted evidence adequately supports the claims that OCM™ demonstrates antimicrobial properties and patient safety. Additional 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, would help inform our assessment of whether OCM™ demonstrates substantial clinical improvement over the standard of care and existing technologies.

For its sixth claim, the applicant asserted that study results demonstrated patient safety of OCM™. In support of this claim, the applicant provided one consumer research study – Princeton Consumer Research Corp. (2019) – of 25 subjects showing no immediate allergic reaction to OCM™. We note that, similar to our previously stated concerns, the study did not include a direct comparison to predicate or reference devices despite claiming an improvement over standard of care treatment. Additionally, this study was also sponsored by the manufacturer and, therefore, not an independent study. Furthermore, since this study only included one type of adverse effect (allergenicity), and was limited to only 25 research subjects, there are limitations in demonstrating safety. We note that the submitted evidence does not adequately support the claims that OCM™ demonstrates substantial clinical improvement in product safety in comparison to similar products.

Finally, we note that OCM™ may not demonstrate that it substantially improves the diagnosis or treatment of an illness when compared to the benefits of other available treatments. OCM™ was determined to be substantially equivalent to a legally marketed device, the SweetBio Apis, which received 510(k) clearance on April 29, 2019. The FDA 510(k) summary

for OCM™ indicated that both devices share similar technological characteristics. Per FDA⁵⁹, the main differences between OCM™ and the predicate are the specific collagen source (OCM™ uses whitefish skin-derived collagen, while the SweetBio Apis uses porcine skin-derived collagen) and the specific identity of the supplemental components (which serve the same fundamental purpose in enabling each wound dressing to achieve the shared intended use).

We are inviting public comment on whether OCM™ meets the device category criterion at § 419.66(c)(2)(i).

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 provided the following information in support of the cost significance requirements. The applicant stated that OCM™ would be reported with HCPCS codes as shown in Table 57.

Table 57: HCPCS CODES REPORTED WITH OCM™

HCPCS Code	Long Descriptor	SI	APC
A2014**	Amorphous solid malleable sheet for hard to treat or chronic wounds	N	
11042	Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq cm or less	T	5052
11043	Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); first 20 sq cm or less	T	5053
11044	Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq cm or less	J1	5072
97597	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less	T	5051
97598**	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel	N	

⁵⁹ The SweetBio Apis is FDA cleared and marketed under 510(k) since 2019 (FDA 510(k)) letter: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211972.pdf

	and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (list separately in addition to code for primary procedure		
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**Denotes a HCPCS code that was not included in the corrected Addendum P to the CY 2024 OPPS/ASC final rule with comment period, with no CY 2024 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2024 payment rates for the three tests of the cost criterion. We used the CY 2024 HCPCS/CPT code level device offset amounts for the HCPCS/CPT codes included in the corrected Addendum P 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 utilized the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5052, which had a CY 2024 payment rate of \$379.92 at the time the application was received. HCPCS code 11042 in APC 5052 had a device offset amount of \$0.04 at the time the application was received. According to the applicant, the cost of OCM™ is \$1,320.00.

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 \$1,320.00 of OCM™ is 347.44 percent of the applicable APC payment amount for the service related to the category of devices of \$379.92 ($(\$1,320.00/\$379.92) \times 100 = 347.44$ percent). Therefore, we believe OCM™ 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 \$1,320.00 for OCM™ is 3,300,000.00 percent of the cost of the device-related portion of the APC payment amount for the related service of \$0.04 ($(\$1,320.00/\$0.04) \times 100 = 3,300,000.00$ percent).

Therefore, we believe that OCM™ 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 \$1,320.00 for OCM™ and the portion of the APC payment amount for the device of \$0.04 is 347.43 percent of the APC payment amount for the related service of \$379.92 ($(\$1,320.00 - \$0.04)/\$379.92 \times 100 = 347.43$ percent). Therefore, we believe that OCM™ meets the third cost significance requirement.

We are inviting public comment on whether OCM™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(c) OPN NC

SIS Medical AG submitted an application for a new device category for transitional pass-through payment status for OPN NC for CY 2025. Per the applicant, OPN NC percutaneous transluminal coronary angioplasty (PTCA) dilatation catheter is a sterile, single-use, rapid exchange catheter with a distal non-compliant double layer balloon attached to a flexible distal polymer shaft. The applicant explained that OPN NC is intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. Per the applicant, the balloon dilatation catheter is also indicated for post

deployment expansion of balloon expandable coronary stents. The applicant asserted that the device is inserted to position a balloon in a calcified coronary lesion where super-high pressure is used with the intention of achieving acceptable expansion of the lesion. Per the applicant, radiopaque balloon marker bands enable accurate positioning of the device, and shaft markers for brachial and femoral techniques are also in place. According to the applicant, OPN NC is intended for all patient populations.

Please refer to the online application posting for OPN NC, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP231214L8XQC> , for additional detail describing the device and the disease treated by the device.

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), on March 14, 2022, the applicant received 510(k) clearance from FDA for OPN NC as a device intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The balloon dilatation catheter is also indicated for post deployment expansion of balloon expandable coronary stents. We received the application for a new device category for transitional pass-through payment status for OPN NC on December 14, 2023, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether OPN NC 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, 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, OPN NC is integral to the service provided and is used for one patient only. While the applicant did not explicitly state whether the device is surgically inserted or comes in contact with human tissue, per the device description, OPN NC is inserted into the patient for balloon

dilation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

We are inviting public comments on whether OPN NC meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant did not address whether OPN NC is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if OPN NC is a supply or material furnished incident to a service.

We are inviting public comments on whether OPN NC 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. The applicant described OPN NC as a percutaneous transluminal coronary angioplasty (PTCA) dilatation catheter with a distal non-compliant double layer balloon attached to a flexible distal polymer shaft. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the OPN NC. Per the applicant, the device category, C1725 (Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)) does not appropriately describe OPN NC because OPN NC is a super high pressure, non-compliant

double (twin) layer balloon. Based on the description the applicant provided, OPN NC is a transluminal vascular dilatation catheter with a balloon intended for dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion, which is consistent with the devices described by C1725. In this context, we believe OPN NC may be similar to the devices described by C1725, and therefore, OPN NC may also be appropriately described by C1725.

We are inviting public comment on whether OPN NC 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. According to the applicant, OPN NC represents a substantial clinical improvement over existing technologies in the management of patients with highly calcified coronary lesions by providing optimal lumen expansion and demonstrating better outcomes in lesion treatment compared to other devices.

The applicant provided the following evidence to support its claim: three peer-reviewed studies; a PowerPoint presenting an indirect comparison of OPN NC versus another device, Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 Coronary Intravascular

Lithotripsy (IVL) Catheter (Shockwave),⁶⁰ that uses intravascular lithotripsy (IVL) to treat calcium lesions; a spreadsheet summarizing the data presented in the PowerPoint document comparing OPN NC and Shockwave; and a background article providing an expert consensus statement from the Society for Cardiovascular Angiography & Interventions on management of in-stent restenosis and stent thrombosis.⁶¹ Table 58 summarizes the applicant’s assertion regarding the substantial clinical improvement criterion. Please see the online posting for OPN NC for the applicant’s complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Table 58: Substantial Clinical Improvement Assertions

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	Supporting evidence provided by the applicant	Reference title
Highly calcified unresponsive lumen expansion. OPN NC provides optimal lumen expansion.	Expansion of ≥ 80 percent was achieved in 40 out of 50 cases (80 percent) with a mean final expansion post intervention of 85.7 percent \pm 8.9. Calcium fractures were documented in 49 (98 percent) cases; multiple in 37 (74 percent). There was 1 flow limiting dissection requiring stent deployment and 3 non-cardiovascular related deaths in 6 months follow-up. No records of perforation, no-reflow or other major adverse events. Among patients with heavy calcified lesions undergoing OCT guided intervention with OPN NC, acceptable expansion was achieved in most cases without procedure related complications.	Natalia Pinilla-Echeverri, Matthias Bossard, Ali Hillani, Jorge A Chavarria, Giacomo M Cioffi, Gustavo Dutra, Fernando Guerrero, Mehdi Madanchi, Adrian Attinger, Ellen Kossmann, Matthew Sibbald, Florim Cuculi, Tej Sheth. Treatment of Calcified Lesions Using a Dedicated Super-High Pressure Balloon: Multicenter Optical Coherence Tomography Registry. <i>Cardiovasc Revasc Med.</i> 2023; 52:49-58. doi: 10.1016/j.carrev.2023.02.020.

⁶⁰ CMS approved an application for the Shockwave IVL System with Shockwave C2 Coronary IVL Catheter as a new device category for transitional pass-through payment status and established HCPCS code C1761 as a new device category effective July 1, 2021. We refer readers to the CY 2022 OPPI/ASC final rule with comment period (86 FR 63577 through 63583) for a full discussion the Shockwave IVL System with Shockwave C2 Coronary IVL Catheter application and decision.

⁶¹ Background articles are not included in the following table but can be accessed via the online posting for the technology.

<p>The unique possibility offered by the OPN super-high pressure dedicated balloon provides an effective and easy strategy for treatment of resistant coronary lesions non-responsive to conventional NC balloon dilatation. Moreover, our data suggest that the unique twin-layer technology offered by the OPN balloon achieves uniform balloon expansion reducing the use of additional debulking devices.</p> <p>Angiographic success was achieved in 97.5 percent, procedural success in 96.6 percent; 53 percent of the lesions were responsive to a slower inflation pressure (Group I) while in the remaining 47 percent, the optimal expansion required a pressure > 40 atmosphere (Group II). The OPN alone was able to achieve adequate expansion in > 90 percent. 0.9 percent days major adverse cardiovascular events (MACE) were reported. The OPN-dedicated high-pressure balloon provides an effective and safe strategy for treatment of severe resistant coronary lesions.</p>	<p>Gioel Gabrio Secco, Achim Buettner, Rosario Parisi, Gianfranco Pistis, Matteo Vercellino, Andrea Audo, Mashayekhi Kambis, Roberto Garbo, Italo Porto, Giuseppe Tarantini, Carlo Di Mario. Clinical Experience with Very High-Pressure Dilatation for Resistant Coronary Lesions. <i>Cardiovasc Revasc Med.</i> 2019; 20(12):1083-1087. doi: 10.1016/j.carrev.2019.02.026</p>
<p>Systematic report focusing on the super-high-pressure OPN NC for treatment of In-stent restenosis (ISR). Using this dedicated NC balloon at very high pressures is safe. Moreover, its use not only appears to be efficient in tackling moderately to severely calcified ISR lesions, but also seems to lead to a low rate of TLF/TVF in complex ISR lesions during long-term follow-up. The OPN NC might therefore represent an efficient and less expensive alternative for ISR management compared to other commonly used tools.</p>	<p>Thomas Seiler, Adrian Attinger-Toller, Giacomo Maria Cioffi, Mehdi Madanchi, Mario Teufer, Mathias Wolfrum, Federico Moccetti, Stefan Toggweiler, Richard Kobza, Matthias Bossard, Florim Cuculi. Treatment of In-Stent Restenosis Using a Dedicated Super High-Pressure Balloon. <i>Cardiovasc Revasc Med.</i> 2023; 46:29-35. doi: 10.1016/j.carrev.2022.08.018</p>
<p>Double layer, noncompliant coronary balloons (OPN NC, SIS Medical) capable of inflation pressures ranging from 35 to 55 atm have recently become available in the United States. This class of percutaneous transluminal coronary angioplasty balloon has performed favorably in severely calcified de novo lesions and may be a consideration in ISR secondary to an under expanded stent.</p>	<p>Lloyd W. Klein, Sandeep Nathan, Akiko Maehara, John Messenger, Gary S. Mintz, Ziad A. Ali, Jennifer Rymer, Yader Sandoval, Karim Al-Azizi, Roxana Mehran, Sunil V. Rao, Amir Lotfi. SCAI Expert Consensus Statement on Management of In-Stent Restenosis and Stent Thrombosis. <i>JSCAI.</i> 2023; 2(23):100971. doi: 10.1016/j.jscai.2023.100971*</p>

*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.

After review of the information provided by the applicant, we have the following concerns regarding whether OPN NC meets the substantial clinical improvement criterion. The applicant presented the published results of one study of 50 patients undergoing optical coherence tomography (OCT)-guided percutaneous coronary interventions, including OPN NC, to treat calcified lesions (Natalia Pinilla-Echeverri, et al., 2023). The retrospective study aimed to gain a better understanding of OPN NC calcium modification mechanisms, such as creating deep and wide calcium fractures during percutaneous coronary interventions with the intended clinical outcome of improving myocardial perfusion. Per the applicant, the study showed a primary efficacy endpoint of ≥ 80 percent expansion of the mean reference lumen area achieved in 80 percent of the patients treated. The applicant also presented a retrospective study evaluating 326 highly resistant coronary lesions that had failed to achieve adequate post-dilatation luminal gain with conventional NC-balloons (Secco et al., 2019). Per the study authors, an OPN NC balloon was inflated to achieve a uniform balloon expansion after the failed attempts with conventional NC-balloons. According to the authors, 413 OPN NC balloons were used (1.26 per lesion), and angiographic success was achieved in 318 lesions (97.5 percent), procedural success was achieved in 315 lesions (96.6 percent), and technical success was achieved in 288 patients (90.5 percent). The study authors also reported that the OPN NC balloon alone was able to achieve adequate expansion in 288 cases (90.5 percent), while in 30 patients, rotational atherectomy was needed and performed because of the impossibility to cross the lesion with a proper sized OPN NC balloon. The applicant presented a third study focused on patients needing treatment of in-stent restenosis (ISR) (Seiler et al., 2023). According to the authors, 208 ISR lesions were treated in 188 patients. The study authors concluded that the use of OPN NC for treatment of ISR lesions was safe (primary endpoint of the study) and may lead

to a low rate of target lesion/vessel failure (TLF/TVF) during long-term follow-up. We note that these studies were not randomized clinical trials with a comparator to demonstrate clinical improvement. Instead, the applicant presented results from registries using non-randomized, retrospective study designs without a control group, which we believe may reduce the strength of the evidence presented to support the claim. The authors noted in all three studies that randomized trials may be needed to compare OPN NC to other similar devices.

Further, we also note that in one of the studies (Natalia Pinilla-Echeverri, et al., 2023), the study authors indicated that use of other calcium lesion modification devices prior to applying OPN NC to the patients in that study is a potential confounder that could result in overestimation of OPN NC effectiveness. The study authors stated that this was controlled by having an exclusive OCT pullback pre-OPN NC, but indicated that calcium plaque modification caused by other devices may not be evident on OCT. The study authors further noted that since other devices were used before OPN NC, they could not comment on calcium modification from OPN NC use upfront or an OPN NC-only strategy. We would welcome any additional evidence supporting the claim that that OPN NC provides optimal lumen expansion and the impact of using other calcium lesion modification devices prior to applying OPN NC to a patient.

With regards to safety, in the Natalia Pinilla-Echeverri, et al. (2023) study, one patient was found to have had a flow limiting dissection requiring stent deployment; however, no coronary perforations or no-reflow were reported. In the Secco et al. (2019) study, three patients (0.9 percent) were reported to have experienced coronary rupture after balloon inflation and were successfully treated with stent implantation. In the Seiler, et al. (2023) study, coronary perforation was reported to have occurred twice (0.96 percent) with both successfully treated by balloon inflation and implantation of a covered stent; a total of nine (4.3 percent) locally limited, but flow limiting dissections were reported to have occurred and were successfully treated with implantation of a drug-eluting stent; 4 (1.9 percent) cases of flow deterioration due to embolization of thrombotic material (no-reflow) were found; and one patient (0.5 percent) was

reported to have suffered from immediate vessel closure after stent implantation. The application did not address whether the use of the device is safe beyond the data on safety endpoints presented in the studies provided. We would welcome additional studies or evidence discussing the risk of adverse events with the use of these types of non-compliant balloons.

Finally, we are concerned that the evidence may not demonstrate that OPN NC substantially improves the treatment of an illness when compared to the benefits of other available treatments. The applicant asserted in a supporting document included in the application that OPN NC is not the only FDA-authorized device with an indication for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion and also an indication for post deployment expansion of balloon expandable coronary stents. OPN NC was determined to be substantially equivalent to a legally marketed device, the NC Euphora Rapid Exchange Balloon Dilatation Catheter (Medtronic Inc; K141090), which received 510(k) clearance on August 15, 2014. The FDA 510(k) summary for OPN NC indicated that the devices share similar technological characteristics. In fact, the FDA 510(k) summary indicated that OPN NC differs only in the rated burst pressure of the balloon. We note that the applicant did not compare the nominated device with the NC Euphora Rapid Exchange Balloon Dilatation Catheter, which we believe may be similar. While the applicant asserted that OPN NC is the only super-high pressure, non-compliant twin layer balloon dilatation catheter available in the U.S. and the only device on the market of this nature and capability, we would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical benefit in comparison to other similar NC balloon devices.

We are inviting public comment on whether OPN NC meets the substantial clinical improvement 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 provided the following information in support of the cost significance requirements. The applicant stated that OPN NC would be reported with HCPCS codes shown in Table 59.

Table 59: HCPCS CODES REPORTED WITH OPN NC

HCPCS Code	Long Descriptor	SI	APC
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch.	J1	5192
C1725**	Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)	N	

**Denotes a HCPCS code that was not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, with no CY 2023 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. We used the CY 2023 HCPCS/CPT code level device offset amount for the HCPCS/CPT code included in Addendum P 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 did not provide details regarding the payment rates it applied for the three tests of the cost criterion. For our calculations, we used APC 5192, which had a CY 2023 payment rate of \$5,215.40 at the time the application was received. HCPCS code 92920 in APC 5192 had a CY 2023 device offset amount of \$1609.99 at the time the application was received.

We note that the applicant provided two cost amounts for OPN NC: 1) a price list showing the cost of OPN NC as \$2,200.00; and 2) a product list that lists the cost of OPN NC as \$1,200.00. We further note that the cost included on the product list provided by the applicant for OPN NC (\$1,200.00) does not pass any of the three tests of the cost criterion, but the cost included on the price list for OPN NC (\$2,200.00) passes all three tests of the cost criterion.

When performed with the price list cost for OPN NC of \$2,200.00, we note the following calculation outcomes: 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 \$2,200.00 for OPN NC is 42.18 percent of the applicable APC payment amount for the service related to the category of devices of \$5,215.40 ($(\$2,200.00/\$5,215.40) \times 100 = 42.18$ percent). Therefore, when utilizing the price list cost of \$2,200.00 provided, we believe OPN NC 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 \$2,200.00 for OPN NC is 136.65 percent of the cost of the device-related portion of the APC payment amount for the related service of \$1,609.99 ($\$2,200.00/\$1,609.99 \times 100 = 136.65$ percent). Therefore, when utilizing the price list cost of \$2,200.00 provided, we believe that OPN NC 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 \$2,200.00 for OPN NC and the portion of the APC payment amount for the device of \$1,609.99 is 11.31 percent of the APC payment amount for the related service of \$5,215.40 ($((\$2,200.00 - \$1,609.99)/\$5,215.40) \times 100 = 11.31$ percent). Therefore, when utilizing the price list cost of \$2,200.00 provided, we believe that OPN NC meets the third cost significance requirement.

When performed with the product list cost for OPN NC of \$1,200.00, we note the following calculation outcomes: 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 \$1,200.00 for OPN NC is 23.01 percent of the applicable APC payment amount for the service related to the category of devices of \$5,215.40 ($(\$1,200.00/\$5,215.40) \times 100 = 23.01$ percent). Therefore, when utilizing the product list cost of \$1,200.00 provided, we believe OPN NC does not meet 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 \$1,200.00 for OPN NC is 74.53 percent of the cost of the device-related portion of the APC payment amount for the related service of \$1,609.99 ($(\$1,200.00/\$1,609.99) \times 100 = 74.53$ percent). Therefore, when utilizing the product list cost of \$1,200.00 provided, we believe OPN NC does not meet 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 \$1,200.00 for OPN NC and the portion of the APC payment amount for the device of \$1,609.99 is negative 7.86 percent of the APC payment amount for the related service of \$5,215.40 ($((\$1,200.00 - \$1,609.99)/\$5,215) \times 100 = -7.86$ percent). Therefore, when utilizing the product list cost of \$1,200.00 provided, we believe that OPN NC does not meet the third cost significance requirement.

Based on the conflicting amounts provided for the reasonable cost of OPN NC, we question whether OPN NC meets the cost significance criterion. We would welcome additional information regarding this inconsistency on the estimated average reasonable cost of OPN NC.

We are inviting public comment on whether the OPN NC meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(d) OSCAR® Peripheral Multifunctional Catheter

Biotronik, Inc. submitted an application for a new device category for transitional pass-through payment status for OSCAR® Peripheral Multifunctional Catheter (OSCAR®) for CY 2025. According to the applicant, OSCAR® is a tool used to simplify the treatment of peripheral artery disease (PAD), a disease process characterized by the narrowing of arteries that supply blood to the limbs, usually the legs. In severe cases PAD can cause tissue death and gangrene, leading to amputation. Per the applicant, OSCAR® can simplify the process of peripheral interventions, reduce the time required to perform the procedure and the need for repeat procedures, reduce the risk of complications associated with changing out multiple medical devices, minimize radiation exposure, and enhance patient comfort.

Please refer to the online application posting for OSCAR®, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP230601F6NM2> , for additional detail describing the device and the disease treated by the device.

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), on July 5, 2022, the applicant received 510k clearance from FDA for OSCAR® as a device to be used for percutaneous transluminal interventions in the peripheral vasculature to provide support during access into and to dilate stenoses in femoral, popliteal and infrapopliteal arteries. The product is also intended for injecting radiopaque contrast media for angiography. We received the application for a new device category for transitional pass-

through payment status for OSCAR® on June 1, 2023, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether OSCAR® 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, 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. The applicant did not explicitly state whether OSCAR® is integral to the service provided. While the applicant did not explicitly state whether the device is used for one patient only or whether it comes in contact with human tissue, per the device description, OSCAR® is surgically inserted into the lower extremity peripheral vascular system and is single-use. We are inviting public comments on whether OSCAR® meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 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). The applicant did not indicate whether OSCAR® is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if OSCAR® is a supply or material furnished incident to a service.

We are inviting public comments on whether OSCAR® 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. The applicant asserted that OSCAR® is a combination device authorized by FDA with an indication to diagnose and treat peripheral vascular lesions, identify obstructions, and cross the areas of obstruction and restore blood flow using a single system. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe OSCAR®. Per the applicant, OSCAR® has the functionality of multiple devices currently used during lower extremity peripheral vasculature interventions. The applicant provided multiple HCPCS codes that could describe some of the components of OSCAR®; however, only one of the codes provided, C1725, is a device category HCPCS code, and, therefore, C1725 is the only device category we evaluated for this criterion. Per the applicant, the device category C1725 (Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)) does not appropriately describe OSCAR® because OSCAR® can cover the functionality of support catheters, several sizes of angioplasty balloons, chronic total occlusion crossing devices, reentry catheters, resistant lesion preparation devices, and dissection-reducing devices. According to the applicant, current pass-through coding does not adequately capture OSCAR®'s full functionality and the added clinical and economic value derived from its simplification of peripheral vascular interventions.

We note, based on the description the applicant provided, that when the OSCAR® support catheter and OSCAR® dilator are combined with the OSCAR® PTA balloon, the device is used to complete a transluminal angioplasty, which is consistent with the devices described by C1725. In this context, we believe that OSCAR® may be similar to the devices described by C1725 and, therefore, may be appropriately described by C1725.

We are inviting public comment on whether OSCAR® 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 applicant claimed that OSCAR® represents a substantial clinical improvement over existing technologies in the diagnosis and management of peripheral artery disease because it uses less equipment, cuts down procedure time, and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety.

The applicant provided four background documents supporting its substantial clinical improvement claim.⁶² Please see the online posting for OSCAR® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

⁶² Background articles are not included in the following table but can be accessed via the online posting for the technology.

Table 60: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement: The technology significantly improves clinical outcomes relative to services or technologies previously available		
Applicant statements in support	Supporting evidence provided by the applicant	Reference Title
OSCAR matches its counterparts in diagnostic and therapeutic prowess. Its unique advantage lies in the ability to achieve these objectives using less equipment. This cuts down procedure time and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety.	This clinical evaluation report demonstrates that the OSCAR Peripheral Multifunctional Catheter, FDA approved in July 2022 for peripheral vasculature interventions, demonstrated high efficacy and safety in a U.S. study.	Deloose, K., Li, S., Salehi Evard, B. (2023) Clinical Evaluation Report. Biotronik. Unpublished.
	The Oscar Catheter presents a 93 percent success in reducing stenosis with 0percent procedural complications, surpassing other methods. It has a 90.1 percent crossing success, and 75 percent of users reported shorter procedural times, enhancing efficiency and patient safety.	Clinical Benefit Table for OSCAR. Biotronik. Unpublished.
	This document is an Evaluation of Market Acceptance for the OSCAR Peripheral Multifunctional Catheter system (EMA).	Biotronik (2024, February 7). OSCAR Peripheral Multifunctional Catheter: Real-World User Evaluation [PowerPoint slides].
	The Oscar EMA Evaluation of Market Acceptance (EMA) conducted from September 13, 2022, to November 10, 2022, assessed the performance and acceptance of Oscar Kits in 78 cases across 12 centers in the USA. The evaluation met all its ending criteria with impressive results.	Schroeder, H. (2023) Clinical OSCAR Evaluation of Market Acceptance Report. Biotronik. Unpublished.

After review of the information provided by the applicant, we have the following concerns regarding whether OSCAR® meets the substantial clinical improvement criterion. First, the applicant did not submit peer-reviewed or published clinical evidence to substantiate clinical improvement over existing devices. The applicant submitted four background

documents in support of OSCAR®: (1) a clinical benefit table, (2) a presentation on the Evaluation of Market Acceptance, (3) the OSCAR® US Evaluation of Market Acceptance Report, and the (4) OSCAR® Clinical Evaluation Report. All four of these documents rely on data from the Evaluation of Market Acceptance. We note these documents are not published or peer-reviewed, and reflect data collected for marketing purposes rather than clinical improvement purposes. The data included appear to be opinion-based survey questions asked of physicians recruited by the applicant for the purpose of the Evaluation of Market Acceptance and note that these documents suggest an implicit bias. We question the link between these documents and the claims the applicant made that OSCAR® shows substantial clinical improvement because it uses less equipment, cuts down procedure time, and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety. We request clarification on how the support documents directly relate to the substantial clinical improvement claims.

Further, we question how a collection of devices currently available on the market consolidated into a single packaged product demonstrates substantial clinical improvement. According to the applicant, with OSCAR® some procedures may be performed with a single device which cuts down procedure time and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety. The applicant asserted several benefits of using OSCAR® over multiple devices, including reducing (1) the need to remove and replace multiple devices, which may reduce the incidence of complications like infection and vessel damage; (2) the need to use ill-fitting devices; (3) the need for multiple guidewires in several procedures; and (4) the incidence of complications, such as infections and vessel damage. However, we did not receive comparative data supporting the claim that OSCAR® offers superiority over currently available treatments in terms of clinical benefit or safety. The evidence provided did not discuss any advantages of using a single system of

devices rather than multiple individual devices with diverse functionalities. We would welcome any additional evidence supporting these claims.

Furthermore, per the applicant, OSCAR® is effective in preparing intravascular lesions for advanced interventions, particularly stenting, and by ensuring optimal lesion preparation, OSCAR® elevates the success rate of these procedures, enhances patient safety, and streamlines institutional operations. According to the applicant, OSCAR® handles chronic total occlusions (CTOs) and incorporates reentry capabilities, features traditionally found in standalone devices. The applicant asserted this integration enhances patient safety, simplifies procedures, and elevates the efficiency of operations. However, we note that the applicant did not provide clinical information in support of these claims. Again, we would welcome any additional evidence supporting these claims.

Finally, we question whether OSCAR® can be sufficiently distinguished from similar existing technologies to demonstrate substantial clinical improvement. OSCAR® was determined to be substantially equivalent to a legally marketed device, the INFINITY Angioplasty Balloon Catheter™, which received 510(k) clearance on May 20, 2020. The FDA 510(k) summary for OSCAR® indicated that the devices share similar technological characteristics, and that OSCAR® differs only in that it combines support catheters to be used with the dilator and balloon catheter. We did not receive data demonstrating how OSCAR® offers a substantial clinical improvement compared to the INFINITY Angioplasty Balloon Catheter. We would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical benefit in comparison to INFINITY Angioplasty Balloon Catheter.

Further, per the applicant, there are six device types that it believed OSCAR® is most closely related to: (1) workhorse guidewires (Abbott, Boston Scientific, Terumo, Medtronic, Biotronik, Cook Medical, Cordis); (2) premium guidewires (Abbott, Asahi Intecc, Boston Scientific, Cook Medical and more); (3) workhorse & premium support catheters (Philips,

Boston Scientific, Cook Medical, Medtronic, Asahi Intecc, Teleflex and more); (4) angioplasty balloons (Abbott, BD Interventional, Biotronik, Cook Medical, Medtronic and more); (5) lesion preparation balloons (Philips, Medtronic, BD Interventional and Cagent Vascular); and (6) chronic total occlusion and reentry devices. We do not believe that OSCAR® is similar to the workhorse guidewires and premium guidewires listed because OSCAR® does not include guidewires. We would welcome additional information illustrating how OSCAR® is similar to the listed workhorse guidewires and premium guidewires and evidence demonstrating the benefits of OSCAR® over these other devices.

While we note that OSCAR® is comparable, we did not receive data demonstrating how OSCAR® offers a substantial clinical improvement compared to the workhorse and premium support catheters, angioplasty balloons, lesion preparation balloons, or chronic total occlusion and reentry devices and would be interested in additional evidence demonstrating the substantial clinical benefits of OSCAR® over these other devices.

Additional evidence comparing OSCAR® to existing technologies would be particularly helpful to determine whether the device demonstrates substantial clinical improvements over currently available treatments in the clinical setting where it is most likely to be used. Specifically, we would welcome 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.

We are inviting public comment on whether OSCAR® meets the device category criterion at § 419.66(c)(2)(i).

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 provided

the following information in support of the cost significance requirements. The applicant stated that OSCAR® would be reported with HCPCS codes as shown in Table 61.

Table 61: HCPCS CODES REPORTED WITH OSCAR®

HCPCS Code	Long Descriptor	SI	APC
36200**	Introduction of catheter, aorta	N	
36245**	Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family	N	
36246**	Selective catheter placement, arterial system; initial second order abdominal, pelvic, or lower extremity artery branch, within a vascular family	N	
36247**	Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family	N	
36248**	Selective catheter placement, arterial system; additional second order, third order, and beyond, abdominal, pelvic, or lower extremity artery branch, within a vascular family (List in addition to code for initial second or third order vessel as appropriate)	N	
37184	Primary percutaneous transluminal mechanical thrombectomy, noncoronary, non-intracranial, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); initial vessel	J1	5193
37220	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty	J1	5192
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	J1	5193
37222**	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	N	
37223**	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	N	
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty	J1	5192
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed	J1	5193

HCPCS Code	Long Descriptor	SI	APC
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	J1	5193
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed	J1	5194
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty	J1	5193
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed	J1	5194
37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	J1	5194
37231	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed	J1	5194
37232**	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	N	
37233**	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	N	
37234**	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	N	
37235**	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	N	
75625	Aortography, abdominal, by serialography, radiological supervision and interpretation	Q2	5183
75630	Aortography, abdominal plus bilateral iliofemoral lower extremity, catheter, by serialography, radiological supervision and interpretation	Q2	5183
75710	Angiography, extremity, unilateral, radiological supervision and interpretation	Q2	5183

HCPCS Code	Long Descriptor	SI	APC
75716	Angiography, extremity, bilateral, radiological supervision and interpretation	Q2	5183
75774**	Angiography, selective, each additional vessel studied after basic examination, radiological supervision and interpretation (List separately in addition to code for primary procedure)	N	
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel	J1	5194

**Denotes a HCPCS code that was not included in Addendum P to the CY 2023 OPSS/ASC final rule with comment period, with no CY 2023 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. We used the CY 2023 HCPCS/CPT code level device offset amounts for the HCPCS/CPT codes included in Addendum P 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 OPSS 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 2023 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5183, which had a CY 2023 payment rate of \$2,978.97 at the time the application was received. HCPCS code 75625 in APC 5183 had a CY 2023 device offset amount of \$530.85 at the time the application was received.⁶³ According to the applicant, the cost of OSCAR® is \$2,020.00.

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

⁶³ We note the applicant selected APC 5192 and an APC payment rate of \$5,061.89 for the three tests of the cost criteria. However, for our calculation, we selected APC 5183, which we believe had the lowest applicable APC payment rate of \$2,978.97 found in Addendum P to the CY 2023 OPSS/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 \$530.85 related to HCPCS 75625 in APC 5183. Based on our initial assessment for this proposed rule, using the APC payment rate of \$2,978.97 and the device offset amount of \$530.85 would result in OSCAR® meeting the cost significance requirement.

payment amount for the service related to the category of devices. The estimated average reasonable cost of \$2,020.00 for OSCAR is 67.81 percent of the applicable APC payment amount for the service related to the category of devices of \$2,978.97 ($(\$2,020.00/\$2,978.97) \times 100 = 67.81$ percent). Therefore, we believe OSCAR 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 \$2,020.00 for OSCAR® is 380.52 percent of the cost of the device-related portion of the APC payment amount for the related service of \$530.85 ($(\$2,020.00/\$530.85) \times 100 = 380.52$ percent). Therefore, we believe that OSCAR® 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 \$2,020.00 for OSCAR® and the portion of the APC payment amount for the device of \$530.85 is 49.99 percent of the APC payment amount for the related service of \$2,978.97 ($((\$2,020.00 - \$530.85)/\$2,978.97) \times 100 = 49.99$ percent). Therefore, we believe that OSCAR® meets the third cost significance requirement.

We are inviting public comment on whether the OSCAR® meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

B. Proposed Device-Intensive Procedures

1. Background

Under the OPPTS, 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 OPPTS/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 OPPTS/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 OPPTS 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 OPPI/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 OPPI/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 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 OPPI/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.

a. Proposed Change to the Device-Intensive Status Default Offset Methodology for new HCPCS Codes

As described above, under our existing policies for assigning a device offset percentage to new HCPCS codes, we first rely on the associated claims data for new HCPCS codes. For new HCPCS codes that do not have available claims data yet, we rely on any available claims data from a predecessor code for the new HCPCS code, as described by CPT coding guidance. We assign the device offset percentage to the new HCPCS code that is the device offset percentage of the predecessor code for which we have available claims data. If claims data from the new HCPCS or any predecessor code is unavailable, 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 a device offset percentage 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. If a clinically similar procedure that uses the same devices is not available, then for new HCPCS codes describing procedures requiring the insertion or implantation of devices that do not yet have

claims data (from either the new HCPCS code or any predecessor code), we apply a default device offset set at 31 percent.

As we stated previously, the purpose of applying the default device offset to new codes that describe procedures that implant or insert devices is to ensure access in the ASC setting for new procedures until claims data become available. Also, under the OPSS, the default device offset is useful for establishing a device amount for new device-intensive procedures. For example, under our policy for no cost/full credit or partial credit devices, we reduce the OPSS payment for device-intensive procedures by the lesser of the full or partial credit a hospital receives for a replaced device or the device offset amount. Additionally, we may remove the device offset amount from the OPSS payment for procedures that are terminated prior to administering anesthesia (since the device was not used for the procedure).

While we do allow for additional information in consideration of a higher offset percentage than the default device offset, it would be extremely rare that the appropriate determination of a device offset percentage would rely on pricing data or invoices from a device manufacturer rather than the default device offset percentage. However, we are aware that there may be certain situations where the default device offset percentage would not adequately reflect the existing device portion of the procedure's costs when compared to the cost of similar devices. This difference could impede our ability to accurately remove device offset amounts from new device-intensive procedures under the OPSS. As HOPDs and ASCs perform new procedures with significant device costs, we believe it is appropriate to modify our default device offset methodology to pay HOPDs and ASCs more appropriately when we lack claims data for these newer procedures. Therefore, for this CY 2025 OPSS/ASC proposed rule and subsequent calendar years, we propose to modify our default device offset percentage policy for new device-intensive procedures. Specifically, for new HCPCS codes that describe a procedure that requires the implantation or insertion of a single-use device that meets our requirements of a device as described above and the procedure lacks claims data (from either the new HCPCS code

or any predecessor code), 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 propose this methodological change for both the OPSS and ASC Payment System for CY 2025 and subsequent calendar years. 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 propose to modify our default device offset percentage for new device-intensive procedures that describe the implantation or insertion of a single-use device that meets our requirements of a device (as described above) and that do not yet have associated claims data, by applying 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. This proposal would apply to new procedures assigned to clinical APCs, but not new procedures assigned to New Technology APCs.

As we indicated in the CY 2019 OPSS/ASC proposed rule and final rule with comment period, we may consider additional information for an offset percentage greater than the default offset percentage (which, for this proposed rule, is the greater of 31 percent or the APC-level 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. This would be for our consideration in extremely rare circumstances, such as an extremely high-cost implantable device. While we believe our proposed modification of a default device offset will improve payment under the OPSS and ASC payment system, we will continue to accept additional information in consideration of an

alternative offset percentage. This information 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 at outpatientpps@cms.hhs.gov. Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment 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 2025 device-intensive procedures, which incorporates our proposed changes to the default device offset policy, 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 2025 OPPS/ASC proposed rule on our website at:

<https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

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 OPPI/ASC final rule with comment period (80 FR 70422)), will satisfy the edit.

In the CY 2017 OPPI/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 OPPI/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 OPPI/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, 0616T, 0617T, and 0618T. While we noted that interested parties have previously recommended in past rulemaking that we reestablish all of our previous procedure-to-device edits, we did 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.

Additionally, in our review of claims data for some of the procedures, we noticed unusual coding, charge, and cost data. These claims had an outsized impact because of the low volume of claims for the APC which impeded our ability to determine a payment rate accurately and appropriately for APC 5496 (Level 6 Intraocular Procedures). Further, because of the low volume of procedures assigned to this APC, we did not believe the reinstatement of procedure-to-device edits for the four procedures assigned to this APC would be administratively burdensome to hospitals. We finalized our proposal to modify our device edits policy to require a procedure-to-device edit for procedures assigned to APC 5496 (Level 6 Intraocular Procedures) for CY 2024. We propose to continue this policy for APC 5496 (Level 6 Intraocular Procedures) for CY 2025 and subsequent CYs and note that new CPT placeholder code 6X004 (Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed) is replacing CPT code 0616T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens) effective January 1, 2025. Additionally, CPT codes 0617T and 0618T currently assigned to APC 5496 (Level 6 Intraocular Procedures) will be deleted effective January 1, 2025. Therefore, for CY 2025, the procedure-to-device edit for procedures assigned to APC 5496 (Level 6 Intraocular Procedures) will apply to CPT code 0308T and 6X004.

We are not proposing any other changes to our device edit policy for CY 2025.

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 2025.

V. Proposed OPSS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPSS 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. Throughout this proposed rule, the term “biological” is used because this is the term that appears in section 1861(t) of the Act. 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. 106113), 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 OPSS 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 OPSS 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 2025 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).⁶⁴

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. These regulations 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: <https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price>.

⁶⁴ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>

The pass-through application⁶⁵ 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. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a drug's or biological's pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through drugs and biologicals approved in CY 2017 and subsequent calendar years, to allow for a 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 for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a

⁶⁵ 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 January 31, 2025.

prospective basis, for the maximum pass-through payment period for each pass-through drug 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 2024

There are 25 drugs and biologicals for which pass-through payment status expires by December 31, 2024, as listed in Table 62. These drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2021 through December 31, 2024. In accordance with the policy finalized in CY 2017 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 radiopharmaceuticals⁶⁶ 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 2025 for all drugs, biologicals, and therapeutic radiopharmaceuticals (for diagnostic radiopharmaceuticals we propose separate payment when their per day cost exceeds the proposed threshold of \$630). These proposals 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

⁶⁶ We propose to pay separately for diagnostic radiopharmaceuticals with per-day costs above a proposed threshold. If our proposal is finalized, this category of policy-packaged drugs that function as supplies in a diagnostic test or procedure would include diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to Section II.A.3.c. for more information regarding our proposal.

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.

TABLE 62: DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL END BY DECEMBER 31, 2024

CY 2024 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0224	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024
J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	03/31/2024
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409	07/01/2021	06/30/2024
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410	07/01/2021	06/30/2024
J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414	07/01/2021	06/30/2024
J1305	Injection, evinacumab-dgnb, 5mg	G	9416	07/01/2021	06/30/2024
J1426	Injection, casimersen, 10 mg	G	9412	07/01/2021	06/30/2024
J1448	Injection, trilaciclib, 1mg	G	9415	07/01/2021	06/30/2024
J9247	Injection, melphalan flufenamide, 1mg	G	9417	07/01/2021	06/30/2024
J9348	Injection, naxitamab-gqgk, 1 mg	G	9408	07/01/2021	06/30/2024
J9353	Injection, margetuximab-cmkb, 5 mg	G	9418	07/01/2021	06/30/2024
Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and	G	9413	07/01/2021	06/30/2024

CY 2024 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
	dose preparation procedures, per therapeutic dose				
Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	G	9411	07/01/2021	06/30/2024
J1823	Injection, inebilizumab-cdon, 1 mg	G	9394	10/01/2021	09/30/2024
J2406	Injection, oritavancin (kimyrsa), 10 mg	G	9427	10/01/2021	09/30/2024
J9061	Injection, amivantamab-vmjw, 10 mg	G	9432	10/01/2021	09/30/2024
J9272	Injection, dostarlimab-gxly, 100 mg	G	9431	10/01/2021	09/30/2024
J9359	Injection, loncastuximab tesirine-lpyl, 0.075 mg	G	9205	10/01/2021	09/30/2024
Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422	10/01/2021	09/30/2024
A9595	Piflufolastat f-18, diagnostic, 1 millicurie	G	9430	01/01/2022	12/31/2024
J0219	Injection, avalglucosidase alfa-ngpt, 4 mg	G	9433	01/01/2022	12/31/2024
J0491	Injection, anifrolumab-fnia, 1 mg	G	9434	01/01/2022	12/31/2024
J9021	Injection, asparaginase, recombinant, (rylaze), 0.1 mg	G	9437	01/01/2022	12/31/2024
J9071	Injection, cyclophosphamide, (auromedics), 5 mg	G	9203	01/01/2022	12/31/2024

4. Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Expiring in CY 2025

We propose to end pass-through payment status in CY 2025 for 28 drugs and biologicals.

These drugs and biologicals, which were initially approved for pass-through payment status

between April 1, 2022 and January 1, 2023, are listed in Table 63. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2025, 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).⁶⁷ 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 biological. For CY 2025, 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 2025. 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 would continue to be paid for pass-through drugs and biologicals under the CY 2025 OPDS 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 radiopharmaceuticals⁶⁸ that function as supplies when used in a

⁶⁷ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>

⁶⁸ We propose to pay separately for diagnostic radiopharmaceuticals with per-day costs above a proposed threshold. If our proposal is finalized, this category of policy-packaged drugs that function as supplies in a diagnostic test or procedure would include diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to Section II.A.3.c. for more information regarding our proposal.

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 2025, 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 will continue our policy to update pass-through payment rates on a quarterly basis on the CMS website during CY 2025 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 2025, consistent with our CY 2024 policy for diagnostic and therapeutic radiopharmaceuticals, we would 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 2025, we would 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 would 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 would continue to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We refer readers to Table 63 below for the list of drugs and biologicals with pass-through payment status expiring during CY 2025.

TABLE 63: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING IN CY 2025

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0248	J0248	Injection, remdesivir, 1 mg	G	9200	04/01/2022	03/31/2025
J9304	J9304	Injection, pemetrexed (PEMFEXY), 10mg	G	9442	04/01/2022	03/31/2025
J3299	J3299	Injection, triamcinolone acetonide (xipere), 1 mg	G	9358	04/01/2022	03/31/2025
J2779	J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg	G	9439	04/01/2022	03/31/2025
J9331	J9331	Injection, sirolimus protein-bound particles, 1 mg	G	9241	04/01/2022	03/31/2025
J2998	J2998	Injection, plasminogen, human-tvmh, 1 mg	G	9206	04/01/2022	03/31/2025
J9273	J9273	Injection, tisotumab vedotin-tftv, 1 mg	G	9204	04/01/2022	03/31/2025
C9088	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	G	9440	04/01/2022	03/31/2025
Q2056	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and	G	9498	07/01/2022	06/30/2025

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		dose preparation procedures, per therapeutic dose				
J1302	J1302	Injection, sutimlimab-jome, 10 mg	G	9444	07/01/2022	06/30/2025
A9596	A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie	G	9443	07/01/2022	06/30/2025
J9274	J9274	Injection, tebentafusp-tebn, 1 microgram	G	9446	07/01/2022	06/30/2025
J1306	J1306	Injection, inclisiran, 1 mg	G	9004	07/01/2022	06/30/2025
Q5125	Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram	G	9447	07/01/2022	06/30/2025
J2356	J2356	Injection, tezepelumab-ekko, 1 mg	G	9008	07/01/2022	06/30/2025
J2777	J2777	Injection, faricimab-svoa, 0.1 mg	G	9496	07/01/2022	06/30/2025
J9332	J9332	Injection, efgartigimod alfa-fcab, 2 mg	G	9010	07/01/2022	06/30/2025
A9800	A9800	Gallium ga-68 gozetotide, diagnostic, (locametz), 1 millicurie	G	9055	10/01/2022	09/30/2025
C9101	C9101	Injection, oliceridine, 0.1 mg	G	9049	10/01/2022	09/30/2025
A9607	A9607	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie	G	9054	10/01/2022	09/30/2025
J9298	J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg	G	9057	10/01/2022	09/30/2025

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9602	A9602	Fluorodopa f-18, diagnostic, per millicurie	G	9053	10/01/2022	09/30/2025
J1952	J1952	Leuprolide injectable, camcevi, 1 mg	G	9050	10/01/2022	09/30/2025
Q5126	Q5126	Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg	G	9048	10/01/2022	09/30/2025
J0225	J0225	Injection, vutrisiran, 1 mg	G	9009	01/01/2023	12/31/2025
J1932	J1932	Injection, lanreotide, (ciplā), 1 mg	G	9051	01/01/2023	12/31/2025
J2327	J2327	Injection, risankizumab-rzaa, intravenous, 1 mg	G	9013	01/01/2023	12/31/2025
Q5124	Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg	G	9017	01/01/2023	12/31/2025

5. Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Continuing through CY 2025

We propose to continue pass-through payment status in CY 2025 for 57 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2023 and April 1, 2024, are listed in Table 64. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that would continue after December 31, 2025, are assigned status indicator “G” in Addenda A and B to this proposed rule (which are available on the CMS website).⁶⁹

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

⁶⁹ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>

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 2025, 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 2025. 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 2025 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 radiopharmaceuticals⁷⁰ 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 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 2025, 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 2025 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

⁷⁰ We propose to pay separately for diagnostic radiopharmaceuticals with per-day costs above a proposed threshold. If our proposal is finalized, the category of policy-packaged drugs that function as supplies in a diagnostic test or procedure would include diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to Section II.A.3.c. for more information regarding our proposal.

payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPTS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2025, consistent with our CY 2024 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 OPPTS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2025, 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, 2025, are shown in Table 64.

TABLE 64: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING AFTER CY 2025

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 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, (apronvie), 1 mg	G	9107	04/01/2023	03/31/2026

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
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), 7.5 mg	G	9136	04/01/2023	03/31/2026
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 (fynetra), 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

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1440	J1440	Fecal microbiota, live - jslm, 1 ml	G	9142	07/01/2023	6/30/2026
Q5129	Q5129	Injection, bevacizumab-adcd (vezzelma), 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 (altuviio), 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
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	G	0733	10/01/2023	9/30/2026

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		(brixadi), greater than 7 days and up to 28 days of therapy				
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
J9072	J9072	Injection, cyclophosphamide, (dr. reddy's), 5 mg	G	0719	01/01/2024	12/31/2026

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0589	J0589	Injection, daxibotulinumtoxinalanm, 1 unit	G	0703	01/01/2024	12/31/2026
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, valoctogene roxaparvovec-rvox, per mL, containing nominal 2×10^{13} vector genomes	G	0713	01/01/2024	12/31/2026

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
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
C9167	C9167	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	C9168	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	C9166	Injection, secukinumab, intravenous, 1 mg	G	0725	04/01/2024	03/31/2027

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status

1. Proposed 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 in order 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 OPPTS/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 \$135 for CY 2024 (88 FR 81776 through 81777).

Following the CY 2007 methodology, for this proposed rule, we 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 2025 and round the resulting dollar amount (\$140.81) to the nearest \$5 increment, which yielded 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 the various price indexes including the PPI Pharmaceuticals for Human Use (Prescription). Based on these calculations using the CY 2007 OPPTS methodology, we propose a packaging threshold for CY 2025 of \$140 for drugs, biologicals, and therapeutic radiopharmaceuticals.

We propose in section II.A.3.c of this proposed rule to pay separately for diagnostic radiopharmaceuticals with a per-day cost above the proposed packaging threshold for CY 2025 of \$630. We also propose 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 propose to use the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPTS/ASC final rule with comment period (71 FR 68085 and 68086)) to calculate the update to the OPPTS drug packaging

threshold. Specifically, we propose that starting for the CY 2026 rulemaking, we would use the most recently available four quarter moving average PPI levels to trend the final CY 2025 threshold forward from the third quarter of CY 2024 to the third quarter of CY 2025 and round the resulting dollar amount to the nearest \$5 increment. We refer readers to section II.A.3.c.(4) of this proposed rule for information regarding our proposal to update the proposed diagnostic radiopharmaceutical packaging threshold in future years.

We also propose that if more recent data are subsequently available (for example, a more recent estimate of the PPI for Pharmaceutical Preparations (Prescription), we would use such data, if appropriate, to determine the CY 2025 packaging threshold for drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals for the CY 2025 OPPS/ASC final rule with comment period.

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 2025 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 2023 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2023 claims processed through December 31, 2023, 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 2025: 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., 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 2025, 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 propose for separately payable drugs and biologicals for CY 2025, as discussed in more detail in section V.A.1 of this proposed rule) to calculate the CY 2025 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2023 (data that were used for payment purposes in the physician's office setting, effective April 1, 2024) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2025, we propose to use payment rates based on the ASP data from the fourth quarter of CY 2023 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 2025 OPPS proposed rule. These data also are the basis for drug payments in the physician's office setting, effective April 1, 2024. Exceptions to our standard methodology include:

- For therapeutic radiopharmaceuticals that do not have pass-through status as of October 1, 2024, 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 this proposed rule. We used their mean unit cost derived from the CY 2023 hospital claims data to determine their per day cost.

- For diagnostic radiopharmaceuticals that do not have pass-through status as of October 1, 2024, we used their mean unit cost derived from the CY 2023 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 this proposed rule.

- 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 2023 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 \$630 and identify items with a per day cost greater than \$630 as separately payable. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2023 HCPCS codes that were reported to the CY 2023 HCPCS codes that we display in Addendum B to this proposed rule (which is available on the CMS website)⁷¹ for proposed payment in CY 2025.

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. 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

⁷¹ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>

update year. 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 2023, 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, 2024, along with updated hospital claims data from CY 2023. We note that we also propose to use these data for budget neutrality estimates and impact analyses for this proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of this proposed rule are based on ASP data from the second quarter of CY 2024. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2024. These payment rates would then be updated in the January 2025 OPSS update, based on the most recent ASP data to be used for physicians' office and OPSS payment as of January 1, 2025. 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 calculate their mean unit cost from all of the CY 2023 claims data and updated cost report information available for this proposed rule to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and radiopharmaceuticals in the OPSS/ASC proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for this final rule with comment period. Under such circumstances, we propose to continue to follow the established policies initially adopted for the CY 2005 OPSS (69 FR 65780) in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2025 OPSS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2024. These

established policies have not changed for many years and are the same as described in the CY 2016 OPPI/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2025 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 2024 and that are proposed for separate payment in CY 2025, and that then have per day costs equal to or less than the CY 2025 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2025 final rule, would continue to receive separate payment in CY 2025.
- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were packaged in CY 2024 and that are proposed for separate payment in CY 2025, and that then have per day costs equal to or less than the CY 2025 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2025 final rule, would remain packaged in CY 2025.
- HCPCS codes for drugs, biologicals, and radiopharmaceuticals for which we proposed packaged payment in CY 2025 but that then have per-day costs greater than the CY 2025 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2025 final rule, would receive separate payment in CY 2025.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPI, 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 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,⁷² 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 proposed diagnostic radiopharmaceutical packaging threshold that we discussed in

⁷² We propose to pay separately for diagnostic radiopharmaceuticals with per-day costs above a proposed threshold. If our proposal is finalized, this category of policy-packaged drugs that function as supplies in a diagnostic test or procedure would include diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to Section II.A.3.c. for more information regarding our proposal.

section II.A.3 of this proposed rule,⁷³ contrast agents, stress agents, and some other products.

The category described by § 419.2(b)(16) 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).

We welcome ongoing dialogue and engagement from interested parties regarding suggestions for payment changes for consideration in future rulemaking.

d. Packaging Determination for HCPCS Codes that Describe the Same Drug or Biological but Different Dosages

In the CY 2010 OPPI/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 2025.

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 2023

⁷³ In section II.A.3 of this proposed rule, we propose to pay separately for diagnostic radiopharmaceuticals with per-day costs above a proposed threshold. If our proposal is finalized, this category of policy-packaged drugs that function as supplies in a diagnostic test or procedure would include diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to Section II.A.3.c. for more information regarding our proposal.

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 2023 claims data to make the proposed packaging determinations for them: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); HCPCS code J3471 (injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)); 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 2025 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 2025 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 2025 is displayed in Table 65.

TABLE 65: HCPCS CODES TO WHICH THE CY 2025 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2025 HCPCS Code	CY 2025 Long Descriptor	CY 2025 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 2025 would also apply to diagnostic radiopharmaceuticals. In order 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 2023 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 2025 diagnostic

radiopharmaceutical packaging threshold of \$630 (in which case all HCPCS codes for the same diagnostic radiopharmaceutical would be packaged) or greater than the proposed CY 2025 diagnostic radiopharmaceutical packaging threshold of \$630 (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. Proposed 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.⁷⁴

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

⁷⁴ 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 2024.

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. 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 OPSS. 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 or biological 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 and biologicals 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).⁷⁵ These addenda provide the proposed CY 2025 payment rates based on the ASP methodology for separately payable nonpass-through drugs, biologicals, and radiopharmaceuticals and the ASP methodology for pass-through drugs, biologicals, and radiopharmaceuticals. Except for proposed payment rates for 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, 2024, or WAC, AWP, or mean unit cost from CY 2023 claims data and updated cost report information available for this proposed rule. For nonpass-through therapeutic radiopharmaceuticals, payment rates are based on ASP data or mean unit cost. We propose in

⁷⁵ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>

section II.A.3.c.(5) 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. In general, these published proposed payment rates are not the same as the actual January 2025 payment rates. This is because payment rates for drugs, biologicals, and therapeutic radiopharmaceuticals with ASP information for January 2025 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2024 (July 1, 2024, through September 30, 2024) will be used to set the payment rates that are released for the quarter beginning in January 2025 in December 2024. 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 2024, as well as all separately payable diagnostic radiopharmaceuticals, are based on mean unit cost in the available CY 2023 claims data. If new pricing information becomes available for payment for the quarter beginning in January 2025, 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 this proposed rule (reflecting April 2024 ASP data) that do not have ASP, WAC, or AWP information available for the quarter beginning in January 2025. These drugs, biologicals and therapeutic radiopharmaceuticals would then be paid based on mean unit cost data derived from CY 2023 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2025 payment purposes and are only illustrative of the CY 2025 OPPS payment methodology using the most recently available information at the time of issuance of this 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.

For CY 2025, we propose to clarify 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 OPSS as described further in section V.B.3.a of this proposed rule. We propose for CY 2025 to use mean unit cost data to set payment rates for separately payable nonpass-through diagnostic radiopharmaceuticals for which we propose separate payment because their cost exceeds the per-day threshold. Otherwise, we are not proposing any changes to our policies for payment for separately payable drugs and biologicals; and 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 OPSS 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.

d. Invoice Drug Pricing Proposal for CY 2026

We have observed that in recent years there has been an increasing number of drug and biological HCPCS codes for which ASP, WAC, AWP, and mean unit cost information is not available. These are often HCPCS codes for new drugs or biologicals that have been approved for marketing, but for which the manufacturer does not have sales data, and WAC, AWP, and mean unit cost information is not available. As a result, we are unable to assign a payable status indicator to these drugs or biologicals due to of a lack of payment data. The numbers of drug and biological HCPCS codes without payment rates from Addendum B for the CY 2022 through CY 2024 OPPTS/ASC final rules with comment period are listed in Table 66.

TABLE 66: NUMBER OF DRUG AND BIOLOGICAL HCPCS CODES WITHOUT PAYMENT INFORMATION FOR CY 2022 TO CY 2024

	CY 2022 Final Rule	CY 2023 Final Rule	CY 2024 Final Rule
Number of drug and biological HCPCS codes without payment information	77	85	109

In order to provide appropriate payment rates for these drugs and biologicals without pricing data, we propose to adopt an invoice pricing policy beginning in CY 2026. Because this policy necessitates significant operational changes to implement, we propose to implement it beginning in CY 2026, rather than CY 2025. For CY 2025, the affected drugs and biologicals would continue to be assigned a non-payable status indicator until we implement our invoice pricing policy, if adopted. We believe invoice pricing is appropriate for use under the OPPTS

because it provides temporary drug or biological cost information to generate a representative payment rate for a drug or biological and supports the utilization of new drug or biological HCPCS codes. Otherwise, the new drug and biological HCPCS codes would not receive payment under the OPSS, which would discourage their use by providers. Currently, the Physician Fee Schedule utilizes invoice pricing for drugs and biologicals when other types of pricing information are not available.

We propose 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, we propose that 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 would expect invoice pricing to be temporary, lasting two to three quarters, for qualified drugs required to report ASP under 1847A of the Act. For drug products that are not required to report ASP under 1847A of the Act (i.e., diagnostic pharmaceuticals), invoice pricing may be used longer term until a MUC can be calculated. We propose that we would not begin using invoice pricing for drugs, biologicals, and radiopharmaceuticals without pricing information until CY 2026 because we would need to make technical updates to outpatient hospital claims to allow the hospitals to report drug invoice pricing. We intend to work with the National Uniform Billing Committee (NUBC) in order to

create a value code that would allow for the reporting of invoice prices of drugs, biologicals, and radiopharmaceuticals for purposes of this policy.

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 2025.

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 2025. 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 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 2025. 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.

We note that in the CY 2024 OPPS final rule with comment period (88 FR 81786), we stated that the ASP payment methodology for separately payable nonpass-through therapeutic

radiopharmaceuticals did allow for using WAC or AWP to establish a payment rate for these items. This was an error and conflicted with the policy implemented in CY 2010 and continued in subsequent years. The statement also conflicted with the policy that we proposed and finalized for CY 2023 and subsequent years in the CY 2023 OPPTS/ASC final rule with comment period (87 FR 71969). The policy implemented in CY 2010 regarding ASP payment for separately payable nonpass-through therapeutic radiopharmaceuticals remains our intended policy. Therefore, we will pay for all nonpass-through separately payable therapeutic radiopharmaceuticals at ASP plus 6 percent based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60520 through 60521). We will rely on CY 2023 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 2025 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).⁷⁶

b. Payment Policy for Diagnostic Radiopharmaceuticals

For CY 2025, we propose, as described in section II.A.3 of this proposed rule, to pay separately for diagnostic radiopharmaceuticals with a per day cost above our proposed diagnostic radiopharmaceutical packaging threshold (proposed at \$630 for CY 2025). We propose to pay for pass-through diagnostic radiopharmaceuticals based on ASP WAC, and AWP.

⁷⁶ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>

We propose to base the payment rate for separately payable nonpass-through diagnostic radiopharmaceuticals on mean unit cost data derived from hospital claims. As discussed in Section II.A.3.c.(5), we are not proposing to use ASP data when mean unit cost data are available for a separately payable nonpass-through diagnostic radiopharmaceutical, but we are seeking comment on using ASP for setting the payment rate for nonpass-through diagnostic radiopharmaceuticals in the future. Additionally, we are not proposing to use WAC or AWP as a basis for payment for nonpass-through diagnostic radiopharmaceuticals when mean unit cost data derived from hospital claims is available. We believe that paying for nonpass-through diagnostic radiopharmaceuticals using 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, we propose 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. If the WAC also is unavailable, we propose 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 until a MUC is established for new

diagnostic radiopharmaceuticals with HCPCS codes that do not have passthrough status or claims data.

The proposed CY 2025 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).⁷⁷

4. Proposed Payment for Blood Clotting Factors

For CY 2025, 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 OPSS 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 OPSS/ASC final rule with comment period (87 FR 71969 through 71970). In accordance with our policy as finalized in the CY 2008 OPSS/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. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but Without OPSS Hospital Claims Data

In the CY 2023 OPSS/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 OPSS hospital claims data for CY 2023 and subsequent years. Therefore, for CY 2025, this policy will continue to apply. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPSS/ASC final rule with comment period (80 FR 70442 through 70443). Consistent with our

⁷⁷ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>

policy, because 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.

6. Requirement in the CY 2025 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. The CY 2025 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 and CY 2024 notice in the OPPI/ASC proposed rule (87 FR 71988), we wanted to ensure interested parties were aware of these proposals and knew to refer to the CY 2025 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 2025 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2025 PFS final rule with comment period.

7. High-Cost/Low-Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPPI/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical 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 OP/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 HCPCS codes 15271 through 15278. Skin substitutes assigned to the low-cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin substitutes that are assigned to each group. Specifically, claims billed with HCPCS 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 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).

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 2024, the payment rate for APC 5053 (Level 3 Skin Procedures) was \$599.02, the payment rate for APC 5054 (Level 4 Skin Procedures) was \$1,739.33, and the payment rate for APC 5055 (Level 5 Skin Procedures) was \$3,421.82. This information is also available in Addenda A and B of the CY 2024 final rule with comment period (88 FR 81540) (the Addenda A and B are available on the CMS website <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>).

We have continued the high-cost/low-cost categories policy since CY 2014. Under the current policy, skin substitutes in the high-cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low-cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high-cost group or the low-cost group, we refer readers to the CY 2014 OPPI/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPI/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high-cost/low-cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPI/ASC final rule with comment period (80 FR 70434 through 70435). Beginning in CY 2016, we adopted a policy where we determined 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) (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 assigned each skin substitute that exceeded either the MUC threshold or the PDC threshold to the high-cost group. In addition, we assigned any skin substitute with a MUC or a PDC that did not exceed either the MUC threshold or the PDC threshold to the low-cost group (87 FR 71976).

However, some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year using the methodology developed in CY 2016. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high-cost group to the low-cost group, which, under current payment rates, can be a difference of over \$1,000 in the payment amount for the same procedure. In addition, these interested parties were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute interested parties requested that CMS

consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and whether it might be appropriate to establish a new cost group in between the low-cost group and the high-cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year-to-year shifts for skin substitute products between the high-cost and low-cost groups through multiple initiatives implemented since CY 2014, including: establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP plus 6 percent as the primary methodology to assign products to the high-cost or low-cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high-cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from interested parties about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPI/ASC proposed rule (82 FR 33627), we proposed that a skin substitute that was assigned to the high-cost group for CY 2017 would be assigned to the high-cost group for CY 2018, even if it did not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPI/ASC final rule with comment period (82 FR 59347). For more detailed information and discussion regarding the goals of this policy and the subsequent comment solicitations in CY 2019 and CY 2020 regarding possible alternative payment methodologies for graft skin substitute products, please refer to the CY 2018 OPPI/ASC final rule with comment period (82 FR 59347); the CY 2019 OPPI/ASC final rule with comment period (83 FR 58967 to 58968); and the CY 2020 OPPI/ASC final rule with comment period (84 FR 61328 to 61331).

b. Proposals for Packaged Skin Substitutes for CY 2025

For CY 2025, consistent with our policy since CY 2016, we propose to continue to determine the high-cost/low-cost status for each skin substitute product based on either a product's geometric MUC exceeding the geometric MUC threshold or the product's PDC (the total units of a skin substitute multiplied by the MUC and divided by the total number of days) exceeding the PDC threshold. Consistent with the methodology as established in the CY 2014 OPPTS/ASC through CY 2018 OPPTS/ASC final rules with comment period, we analyzed CY 2023 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2025 MUC threshold is \$50 per cm² (rounded to the nearest \$1) and the proposed CY 2025 PDC threshold is \$840 (rounded to the nearest \$1). Also, the availability of a HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2025, as we did for CY 2024, we propose to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high-cost group. In addition, we propose to assign any skin substitute that does not exceed either the MUC threshold or the PDC threshold to the low-cost group except that we propose that any skin substitute product that is assigned to the high-cost group in CY 2024 would be assigned to the high-cost group for CY 2025, regardless of whether it exceeds or falls below the CY 2025 MUC or PDC threshold. This policy was established in the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59346 through 59348).

For CY 2025, we propose to continue to assign skin substitutes with pass-through payment status to the high-cost category. We propose to assign skin substitutes with pricing information but without claims data 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 propose to use 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 propose to use 95 percent of AWP to assign a skin substitute to either the high-cost or low-cost category. We propose to continue to use WAC plus 3 percent instead of WAC plus 6 percent to conform to our proposed policy described in section V.B.2.b of this proposed rule to establish a payment rate of WAC plus 3 percent for separately payable drugs and biologicals that do not have ASP data available. We propose that any skin substitute product that is assigned a code in the HCPCS A2XXX series would be 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 would be assigned to the low-cost category until pricing information is available to compare to the CY 2024 MUC and PDC thresholds. For a discussion of our policy under which we assign skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series to the low-cost category until pricing information is available, we refer readers to the CY 2016 OPPI/ASC final rule with comment period (80 FR 70436).

Table 67 includes the proposed CY 2025 cost category assignment for each skin substitute product.

TABLE 67: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH-COST AND LOW-COST GROUPS FOR CY 2025

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
A2001	Innovamatrix ac, per sq cm	High	High
A2002	Mirragen adv wnd mat per sq	High	High

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
A2005	Microlyte matrix, per sq cm	High	High
A2006	Novosorb synpath per sq cm	High	High
A2007	Restrata, per sq cm	High	High
A2008	Theragenesis, per sq cm	High	High
A2009	Symphony, per sq cm	High	High
A2010	Apis, per square centimeter	High	High
A2011	Supra sdrm, per sq cm	High	High
A2012	Suprathel, per sq cm	High	High
A2013	Innovamatrix fs, per sq cm	High	High
A2015	Phoenix wnd mtrx, per sq cm	High	High
A2016	Permeaderm b, per sq cm	High	High
A2017	Permeaderm glove, each	High	High
A2018	Permeaderm c, per sq cm	High	High
A2019	kerecis marigen shld sq cm	High	High
A2020	ac5 wound system	High	High
A2021	neomatrix per sq cm	High	High
A2022	Innovabrn/innovamatx xl sqcm	High	High
A2024	Resolve matrix per sq cm	High	High
A2025	Miro3d per cubic cm	High	High
A4100	Skin sub fda clrd as dev nos	Low	Low
C9363	Integra meshed bil wound mat	High	High
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High*
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	High	High
Q4106	Dermagraft	High	High
Q4107	Graftjacket	High	High
Q4108	Integra matrix	High	High
Q4110	Primatrix	High	High
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High
Q4122	Dermacell	High	High
Q4123	Alloskin	High	High*
Q4124	Oasis tri-layer wound matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High
Q4127	Talymed	High	High
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	High	High
Q4135	Mediskin	High	High

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4136	Ezderm	Low	High
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High*
Q4146	Tensix, 1cm	High	High*
Q4147	Architect ecm px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High*
Q4158	Kerecis omega3, per sq cm	High	High*
Q4159	Affinity 1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High*
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High*
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per square centimeter	High	High
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	High	High*
Q4173	Palingen or palingen xplus	High	High*
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High*
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Tranocyte, per sq centimeter	High	High
Q4183	Surgigraft, 1 sq cm	High	High
Q4184	Cellesta or duo per sq cm	High	High*
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	High	High*
Q4190	Artacent ac 1 sq cm	High	High*
Q4191	Restorigin 1 sq cm	High	High*
Q4193	Coll-e-derm 1 sq cm	High	High
Q4194	Novachor 1 sq cm	High	High*
Q4195	Puraply 1 sq cm	High	High
Q4196	Puraply am 1 sq cm	High	High

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sq cm	High	High
Q4199	Cygnus matrix, per sq cm	High	High
Q4200	Skin te 1 sq cm	High	High*
Q4201	Matrion 1 sq cm	High	High
Q4203	Derma-gide, 1 sq cm	High	High
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	High	High
Q4208	Novafix per sq cm	High	High
Q4209	Surgraft per sq cm	High	High*
Q4211	Amnion bio or axobio sq cm	High	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	High
Q4217	Woundfix biowound plus xplus	High	High*
Q4218	Surgicord per sq cm	High	High*
Q4219	Surgigraft dual per sq cm	High	High*
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	High	High
Q4222	Progenamatrix, per sq cm	High	High*
Q4224	Hhf10-p per sq cm	Low	Low
Q4225	Amniobind, per sq cm	Low	Low
Q4226	Myown harv prep proc sq cm	High	High
Q4227	Amniocore per sq cm	High	High
Q4229	Cogenex amnio memb per sq cm	High	High*
Q4232	Corplex, per sq cm	High	High
Q4234	Xcellerate, per sq cm	High	High
Q4235	Amniorepair or altiply sq cm	High	High
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	High	High*
Q4238	Derm-maxx, per sq cm	High	High
Q4239	Amnio-maxx or lite per sq cm	High	High*
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	High	High
Q4249	Amniply, per sq cm	High	High*
Q4250	AmnioAMP-MP per sq cm	High	High
Q4251	Vim, per square centimeter	Low	Low
Q4252	Vendaje, per square centimet	Low	Low
Q4253	Zenith amniotic membrane psc	High	High*
Q4254	Novafix dl per sq cm	High	High*
Q4255	Reguard, topical use per sq	Low	Low
Q4256	Mlg complet, per sq cm	Low	Low
Q4257	Relese, per sq cm	Low	Low
Q4258	Enverse, per sq cm	High	High*
Q4259	Celera per sq cm	Low	Low
Q4260	Signature apatch, per sq cm	Low	Low
Q4261	Tag, per square centimeter	Low	Low

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4262	Dual layer impax, per sq cm	Low	High
Q4263	Surgraft tl, per sq cm	Low	Low
Q4264	Cocoon membrane, per sq cm	Low	Low
Q4265	Neostim tl per sq cm	Low	Low
Q4266	Neostim per sq cm	Low	Low
Q4267	Neostim dl per sq cm	Low	Low
Q4268	Surgraft ft per sq cm	Low	High
Q4269	Surgraft xt per sq cm	Low	Low
Q4270	Complete sl per sq cm	Low	Low
Q4271	Complete ft per sq cm	Low	Low
Q4272	Esano a, per sq cm	Low	Low
Q4273	Esano aaa, per sq cm	Low	Low
Q4274	Esano ac, per sq cm	Low	Low
Q4275	Esano aca, per sq cm	Low	Low
Q4276	Orion, per sq cm	Low	Low
Q4278	Epieffect, per sq cm	High	High*
Q4279	Vendaje ac, per sq cm	Low	Low
Q4280	Xcell amnio matrix per sq cm	Low	Low
Q4281	Barrera slor dl per sq cm	Low	Low
Q4282	Cygnus dual per sq cm	High	High
Q4283	Biovance tri or 3l, sq cm	Low	Low
Q4284	Dermabind sl, per sq cm	Low	Low
Q4285	Nudyn dl or dl mesh pr sq cm	Low	Low
Q4286	Nudyn sl or slw, per sq cm	Low	Low
Q4287	Dermabind dl, per sq cm	Low	Low
Q4288	Dermabind ch, per sq cm	Low	Low
Q4289	Revoshield+ amnio, per sq cm	Low	Low
Q4290	Membrane wrap hydr per sq cm	Low	Low
Q4291	Lamellas xt, per sq cm	Low	Low
Q4292	Lamellas, per sq cm	Low	Low
Q4293	Acesso dl, per sq cm	Low	Low
Q4294	Amnio quad-core, per sq cm	Low	Low
Q4295	Amnio tri-core, per sq cm	Low	Low
Q4296	Rebound matrix, per sq cm	Low	Low
Q4297	Emerge matrix, per sq cm	Low	Low
Q4298	Amnicore pro, per sq cm	Low	Low
Q4299	Amnicore pro+, per sq cm	Low	Low
Q4300	Acesso tl, per sq cm	Low	Low
Q4301	Activate matrix, per sq cm	Low	Low
Q4302	Complete aca, per sq cm	Low	Low
Q4303	Complete aa, per sq cm	Low	Low
Q4304	Grafix plus, per sq cm	Low	Low
Q4305	Amer am ac tri-lay per sq cm	Low	Low
Q4306	Americ amnion ac per sq cm	Low	Low
Q4307	American amnion, per sq cm	Low	Low
Q4308	Sanopellis, per sq cm	Low	Low

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4309	Via matrix, per sq cm	Low	Low

* These products do not exceed either the MUC or PDC threshold for CY 2025 but are assigned to the high-cost group because they were assigned to the high-cost group in CY 2024.

8. Radioisotopes Derived from Non-Highly Enriched Uranium (non-HEU) Sources

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). Historically, most of the Mo-99 used in the United States was produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States wanted to eliminate domestic reliance on these reactors and promoted the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, but it was expected that this change in the supply source for the radioisotope used for modern medical imaging would introduce increased costs into the payment system that would not be fully accounted for in the historical claims data until all Tc-99m was produced from non-HEU sources.

Therefore, beginning 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 report 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 furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68323).

We stated in the CY 2013 OPPI/ASC final rule with comment period (77 FR 68321) that our expectation was that this additional payment would be needed for the duration of the

industry's conversion to alternative methods of producing Tc-99m without HEU. We also stated that we would reassess, and propose, if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68321). The Secretaries of Energy and Health and Human Services issued a certification regarding the supply of non-HEU-sourced Mo-99 effective January 2, 2022 (86 FR 73270). Mo-99 is the precursor material from which Tc-99m is sourced. The certification by the Secretary of Energy stated that there was a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States. In the CY 2023 OPPTS/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).

In the OPPTS, diagnostic radiopharmaceuticals are currently packaged into the cost of the associated diagnostic imaging procedure no matter the per day cost of the radiopharmaceutical (though we are proposing in this rule to provide separate payment for high-cost diagnostic radiopharmaceuticals starting in CY 2025). The cost of the radiopharmaceutical is included as a part of the cost of the diagnostic imaging procedure and is reported through Medicare claims data. Medicare claims data used to set payment rates under the OPPTS generally is from 2 years prior to the payment year.

As we explained in the CY 2023 OPPTS/ASC final rule with comment period (87 FR 71987), the claims data we used to set payment rates for CY 2024 (generally CY 2022 claims data) contained claims for diagnostic radiopharmaceuticals that reflect both HEU-sourced Tc-99m and non-HEU-sourced Tc-99m, rather than radiopharmaceuticals sourced solely from non-HEU Tc-99m. The cost of HEU-sourced Tc-99m is substantially lower than the cost of non-HEU-sourced Tc-99m. Therefore, we explained that providers who use radiopharmaceuticals in CY 2024 that contain only non-HEU-sourced Tc-99m might not receive

a payment that is reflective of the radiopharmaceutical's current cost without the add-on payment. We believed that extending the additional \$10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2024 would ensure adequate payment for non-HEU-sourced Tc-99m. Starting in CY 2025, we believed 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.

The conversion of the last major global Mo-99 producer from HEU to Low Enriched Uranium (LEU) was previously expected to complete by December 31, 2022 but did not occur until March 2023, so it is possible that some claims for diagnostic radiopharmaceuticals in CY 2023 would report the cost of HEU-sourced Tc-99m. This means that in CY 2025, as in CY 2024, there is the possibility that the payment rate for procedures using diagnostic radiopharmaceuticals could be lower than the costs providers will face for these procedures because providers will only have access to non-HEU-sourced Tc-99m. Therefore, we adopted a policy in the CY 2024 OPPTS final rule with comment period (88 FR 81803) to extend 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.

Recently, 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, government-subsidized prices have created a disincentive for investments in Mo-99 production infrastructure, and they also created a barrier to entry for new

producers, including U.S. companies. This in turn has resulted in unreliable production and periodic shortages. In response to the 2009-2010 shortages, Congress passed the American Medical Isotopes Production Act of 2012 (AMIPA), which directs the Secretary of Energy to provide financial and technical support to U.S. companies working to build new irradiation and manufacturing facilities to produce Mo-99 without HEU.

It was expected that the transition from HEU to LEU-based production would also involve the transition to a Full Cost Recovery pricing model; however, it does not appear that this transition has occurred in practice. Foreign producers continue to rely on multipurpose nuclear research reactors for Mo-99 production, and the global Mo-99 supply chain has not established a system of verifying that all of the costs attributable to Mo-99 production are being incorporated into the price of the product.

U.S. companies have made significant progress towards establishing the infrastructure needed for large-scale Mo-99 production. 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 the differences in pricing models, U.S. companies have experienced challenges in competing with foreign producers for customers. Currently, there is no domestic production of Mo-99.

Once U.S. companies initiate or resume 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. We propose to address the payment inequity resulting from the higher cost of domestically produced Tc-99m 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 believe the \$10 add-on payment for domestically produced Tc-99m would ensure equitable payments by paying providers who use domestically produced Tc-99m

radiopharmaceuticals when available an amount that reflects the anticipated higher cost of these products. The \$10 add-on payment will help to preserve provider and beneficiary access to domestically produced Tc-99m radiopharmaceuticals by providing an additional payment amount that addresses the additional costs of domestically produced Tc-99m radiopharmaceuticals. DOE/NNSA would establish the criteria to certify whether the Tc-99m radiopharmaceutical dose is domestically produced and eligible for the add-on payment, which would be included in the CY 2026 OPPS/ASC proposed rule. The CY 2026 OPPS/ASC proposed rule would include additional details on how providers would bill for this add-on payment in CY 2026.

VI. 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 2025 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 2025. The CY 2008 OPPTS/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 2024 or beginning in CY 2025. The sum of the proposed CY 2025 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2025 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 2014 OPPTS/ASC final rule with comment period (78 FR 75034 through 75036). 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), in the proposed rule, we propose to 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 2025, 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 2025, and therefore our estimate of drug and biological pass-through payment for CY 2025 for this group of items is \$10.2 million.

Payment for certain drugs, specifically diagnostic radiopharmaceuticals and 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 all non-pass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, drugs and biologicals that function as supplies when used in a surgical procedure, drugs and biologicals used 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, we propose that all of these policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2025, 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 2025 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 section V.A.6 of this proposed rule, we discuss 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 costs of the APCs that are associated with the drug receiving pass-through payment, we propose to 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, 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 2025. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2024 or beginning in CY 2025. The sum of the CY 2025 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2025 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending for CY 2025

For CY 2025, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPSS payments for CY 2025, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPSS policy from CY 2004 through CY 2024 (88 FR 81805). 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 2025, there are 8 active categories for CY 2025. The active categories are described by HCPCS codes C1747, C1826, C1827, C1600, C1601, C1602, C1603 and C1604. Based on the information

from the device manufacturers, we estimate that HCPCS code C1747 will cost \$19.5 million in pass-through expenditures in CY 2025, HCPCS code C1826 will cost \$151,991 in pass-through expenditures in CY 2025, HCPCS code C1827 will cost \$364,793 in pass-through expenditures in CY 2025, HCPCS code C1600 will cost \$21.9 million in pass-through expenditures in CY 2025, HCPCS code C1601 will cost \$14.4 million in pass-through expenditures in CY 2025, HCPCS code C1602 will cost \$8.2 million in pass-through expenditures in CY 2025, HCPCS code C1603 will cost \$6.6 million in pass-through expenditures in CY 2025, and HCPCS code C1604 will cost \$20.0 million in pass-through expenditures in CY 2025. Therefore, we propose an estimate for the first group of devices of \$91.1 million.

In estimating our proposed CY 2025 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 2025; (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, 2025; and (3) contingent projections for new device categories established in the second through fourth quarters of CY 2025. For CY 2025, we propose to use the general methodology described in the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPTS experience in approving new pass-through device categories. For this proposed rule, the proposed estimate of CY 2025 pass-through spending for this second group of device categories was \$523.7 million.

To estimate proposed CY 2025 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 2025, we propose to use the CY 2023 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 2025 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals 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 2025, 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 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 2025 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. Given the proposal to pay separately for diagnostic radiopharmaceuticals that exceed the proposed per-day threshold referenced in section II.A.3.c of this proposed rule, for CY 2025, all diagnostic radiopharmaceuticals that are currently on pass-through will be separately payable once their pass-through status has expired. For this first group of policy-packaged drugs and biologicals, we estimate pass-through spending for CY 2025 of \$200,000 as compared to \$90 million for CY 2024 OPPS/ASC final rule (88 FR 81806).

To estimate proposed CY 2025 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 2024, 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, 2025, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2025), 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 2025 pass-through payment estimate. We also propose to consider the most recent OPSS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2025 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 2025 and the amount of pass-through spending for those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2025 would be approximately \$625 million (approximately \$614.8 million for device categories and approximately \$10.2 million for drugs and biologicals), which represents only 0.71 percent of total projected OPSS payments for CY 2025 (approximately \$88.2 billion). Therefore, we estimate that pass-through spending in CY 2025 would not exceed the 2.0 percent of total projected OPSS CY 2025 program spending limit provided for in section 1833(t)(6)(E) of the Act.

VII. Proposed OPSS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2025, 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 OPPTS/ASC final rule with comment period (80 FR 70448). We also propose to continue our payment policy for critical care services for CY 2025. For a description of this policy, we refer readers to the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70449), and for the history of this payment policy, we refer readers to the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75043).

As we stated in the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63663), the volume control method for clinic visits furnished by non-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 beyond. The PFS-equivalent rate for CY 2025 is 40 percent of the proposed OPPTS payment. Under this policy, these departments will be paid approximately 40 percent of the OPPTS rate for the clinic visit service in CY 2025.

In the CY 2023 OPPTS/ASC final rule with comment period (87 FR 71748), we finalized a policy that excepted off-campus provider-based departments (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 OPPTS/ASC final rule with comment period (87 FR 72047 through 72051). For CY 2025, we propose to continue to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy. We will continue to monitor the effect of this change in Medicare payment policy, including on the volume of these types of OPD services.

VIII. 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 OPSS. 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.

Partial hospitalization program policies and payment have been addressed under OPSS 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 OPSS/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 OPSS/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) and instituted a two-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 OPSS/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 OPSS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPSS 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 through 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 (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. Since the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor, a floor was not necessary at the time, and we did not finalize the proposed cost floors in the CY 2021 OPPS/ASC final rule with comment period.

In the CY 2022 OPSS/ASC final rule with comment period (86 FR 63665 through 63666), we explained that we observed a number of changes, likely as a result of the COVID-19 PHE, in the CY 2020 OPSS claims that we would have ordinarily used for CY 2022 ratesetting, and this included changes in the claims for partial hospitalization. We explained that significant decreases in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims led us to believe that CY 2020 data were not the best overall approximation of expected PHP services in CY 2022. Therefore, 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 OPSS 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 OPSS/ASC final rule with comment period (87 FR 71995), we explained that we continued to observe a decrease in the number of hospital-based and CMHC PHP days in our trimmed dataset due to the continued effects of COVID-19; however, the Medicare outpatient service volumes appeared to be returning to more normal, pre-pandemic levels. Therefore, 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 OPSS standard methodology, including the effect of budget neutralizing all other OPSS 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, in the interest of accurately paying for CMHC PHP services, under the unique circumstances of budget neutralizing all other OPSS policy changes for CY 2023, and in keeping with our longstanding goal of protecting continued access to PHP services provided by CMHCs by ensuring that CMHCs remain a viable option as

providers of mental health care in the beneficiary's own community, 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 OPSS 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 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 OPSS/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 OPSS/ASC final rule, 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, which are discussed in greater detail in the following sections of this CY 2025 OPSS/ASC proposed rule.

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, a CMHC, 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 OPSS/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). We refer readers to the CY 2025 Physician Fee Schedule (PFS) proposed rule, published elsewhere in the **Federal Register**, for additional information regarding CY 2025 proposed payment policies for IOP services furnished by FQHCs and RHCs.

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 OPPTS. 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.

We also established payment for IOP provided by an RHC or FQHC at the same rate as APC 5861, which is the 3-service hospital-based IOP rate (§ 405.2462(j)). Furthermore, we established a payment adjustment for IOP provided by an OTP based on 3 times the payment rate for APC 5861 beginning in CY 2024 (§ 410.67(d)(4)(i)(F)). As noted earlier in this CY 2025 OPSS/ASC proposed rule, additional information regarding CY 2025 proposed payment policies for IOP services furnished by FQHCs and RHCs can be found in the CY 2025 PFS proposed rule, published elsewhere in the **Federal Register**.

B. Coding and Billing for PHP and IOP Services under the OPSS

In the CY 2024 OPSS/ASC final rule, 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 final OPSS rule 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 OPSS final rule 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 OPSS/ASC final rule 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 OPSS final rule for a detailed discussion of this policy (88 FR 81823 through 81825).

As finalized in the CY 2024 OPSS final rule, 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 crosswalked 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. We note that for CY 2025, we are not proposing to 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 2025 Payment Rates for PHP and IOP

1. Background

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 OPSS data set, instead of using hospital-based PHP data only. We explained that using the broader OPSS 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 OPSS 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 OPSS/ASC final rule, 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 OPSS/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 OPSS/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.

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 OPSS/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 have typically included a discussion of PHP-specific data trims, exclusions, and CCR adjustments; we did not include that discussion in the CY 2024 OPSS/ASC proposed or final rule. 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 OPSS 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 (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.

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.

2. CY 2025 Payment Rate Methodology for PHP and IOP

For CY 2025, we propose to use 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 2023 OPPS claims to update the payment rates for the four PHP APCs and the four IOP APCs finalized in the CY 2024 OPPS/ASC final rule. 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, we propose to base the payment rate for each PHP APC on the geometric mean per diem cost for days with 3 services and 4 or more services, calculated separately for CMHCs and hospital outpatient departments. 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 four IOP APCs based on the geometric mean per diem cost for PHP days with 3 services and 4 or more services, calculated separately for CMHCs and hospital outpatient departments. Lastly, we propose that if more recent data subsequently become available after the publication of this proposed rule, we would use such updated data, if appropriate, to determine the CY 2025

payment rates for the four PHP APCs and the four IOP APCs finalized in the CY 2024

OPPS/ASC final rule.

Table 68 below shows the proposed APCs and the calculated geometric mean per diem costs for the CY 2025 OPPS/ASC proposed rule. Additional information about the data trims, data exclusions, and CCR adjustments applicable to the data used for this final rule can be found online at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>).⁷⁸

TABLE 68: PROPOSED CY 2025 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2025 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	\$118.69
5852	Intensive Outpatient (4 or more services per day) for CMHCs	\$164.84
5853	Partial Hospitalization (3 services per day) for CMHCs	\$118.69
5854	Partial Hospitalization (4 or more services per day) for CMHCs	\$164.84
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	\$279.97
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	\$428.39
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	\$279.97
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	\$428.39

For beneficiaries in a PHP or IOP, we propose to apply the four-service 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 propose to apply the three-service 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), which is consistent with the policy we established in the CY 2024 OPPS/ASC final rule (88 FR 81833). As we noted in the CY 2024 OPPS/ASC final rule, we expect days with

⁷⁸ Click on the link labeled “CY 2025 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 “2025 NPRM OPPS Claims Accounting (PDF)”.

fewer than three services would be very infrequent, and we intend to monitor the provision of these days among providers and individual patients.

D. Proposed Outlier Policy for CMHCs

For CY 2025, 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 OPSS/ASC final rule with comment period (88 FR 81834 through 81836) for more details on CMHC outlier policies, and to section II.G.1 of this proposed rule for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPSS final rule with comment period (68 FR 63469 through 63470), we created a separate outlier policy specific to the estimated costs and OPSS payments provided to CMHCs. We designated a portion of the estimated OPSS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPSS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

2. CMHC Outlier Percentage

In the CY 2018 OPSS/ASC final rule with comment period (82 FR 59267 through 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 OPSS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPSS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPSS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPSS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPSS/ASC final rule with comment period (85 FR 86082). We are not proposing any changes to the CMHC outlier percentage policy for CY 2025.

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 through 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 through 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). For CY 2024, we extended this policy to intensive outpatient services. We are not proposing any changes to the cutoff point and payment amount policy for CY 2025.

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 OPPTS/ASC and CY 2019 OPPTS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680, respectively). We are not proposing any changes to the outlier reconciliation policy for CY 2025.

5. Outlier Payment Cap

In the CY 2017 OPPTS/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 cost 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 through 79695) to limit the impact of inflated CMHC charges on outlier payments. 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 2025.

6. Fixed-Dollar Threshold

In the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59267 through 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 2024, CMHC PHP APCs (5853 or 5854) and IOP APCs (5851 or 5852) are the only APCs for which CMHCs may receive payment under the OPSS, and these APCs are for providing a defined set of services that are relatively low cost when compared to other OPSS 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 OPSS/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 OPSS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPSS/ASC final rule with comment period (85 FR 86083), the CY 2022 OPSS/ASC final rule with comment period (86 FR 63508), the CY 2023 OPSS/ASC final rule with comment period (87 FR 72004), and the CY 2024 OPSS/ASC final rule with comment period (88 FR 81836). We are not proposing any changes to the fixed-dollar threshold policy for CY 2025.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

Established in rulemaking as part of the initial implementation of the OPSS, the inpatient only (IPO) list identifies services for which Medicare will only make payment when the services are furnished in the inpatient hospital setting because of the invasive nature of the procedure, the underlying physical condition of the 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 IPO list was created based on the premise (rooted in the practice of medicine at that time), that Medicare should not pay for procedures furnished as outpatient services that are performed on an inpatient basis virtually all of the time for the Medicare population, for the reasons described above, because performing these procedures on an outpatient basis would not be safe or

appropriate, and therefore not reasonable and necessary under Medicare rules (63 FR 47571). Services included on the IPO list were those determined to require inpatient care, such as those that are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care (65 FR 67826). There are some services designated as inpatient only that, given their clinical intensity, would not be expected to be performed in the hospital outpatient setting. For example, we have traditionally considered certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, to require inpatient care (65 FR 18456). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but rather 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 fact that a procedure is not on the IPO list should not be interpreted to mean the procedure is only appropriately performed in the hospital outpatient setting (70 FR 68696).

As part of the annual update process, we have historically worked with interested parties, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and to determine whether services should be added to or removed from the list. Interested parties are encouraged to request reviews for a particular code or group of codes; and we have asked that their requests include evidence that demonstrates that the procedure was performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals—including but not limited to—operative reports of actual cases, peer-reviewed medical literature, community medical standards and practice, physician comments, outcome data, and post-procedure care data (67 FR 66740).

We traditionally have used five longstanding criteria to determine whether a procedure should be removed from the IPO list. As noted in the CY 2012 OPSS/ASC final rule with comment period (76 FR 74353), we assess whether a procedure or service meets these criteria to

determine whether it should be removed from the IPO list and assigned to an APC group for payment under the OPSS 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 as follows:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be furnished in most outpatient departments.
- The procedure is related to codes that we have already removed from the IPO list.
- A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC covered procedures list.

In the past, we have requested that interested parties submit corresponding evidence in support of their claims that a code or group of codes meet the longstanding criteria for removal from the IPO list and are 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. Our clinicians then thoroughly review all information submitted within the context of the established criteria and if, following this review, we determine that there is sufficient evidence to confirm that the code could be safely and appropriately performed on an outpatient basis, we assign the service to an APC and include it as a payable procedure under the OPSS (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 by reviewing the Medicare Severity Diagnosis Related Groups (MS-DRG) rate for the service under the IPPS, though we note 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.

We stated in prior rulemaking that, over time, given advances in technology and surgical technique, we would continue to evaluate services to determine whether they should be removed from the IPO list. Our goal is to ensure that inpatient only designations are consistent with the current standards of practice. We have asserted in prior rulemaking that, insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we would be prepared to remove procedures from the IPO list and provide payment for them under the OPPS (65 FR 18443). Further, CMS has at times had to reclassify codes as inpatient only services with the emergence of new information.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full discussion of our historic policies for identifying services that are typically provided only in an inpatient setting and that, therefore, will not be paid by Medicare under the OPPS, as well as the criteria we have used to review the IPO list to determine whether any services should be removed.

B. Changes to the Inpatient Only (IPO) List

As stated above, we encourage interested parties to request reviews for a particular code or group of codes for removal from the IPO list. For the CY 2025 OPPS/ASC proposed rule, we received requests from interested parties recommending that certain services be removed from the IPO list. Following our clinical review using the five criteria listed above, we did not find sufficient evidence that any of those services meet the criteria to be removed from the IPO list for CY 2025. Therefore, we are not proposing to remove any services from the IPO list for CY 2025. Interested parties may comment on this proposed rule if they believe a service should

be removed from the IPO list for CY 2025 and we will consider that recommendation and address the comment in the CY 2025 OPPS/ASC final rule.

We propose to add three services for which codes were newly created by the AMA CPT Editorial Panel for CY 2025 to the IPO list. These new services are described by CPT codes 0894T, 0895T, and 0896T, which will be effective on January 1, 2025. After clinical review of these services, we found that they require a hospital inpatient admission or stay and are not appropriate for payment under the OPPS. We propose to assign these services to status indicator “C” (Inpatient Only) for CY 2025. The CPT codes, long descriptors, and the proposed CY 2025 payment indicators are displayed in Table 69.

Table 69 below contains the proposed changes to the IPO list for CY 2025. The complete list of codes describing services that we propose to designate as inpatient only services beginning in CY 2025 is also included as Addendum E to this proposed rule, which is available via the internet on the CMS website.

TABLE 69: PROPOSED CHANGES TO THE INPATIENT ONLY (IPO) LIST FOR CY 2025

CY 2025 CPT Code	CY 2025 Long Descriptor	Action	CY 2025 Proposed Status Indicator
0894T	Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion	Add to the IPO list	C
0895T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary	Add to the IPO list	C
0896T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)	Add to the IPO list	C

X. Nonrecurring Policy Changes

A. Remote Services

1. Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy When Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communications Technology

Section 1861(p) of the Act establishes the benefit category for outpatient PT, SLP and OT services (expressly for PT services and, through section 1861(ll)(2) of the Act, for outpatient SLP services and, through section 1861(g) of the Act, for outpatient OT services).

Section 1861(p) of the Act defines outpatient therapy services in the three disciplines as those furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient; and those furnished by a therapist not under arrangements with a provider of services, clinic, rehabilitation agency, or a public health agency. As such, section 1861(p) of the Act defines outpatient therapy services very broadly to include those furnished by providers and other institutional settings, as well as those furnished in office settings. Section 1834(k)(3) of the Act requires payment for outpatient therapy services to be made based on the PFS (via section 1848 of the Act), for all institutional providers listed at sections 1833(a)(8) and (9) of the Act. These providers include clinics, rehabilitation agencies, public health agencies, comprehensive outpatient rehabilitation agencies (CORFs), SNFs, home health agencies (HHAs) (to individuals who are not homebound), hospitals to outpatients or hospital inpatients who are entitled to benefits under Part A but have exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under Part A, and all other CORF services.

Section 1861(qq) of the Act defines Diabetes Self-Management Training (DSMT) services and authorizes CMS to regulate Medicare DSMT outpatient services. A “certified provider” of DSMT is further defined in section 1861(qq)(2)(A) of the Act as a physician or other individual or entity designated by the Secretary who meets certain quality requirements

described in section 1861(qq)(2)(B) of the Act. In CY 2000, we finalized a standalone rule titled “Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements.” In that rule, we finalized that payment for outpatient DSMT would be made under the PFS (65 FR 83132). We further established that, in the case of payments made to other approved entities, such as hospital outpatient departments, ESRD facilities, and durable medical equipment suppliers, the payment would be equal to the amounts established under the PFS and made under the appropriate payment systems (65 FR 83142).

Section 1861(s)(2)(V) of the Act authorizes Medicare Part B coverage of medical nutrition therapy services (MNT) for certain beneficiaries who have diabetes or a renal disease. In the CY 2000 PFS final rule, we established that payment for MNT services furnished in the institutional setting, including hospital outpatient departments (HOPDs), would be made under the PFS, not under the hospital Outpatient Prospective Payment System (OPPS) (66 FR 55279). Telehealth services may be paid under the PFS only when the services are furnished to a beneficiary at an originating site (defined at 410.78), which prior to the PHE was not typically defined to include a beneficiary’s home.

During the PHE for COVID–19, outpatient therapy services, DSMT, and MNT could be furnished via a telecommunications system to beneficiaries in their homes, and bills for these services were submitted and paid either separately or as part of a bundled payment, when either personally provided by the billing practitioner or provided by institutional staff and billed for by institutions, such as HOPDs, SNFs, and HHAs. For professionals, CMS used waiver authority provided under section 1135 of the Act to expand the range of practitioners that could serve as distant site practitioners for Medicare telehealth services as described in section 1834(m)(4)(E) of the Act and 42 CFR 410.78(b)(2), as well as to waive the originating site requirements for Medicare telehealth services described in section 1834(m)(4)(C) of the Act. This allowed for outpatient therapy services to be furnished and billed by therapists (PTs, OTs and SLPs) in private practice, and for DSMT and MNT to be furnished via Medicare telehealth to

beneficiaries in urban areas, as well as rural areas, including to beneficiaries located in their homes.⁷⁹

When CMS expanded the types of practitioners who may bill for their services when furnished as Medicare telehealth services from a distant site to include therapists using section 1135 waiver authority during the PHE for COVID-19, CMS generally took the position for services furnished in HOPDs that separate waiver authority was needed to allow hospitals to bill for services furnished by hospital staff through communication technology to beneficiaries in their homes. CMS implemented the Hospitals Without Walls (HWW) policy that relied on waiver authority, which allowed hospitals to reclassify patients' homes as part of the hospital. HWW allowed hospitals to bill two different kinds of fees for services furnished remotely to patients in their homes: (1) hospital facility payment in association with professional services billed under the PFS; and (2) single payment for a limited number of practitioner services, when statute or other applicable rules only allow the hospital to bill for services personally provided by their staff. These services are either billed by hospitals or by professionals, there would not be separate facility and professional billing. This latter category includes outpatient therapy services, DSMT, and MNT. However, while CMS relied upon PHE-specific waiver authority to allow hospital billing for these services, CMS also issued guidance instructing HOPDs to bill using modifiers consistent with those used for Medicare telehealth services. For further background, we refer readers to <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>. In the same referenced document, CMS also issued specific guidance for other institutional providers of therapy services to use modifier 95 (indicating a Medicare telehealth service), along with the specific bill types for outpatient therapy services furnished by their staff.

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-328) extended many of the flexibilities that were available for Medicare telehealth services during the PHE for COVID-

⁷⁹ <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>

19 under emergency waiver authorities, including adding PTs, OTs and SLPs as distant site practitioners through the end of CY 2024. In developing post-PHE guidance, CMS initially took the position that institutions billing for services furnished remotely by their employed practitioners (where the practitioners do not bill for their own services), would end with the PHE for COVID–19 along with the HWW waivers).⁸⁰ However, after reviewing input from interested parties, as well as relevant guidance, including applicable billing instructions, we considered whether certain institutions, as the furnishing providers, can bill for certain remotely furnished services personally performed by employed practitioners.

In the CY 2024 PFS final rule, we stated that, while we considered how we might address this topic in future rulemaking, in the interests of maintaining access to outpatient therapy, DSMT, and MNT services furnished remotely by institutional staff to beneficiaries in their homes consistent with the accessibility of these services when furnished by professionals via Medicare telehealth, we finalized that we would continue to allow institutional providers to bill for these services when furnished remotely in the same manner they have during the PHE for COVID–19 through the end of CY 2024. We sought comment on current practice for these services when billed, including how and to what degree they continue to be provided remotely to beneficiaries in their homes. We sought comment as to whether these services may fall within the scope of Medicare telehealth at section 1834(m) of the Act or if there are other relevant authorities CMS might consider in future rulemaking. For further information on this comment solicitation, please see the discussion in the CY 2024 PFS final rule (88 FR 78886 through 78888).

For DSMT specifically, we stated that the clinical staff personally delivering the service may be a type of practitioner authorized to furnish Medicare telehealth services under

⁸⁰ <https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf>

section 1834(m) of the Act; but we also understood that DSMT may be provided by other types of staff. Accordingly, we noted in an FAQ that we were exercising enforcement discretion in reviewing the telehealth eligibility status of the practitioner personally providing any part of a remotely furnished DSMT service, so long as the persons were otherwise qualified to provide the service until the end of 2024. For more background we refer readers to <https://www.cms.gov/files/document/frequently-asked-questionscms-waivers-flexibilities-and-end-covid19-public-health-emergency.pdf>.

While the amendments made by section 4113 of the CAA, 2023 to section 1834(m) of the Act have continued to expand the range of practitioners eligible to furnish telehealth services through CY 2024, without subsequent legislation these practitioners will no longer be able to bill for Medicare telehealth services beginning January 1, 2025.

In the CY 2024 PFS final rule, we articulated the importance of maintaining access to outpatient therapy, DSMT, and MNT services furnished remotely by institutional staff to beneficiaries in their homes consistent with the availability of these services when furnished by professionals via Medicare telehealth as part of our rationale for allowing institutional providers to bill for these services when furnished remotely in the same manner they have during the PHE for COVID-19 through the end of CY 2024.

We recognize that for the past several years, through the PHE for COVID-19 and several legislative extensions of PHE-related flexibilities for Medicare telehealth services under section 1834(m) of the Act, we have generally aligned payment policies for outpatient therapy, DSMT, and MNT services furnished remotely by hospital staff to beneficiaries in their homes with policies for Medicare telehealth services. To the extent that therapists and DSMT and MNT practitioners continue to be distant site practitioners for purposes of Medicare telehealth services, we anticipate aligning our policy for these services with policies under the PFS and continuing to make payment to the hospital for these services when furnished by hospital staff.

2. Periodic In-Person Visits for Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

In the CY 2023 OPPTS/ASC final rule with comment period (87 FR 72017), we finalized a requirement that payment for mental health services furnished remotely to beneficiaries in their homes using telecommunications technology may only be made if the beneficiary receives an in-person service within 6 months prior to the first time the hospital clinical staff provides the mental health services remotely; and that there must be an in-person service without the use of telecommunications technology within 12 months of each mental health service furnished remotely by the hospital clinical staff. We also finalized that we would permit exceptions to the requirement that there be an in-person service without the use of communications technology within 12 months of each remotely furnished mental health service when the hospital clinical staff member and beneficiary agree that the risks and burdens of an in-person service outweigh the benefits of it. We stated that exceptions to the in-person visit requirement should involve a clear justification documented in the beneficiary's medical record including the clinician's professional judgement that the patient is clinically stable and/or that an in-person visit has the risk of worsening the person's condition, creating undue hardship on the person or their family, or would otherwise result in disengaging with care that has been effective in managing the person's illness. We also finalized that hospitals must document that the patient has a regular source of general medical care and has the ability to obtain any needed point of care testing, including vital sign monitoring and laboratory studies. We finalized that these requirements would not go into effect until the 152nd day after the PHE for COVID-19 ends to maintain consistency with similar policies implemented for professional services paid under the PFS, and for RHCs/FQHCs (87 FR 72018).

Section 4113(d) of the CAA, 2023, extended the delay in implementing the in-person visit requirements until January 1, 2025, for both professionals billing for mental health services via Medicare telehealth and for RHCs/FQHCs furnishing remote mental health visits. In the

CY 2024 OPSS we reiterated that we believe it is important to maintain consistent requirements for these policies across payment systems; therefore, we finalized delaying the in-person visit requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025. As such, these in-person visit requirements are currently set to take effect for services furnished on or after January 1, 2025 (88 FR 81874).

However, to the extent that these in-person visit requirements are delayed in the future for professionals billing for mental health services via Medicare telehealth, we anticipate that we would align the requirements for mental health services furnished remotely to beneficiaries in their homes through communications technology with mental health services furnished via Medicare telehealth in future rulemaking.

3. Proposed HOPD Payment for Telemedicine Evaluation and Management Services

The CPT Editorial Panel created 17 new codes describing audio/video and audio-only telemedicine E/M services. For further discussion of these 17 new codes and CMS' related proposals, please see section II.E.4.18 of the CY 2025 PFS proposed rule.

In 2014, CMS established HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) to describe the service associated with a hospital outpatient clinic visit for assessment and management of a patient. In the CY 2014 OPSS/ASC final rule with comment period (78 FR 75042), we stated that the code is applicable for hospital use only representing any clinic visit under the OPSS. We further stated that HCPCS code G0463 replaces evaluation and management (E/M) CPT codes 99201 – 99205 (new patient) and 99211 – 99215 (established patient), thereby eliminating the distinction between new and established clinic visits.

Given the similarities between the new telemedicine E/M code set and the office/outpatient E/M code set, we believe that the telemedicine E/M codes fall within the scope of the hospital outpatient clinic visit policy because the predecessor codes (the office/outpatient E/M code set) would be reported by hospitals using HCPCS code G0463. Under the hospital

outpatient clinic visit policy, the CPT codes describing office/outpatient E/M visits are not recognized under OPPS and instead hospitals report HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) when billing for the facility costs associated with an outpatient E/M visit. Therefore, we propose not to recognize the telemedicine E/M code set under OPPS. We are, however, seeking comment on the hospital resources associated with the telemedicine E/M services, particularly any resource costs that would not be included in the payment for HCPCS code G0463. We are also seeking comment, should CMS finalize separate payment for these telemedicine E/M codes under the PFS, on the resource costs that would be associated with these services for hospitals and whether we should develop separate coding to describe the resource costs associated with a telemedicine E/M service.

B. 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)(B)(I))

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)⁸¹ to provide that, during a Public Health Emergency 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

⁸¹ 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).

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)⁸² 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).

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 to include the presence of the supervising practitioner through two-way, audio/video telecommunications technology 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)(I)⁸³ to allow for the direct supervision requirement for CR, ICR, and PR 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).

b. Virtual Direct Supervision of Diagnostic Services Furnished to Hospital Outpatients (42 CFR § 410.28(e)(2)(iii))

⁸² Ibid.

⁸³ Ibid.

In the April 6th COVID–19 IFC, for consistency with the revisions made to 42 CFR 410.27(a)(1)(iv)(D)⁸⁴ and 410.32(b)(3)(ii), we changed the regulation at 42 CFR 410.28(e) to provide that, during a Public Health Emergency 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).

In the CY 2023 OPPTS/ASC final rule with comment period, 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, we revised § 410.28(e) to extend the end date of the flexibility allowing for the virtual supervision of outpatient diagnostic services through audio/video real-time communications technology (excluding audio-only) from the end of the PHE to the end of the calendar year in which the PHE ends (87 FR 72024 through 72026).

In the CY 2024 final OPPTS rule with comment period, to again ensure consistency with further 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, we revised § 410.28(e) to extend the end date of the flexibility allowing for the virtual supervision of outpatient diagnostic services through audio/video real-time communications technology (excluding audio-only) through December 31, 2024 (88 FR 81866 and 81867).

2. Extension of Virtual Direct Supervision of CR, ICR, PR Services and Diagnostic Services Furnished to Hospital Outpatients through December 31, 2025.

⁸⁴ Ibid.

In the CY 2025 PFS proposed rule, we propose to revise the definition of direct supervision at § 410.32(b)(3)(ii) to extend the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through December 31, 2025. As explained in that proposed rule, we propose this extension based on our concern that an immediate reversion to the pre-PHE definition of direct supervision would prohibit virtual direct supervision, which may present a barrier to access to many services that have been facilitated by our PHE-related policy over the past several years; and that physicians and other practitioners need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. For the complete discussion of the proposed revision to § 410.32(b)(3)(ii), we refer readers to the CY 2025 PFS proposed rule.

In addition to desiring uniformity under the PFS and OPPTS in how regulations are applied to similarly situated providers, the beneficiary access and provider preparedness concerns motivating us to propose extending the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through December 31, 2025, are also concerns with respect to the direct supervision of CR, ICR, PR and diagnostic services under the OPPTS. Consequently, we propose to revise § 410.27(a)(1)(iv)(B)(1) and § 410.28(e)(2)(iii) to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) through December 31, 2025.

C. All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

1. Background

In the CY 2000 OPPTS 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 this final rule, we noted that the OPPTS 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 OPPTS/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 OPPTS.

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.⁸⁵ Due to the higher cost of living in Alaska, separate rates are calculated for Alaska and the lower 48 States. For CY 2024, the Medicare Outpatient per Visit Rate is \$667 for the lower 48 states and \$961 for Alaska.⁸⁶

IHS and tribal facilities have continued to expand the breadth of services that they provide to their communities. Increasingly, this has meant providing higher-cost drugs along with more complex and expensive services. While the majority of IHS and tribal facilities appear to be well served by the AIR, some IHS and tribal facilities provide specialized services for which the AIR might not adequately represent Medicare’s share of costs. If providing a drug or service costs IHS and tribal facilities thousands of dollars more than the payment they receive through the AIR, it is likely not financially feasible for these facilities to routinely provide that drug or service. For example, the cost of providing a frequently used cancer drug such as Opdualag (HCPCS code 00003-7125), which has a per day cost of \$28,975, greatly exceeds the \$667 payment a IHS or tribal facility receives through the AIR. We are concerned that, if payments under the AIR are inadequate for high-cost drugs, this could potentially threaten the viability of the few IHS and tribal hospital outpatient specialty programs currently in operation

⁸⁵ <https://www.ihs.gov/BusinessOffice/reimbursement-rates/>

⁸⁶ <https://www.federalregister.gov/documents/2023/12/19/2023-27815/reimbursement-rates-for-calendar-year-2024>

and provide less incentive to IHS hospitals and tribal facilities not currently offering specialty services to begin doing so. This constitutes a significant equity and beneficiary access concern if IHS and tribal hospitals are not able to provide oncology services or other services that require high-cost drugs because the hospital would always receive payment for those services that is far below what it would have to pay to acquire those high-cost drugs.

Consequently, in the CY 2024 OPPTS/ASC proposed rule, we sought comment on whether Medicare should pay separately for certain high-cost drugs provided by IHS and tribal facilities and, if so, how we might do so. Among other topics, we specifically requested input on which drugs it would be appropriate to pay separately for (high-cost oncology drugs or all high-cost drugs), how we might define high-cost drugs (for example, a list of named drugs versus any drugs exceeding a certain cost threshold), and what the appropriate payment amount for the separately paid drugs should be (ASP plus 6 percent, which is what hospitals are generally paid under the OPPTS for separately payable drugs, or the Federal Supply Schedule (FSS), which is where IHS and tribal hospitals acquire the majority of their drugs at rates significantly lower than ASP plus 6 percent). For a full discussion of the comment solicitation, we refer readers to the CY 2024 OPPTS/ASC proposed rule (88 FR 49741 through 49742).

Commenters, including a tribal facility, the CMS Tribal Technical Advisory Group (TTAG), organizations representing tribal healthcare providers, pharmaceutical companies, and other interested parties, expressed universal support for establishing a policy that would allow IHS and tribal healthcare facilities to receive separate payment outside of the AIR for high-cost drugs. The preferred approach of those commenters who provided input on how to define a high-cost drug eligible for separate payment was to treat the amount of the Medicare Outpatient per Visit Rate for the lower 48 States' AIR (hereinafter referred to as "the lower 48 AIR") as a payment threshold. Under this approach, if the cost of a particular drug is less than or equal to the lower 48 AIR, the provider would not receive a separate payment for the drug and if the cost of the drug was more than the lower 48 AIR, then the provider would receive a separate payment

for the drug. Commenters noted that this payment approach is currently being used for all drugs (oncology and otherwise) receiving payment through Arizona Medicaid (AHCCCS) for IHS and tribal facilities located in Arizona. With respect to the payment amount, several commenters requested that separately payable drugs furnished by IHS and tribal facilities be paid at a rate of ASP plus 6 percent rather than the FSS rate. These commenters argued that the IHS is chronically underfunded and that paying ASP plus 6 percent for high-cost drugs could help with remedying those funding issues. For a full discussion of the comments we received as a result of our comment solicitation and our responses to those comments, we refer readers to the CY 2024 OPPTS/ASC final rule with comment period (88 FR 81896 through 81897).

2. Proposed AIR Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

In light of the equity and beneficiary access concerns that prompted our CY 2024 comment solicitation and the input received in response to that solicitation, we propose, starting January 1, 2025, to separately pay IHS and tribal hospitals⁸⁷ for high-cost drugs furnished in hospital outpatient departments through an add-on payment in addition to the AIR using the authority under which the annual AIR is calculated.⁸⁸ We emphasize the amount of this proposed add-on payment would *not* be carved out of the annual AIR payment amount calculation. In other words, we propose that the add-on payment would have no effect on the calculation of the annual AIR payment amount. We seek comment on separately paying IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through the establishment of an add-on payment to the AIR using the authority under which the annual AIR is calculated.

⁸⁷ IHS Critical Access Hospitals (CAHs) are paid for covered outpatient services based on 101 percent of an all-inclusive facility specific rate rather than the national AIR rate. Consequently, they are excluded from the proposed separate payment policy.

⁸⁸ Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

We propose that the drugs to which the add-on payment would apply would not be limited to high-cost oncology drugs but would include all high-cost drugs furnished in hospital outpatient departments of IHS and tribal hospitals to the extent those drugs are covered under Medicare Part B and would be paid for under the OPSS if furnished by a hospital paid under that system. In determining which drugs would be eligible for the add-on payment, we considered limiting the add-on payment to high-cost oncology drugs. However, we determined that it would be appropriate to apply the add-on payment to all high-cost drugs for several reasons. First, the same equity and access concerns that support utilizing an add-on payment for oncology drugs also support utilizing an add-on for high-cost drugs used in other care specialties. Although this issue arose in the context of removing barriers to beneficiaries' access to high-cost oncology drugs, there are presumably similar barriers to other specialties that use high-cost drugs that would be addressed through a broader application of the add-on payment. Second, applying the add-on payment to all high-cost drugs would eliminate the possibility of unintentionally excluding an oncology drug from separate payment due to the inherent challenge of defining a class of drugs. Third, the proposal would parallel how drugs are being paid for under Arizona Medicaid (AHCCCS) for IHS and tribal facilities. We seek comment on applying the add-on payment to all high-cost drugs furnished in hospital outpatient departments of IHS and tribal hospitals to the extent those drugs are covered under Medicare Part B and would be paid for under the OPSS if furnished by a hospital paid under that system.

As to what constitutes a high-cost drug, we propose to define high-cost drugs for the purpose of this policy as all drugs covered under Medicare Part B and for which payment would otherwise be made under the OPSS whose per day cost exceeds two times the lower 48 AIR (\$1,334 in CY 2024). We propose a threshold greater than the lower 48 AIR to account for the fact that IHS and tribal hospitals would continue to receive the lower 48 AIR payment, in addition to the add-on payment, for encounters that include a high-cost drug. While it is true that under the Arizona Medicaid program, IHS and tribal hospitals are paid the lower 48 AIR

payment in addition to an add-on payment for drugs whose costs exceed the lower 48 AIR, we are concerned that providing separate payment for drugs whose costs only slightly exceed the lower 48 AIR could result in excessive payment for those drugs. For example, for a drug that costs \$700, using the CY 2024 lower 48 AIR as the threshold for our proposal would result in a payment of at least \$1,367 (the \$667 AIR encounter payment plus an add-on payment for the high-cost drug as calculated under the payment methodology we propose later in this section) for the provision of a drug whose cost exceeds the lower 48 AIR by only \$33.00. Such an outcome would be at odds with the objective of the proposed policy, which is to provide adequate payment for drugs that are high cost in relation to the lower 48 AIR. Consequently, we propose two times the lower 48 AIR as the threshold triggering the add-on payment because this amount would ensure that the add-on payment would apply only to drugs whose costs significantly exceed the lower 48 AIR. This cost-multiplier approach is also consistent with how CMS has implemented thresholds relating to payments to hospitals under other payment systems. For example, the OPPS outlier policy⁸⁹ requires that the cost of a service exceed 1.75 times the payment amount for the service to qualify for an additional payment. Similarly, the OPPS two-times rule requires that the highest calculated cost of an individual procedure categorized to any given Ambulatory Payment Classification (APC) not exceed two times the calculated cost of the lowest cost procedure categorized to that same APC.

An alternative to our proposal to set the threshold at two times the lower 48 AIR would be to set the threshold at the lower 48 AIR despite our previously described concerns. Another alternative would be to set the threshold at 1.75 times the lower 48 AIR (\$1,167.25 in CY 2024) to align it with the multiplier used to calculate the threshold triggering outlier payments under

⁸⁹ 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. Outlier payments are provided on a service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by 1.75) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount).

the OPSS. We seek comment on the alternatives of using the lower 48 AIR or 1.75 times the lower 48 AIR as the threshold amount for triggering the add-on payment for high-cost drugs.

We also seek comment on whether we should adopt an exception to whichever AIR-based threshold we adopt that would parallel the drug packaging threshold exception for biosimilars⁹⁰ under the OPSS. Under the OPSS, if a drug's per-day cost is less than or equal to the drug packaging threshold, then payment for the drug is packaged. Conversely, if a drug's per-day cost exceeds the drug packaging threshold, then it is paid for separately. For a more detailed discussion of the drug packaging threshold, we refer readers to the CY 2024 OPSS/ASC final rule with comment period (88 FR 81776 through 81778). In CY 2024, we established an exception to this threshold for biosimilars when the biosimilar's per-day cost does not exceed the threshold, but its reference product's per-day cost does. In other words, if the biosimilar's reference product is paid separately (because its per-day cost exceeds the threshold), then we also pay separately for the biosimilar even if its per-day cost does not exceed the threshold. This exception was based on our concern that packaging biosimilars when the reference product or other marketed biosimilars are separately paid might create financial incentives for providers to select more expensive, but clinically similar, products. For a more detailed discussion of the exception for biosimilars to the drug packaging threshold, we refer readers to the CY 2024 OPSS/ASC final rule with comment period (88 FR 81783 through 81786). Because we propose to use a threshold to trigger application of the add-on payment for high-cost drugs to IHS and tribal hospitals, we have the same concerns about financial incentives that motivated us to establish the exception for biosimilars to the drug packaging threshold. Consequently, we seek comment on whether we should pay the add-on payment to IHS and tribal hospitals for

⁹⁰ A biosimilar is a biologic medication. It is highly similar to a biologic medication already approved by FDA – the original biologic (also called the reference product).

biosimilars whose per-day costs do not exceed the threshold but whose reference products do exceed the threshold.

We also propose 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). This payment amount would be consistent with what hospitals receive as payment for most drugs under the OPPTS (ASP plus 6 percent) but would exclude the 6 percent additional payment in recognition of the fact that IHS and tribal facilities, unlike hospitals paid under the OPPTS, primarily obtain their drugs through the FSS, whose rates are significantly lower than ASP. This approach is also consistent with our existing policies of paying ASP without any additional payment for certain Opioid Treatment Program drugs under 42 CFR 410.67(d)(2)(i)(A) and (B). In the event ASP pricing information is not available for a particular drug, we propose to pay the Wholesale Acquisition Cost (WAC) plus 0 percent. If WAC pricing information is not available, we propose to pay 89.6 percent of Average Wholesale Price (AWP).

We seek comment on whether we should instead pay ASP plus 6 percent. If we were to adopt this alternative policy and pricing information is not available for a particular drug, we would pay WAC plus 6 percent and if WAC pricing information is not available, we would pay 95 percent of AWP. We seek comment on our proposal to pay an add-on of ASP plus 0 percent in addition to the AIR for drugs administered by IHS and tribal facilities with costs that exceed two times the lower 48 AIR. We also seek comment on our proposed pricing hierarchy for drugs for which ASP pricing information is not available.

To implement this policy, we propose that, starting with IHS's annual announcement in the Federal Register in December 2024 of the lower 48 AIR amount for CY 2025, we would multiply the lower 48 AIR amount by two and then compare the result to the estimated per day costs of all drugs covered under Part B for which payment would otherwise be made under the OPPTS. To determine the calculated per day cost for each drug and biological HCPCS code, we propose to follow a methodology similar to our longstanding methodology used to calculate the

per day cost of drugs and biologicals for OPPS payment purposes as discussed in section V.B.1.b of this proposed rule. Specifically, to calculate the per day cost, we propose to use an estimated payment rate based on the ASP methodology payment rate, which for purposes of this proposal is generally ASP plus 0 percent (which is the payment rate we propose for separately payable IHS drugs and biologicals) for CY 2025 to calculate the CY 2025 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2023 to determine the proposed rule per day cost. For drugs and biologicals that did not have either an ASP-based payment rate or a payment rate based on WAC, we used mean unit cost of the items derived from the CY 2023 hospital claims data to determine their per day cost.

A list of drugs whose costs exceeds two times the lower 48 AIR would be generated and communicated to IHS and tribal hospitals prior to January 1, 2025. During CY 2025, IHS and tribal hospitals would submit claims for drugs included on this list. The list of drugs would be updated on a quarterly basis using existing drug compendia and CMS ASP quarterly reporting only to account for newly introduced drugs. The payment rates for drugs on the list would be updated quarterly as well based on changes in drug prices. We would then repeat this process on an annual basis each December when the lower 48 AIR amount for the following calendar year is announced by IHS. For example, had our proposed policy been in place for CY 2024, the drugs for which the add-on payment would have been made (drugs with a per day cost exceeding two times the CY 2024 lower 48 AIR) are those listed in Addendum Q. We seek comment on this proposed implementation plan.

Finally, we propose to implement this policy on a permanent basis but may revisit it in the future if we have any concerns about its impact once it has been implemented.

D. Request for Information - Paying all IHS and Tribally Operated Clinics the IHS Medicare Outpatient All Inclusive Rate

CMS established a Tribal Technical Advisory Group (TTAG) in 2004 to provide advice and input to CMS on policy and program issues impacting AI/AN populations served by CMS

programs. Although not a substitute for formal consultation with tribal leaders, the TTAG enhances the government-to-government relationship between HHS and federally recognized tribes and improves understanding between CMS and tribes. The TTAG has subject specific subcommittees that meet on a regular basis in order to be more effective and perform in-depth analysis of Medicare, Medicaid, CHIP, and Health Insurance Marketplace^{®91} policies that have tribal implications. The TTAG is composed of 17 representatives. It has historically included an elected tribal leader or an appointed representative from each of the 12 geographic areas of the IHS delivery system and a representative from each of the national Indian organizations headquartered in Washington, DC—the National Indian Health Board, the National Congress of American Indians, and the Tribal Self-Governance Advisory Group. Section 5006(e)(1) of the American Recovery and Reinvestment Act of 2009, which became effective July 1, 2009, mandates that TTAG shall be maintained within CMS and added two new representatives: a representative from a national urban Indian health organization; and a representative from the IHS.

In June 2020, the TTAG requested that CMS amend its Medicare regulations to make all IHS and tribally-operated outpatient facilities eligible for Medicare payment at the IHS Medicare outpatient per visit rate/AIR. The TTAG explained that outpatient clinics, which are otherwise similar to grandfathered tribal FQHCs, are paid at different rates depending upon whether they meet the requirements as a provider-based facility, a grandfathered tribal FQHC, a non-grandfathered tribal FQHC, or none of the above. TTAG's position is that the rates vary based on Medicare regulatory definitions, rather than the actual costs of the outpatient clinic.⁹² There are varying payment differentials among Medicare enrolled providers and suppliers under

⁹¹ Health Insurance Marketplace[®] is a registered service mark of the U.S. Department of Health & Human Services.

⁹² <https://www.nihb.org/tribalhealthreform/wp-content/uploads/2020/06/TTAG-letter-to-CMS-requesting-IHS-rate-for-all-tribal-clinics-06.10.2020.pdf>

the authorities of the SSA. For example, ASCs are paid differently than HOPDs; which are paid differently depending on whether they are located in a critical access hospital.

In the CY 2022 PFS proposed rule (86 FR 39240), we acknowledged that the TTAG is concerned about ensuring appropriate Medicare payments for similar services and is also concerned about the impact on tribal Medicare beneficiaries and on ensuring equitable access to healthcare. We take these concerns seriously but noted in the CY 2022 PFS proposed rule that we had insufficient information to evaluate the costs and benefits of potential changes to these policies. Therefore, we solicited comments on the TTAG's request for CMS to amend its Medicare regulations to make all IHS- and tribally operated outpatient facilities/clinics eligible for payment at the Medicare outpatient per visit rate/AIR, regardless of whether they were owned, operated, or leased by IHS. In response to the solicitation, we did not receive specific information on costs or specific types of clinics; however, in the CY 2022 PFS final rule (86 FR 65211 through 65214), we stated we would like to continue these discussions to evaluate the impact of the commenters' proposed changes to the current Medicare payment policies and will consider these recommendations for future rulemaking. Thus, to continue these discussions, we would like to request this information again in this proposed rule.

Beginning in the Fall of 2023, CMS began participating in a workgroup related to the TTAG's Medicare priority to make the IHS Medicare outpatient AIR available to all IHS and tribally operated outpatient facilities that request it. Although we have received some information through the workgroup, we would like to request information consistent with our comment solicitation in the CY 2022 PFS proposed rule.

We seek information on the kinds of and number of facilities or clinics that the Medicare outpatient IHS AIR could apply to; that is, it is unclear whether TTAG anticipates that these facilities enroll in Medicare as FQHCs going forward, or whether they are referring to FQHCs that are currently paid under the FQHC PPS. Moreover, we request information on whether the facilities in question are freestanding or provider-based. We would like commenters to confirm

or clarify whether the clinics are physician offices, or whether they are recommending establishment of a new provider type. We seek information regarding the relative operating costs of tribally operated outpatient clinics, as well as feedback and supporting evidence to address whether or why payment set at the IHS AIR would be more appropriate than payment rates under the FQHC PPS, the physician fee schedule, or other some other Medicare payment system. Further, we seek comment on how the Medicare outpatient AIR, which is based upon a limited number of hospital cost reports, relates to costs in tribal clinics and the kinds of services that the clinics furnish. Finally, we seek comment on the concerns that the AI/AN community may have regarding access to or inequity of care in situations where a payment differential exists.

We have information on historically excepted FQHCs, the outpatient provider-based clinics to the hospital, and some general information about the composition of IHS and tribal facilities and clinics. However, there are still gaps in the data and therefore we are soliciting answers to the following questions: If the clinic or facilities in question are not enrolled in Medicare as an FQHC or provider-based to a hospital, are they physician practices? How are these facilities organized and related?

Because paying the Medicare outpatient AIR to additional IHS and tribally operated facilities that are currently paid under another Medicare payment methodology or not yet enrolled in Medicare as all would potentially increase expenditures, we also solicit information on how tribally operated facilities participate in Medicare currently, which would help us to estimate the impacts of such a policy change.

E. Coverage Changes for Colorectal Cancer (CRC) Screening Services

Medicare coverage for colorectal cancer (CRC) screening tests under Part B is described in statutes (sections 1861(s)(2)(R), 1861(pp), 1862(a)(1)(H) and 1834(d) of the Social Security Act (the Act)), regulation (42 CFR 410.37), and a National Coverage Determination (NCD) (Section 210.3 of the Medicare National Coverage Determinations Manual). Section

1861(pp)(1)(D) of the Act includes in its definition of colorectal cancer screening test “[s]uch other tests or procedures, and modifications to the tests and procedures described under this subsection, with such frequency and payment limits as the Secretary determines appropriate, in consultation with appropriate organizations.”

42 CFR 410.37 lists and defines the tests and procedures covered by Medicare as colorectal cancer screening tests. Specifically, the following tests and procedures furnished to an individual for the purpose of early detection of colorectal cancer are covered by Medicare:

- Screening fecal-occult blood tests.
- Screening flexible sigmoidoscopies.
- Screening colonoscopies, including anesthesia furnished in conjunction with the service.
- Screening barium enemas.
- Other tests or procedures established by a national coverage determination, and modifications to tests under this paragraph, with such frequency and payment limits as CMS determines appropriate, in consultation with appropriate organizations.

In recent years we have received recommendations from the public to remove Medicare coverage for the barium enema test since the test no longer meets modern clinical standards and is no longer recommended in clinical guidelines. As a replacement to the barium enema test, organizations have suggested the use of CT colonography, which is a more effective test for colorectal cancer screening. For a more extensive discussion on the background and proposal to revise the Medicare coverage for colorectal cancer screening services, we refer readers to the CY 2025 Physician Fee Schedule (PFS) proposed rule.

For CY 2025, based on public input and consultation with specialty societies, and as discussed in the CY 2025 PFS proposed rule, we propose to exercise our authority under section 1861(pp)(1)(D) of the Act to update and expand coverage for CRC screening. As discussed in the CY 2025 PFS proposed rule, we propose to make the following revisions to § 410.37:

- Remove coverage for the barium enema procedure.
- Add coverage for the computed tomography colonography (CTC) procedure.
- Expand the existing definition of a “complete colorectal cancer screening” to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3).

The above screening tests are currently described by existing HCPCS codes. These HCPCS codes are listed in Table 70 along with their long descriptors.

TABLE 70: SCREENING HCPCS CODES FOR BARIUM ENEMA, COMPUTED TOMOGRAPHY COLONOGRAPHY, AND BLOOD-BASED BIOMARKER TESTS

Colorectal Cancer (CRC) Screening Test	HCPCS Code	Long Descriptor
Barium enema	G0106	Colorectal cancer screening; alternative to g0104, screening sigmoidoscopy, barium enema
Barium enema	G0120	Colorectal cancer screening; alternative to g0105, screening colonoscopy, barium enema
Computed tomography colonography (CTC)/Virtual colonoscopy	74263	Computed tomographic (ct) colonography, screening, including image postprocessing
Blood-based biomarker	G0327	Colorectal cancer screening; blood-based biomarker

Based on the proposed coverage changes for CRC screening, we propose to make the following changes under the OPPS for CY 2025:

- HCPCS codes G0106 and G0120 (screening barium enema): These codes were established by CMS effective January 1, 1998, to implement Medicare coverage for barium enema as a test for colorectal cancer screening. Since we propose to remove Medicare coverage for barium enema effective January 1, 2025, and we no longer need to keep these codes active, we propose to delete them on December 31, 2024. Therefore, we are revising the status indicator for the HCPCS codes from status indicator “S” (Procedure or Service, Not Discounted When Multiple. Paid under OPPS; separate APC payment.) to “D” (Discontinued code) to indicate that

HCPCS codes G0106 and G0120 will be deleted on December 31, 2024. In addition to the deletion of these codes, we also propose to delete HCPCS code G0122 (Colorectal cancer screening; barium enema), which is already non-covered by Medicare, on December 31, 2024.

- CPT code 74263 (screening computed tomography colonography (CTC)/virtual colonoscopy): We are reassigning this code from status indicator “E1” (not covered/not payable) to status indicator “S” and APC 5522 (Level 2 Imaging Without Contrast) to indicate that the code is separately payable. Based on our review, the time and resources associated with performing a screening virtual colonoscopy is similar to a diagnostic virtual colonoscopy, which is described by CPT code 74261 (Computed tomographic (ct) colonography, diagnostic, including image postprocessing; without contrast material). Consequently, the proposed APC assignment for CPT code 74263 is based on its clinical and resource homogeneity to CPT code 74261, which is assigned to APC 5522.

- HCPCS code G0327 (screening blood-based biomarker): This HCPCS code is currently assigned to status indicator “A” to indicate that the test is paid separately under a different Medicare payment system than the OPSS. Since HCPCS G0327 is currently separately payable under the Clinical Laboratory Fee Schedule (CLFS), we are not proposing to revise the status indicator. Specifically, with the expanded coverage to include blood-based biomarker as a screening test to detect colorectal cancer, we propose to continue to assign HCPCS code G0327 to status indicator “A” for CY 2025.

In summary, based on the proposed coverage changes for colorectal cancer screening services, we propose to revise the OPSS status indicator for certain HCPCS codes for CY 2025. Table 71 shows the long descriptors, current CY 2024 OPSS status indicators, and proposed CY 2025 OPSS status indicators for HCPCS codes G0106, G0120, G0122, 74263, and G0327. The proposed CY 2025 OPSS payment rates, where applicable, for these HCPCS codes can be found in Addendum B to this proposed rule. In addition, for the complete list of the proposed status indicators and their definitions, refer to Addendum D1 of this proposed rule.

TABLE 71: PROPOSED CY 2025 OPPTS STATUS INDICATOR AND APC ASSIGNMENT FOR HCPCS CODES G0106, G0120, G0122, 74263, AND G0327

HCPCS Code	Long Descriptor	CY 2024 OPPTS SI	CY 2024 OPPTS APC	Proposed CY 2025 OPPTS SI	Proposed CY 2025 OPPTS APC
G0106	Colorectal cancer screening; alternative to g0104, screening sigmoidoscopy, barium enema	S	5571	D	
G0120	Colorectal cancer screening; alternative to g0105, screening colonoscopy, barium enema	S	5572	D	
G0122	Colorectal cancer screening; barium enema (Non-covered)	E1		D	
74263	Computed tomographic (ct) colonography, screening, including image postprocessing	E1		S	5522
G0327	Colorectal cancer screening; blood-based biomarker	A		A	

F. Request for Comment on Payment Adjustments under the IPPS and OPPTS for Domestic

Personal Protective Equipment

1. General Background

As discussed in the FY 2023 IPPS/LTCH PPS and CY 2023 OPPTS/ASC rules, President Biden issued Executive Order (E.O.) 13987 “Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID–19 and To Provide United States Leadership on Global Health and Security” on January 20, 2021 (86 FR 7019). This order launched a whole-of-government effort to combat the coronavirus disease 2019 (COVID-19) and prepare for future biological and pandemic threats. As the COVID-19 pandemic eased, work has continued to prepare for future pandemics. As the COVID-19 pandemic demonstrated, sufficient availability of personal protective equipment (PPE) in the health care sector is a critical component of preparedness.

The CY 2023 OPPTS/ASC final rule implemented payment adjustments under the OPPTS and IPPS to support a resilient and reliable supply of surgical N95 respirators—a specific type of filtering facepiece respirator that is a subset of N95 masks used in some clinical settings under

conditions requiring respiratory protection from airborne pathogens and splash protection from exposure to fluids. Early on in the COVID-19 pandemic, “just-in-time” supply chains, minimal stockpiling, and overreliance on foreign imports left U.S. hospitals unable to obtain enough N95 respirators to protect health care workers. Prices for surgical N95s soared from an estimated \$0.25–\$0.40/unit to \$5.75/unit (and up to \$12.00/unit in some reported cases). Unable to obtain surgical N95s regulated by NIOSH, hospitals had to turn to KN95s—a Chinese standard respirator—and other non-NIOSH-approved respirators under Emergency Use Authorization (EUA). Skyrocketing demand during the COVID-19 pandemic also raised counterfeit respirator concerns.

Currently available payment adjustments offset the marginal costs that hospitals face in procuring domestically made NIOSH-approved and FDA-certified surgical N95 respirators. These marginal costs are due to higher per-unit acquisition prices that stem from higher costs of inputs and labor in the U.S., as compared to international suppliers, where many N95 and other respirators are made, as well as a demonstrated record of more consistent high quality for domestically made products.⁹³ These payment adjustments offset the additional marginal costs of hospitals that purchase domestically made NIOSH-approved surgical N95 respirators to help sustain demand for—and thus domestic production of—high-quality domestically made respirators in order to ensure quality PPE is available to health care personnel when needed.

The policy goal to maintain a baseline domestic production capacity of high-quality PPE in order to ensure that quality PPE is readily available to health care personnel when needed is emphasized in the National Strategy for a Resilient Public Health Supply Chain, published in July 2021 as directed by President Biden’s Executive Order 14001 on “A Sustainable Public Health Supply Chain.” The U.S. Government has committed to purchase wholly domestically-

⁹³ <https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html>

made PPE in line with section 70953 of the Infrastructure Investment and Jobs Act (Pub. L. 117-58).

2. Potential Modifications to Payment Adjustments for Domestic NIOSH-Approved Surgical N95 Respirators

Although the payment adjustments for domestic NIOSH-approved surgical N95 respirators under the OPSS and IPPS have applied to cost reporting periods beginning on or after January 1, 2023, use of the payment adjustments has been limited. Furthermore, market data suggests that a majority of surgical N95 respirators purchased by hospitals are not wholly domestically made. In the CY 2023 OPSS/ASC final rule, we stated that as we gain more experience with this policy and the data collected, we may also consider modifications to the reasonable cost-based payment approach we were finalizing. HHS has conducted stakeholder outreach to better understand barriers to awareness and uptake and seek feedback on potential modifications that could increase effectiveness, and continues to engage hospitals and other manufacturers on these payment adjustments. We are interested in feedback and comments on potential modifications to the payment adjustment in order to reduce reporting burden and achieve the policy goal to maintain a baseline domestic production capacity of PPE in order to ensure that quality PPE is readily available to health care personnel when needed.

Payment adjustment methodology: In the CY 2023 OPSS/ASC final rule, we finalized to initially base the payment adjustments on the IPPS and OPSS shares of the estimated difference in the reasonable costs. We created a new supplemental cost reporting form to enable calculation of a hospital-specific unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators. We noted that, based on available data, our best estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators was \$0.20. In the CY 2023 OPSS/ASC final rule, we also noted that MedPAC, while not supportive of the proposed payment adjustments, stated that CMS should set the unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators at a

national level (rather than on a hospital-by-hospital basis). MedPAC believed this would reduce the administrative burden on hospitals, encourage hospitals to purchase the most economical domestically made product, and reduce the ability of hospitals to increase their payments by artificially inflating reported N95 costs. We solicit comment on the following questions:

- Should we consider modifying the payment adjustment methodology calculation to provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators (rather than on a hospital-by-hospital basis)?
- If so, how should we calculate that standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators, and what should the current unit cost differential be?
- If we modified the payment adjustment methodology calculation to provide a national standard unit cost differential, would it be appropriate to calculate the payment adjustment by multiplying the unit cost differential by the total quantity of domestic NIOSH-approved surgical N95 respirators used by the hospital, and then multiplying by the Medicare Part A hospital inpatient cost share (to calculate the IPPS payment adjustment) or the Medicare Part B hospital outpatient cost share (to calculate the OPSS payment adjustment)?
- Do hospitals need additional support to purchase domestic-made surgical N95 respirators as opposed to non-domestic surgical N95 respirators? If so, how much support is needed, and in what form?

Payment adjustment eligibility: In the CY 2023 OPSS/ASC final rule, we stated that we recognize that a hospital cannot fully independently determine if a NIOSH-approved surgical N95 respirator it purchases is domestic under our definition. Therefore, we finalized that a hospital may rely on a written statement from the manufacturer stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under our definition. We solicit comment on the following questions:

- Do hospitals have sufficient access to information on which surgical N95 models on the market are wholly domestically made?
- Have hospitals been able to obtain written statements from manufacturers stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under our definition?
- Would a publicly available list of products eligible for the payment adjustment (for example, if provided by CMS, NIOSH, or another government entity) make it easier for hospitals to locate products eligible for the payment adjustment?
- If we modified the payment adjustment such that hospitals that attested to purchasing wholly domestically made surgical N95 models from such a list did not need to obtain a written statement from the manufacturer, would hospitals more easily be able to utilize the payment adjustment?

Types of N95 respirators: In the CY 2023 OPPTS/ASC proposed rule, for purposes of the payment adjustment policy, we proposed to categorize all NIOSH-approved surgical N95 respirators purchased by hospitals into two categories: (1) Domestic NIOSH-approved surgical N95 respirators; and (2) Non-domestic NIOSH-approved surgical N95 respirators. Feedback from external stakeholders has suggested that it is a challenge that the payment adjustments are limited to surgical N95 respirators, given some hospitals also procure non-surgical N95 respirators. Both surgical N95 respirators and non-surgical N95 respirators are primarily used to protect the wearer from inhaling airborne particles, including infectious agents like bacteria and viruses. They are highly efficient at filtering out at least 95% of airborne particles and are commonly used by healthcare workers during procedures that may generate aerosols, such as intubation or suctioning, or when caring for patients with infectious respiratory diseases like tuberculosis or coronavirus. Both types of N95 respirators serve as frontline defense for medical professionals. They are crucial for preventing the transmission of diseases within healthcare settings and safeguarding the health and well-being of both healthcare workers and patients.

Surgical N95 respirators have the added protection against fluid penetration, and may be most useful in specialized health care settings (e.g., ICU, Emergency Department, Operating Room) where the risk of fluid exposure may be greater. Additionally, during the COVID-19 pandemic, both types of N95 respirators saw issues around lack of availability and risk of counterfeit outlined in the CY 2023 OPPI/ASC final rule—issues which could compromise the safety of health care personnel and patients. We solicit comment on the following questions:

- Do hospitals procure both surgical N95 respirators and non-surgical N95 respirators?
- Has the payment adjustment's current focus on surgical N95 respirators inhibited uptake of the payment adjustments?
- Are the quality differentials between domestic and non-domestic surgical respirators also applicable to non-surgical respirators, and is a sustained and reliable source of domestically made non-surgical N95 respirators important for strengthening hospitals' ability to protect the health and safety of personnel and patients in a public health emergency?
- Should CMS consider expanding the payment adjustments to include all domestic NIOSH-approved N95 respirators—i.e., non-surgical and surgical N95 respirators?
- If we expanded the payment adjustments to include all domestic NIOSH-approved N95 respirators, and if we modified the payment adjustment methodology calculation to provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators (rather than on a hospital-by-hospital basis), would the unit cost differential for non-surgical N95 respirators be different than the one for surgical N95 respirators?

3. Potential Modifications to Include Nitrile Gloves

In addition to N95 respirators, nitrile gloves are another type of PPE for which it is particularly crucial to maintain a resilient, quality supply. Nitrile gloves protect health care workers and patients from the spread of micro-organisms that may potentially cause infection or

illness during medical procedures and examination. They create a barrier between germs and the wearer's hands, and are generally worn anytime a health care worker touches blood, bodily fluids, bodily tissues, mucous membranes, or broken skin. They are disposable, enabling the use of new gloves for each patient. A resilient healthcare system needs readily available, high-quality nitrile gloves to respond efficiently and effectively to public health emergencies. During the COVID-19 pandemic, supply chain breakdowns limited the supply of quality nitrile gloves, putting U.S. health care workers and patients at risk. As with N95 respirators, non-domestic-sourced gloves during the COVID-19 pandemic saw counterfeit and quality challenges. The receipt of non-U.S.-made counterfeit or already-used gloves put the safety of health care workers and patients at risk.^{94,95} Prior to 2020, over 95 percent of nitrile gloves sold in the U.S. came from other countries. As the pandemic escalated in 2020, U.S. demand for gloves outstripped available supply, leading to shortages. Around the same time, supply was also limited by coronavirus-related lockdowns in other countries that decreased production capacity, and by export restrictions of PPE. Further adding to supply pressures, forced labor violations by subsidiaries of a major glove producer led U.S. Customs and Border Protection (CBP) to issue a Withhold and Release Order, resulting in seizure of all listed products, including nitrile gloves, at CBP inspections. During the initial months of the pandemic, the cost of gloves increased, rising 18 percent from July to August 2020 (to \$0.03 per glove) and then an additional 20 percent from November to December 2020 (to \$0.05 per glove).⁹⁶

During the pandemic, the U.S. government has invested in domestic glove manufacturing capabilities. U.S. glove-manufacturing projects received approximately **\$290 million** in public funding as part of a broader **\$1.5-billion** investment to support domestic glove manufacturing. These investments have resulted in an increase of 3.91 billion in annual production capacity for

⁹⁴ <https://www.cnn.com/2021/10/24/health/medical-gloves-us-thailand-investigation-cmd-intl/index.html>

⁹⁵ <https://www.propublica.org/article/ppe-covid-scams-fraud-nitrile-gloves>

⁹⁶ Glove Story Global Glove Production Amidst the COVID-19 Pandemic (usitc.gov)

domestically manufactured nitrile gloves. The U.S. government also invested in manufacturing capacity for nitrile glove inputs such as nitrile butadiene rubber, and this manufacturing capacity is expected to become available in 2026.

However, since the pandemic began, some U.S. factories have been forced to consolidate operations or exit the industry. Further, non-U.S. nitrile glove producers have deployed cost-cutting tactics such as using lower-grade raw materials, prompting some purchasers to seek other sources out of concern for quality.⁹⁷ Producers of these lower quality products began selling gloves for the price of \$0.02 each, rapidly increasing U.S. market share, going from 13% of U.S. market share in July 2020 to 19 percent in February 2021. As of 2024, only three producers of nitrile gloves are left in the United States, and they supply an estimated .05% percent of U.S. demand for nitrile gloves.

As with N95 respirators, a resilient public health industrial base requires baseline manufacturing capacity for nitrile gloves as critical PPE items, to ensure that hospitals and other institutions will be able to procure high quality gloves reliably. To help achieve this goal, certain U.S. Government departments have committed to purchase wholly domestically made nitrile gloves in line with the requirements in section 70953 of the Infrastructure Investment and Jobs Act. However, federal demand alone cannot sustain a baseline level of nitrile glove production in the U.S. Private medical and health care users are the primary purchasers and users of medical-grade PPE, including nitrile gloves.

To ensure access to high quality products, as with N95 respirators, it is critically important to ensure that a sufficient share of nitrile gloves is wholly made in the U.S.—that is, including raw materials and components. In the CY 2023 OPPTS/ASC rule, we stated our belief that the most appropriate framework for determining if a NIOSH-approved surgical N95 respirator is wholly made in the U.S. and therefore, considered domestic for purposes of the

⁹⁷ Glove Story Global Glove Production Amidst the COVID-19 Pandemic (usitc.gov)

proposed adjustments, is the Berry Amendment. The Berry Amendment is a statutory requirement familiar to manufacturers that restricts the Department of Defense (DoD) from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the United States. For nitrile gloves, which are not covered by the Berry Amendment, we believe the Make PPE in America domestic content requirements outlined in section 70953 of the Infrastructure Investment and Jobs Act is the most appropriate framework for determining if a nitrile glove is wholly made in the U.S. These statutory requirements, which apply to procurement of nitrile gloves and other PPE by the U.S. Departments of Health and Human Services, and Veterans Affairs, and Homeland Security, require the procurement PPE, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the U.S. These statutory requirements have become familiar to manufacturers of nitrile gloves and other PPE. With respect to domestic manufacturing capabilities for raw materials and components, we understand that nitrile butadiene rubber (NBR), a key nitrile glove input, is currently not yet available domestically in sufficient quantity or quality to meet market needs. We understand that U.S. manufacturers do anticipate having the capability to source and manufacture all glove components domestically within the next two years.

Wholly domestically made, high quality nitrile gloves are generally more expensive than foreign-made ones, especially those of lower quality. This fact is also true for domestically made nitrile gloves that include non-domestically sourced NBR. These higher prices primarily stem from higher costs of manufacturing labor in the U.S. compared to costs in other countries, where most nitrile gloves and their inputs are made, and higher quality standards. These higher prices mean higher marginal costs for hospitals for procuring wholly domestically made nitrile gloves. Based on available data, our best estimate of the difference in the average unit cost of domestic and non-domestic nitrile gloves, is \$0.13 per glove.

As outlined in this section, quality nitrile gloves are a crucial component of PPE needed to ensure the safety of health care workers and patients. The COVID-19 pandemic highlighted how overreliance on foreign imports of gloves jeopardized public health and the health and safety of healthcare workers and patients. We solicit comment on the following questions:

- Would modifying the payment adjustment to include nitrile gloves help offset the marginal costs that hospitals face in procuring high quality domestically made nitrile gloves?
- Would modifying the payment adjustment to include nitrile gloves help to sustain a baseline level of domestic manufacturing of nitrile gloves to ensure that hospitals and other stakeholders have ongoing, reliable access to an adequate supply of quality product?
- Would having access to a sustained and reliable source of domestically made nitrile gloves strengthen hospitals' ability to protect the health and safety of personnel and patients in a public health emergency?
- Are there other reasons why hospitals would benefit from an extension of the payment adjustment to include nitrile gloves not covered in the preceding questions?
- Do stakeholders believe a significant portion of hospitals would use domestic nitrile gloves if the payment adjustment were offered?
- If the payment adjustment was modified to include nitrile gloves, how should CMS define wholly domestically made nitrile gloves? Would it be appropriate to categorize all nitrile gloves purchased by hospitals into two categories: (1) domestic nitrile gloves that—with the exception of nitrile butadiene rubber (NBR)—comply with the Infrastructure Investment and Jobs Act's Make PPE in America Act domestic content requirements; and (2) non-domestic nitrile gloves?
- If the payment adjustment was modified to include nitrile gloves, and the categories were defined as described previously, would it be appropriate to eliminate the domestic content exception for NBR if domestic NBR production reaches a sufficient level to meet market needs?

- If the payment adjustment was modified to include nitrile gloves, should a national standard unit cost differential between domestic and non-domestic nitrile gloves be used to calculate the payment adjustment, and if so, what should the current unit cost differential be (or, what should the data source be)?

4. Potential Modifications to Include Other PPE and Medical Devices

As noted in the CY 2023 OPPTS/ASC final rule, we received many comments urging CMS to expand this policy to cover other forms of PPE and critical medical supplies. A few commenters stated that other forms of PPE suffered shortages during the pandemic similar to surgical N95 respirators and therefore investing in domestic production for these products was also important for future emergency preparedness. We stated that we will consider these comments for future rulemaking if appropriate as we gain more experience with our policy. We seek comment on other PPE types and medical devices that could be appropriate for a similar payment adjustment.

G. Payment for HIV Pre-Exposure Prophylaxis (PrEP) in Hospital Outpatient Departments

On July 12, 2023, CMS proposed to cover Pre-Exposure Prophylaxis (PrEP) to prevent Human Immunodeficiency Virus (HIV) under Medicare Part B. This proposed coverage would include coverage for the HIV PrEP drugs, drug administration, HIV and hepatitis B screening, and individual counseling performed by either physicians or certain other health care practitioners. If finalized as proposed, all of the components would be covered as an additional preventive service without Part B cost-sharing (i.e., deductibles or co-pays), The final National Coverage Determination (NCD) has not been issued as of the issuance of this proposed rule.⁹⁸

The HCPCS codes that describe these services are described in Table 72.

TABLE 72: HCPCS Coding and Long Descriptors for HIV PrEP Drugs and Services

⁹⁸ <https://www.cms.gov/files/document/faq-prep-hiv-06242024.pdf>

HCPCS Code	Long Descriptor
J0739	Injection, cabotegravir, 1mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv)
J0750	Emtricitabine 200mg and tenofovir disoproxil fumarate 300mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)
J0751	Emtricitabine 200mg and tenofovir alafenamide 25mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)
G0011	Individual counseling for pre-exposure prophylaxis (prep) by physician or qualified health care professional (qhp)to prevent human immunodeficiency virus (hiv), includes hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence, 15-30 minutes
G0012	Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle
G0013	Individual counseling for pre-exposure prophylaxis (prep) by clinical staff to prevent human immunodeficiency virus (hiv), includes: hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence
J0799	Fda approved prescription drug, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), not otherwise classified

For CY 2025, we propose to pay for HIV PrEP drugs and related services as additional preventive services under the OPSS, if covered in the final NCD. We believe the resource costs for HCPCS codes listed in Table 72 would be similar across different settings of care, including the HOPD and physician office, and therefore the proposed policies for determining the payment amounts for these services in the CY 2025 PFS proposed rule would be appropriate for use under the OPSS as well. Therefore, we propose to pay for the HCPCS codes listed in Table 72 that are furnished in HOPDs in a similar manner as when these codes are furnished in the physician office.

HCPCS code G0012 (Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle) may be used to describe the injection of a PrEP drug for HIV prevention. For CY 2025, if covered as an additional preventative service, we propose to

assign this HCPCS code to APC 5692 (Level 2 Drug Administration) based on the crosswalk to HCPCS code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular) based on the anticipated similarity in resource use. For the HIV PrEP counseling services performed by hospital staff, specifically HCPCS code G0013, if covered as an additional preventative service, we are proposing to assign this service to a clinical APC with a payment rate that approximates the payment rate in the physician office setting. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website. We are not proposing to pay for HIV PrEP counseling performed by physicians under the OPPS as this is a physician-only service.

To determine the OPPS payment amount for HIV PrEP drugs we propose to utilize the ASP methodology under section 1847A of the Act when ASP data is available. As discussed in the CY 2025 PFS proposed rule, we believe the use of ASP data would be preferable for determining the payment amount for HIV PrEP, for two reasons. First, this approach would determine the payment amount for these drugs in the same way as the payment amount is usually determined for most other drugs that are separately payable under Part B, when possible. This would include the application of payment limit calculations for multiple source drugs, single source drugs and biologicals, and biosimilar biological products, as is done products under section 1847A of the Act, for each applicable billing and payment code. Second, because section 1847A(c)(3) of the Act requires that calculation of the manufacturer's ASP for an NDC must include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program, discounts under the 340B Program, and rebates under the Part B and Part D Medicare inflation rebate program), this would set a payment amount that would likely better reflect acquisition cost of the drug than list prices in available compendia (such as Wholesale Acquisition Cost (WAC)).

Specifically, for HIV PrEP drugs, if ASP data is not available for a particular drug, the PFS proposal describes the use of alternative pricing sources. As previously stated, we believe the resource costs should be similar regardless of whether HIV PrEP drugs are furnished in the HOPD or the physician office, and we propose to use the same method of utilizing alternative pricing sources for drugs paid under the OPPS as additional preventive services as is proposed under the PFS.

If ASP data for HIV PrEP is not available, we propose to determine the payment amount for the applicable billing and payment code using the most recently published amount for the drug in Medicaid's National Average Drug Acquisition Cost (NADAC) survey (OMB control number 0938-1041).⁹⁹ When using NADAC data, we propose to determine the payment amount per billing unit, which would be an average of NADAC prices for all NDCs for the drug. If a drug is available in generic and brand formulations, we propose all NDCs will be averaged together to determine the payment amount.

Most recently published for purposes of this policy means the most recently updated NADAC survey available 30 days after the close of the quarter for which ASP data would have been reported if it were available¹⁰⁰. For example, if NADAC is used to determine the payment amount effective for dates of service in the third calendar quarter, CMS would use the most recent NADAC survey update available on the 30th day after the close of the first calendar quarter. This survey provides a national drug pricing benchmark for certain drugs that is adequately comprehensive to serve as the first alternative pricing source in the case that ASP data is not available. CMS conducts surveys of retail community pharmacy prices to develop the NADAC pricing benchmark in the annual NADAC pricing file. The pricing benchmark is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-

⁹⁹ <https://www.medicaid.gov/medicaid/prescription-drugs/retail-price-survey/index.html>

¹⁰⁰ 42 CFR 414.804(a)(5)

counter covered outpatient drugs. NADAC data is publicly available and it can be accessed at <https://data.medicaid.gov/nadac>.

Since NADAC pricing is only available for drugs typically dispensed through retail community pharmacies, there could be circumstances in which ASP and NADAC are not available for HIV PrEP. Therefore, if both ASP and NADAC pricing data are not available for a DCAPS drug, we propose to use the most recently published and listed prices for pharmaceutical products in the Federal Supply Schedule (FSS) to calculate the payment amount for the applicable billing and payment code. Most recently published for purposes of this policy means the most recently updated FSS survey available 30 days after the close of the quarter for which ASP data would have been reported if it were available¹⁰¹. For example, if FSS is used to determine the payment amount effective for dates of service in the third calendar quarter, CMS would use the most recent FSS update available on the 30th day after the close of the first calendar quarter. When using the FSS, we would calculate the average price per billing unit (as described in the billing and payment code for the drug) for all NDCs listed for a drug. Drug pricing information, including 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/pharmPrices.asp>.

We propose to use FSS data when ASP and NADAC data are not available because FSS data is one of the few existing options for drug pricing that includes a wide variety of drug formulations, including both self-administered drugs typically dispensed through retail community pharmacies and drugs administered incident to a physician's service. For more details on this pricing methodology for the physician office setting, please see the CY 2025 PFS proposed rule.

¹⁰¹ 42 CFR 414.804(a)(5)

We note that the PFS proposal includes a final step of invoice pricing; however, invoice pricing is not currently available under the OPSS, so we are not proposing to adopt that portion of the PFS proposal. However, please see our Invoice Drug Pricing Proposal for CY 2026 in section V.B.2.d. of this proposed rule. Because invoice pricing is not available in the OPSS currently, we propose that if ASP, NADAC, and FSS pricing are not available for a particular drug covered as an additional preventive service, we will use WAC plus 6 percent, or 3 percent if in an initial sales period, consistent with payment for separately payable drugs paid under the OPSS. This would result in different pricing between the OPSS and PFS if ASP, NADAC, and FSS pricing are not available, but we believe it is appropriate because invoice pricing is not an option under the OPSS and this pricing metric should only apply to a small subset of drugs covered as additional preventive services until one of the other pricing metrics becomes available. We are proposing to treat other drugs covered as additional preventative services under this same methodology.

If the HIV PrEP drugs are covered as additional preventative services, we propose to update the payment rates determined using the methodologies previously summarized on January 1, 2025 or the date of coverage, whichever is later, which would be further updated on the same schedule as the ASP pricing file, which is updated each calendar quarter. We propose to assign the drug products covered as additional preventive services to status indicator K (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals; Paid under OPSS; separate APC payment), as this status indicator identifies drugs and biologicals that are separately paid under the OPSS and therefore would allow us to operationalize separate payment for PrEP drugs. If the HIV PrEP drugs are covered as additional preventative services, on January 1, 2025 or the date of coverage, whichever is later, we propose that we would assign each HIV PrEP drug covered as an additional preventative to its own APC, which will have a payment rate assigned according to the previously defined methodology.

HCPCS code J0799 (Hiv prep, fda approved, noc) was created effective January 2, 2024, and may be used to describe an HIV PrEP drug that is FDA approved but is not otherwise classified. We propose to pay 95 percent of AWP for HCPCS code J0799, which is consistent with how unlisted drugs and biologicals are paid under the OPSS when they are reported with HCPCS code C9399 (Unclassified drugs or biologicals). As HCPCS code J0799 and HCPCS code C9399 both describe drugs that are unclassified or not otherwise classified, we believe the payment methodologies should be similarly aligned. 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 OPSS 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 AWP for the drug or biological.

In the CY 2005 OPSS/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 FDA and that does not yet have a HCPCS code by reporting the 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 Shared Systems 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. While the statute does not require drugs that are covered as additional preventive services to be paid at 95 percent of AWP when not assigned to a product specific HCPCS code, we believe it would be appropriate to create a parallel policy given that HCPCS code J0799 and HCPCS code C9399 both describe drugs that are unclassified or not otherwise classified. As the payment amount for HCPCS code C9399 is statutorily mandated at 95 percent of AWP, we believe that the payment amount for HCPCS code J0799 should also be 95 percent of AWP.

Therefore, we propose to establish an identical payment policy for HCPCS code J0799, which may be used to describe drugs that are FDA-approved for PrEP and are covered as additional preventive services. In order to effectuate payment at 95 percent of AWP, we propose to require hospitals to bill for a drug that is newly FDA approved for HIV PrEP, and covered as an additional preventive service, and that does not yet have a HCPCS code, by reporting the NDC for the product along with the newly created HCPCS code J0799. Similar to HCPCS code C9399, when HCPCS code J0799 appears on a claim, the Shared Systems will suspend the claim for manual pricing by the MAC. The MAC would price the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and process the claim for payment. This approach would enable hospitals to bill and receive payment for a drug that is newly FDA approved for HIV PrEP and covered as an additional preventive service concurrent with its approval by the FDA. The hospital would 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 to resubmit claims for adjustment. We would instruct hospitals to 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.

Finally, if covered as an additional preventive service, we propose to assign all HCPCS codes describing pharmacy supplying fees for HIV PrEP to an OPPS status indicator of "B". This

follows the longstanding OPPS practice of assigning HCPCS codes that describe a pharmacy supply or dispensing fee to status indicator “B” (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x); Not paid under OPPS), such as HCPCS code Q0512 (Pharmacy supply fee for oral anti-cancer, oral anti-emetic or immunosuppressive drug(s); for a subsequent prescription in a 30-day period) and HCPCS code Q0513 (Pharmacy dispensing fee for inhalation drug(s); per 30 days).

H. Payment Policy for Devices in Category B Investigational Device Exemption (IDE) Clinical Trials Policy and Drugs/Devices with a Medicare Coverage with Evidence Development (CED) Designation

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72027), and as authorized by section 1833(w) of the Act, we finalized a policy to make a single blended payment for devices and services in Category B IDE studies in order to preserve the scientific validity of these studies by avoiding differences in Medicare payment methods that would otherwise reveal the group (treatment or control) to which a patient has been assigned. Specifically, we codified our process of utilizing a single packaged payment for Category B IDE studies, including the cost of the device and routine care items and services, in the regulation text for payment to hospitals in a new § 419.47. We provided in new § 419.47(a) and (b) that CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which will include both the treatment and control arms, related device(s) of the study, as well as routine care items and services, as specified under 42 CFR 405.201, when CMS determines that the Medicare coverage IDE study criteria at § 405.212 are met, and a new or revised code is necessary to preserve the scientific validity of the IDE study, such as by preventing the unblinding of the study. We finalized that the single blended payment rate would be dependent on the specific trial protocol and would account for the frequency with which the investigational device is used compared to the control where the investigational device is not used. For example, in a study for which CMS determines the Medicare coverage IDE study

criteria in § 405.212 are met and where there is a 1:1 assignment of the device to control (no device), Medicare's payment rate would prospectively average the payment for the device with the zero payment for the control in a 1:1 ratio. Furthermore, costs for routine care items and services in the study, as specified under § 405.201, would be included in the single blended payment (87 FR 72026 through 72027).

Since implementing this policy, we have heard from interested parties that our regulation at § 419.47(a) and (b) excluded clinical trials for which there is no control arm. We appreciate the input. Category B IDE studies with no control arm would be paid normally because an alternative payment methodology would not be necessary to preserve their scientific validity. Our policy at § 419.47 applies only to IDE studies with a control arm and where a payment adjustment is necessary to preserve the scientific validity of such a study. The rule was not intended to suggest that CMS will not pay for Category B IDEs with no control arm, provided the studies meet the coverage criteria. In those circumstances, Medicare payments would be made using the usual Medicare payment methodologies.

In many instances, requests for coding and payment for devices in Category B IDE studies are submitted through our New Technology APC application process and include the submission of cost information. However, we have encountered difficulties determining accurate payment rates for Category B IDE studies in the absence of New Technology APC applications such as when coding for Category B IDE studies is developed through the CPT Editorial Panel process. We encourage interested parties to use the New Technology APC application process where applicable to submit cost information to CMS. Absent information on the resource costs associated with the services and devices in a Category B IDE study, we may assign a SI of E2 to indicate an item, code or service for which pricing information and claims data are not available, and, therefore, the item, code or service is not paid by Medicare when submitted by an outpatient claim.

For CY 2025, we are proposing to utilize a payment methodology similar to the one developed for Category B IDE clinical trials for drugs and devices covered under a national coverage determination (NCD) that uses the Coverage with Evidence Development (CED) paradigm and a payment adjustment is necessary to preserve the scientific validity of such a study. Specifically, we propose to use our authority at section 1833(w) of the Act to develop alternative methods of payment under Medicare Part B for drugs and devices being studied in clinical trials under a CED NCD. These CED NCDs will be listed on the CMS CED website.¹⁰²

Similar to our policy on devices in Category B IDE trials, for devices under a CED NCD, we propose to make a single blended payment rate that would be dependent on the specific trial protocol and would account for the frequency with which the investigational device is used compared to the control where the investigational device is not used. For example, in a study for which there is a 1:1 assignment of the device to control (no device), Medicare's payment rate would prospectively average the payment for the device with the zero payment for the control in a 1:1 ratio.

As described previously and when necessary to preserve the scientific validity of the study, we propose to make payment using an adjusted payment level representing the frequency with which the study drug and placebo, or comparator drug, is furnished. A placebo, or comparator drug, could represent what a beneficiary would typically receive in order to serve as a comparator to assess the effectiveness, or therapeutic benefit, of the study drug. These adjusted payments would protect the scientific validity of the trial by avoiding differences in Medicare payment methods that could otherwise invalidate the scientific validity of the trial, such as by revealing the group (treatment or control) to which a patient has been assigned. We propose to base the payment amount for the study drug, or active comparator drug, on the ASP methodology, that is ASP plus 6 percent if ASP data is available. If ASP data is not available,

¹⁰² <https://www.cms.gov/medicare/coverage/evidence>

then we propose to pay the wholesale acquisition cost (WAC). During an initial sales period, we propose to base the payment on WAC plus 3 percent, otherwise, we propose to base payment on WAC plus 6 percent. If WAC is not available, then we propose to pay 95 percent of average wholesale price (AWP). This payment hierarchy is consistent with CMS payment for non-passthrough separately payable drugs in the OPPS as discussed in section V.B. of this proposed rule.

These payment amounts would be used to calculate the adjusted payment level representing the frequency with which the study drug and placebo, or comparator drug, is furnished. For purposes of setting this adjusted payment level, we propose to use a zero dollar amount for a placebo or comparator. A new, or revised, HCPCS code would be created for the drug and placebo or comparator in the CED study. We propose that we would assign this HCPCS code to its own APC reflecting the payment amount determined appropriate based on available pricing information and the frequency with which the study drug and placebo, or comparator drug, is used.

For example, as most drugs are currently paid per dosage unit, such as per 1 mg, a payment rate, potentially priced per 1 mg of drug, placebo, or active comparator, might be based on the average sales price methodology for the drug averaged with a zero-dollar payment for the placebo, or the applicable payment rate of the comparator drug. A single averaged payment would be made regardless of whether 1 mg of study drug, 1 mg of placebo, or 1 mg of comparator drug is used. If the trial is a 1:1 (treatment: placebo) then the payment rate would be the same for every trial participant and would represent half of the total payment for the drug. In a simplified example, if the ASP plus 6 percent payment rate for Drug X was \$1 per 1 mg then in this example, the payment rate for the blended code of Drug X and placebo would be \$0.50 per 1 mg. If a beneficiary received 100 mg of the study drug, then a \$50 payment would be made. If a beneficiary received 100 mg of the placebo, then a \$50 payment would be made. The same HCPCS code would be billed in both the study drug and placebo examples. The same payment

methodology would apply if the study design was 1:2 (treatment: placebos, which equals payment at 1/3 the cost of the study drug) or 1:3 (treatment: placebos, which equals payment at 1/4 the cost of the study drug). In situations where there are multi-arm, or single-arm, cross over trials where participants receive placebo, or sham, for the first half of the trial and then the study drug for the second half of the trial, the payment would be reflective of this, and set in the same manner as a 1:1 trial, since half of the time the beneficiary would receive the placebo and the other half they would receive the study drug. No matter the trial design, CMS payment would be reflective of the expected frequency with which the study treatment, control, active comparator, or placebo is provided. We note that we propose to assign payment rates based on an adjusted payment level representing the frequency with which the study drug and placebo, or comparator drug, is projected to be furnished for the trial as a whole, and not necessarily the exact frequency with which the study drug and placebo, or comparator drug, is furnished to a particular hospital enrolled as a clinical trial site. Clinical trial sponsors should work with CMS to ensure timely establishment of payment and coding for drugs being studied under a CED designation requiring an adjusted level of payment.

While the items and services furnished as placebo controls may not be considered reasonable and necessary under section 1862(a)(1)(A) of the Act because they have no health benefit, these items and services can be necessary in order to conduct a scientifically valid clinical study. As such, these items can be covered under section 1862(a)(1)(E) of the Act when furnished in the context of a qualifying clinical study.¹⁰³

CMS may cover and pay for routine costs of an approved clinical trial in both the treatment arm and the control (standard of care or placebo). Routine costs include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a

¹⁰³ Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development. November 20, 2014. <https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27>

benefit category for the item or service, coverage is not statutorily excluded for the item or service, and there is not a national non-coverage decision for the item or service) that are provided in either the experimental or the control arms of a clinical trial. Although CMS may cover and pay for routine costs of an CED approved clinical trial in both the treatment arm and the control (standard of care or placebo), there may be circumstances, such as single arm studies, where no unique coding or unique payment would be required to preserve the scientific validity of such a study created for routine costs associated with clinical trials. Similarly, if the routine costs are the exact same between different arms of a trial, and routine billing and payment of those routine costs would not unblind a study, then no unique coding or payment would be required for those costs. There would be no need to include these routine costs in the HCPCS code assigned to a blended payment rate. If covered, these routine costs would be paid according to existing coding and Medicare payment mechanisms. Under the proposed rule an alternate method of payment would be established only when necessary to maintain the scientific validity of the trial, such as to prevent the billing and payment of routine costs from unblinding the trial. These determinations will be made based on the clinical trial protocol communicated to CMS by the clinical trial sponsor, before CMS would establish an appropriate code with an adjusted payment level for routine costs for CED trials. CMS's determination will be different in CED trials from our policy regarding devices and procedures in Category B IDE trials, where the provision of an investigational device usually requires a combination of procedures or services to implant, or administer, the device to a patient. In contrast, the infusion of a drug is typically a more straightforward process, and associated routine costs may not be provided at the same time that the drug is administered, making it impractical to create a single code to describe the study drug and all associated routine costs.

Finally, we want to be sure there are no other instances where Medicare payment methodologies might interfere with the scientific validity of a trial. We are seeking comment on these possible alternative scenarios, such as Medicare payment interfering with clinical trial

recruitment in such a way that could compromise the scientific integrity of a clinical trial and would consider adjustments to our payment policy for devices in Category B IDE clinical trials and devices/drugs in clinical trials with a CED designation in future rulemaking.

We propose to codify our coding and payment policy to Category B IDE clinical trials with control arms through revisions to § 419.47(a) to specify that these are placebo control arms. We also propose to codify our proposed process for developing coding and payment for devices/drugs in CED-designated clinical trials by adding new paragraphs (c) and (d) to § 419.47. Specifically, we propose to provide in new § 419.47(c) that CMS would create a new HCPCS code, or revise an existing HCPCS code, to describe a device/drug studied in a clinical trial with the Medicare CED designation, which would include the study device/drug and control arm, when CMS determines it is necessary to establish a CED designation for a device/drug subsequent to a CED NCD. Additionally, in new § 419.47(d) we propose that when we create a new HCPCS code or revise an existing HCPCS code under proposed paragraph (c), we would make a single payment for the HCPCS code that includes payment for the investigational device/drug and any control.

XI. Proposed CY 2025 OPPS Payment Status and Comment Indicators

A. Proposed CY 2025 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.

For CY 2025 and subsequent years, we propose to create two new status indicators, “K1” and “H1.” We propose these two new status indicators to identify the products that qualify for separate payment under our new payment policy for non-opioid post-surgical pain management drugs, biologicals, and devices, as authorized by section 4135 of the Consolidated Appropriations Act, 2023. This policy is discussed further in section XIII.E of this proposed

rule. The proposed definitions and payment status of proposed status indicators "K1" and "H1" can be found in Table 73.

TABLE 73: PROPOSED DEFINITIONS AND PAYMENT STATUS OF PROPOSED STATUS INDICATORS K1 AND H1

Proposed Status Indicator	Proposed Descriptor	Proposed OPSS Payment Status
K1	Non-Opioid Drugs and Biologicals For Post-Surgical Pain Relief	Paid under OPSS; separate APC payment. Subject to criteria and payment limitation under Section 4135 of the CAA, 2023.
H1	Non-Opioid Medical Devices For Post-Surgical Pain Relief	Separate payment based on hospital's charges adjusted to cost. Subject to criteria and payment limitation under Section 4135 of the CAA, 2023.

For CY 2025 and subsequent years, we propose to modify the definition of status indicator "K" to remove the word "therapeutic" from the phrase "therapeutic radiopharmaceuticals" to indicate that both diagnostic and therapeutic radiopharmaceuticals may be assigned to status indicator "K" in accordance with our policy proposal in section II.A.3.a. of this proposed rule. The proposed definition and payment status of status indicator "K" can be found in Table 74.

TABLE 74: PROPOSED DEFINITIONS AND PAYMENT STATUS OF STATUS INDICATOR K

Proposed Status Indicator	Proposed Descriptor	Proposed OPSS Payment Status
K	Nonpass-Through Drugs and Nonimplantable Biologicals, Including Radiopharmaceuticals	Paid under OPSS; separate APC payment.

We do not propose to make any other changes to the existing definitions of status indicators that are listed 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-notice>.

The complete list of proposed CY 2025 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-notice>.

The proposed CY 2025 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-notice>.

B. Proposed CY 2025 Comment Indicator Definitions

We propose to use four comment indicators for the CY 2025 OPSS. These comment indicators, “CH,” “NC,” “NI,” and “NP,” are in effect for CY 2024; and we propose to continue their use in CY 2025. The proposed CY 2025 OPSS 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 CY 2024 OPSS/ASC 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 OPSS comment indicators for CY 2025 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-notice>.

We solicit public comments on our proposed definitions of the OPSS comment indicators for 2025.

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 stakeholders aware of certain MedPAC recommendations for the OPSS and ASC payment systems as discussed in its March 2024 report.

A. OPSS Payment Rates Update

The March 2024 MedPAC “Report to the Congress: Medicare Payment Policy,” recommended that Congress update Medicare OPSS payment rates by the amount specified in current law plus 1.5 percent. We refer readers to the March 2024 report for a complete discussion of this recommendation.¹⁰⁴ We appreciate MedPAC’s recommendation and, as

¹⁰⁴ Medicare Payment Advisory Committee. March 2024 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, p.49. Available at: <https://www.medpac.gov>.

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 2024 MedPAC “Report to the Congress: Medicare Payment Policy,” MedPAC stated that their recommended update to IPPS and OPPS payment rates of current law plus 1.5 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 a MSNI policy.

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.

C. ASC Cost Data

In the March 2024 MedPAC “Report to the Congress: Medicare Payment Policy,” MedPAC reiterated its longstanding recommendation that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs’ costs over time and analyze Medicare payments relative to the costs of efficient providers. MedPAC suggested that such cost data would enable policymakers to establish payment rates that accurately reflect ASC costs and are also necessary to determine whether an existing Medicare market basket is an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed, stating both the CPI-U and hospital market basket update likely do not reflect an ASC’s cost structure. MedPAC contended that it is feasible for small facilities, such as ASCs, to provide cost information since other small facilities, such as home health agencies, hospices, and rural health

clinics, currently furnish cost data to CMS. Further, ASCs in Pennsylvania submit cost and revenue data annually to a state agency to estimate margins for those ASCs, and that, as businesses, ASCs keep records of their costs for filing taxes and other purposes.¹⁰⁵

While we recognize that the submission of cost data could place additional administrative burden on most ASCs, and we do not propose any cost reporting requirements for ASCs in this proposed rule, as in previous years, we continue to seek public comment on methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. Such cost data would be beneficial in establishing an ASC-specific market basket for updating payment rates under the ASC payment system.

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 2024 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; and 88 FR 81900 through 81961).

¹⁰⁵ Medicare Payment Advisory Committee. March 2024 Report to the Congress. Chapter 10: Ambulatory surgical center services: Status report, p.297. Available at: https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC.pdf.

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, and payment rates for, 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 2025 OPPTS/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 this proposed rule (and respond to those comments in the CY 2025 OPPTS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2025 OPPTS/ASC final rule with comment period (and responding to those comments in the CY 2026 OPPTS/ASC final rule with comment period).

1. April 2024 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2024 update, there were no new CPT codes; however, there were several new Level II HCPCS codes. In the April 2024 ASC quarterly update (Transmittal 12559, dated March 28, 2024, CR 13577), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 75 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2024) of this proposed rule, lists the new Level II HCPCS codes that were implemented April 1, 2024. 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, 2024, 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 are available via the internet on the CMS website.

- ASC Addendum AA: Proposed ASC Covered Surgical Procedures for CY 2025 (Including Surgical Procedures for Which Payment is Packaged),
- ASC Addendum BB: Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for CY 2025 (Including Ancillary Services for Which Payment is Packaged),
- ASC Addendum DD1: Proposed ASC Payment Indicators (PI) for CY 2025,
- ASC Addendum DD2: Proposed ASC Comment Indicators (CI) for CY 2025,
- ASC Addendum EE: Proposed Surgical Procedures to be Excluded from Payment in ASC for CY 2025, and
- ASC Addendum FF: Proposed ASC Device Offset Percentages for CY 2025
- Addendum O: Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-codes, and G-Codes Effective January 1, 2025

We invite public comments on the proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2024 through the quarterly update CRs, as listed in Table 75 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2024) of this proposed rule. We propose to finalize their payment indicators in the CY 2025 OPPTS/ASC final rule with comment period.

TABLE 75: NEW LEVEL II HCPCS CODES FOR ASC COVERED ANCILLARY SERVICES EFFECTIVE APRIL 1, 2024

CY 2024 HCPCS Code	CY 2024 Long Descriptor
C9166	Injection, secukinumab, intravenous, 1 mg
C9167	Injection, adamts13, recombinant-krhn, 10 iu
C9168	Injection, mirikizumab-mrkz, 1 mg
J0177	Injection, aflibercept hd, 1 mg
J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy

J0578	Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit
J0651	Injection, levothyroxine sodium (fresenius kabi) not therapeutically equivalent to J0650, 10 mcg
J0652	Injection, levothyroxine sodium (hikma) not therapeutically equivalent to J0650, 10 mcg
J1203	Injection, cipaglucoasidase alfa-atga, 5 mg
J1323	Injection, elranatamab-bcmm, 1 mg
J2277	Injection, motixafortide, 0.25 mg
J2782	Injection, avacincaptad pegol, 0.1 mg
J2801	Injection, risperidone (rykindo), 0.5 mg
J3055	Injection, talquetamab-tgvs, 0.25 mg
J3424	Injection, hydroxocobalamin, intravenous, 10 grams
J7165	Injection, prothrombin complexconcentrate, human-lans, per i.u. of factor ix activity
J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)
J9073	Injection, cyclophosphamide (ingenus), 5 mg
J9075	Injection, cyclophosphamide, not otherwise specified, 5 mg
J9248	Injection, melphalan (hepzato), 1 mg
Q4305	American amnion ac tri-layer, per square centimeter
Q4306	American amnion ac, per square centimeter
Q4307	American amnion, per square centimeter
Q4308	Sanopellis, per square centimeter
Q4309	Via matrix, per square centimeter
Q4310	Procenta, per 100 mg

2. July 2024 HCPCS Codes Proposed Rule Comment Solicitation

In the July 2024 ASC quarterly update (Transmittal 12673, Change Request 13656, dated June 13, 2024), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 76 (New HCPCS Codes for Covered Surgical Procedures and Covered Ancillary Services Effective July 1, 2024) of this proposed rule, lists the new HCPCS codes that are effective July 1, 2024. 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, 2024, 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 76: NEW LEVEL II HCPCS CODES FOR ASC COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2024

CY 2024 HCPCS Code	CY 2024 Long Descriptor
A9506	Graphite crucible for preparation of technetium Tc 99m-labeled carbon aerosol, each
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation
C1606	Adapter, single-use (i.e. disposable), for attaching ultrasound system to upper gastrointestinal endoscope
J0211	Injection, sodium nitrite 3 mg and sodium thiosulfate 125 mg (nithiodote)
J0687	Injection, cefazolin sodium (wg critical care), not therapeutically equivalent to j0690, 500 mg
J0872	Injection, daptomycin (xellia), unrefrigerated, not therapeutically equivalent to j0878 or j0873, 1 mg
J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for esrd on dialysis adult patients receiving chronic hemodialysis)
J3247	Injection, secukinumab, intravenous, 1 mg
J3263	Injection, toripalimab-tpzi, 1 mg
J3393	Injection, betibeglogene autotemcel, per treatment
J3394	Injection, lovoibeglogene autotemcel, per treatment
J7171	Injection, adamts13, recombinant-krhn, 10 iu
J7355	Injection, travoprost, intracameral implant, 1 microgram
J8611	Methotrexate (jylamvo), oral, 2.5 mg
J8612	Methotrexate (xatmep), oral, 2.5 mg
0621T	Trabeculectomy ab interno by laser;
0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater than or equal to 50 mL
0869T	Injection(s), bone-substitute material for bone and/or soft tissue hardware fixation augmentation, including intraoperative imaging guidance, when performed
0884T	Esophagoscopy, flexible, transoral, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for esophageal stricture, including fluoroscopic guidance, when performed
0885T	Colonoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed
0886T	Sigmoidoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed
0888T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant

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, 2024 and July 1, 2024, through the quarterly update CRs, as listed in Tables 75 and 76. We propose to finalize the payment indicators in the CY 2025 OPPS/ASC final rule with comment period.

3. October 2024 HCPCS Codes Final Rule Comment Solicitation

For CY 2025, consistent with our established policy, we propose that the Level II HCPCS codes that will be effective October 1, 2024, would be flagged with comment indicator “NI” in Addendum BB to the CY 2025 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment status for CY 2024. We will invite public comments in the CY 2025 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2026 OPPS/ASC final rule with comment period.

5. January 2025 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 2025 OPPS/ASC final rule with comment period, January 2025 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2025, 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, 2025, 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 2025 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2026 OPPS/ ASC final rule with comment period.

b. CPT Codes Proposed Rule Comment Solicitation

For the CY 2025 ASC update, we received the CPT codes that will be effective January 1, 2025, 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 2025 OPPS/ASC final rule with comment period. Further, we remind readers that the CPT code descriptors that appear 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 include the 5-digit placeholder codes and their long descriptors for the new CY 2025 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 2025 OPPS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code.” We intend to include the final CPT code numbers the CY 2025 OPPS/ASC final rule with comment period.

In summary, we solicit public comments on the proposed CY 2025 payment indicators for the new Category I and III CPT codes that will be effective January 1, 2025. 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 2025 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, 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 payment indicator and that comments will be accepted on their interim 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 77, 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 77: 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 2024	HCPCS (CPT and Level II codes)	April 1, 2024	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
July 2024	HCPCS (CPT and Level II codes)	July 1, 2024	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
October 2024	HCPCS (CPT and Level II codes)	October 1, 2024	CY 2025	CY 2026

			OPPS/ASC final rule with comment period	OPPS/ASC final rule with comment period
January 2025	CPT Codes	January 1, 2025	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2025	CY 2025 OPPS/ASC final rule with comment period	CY 2026 OPPS/ASC final rule with comment period

6. ASC Payment and Comment Indicators

a. Background

In addition to the payment indicators that we introduced in the August 2, 2007 ASC final rule, 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, or NTIOLs.

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 OPPTS/ASC final rule with comment period (74 FR 60622).

The comment indicator “NP” is used in the OPPTS/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 OPPTS/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 OPPTS/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 OPPTS/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).

b. Proposed ASC Payment and Comment Indicators for CY 2025

For CY 2025, 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 2025 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2025, compared to the CY 2024 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 2025 OPPS/ASC proposed rule.

We propose to modify the descriptor of ASC payment indicator “L6” – “New Technology Intraocular Lens (NTIOL); special payment” 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. More information about this non-opioid policy can be found in section XIII.E of this proposed rule.

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 2025 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 OPFS 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 OPFS/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 OPSS. Under the OPSS, 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 OPSS are always packaged (payment indicator “N1”) under the ASC payment system. Under the OPSS, 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 OPSS (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 2025

We propose to update ASC payment rates for CY 2025 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 OPSS 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 2025 device offset percentages that have been calculated using the standard OPSS APC ratesetting methodology. We propose that payment for office-based procedures would be at the lesser of the proposed CY 2025 MPFS nonfacility PE RVU-based amount or the proposed CY 2025 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2024, for CY 2025, we propose to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPSS (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 OPSS

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 OPSS.

(1) OPSS C-APC Complexity Adjustment Policy

Under the OPSS, 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 2025, 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-notice>).

(2) CY 2025 ASC Special Payment Policy Proposal for OPSS Complexity-Adjusted C-APCs

For CY 2025, we propose to continue the special payment policy and methodology for OPSS complexity-adjusted C-APCs that was finalized in the CY 2023 OPSS/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 2025. 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 2025 can be found in the ASC addenda and the supplemental policy file, which also includes both the existing ASC complexity adjustment codes and proposed additions, is published with the proposed rule on the CMS website at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/asc-regulations-and-notice>. Since the complexity adjustment assignments change each year under the OPSS, the proposed list of ASC complexity adjustment codes eligible for this proposed payment policy has changed slightly from the previous year.

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 this proposed rule, the ASC payment system generally uses OPSS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology.

In the CY 2022 OPSS/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 and shown in Table 78. The four clinical APCs and six brachytherapy APCs meet our criteria of having fewer than 100 single claims in the relevant claims year (CY 2023 for this CY 2025 OPSS/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 2024. Based on data for the CY 2025 OPSS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, hold-198) now meets our criteria to be designated a low volume APC; and we propose to designate it as such for CY 2025.

Table 78 includes the CY 2023 claims available for ratesetting for each of the APCs we propose be designated as low volume APCs for CY 2025. The cost statistics for our proposed 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/ambulatory-surgical-center-asc/asc-regulations-and-notice>; click on the relevant regulation to download the low volume APC cost statistics under the standard (ASC) ratesetting methodology in the downloads section of the web page.

TABLE 78: PROPOSED LOW VOLUME APCS USING STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2025

APC	APC Description	CY 2023 Claims Available for Ratesetting
2632	Iodine I-125 sodium iodide	0*
2635	Brachytx, non-str, HA, P-103	13
2636	Brachy linear, non-str, P-103	1
2642	Brachytx, stranded, C-131	90
2645	Brachytx, non-str, gold-198	86
2647	Brachytx, NS, Non-HDRIr-192	2
5244	Level 4 Blood Product Exchanges and Related Services	2
5494	Level 4 Intraocular Procedures	15
5495	Level 5 Intraocular Procedures	37
5496	Level 6 Intraocular Procedures	14

* For the CY 2025 OPPTS/ASC proposed rule, there were no CY 2023 claims that contain the HCPCS code assigned to APC 2632 (HCPCS code A9527) available for ratesetting.

2. 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 OPPTS. 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 OPPTS 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 OPPTS.

In the CY 2013 OPSS/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 OPSS (status indicators “Q1” and “Q2”). Under the OPSS, 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 OPSS are generally packaged (payment indicator “N1”) under the ASC payment system (except for device removal procedures, as discussed in the CY 2022 OPSS/ASC proposed rule (86 FR 42083)). Thus, our policy generally aligns ASC payment bundles with those under the OPSS (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 OPSS at the OPSS rates and package payment for drugs and biologicals for which payment is packaged under the OPSS. However, as discussed in the CY 2022 OPSS/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 OPSS/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 invoiced 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 OPSS 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 OPSS pass-through payment status.

In the CY 2015 OPSS/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 OPSS 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 OPSS/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 Services for CY 2025

We propose to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPSS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2025 OPSS and ASC payment rates and subsequent years' payment rates. We also propose to continue to set

the CY 2025 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 2025 and subsequent years' payment rates.

Covered ancillary services and their proposed payment indicators for CY 2025 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 final 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, 2025. For a discussion of the PFS rates, we refer readers to the CY 2025 PFS proposed rule, which is available on the CMS website at: <https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notice>.

3. Covered Surgical Procedures Designated as Office-Based Procedures

a. Background

In the August 2, 2007 ASC final rule, 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 2025 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 (described in detail in section XIII.C.1.d of this proposed rule), including their potential designation as office-based. Historically, we would also review the most recent claims volume and utilization data (CY 2023 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2024 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 2023 OPPS/ASC final rule with comment period (86 FR 63769 through 63773).

Our review of the CY 2023 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 two surgical procedures that we believed met the criteria for designation as permanently

office-based. The data indicate that these procedures are 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. The CPT codes that we propose to permanently designate as office-based for CY 2025 are listed in Table 79.

TABLE 79: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2025

CY 2024 CPT/HCPCS Code	Long Descriptor	Final CY 2024 ASC Payment Indicator	Proposed CY 2025 ASC Payment Indicator*
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision	G2	P3*
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)	G2	P2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2025 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2025 PFS proposed rule.

As discussed in the August 2, 2007 ASC final rule (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.

We reviewed CY 2023 volume and utilization data for nine surgical procedures designated as temporarily office-based in the CY 2023 OPPI/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically “P2,” “P3,” or “R2.” In Table 122 of the CY 2024 OPPI/ASC final rule with comment period, we finalized assigning temporary office-based designations to seven surgical procedures for CY 2024 (88 FR 81919). As shown in Table 80, for one of the seven surgical procedures, there

was greater than 50 claims available and the volume and utilization data 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 80: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED FOR CY 2025

CY 2024 CPT/HCPCS Code	Long Descriptor	Final CY 2024 ASC Payment Indicator	Proposed CY 2025 ASC Payment Indicator*
67516	Suprachoroidal space injection of pharmacologic agent (separate procedure)	P3	P3*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2025 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2025 PFS proposed rule.

For six of the seven procedures that were designated as temporarily office-based in the CY 2023 OPPI/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 amount to determine if the office setting was the predominant setting of care for these procedures. Therefore, as shown in Table 81, we propose to continue to designate such procedures as temporarily office-based for CY 2025 and assign one of the office-based payment indicators.

For CY 2025, we propose to designate three new CY 2025 CPT codes for ASC covered surgical procedures as temporarily office-based—CPT codes XX34T (Removal of integrated neurostimulation system, vagus nerve), 15XX3 (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 5XX06 (Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate). After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that CPT code XX34T is most similar to 0588T, which is temporarily designated as

an office-based surgical procedure. Additionally, CPT code 15XX3 is 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), which is designated as an office-based surgical procedure. Lastly, CPT code 5XX06 is most similar to CPT code 51705 (Change of bladder tube) which is also designated as an office-based surgical procedure. Therefore, as shown in Table 81, we propose to also designate these three new CPT codes as temporarily office-based for CY 2025.

TABLE 81: PROPOSED CY 2025 PAYMENT INDICATORS FOR NEW AND EXISTING ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2024 CPT/HCPCS Code / CY 2025 Placeholder Code	Long Descriptor	Final CY 2024 ASC Payment Indicator	Proposed CY 2025 ASC Payment Indicator*
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	R2	J8*
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*
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	R2	R2*
XX34T	Removal of integrated neurostimulation system, vagus nerve	NA	R2*
15XX3	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	NA	R2*
5XX06	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate	NA	P3*
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	R2	R2*
65785	Implantation of intrastromal corneal ring segments	P3	P3*

CY 2024 CPT/HCPCS Code / CY 2025 Placeholder Code	Long Descriptor	Final CY 2024 ASC Payment Indicator	Proposed CY 2025 ASC Payment Indicator*
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	R2	J8*
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*
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	R2	R2*
XX34T	Removal of integrated neurostimulation system, vagus nerve	NA	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 proposed rates according to the ASC standard ratesetting methodology and the CY 2025 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2025 PFS proposed rule.

The procedures for which the proposed office-based designation for CY 2025 is temporary are 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 OPSS/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 2025 Proposed Device Intensive Procedures

In the CY 2019 OPSS/ASC final rule with comment period (83 FR 59040 through 59043), for CY 2019, 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 OPPI/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 OPPI/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 OPSS/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 OPSS (as listed in Addendum J). Each ASC complexity adjustment code's APC assignment is based on its corresponding OPSS complexity adjustment code's APC assignment. In the CY 2023 OPSS/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 OPSS 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.

As discussed in section IV.B of this proposed rule, the purpose of applying the default device offset percentage to new codes that describe procedures that implant or insert devices is to ensure access in the ASC setting for new procedures until claims data become available. Our ratesetting methodology sets the ASC device offset amount constant at the OPSS device offset amount. Device offset amounts under the OPSS and ASC Payment System are the device offset percentages of a procedure multiplied by the OPSS or ASC Payment System payment rate, respectively, for that procedure. While the ASC ratesetting methodology relies on the ASC

conversion factor and the scaled OPPS APC relative weights to construct ASC payment rates, for device-intensive procedures, the device offset percentage of the procedure relies on the higher OPPS conversion factor while the non device portion relies on the lower ASC conversion factor. For non device-intensive procedures for which the payment is based on OPPS relative payment weight, one hundred percent of the procedure's payment rate relies on the ASC conversion factor. Therefore, the greater the device offset percentage under the ASC Payment System, the greater the ASC payment rate.

Device offset percentages, which represent the device cost portion of a procedure's total cost, are determined using the most recent claims data for that procedure. For newer procedures that describe procedures which implant or insert single-use devices that meet our definition of a device and for which the device costs are estimated to be greater than 30 percent of the total procedure cost and lack claims data, we have relied on several policies to determine an appropriate device offset percentage until such claims data becomes available. First, if the new procedure has claims data from a predecessor code, as described by CPT coding guidance, we rely on claims data from the predecessor code in assigning the device offset percentage for the new HCPCS code (88 FR 81919 through 81922). Second, in limited instances where a new device-intensive procedure does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we may 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 use the claims data of the clinically related or similar code(s) for purposes of determining whether to use the device offset percentage of the clinically related or similar code(s) or 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 device(s). If the new device-intensive procedure does not have claims data from a predecessor code or a clinically similar code that uses the same device, we have assigned a default device offset percentage of 31

percent. While we do allow for additional information in our consideration of a higher offset percentage than the default device offset, our payment policies under both the OPSS and ASC Payment System are meant to encourage efficiencies and promote savings to the Medicare program and we believe relying on claims data rather than external pricing data helps put downward pressure on changes in medical device prices. Therefore, it would be extremely rare that the appropriate determination of a device offset percentage would rely on pricing data or invoices from a device manufacturer rather than the default device offset percentage.

However, we are aware that there may be certain situations where newer device-intensive procedures lack claims data from a predecessor code and a clinically similar code that uses the same device, but the default device offset percentage would not adequately reflect the existing device portion of the procedure's costs when compared to the cost of similar devices. The difference in the default device portion and the potential device cost could possibly limit access to newer, more complex, device-intensive procedures in the ASC setting if the cost of the new device does indeed reflect a cost equivalent to that of the similar existing devices. As HOPDs and ASCs perform new procedures with significant device costs, we believe it is appropriate to modify our default device offset methodology to pay HOPDs and ASCs more appropriately when we lack claims data for these newer procedures. Therefore, for this proposed rule and subsequent calendar years, we propose to modify our default device offset percentage for new device-intensive procedures. Specifically, for all new covered surgical HCPCS codes that describe procedures which implant or insert single-use devices that meet our definition of a device and for which the device costs are estimated to be greater than 30 percent of the total procedure cost and lack claims data, 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 propose this methodological change for both the OPSS and ASC Payment System for CY 2025 and subsequent calendar years.

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 and therefore a HCPCS code-level device offset may not be possible, we believe the APC-wide average device offset percentage is, in most 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 propose to modify our methodology for determining the device offset percentage for new procedures that describe the implantation or insertion of a single-use device that meet our definition of a device and for which the device cost is projected to be greater than 30 percent of the total procedure cost that do not yet have associated claims data to apply a 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. This proposal would apply to new device-intensive procedures assigned to clinical APCs and would not apply to new procedures assigned to New Technology APCs.

Under our proposal, we would continue to first rely on the associated claims data for the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. If there is no claims data from the new HCPCS or any predecessor code, we may continue to 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 a device offset percentage 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. For new device-intensive procedures that describe the implantation or insertion of a single-use device that meet our definition of a device and for which the device cost

is significant, projected to be greater than 30 percent of the total procedure cost, and lack claims data, we would then rely on our proposed device offset policy and apply the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned.

We solicit comments on our proposed changes to our default device offset policy for CY 2025 and subsequent calendar years under the OPSS and ASC payment system. The listing of proposed payment indicators for covered surgical procedures as well as their respective proposed device offset percentages and device offset amounts, which incorporates our proposed changes to the default device offset policy, can be found in Addendum FF to this proposed rule (which is available via the Internet on the CMS website).

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 OPSS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPSS/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 OPSS, we finalized our proposal to reduce OPSS 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 OPSS, in the CY 2014 OPSS/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 OPSS, 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 OPPI/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 2025.

5. Requirement in the Physician Fee Schedule CY 2025 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 2025 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 and CY 2024 notice in the OPPS/ASC proposed rules (87 FR 71988 and 88 FR 49760), we wanted to ensure interested parties were aware of these proposals and knew to refer to the CY 2025 Physician Fee Schedule 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 2025 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2025 PFS final rule with comment period. We note that this same notice appears in section V.B.6 of this proposed rule with respect to the OPPS.

D. Proposed Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

1. Proposed Additions to 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 stakeholders.

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 OPPI, 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 OPPTS/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.

In the CY 2024 OPPTS/ASC final rule with comment period, we finalized adding several dental surgical procedures to the ASC CPL that met our regulatory criteria at §§416.166. We note that there are statutory and regulatory limitations regarding Medicare coverage and payment for dental services. Section 1862(a)(12) of the Act generally precludes Medicare Part A or Part B payment for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth (collectively referred to in this section as “dental services”). The regulation at § 411.15(i) similarly prohibits payment for dental services. In the CY 2023 PFS final rule (87 FR 69663), we explained that there are certain instances where dental services are so integral to other medically necessary services that they are not in connection with dental services within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to, and substantially related to the clinical success of, other covered services (hereafter in this section, “inextricably linked”). To provide greater clarity to current policies, the CY 2023 PFS final rule finalized: (1) a clarification of our interpretation of section 1862(a)(12) of the Act to permit payment for dental services that are inextricably linked to other covered services; (2) clarification and codification of certain longstanding Medicare FFS payment policies for dental services that are inextricably linked to other covered services; (3) that, beginning for CY 2023, Medicare Parts A and B payment can be made for certain dental services inextricably linked to Medicare-covered organ transplant,

cardiac valve replacement, or valvuloplasty procedures; and, (4) beginning for CY 2024, that Medicare Parts A and B payment can be made for certain dental services inextricably linked to Medicare-covered services for treatment of head and neck cancers (87 FR 69670 through 69671).

For the ASC setting, services must meet all applicable Medicare conditions for coverage and payment to be paid by Medicare, including those as specified under the CY 2023 PFS final rule (87 FR 69687 through 69688) and § 411.15(i)(3). Medicare payment may be made in the ASC setting for dental services for which payment may be made under Medicare Part B, paid under the OPPS, and that meet the ASC CPL criteria. The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the ASC payment system indicates only how the product, procedure, or service may be paid if covered by the program. MACs will be involved in the final decision regarding whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Therefore, even if a code describing a dental service has an associated payment rate on the ASC CPL, Medicare will only make payment for the service if it meets applicable requirements. We also clarify that adding dental procedures to the ASC CPL does not serve as a coverage determination for dental services under general anesthesia. We direct readers to the CY 2025 PFS proposed rule for additional discussion of Medicare coverage and payment for dental services, which is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

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 2024 OPPS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805; 87 FR 72068 through 72076; and 88 FR 81923 through 81945).

2. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2025

Our current policy, which includes consideration of the general standards and exclusion criteria we have historically used to determine whether a surgical procedure should be added to

the ASC CPL, is intended to ensure that surgical procedures added to the ASC CPL can be performed safely in the ASC setting on the typical Medicare beneficiary.

As part of our evaluation process to add procedures to the CPL, we assess potential procedures against the specific list of ASC CPL criteria at § 416.166. We also examine clinical data on these procedures from multiple sites of services, review literature and experiential data, and analyze claims data trends to ensure that these procedures meet all our criteria and are not expected to pose a significant risk to beneficiary safety when performed in an ASC. For CY 2025, we also reviewed supporting evidence received in the pre-proposed rule nominations process to inform our procedure evaluations. Based upon this review, we propose to update the ASC CPL by adding 20 medical and dental surgical procedures to the list for CY 2025, as shown in Table 82.

After reviewing the clinical characteristics of these twenty procedures and consulting with stakeholders and multiple clinical advisors, we determined that these procedures are separately paid under the OPSS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. These procedures are surgical or surgery-like, clinically similar to procedures in the CPT surgical range that we determined met the general standards for addition to the ASC CPL. These procedures are not excluded from being included on the ASC CPL because they do not generally result in extensive blood loss, require major or prolonged invasion of body cavities, commonly require systemic thrombolytic therapy, or directly involve major blood vessels; are not generally emergent or life-threatening in nature or designated as requiring inpatient care; or can only be reported using a CPT unlisted surgical procedure code or are otherwise excluded under Medicare. Therefore, we believe these procedures may all be appropriately performed in an ASC and propose to include them on the ASC CPL for CY 2025.

We continue to focus on maximizing patient access to care by adding procedures to the ASC CPL when appropriate. While expanding the ASC CPL offers benefits, such as preserving the capacity of hospitals to treat more acute patients and promoting site neutrality, we also believe that any additions to the CPL should be added in a carefully calibrated fashion to ensure that the procedure is safe to be performed in the ASC setting. We encourage interested parties to submit procedure recommendations to be added to the ASC CPL, particularly if there is evidence that these procedures meet our criteria and can be safely performed in the ASC setting. We expect to continue to gradually expand the ASC CPL, as medical practice and technology continue to evolve and advance in future years.

TABLE 82: CY 2025 PROPOSED SURGICAL PROCEDURES FOR THE ASC CPL

CY 2025 CPT/HCPCS/CDT Code	CY 2025 Long Descriptor
0717T	Autologous adipose-derived regenerative cell (adrc) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing, and concentration of adrcs
0718T	Autologous adipose-derived regenerative cell (adrc) therapy for partial thickness rotator cuff tear; injection into supraspinatus tendon including ultrasound guidance, unilateral
0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)
0801T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)
D7251	Coronectomy - intentional partial tooth removal, impacted teeth only
D7280	Exposure of an unerupted tooth
D7410	Excision of benign lesion up to 1.25 cm
D7411	Excision of benign lesion greater than 1.25 cm
D7412	Excision of benign lesion, complicated
D7413	Excision of malignant lesion up to 1.25 cm

CY 2025 CPT/HCPCS/CDT Code	CY 2025 Long Descriptor
D7414	Excision of malignant lesion greater than 1.25 cm
D7415	Excision of malignant lesion, complicated
D7450	Removal of benign odontogenic cyst or tumor-lesion diameter up to 1.25 cm
D7451	Removal of benign odontogenic cyst or tumor-lesion diameter greater than 1.25 cm
D7460	Removal of benign nonodontogenic cyst or tumor-lesion diameter up to 1.25 cm
D7461	Removal of benign nonodontogenic cyst or tumor-lesion diameter greater than 1.25 cm
D7485	Reduction of osseous tuberosity
D7521	Incision and drainage of abscess - extraoral soft tissue - complicated (includes drainage of multiple fascial spaces)
D7530	Removal of foreign body from mucosa, skin, or subcutaneous alveolar tissue
D7540	Removal of reaction-producing foreign bodies-musculoskeletal system

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 propose 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 2025 can be found in section XIII.B of this proposed rule. All ASC covered ancillary services and their final payment indicators for CY 2025 are also included in Addendum BB to this proposed rule (which is available via the Internet on the CMS website).

Claims Processing Limitations for Covered Ancillary Procedures Performed with G0330

We finalized adding HCPCS code G0330 (*Facility services for dental rehabilitation procedure(s) performed on a patient who requires monitored anesthesia (e.g., general, intravenous sedation (monitored anesthesia care) and use of an operating room)*) to the ASC CPL in the CY 2024 OPPS/ASC final rule (88 FR 81924). In ASC Addendum BB, there is a specific and definitive list of covered ancillary dental services with payment indicator of “D1,”

indicating an ancillary dental service or item with no separate payment made. In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81945 through 46), we finalized that code G0330 could only be billed when accompanied by a covered ancillary procedure that has the payment indicator of “D1.” Performance of at least one of these covered ancillary services is integral to each of the surgical procedures that correspond to G0330. This limitation ensures that only covered ancillary services we evaluated for safety in the ASC setting could be performed with code G0330.

While HCPCS code G0330 must be billed with a covered ancillary procedure with a payment indicator of “D1,” these covered ancillary procedures with a payment indicator of “D1” can be billed with surgical procedures other than G0330. When billed with procedures other than code G0330, these ancillary procedures would be packaged in accordance with our policy for covered ancillary procedures. Additionally, other than HCPCS code G0330, procedures assigned to payment indicator “D2”, indicating non office-based dental procedure added in CY 2024 or later, are not required to be billed with a covered ancillary procedure assigned to payment indicator “D1” to receive payment for the procedure.

The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the ASC payment system indicates only how the product, procedure, or service may be paid if covered by the program. MACs will be involved in the final decision regarding whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Therefore, even if a code describing a dental service has an associated payment rate on the ASC CPL, Medicare will only make payment for the service if it meets applicable requirements.

E. ASC Payment Policy for Non-Opioid Post-Surgery Pain Management Drugs, Biologicals, and Devices

1. Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115-271) was enacted. Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPS for opioids and evidence based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered outpatient department (OPD) services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services) assigned to C-APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section 1833(t)(22)(C) of the Act requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B) of the Act, which requires any adjustments to be made in a budget neutral manner. Section 1833(i)(8) of the Act, as added by section 6082(b) of the SUPPORT Act, requires the Secretary to conduct a similar type of review as required for the OPPS and to make revisions to the ASC payment system in an appropriate manner, as determined by the Secretary.

For a detailed discussion of rulemaking on non-opioid alternatives prior to CY 2020, we refer readers to the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59345; 83 FR 58855 through 58860).

For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), as required by section 1833(t)(22)(A)(i) of the Act, we reviewed payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173 through 61180), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, for CY 2020, the only drug that qualified for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply was Exparel.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85896 through 85899), we continued the policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they were furnished in the ASC setting and to continue to package payment for non-opioid

pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021. For CY 2021, only Exparel and Omidria met the criteria as non-opioid pain management drugs that function as surgical supplies in the ASC setting and received separate payment under the ASC payment system.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63483), we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS/ASC drug packaging threshold; and we finalized our proposed regulation text changes at 42 CFR 416.164(a)(4) and (b)(6), 416.171(b)(1), and 416.174 as proposed.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72089), we determined that five products were eligible for separate payment in the ASC setting under our final policy for CY 2022. We noted that future products, or products not discussed in that rulemaking that may be eligible for separate payment under this policy, would be evaluated in future rulemaking (86 FR 63496). In the CY 2023 final rule with comment period, we finalized that five drugs would receive separate payment in the ASC setting for CY 2023 under the policy for non-opioid pain management drugs and biologicals that function as surgical supplies (86 FR 63496).

In the CY 2023 OPPS/ASC final rule with comment period, we finalized a clarification of our policy by codifying the two additional criteria for separate payment for non-opioid pain management drugs and biologicals that function as surgical supplies in the regulatory text at § 416.174 as a technical change. First, we finalized at new § 416.174(a)(3) that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if the drug or biological does not have transitional pass-through payment status

under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that will expire during the calendar year, the drug or biological would qualify for separate payment under § 416.174 during such calendar year on the first day of the next calendar year quarter after its pass-through status expires. Second, we finalized that new § 416.174(a)(4) would reflect that the drug or biological must not already be separately payable in the OPSS or ASC payment system under a policy other than the one specified in § 416.174.

In the CY 2024 OPSS/ASC final rule with comment period, we finalized four drugs as eligible to receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system and which met the criteria at § 416.174(a) for CY 2024. (See Table 83.)

TABLE 83: SUMMARY OF PRODUCTS FINALIZED UNDER THE NON-OPIOID PAIN MANAGEMENT POLICY FOR CY 2024

HCPCS Code	Brand Name	Long Descriptor	CY 2024 OPSS Status Indicator (SI)*	CY 2024 ASC Payment Indicator (PI)*
C9290	Exparel	Injection, bupivacaine liposome, 1 mg	N	K2
J1097	Omidria	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	N	K2
J1096	Dextenza	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	N	K2
C9089	Xaracoll	Bupivacaine, collagen-matrix implant, 1 mg	N	K2

*Please see ASC Addenda BB for applicable payment rates, OPSS Addenda D1 for SI definitions, and ASC Addenda DD1 for PI definitions. All are available via the internet on the CMS website for the CY 2024 OPSS/ASC rule.

F. Proposed CY 2025 Non-Opioid Policy for Pain Relief Under the OPSS 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, subparagraph (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. Subparagraph (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 are required to begin on January 1, 2025. The statute directs CMS to provide “additional payment”, and for purposes of

this proposal, we interrupt 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 OPSS rule and likely more familiar with readers, therefore, to avoid confusion we will be using “separate payment” throughout the rest of this section, which we believe to be synonymous with “additional payment.”

Our proposals to implement the amendments to sections 1833(t)(16) and section 1833(i) of the Act required by section 4135 of the CAA, 2023 are discussed below.

2. Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

a. Statutory Authority for OPSS/ASC Non-Opioid Policy

Prior to CY 2025, the statutory authority for the ASC non-opioid policy is section 1833(i)(8) of the Act, as added by section 6082(b) of the SUPPORT Act. Section 1833(i)(8) of the Act refers to paragraph (t)(22), which states that the Secretary shall conduct a similar type of review as the one required for the OPSS for opioids and evidence based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives and make such revisions as the Secretary determines appropriate. As discussed in the previous section, CMS’s policy for CY 2024 is to provide separate payment in the ASC setting for certain qualifying non-opioid pain management drugs that function as a supply in a surgical procedure.

As noted previously, 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.

(1) 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 that 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 propose that drugs and biologicals that meet the definition of a non-opioid treatment for pain relief for purposes of section 4135 that are currently subject to the ASC policy for non-opioid treatments authorized by section 6082 of the SUPPORT Act, would instead receive separate payments, subject to the limitation, for the duration of the payment period for section 4135. These drugs and biologicals are described in the discussions that follow.

(2) 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.”

(3) Evidence Requirement for Medical Devices

To determine whether a medical device fulfills the 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 propose 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. When interested parties submit non-opioid device recommendations for CY 2025, we encourage them to also submit with their public comments any relevant literature that demonstrates that the named medical device replaces, reduces, or avoids opioid use per this statutory provision. We propose that CMS will review any literature submitted and determine whether it meets this evidence criterion. We are not requiring 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 will not meet this evidence criterion and will therefore not qualify for separate payment under section 4135.

c. 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 propose 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. Products with an indication that does not meet the statutory requirement will not qualify. Table 84 includes citations to the indications of the drugs and biologicals that we propose meet the statutory requirements and should qualify for separate payment for CY 2025.

(2) Indications for Medical Devices

With respect to 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. 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 medical devices, we propose to only approve medical devices with an indication that specifies that the device is used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia and which also have FDA approval, market clearance, or an appropriate exemption from the requirements of section 510(k). Table 84 includes citations to the indication of one device that we propose meets the statutory requirements and should qualify for separate payment for CY 2025.

d. 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. As the language in Section 1833(t)(16)(G)(ii)(II) of the Act is very similar to the transitional pass-through language at section 1833(t)(6)(D)(i) and (ii) of the Act, we propose implementing a similar payment methodology for non-opioid products. A payment offset is the amount reflecting the portion of the non-opioid product in the procedure payment rate. We propose to assign a payment offset of zero dollars for the qualifying drugs, biologicals, and devices for CY 2025. A zero 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 propose this would apply for CY 2025 for all non-opioid drugs, biologicals, and devices that qualify for separate payment. We believe it makes sense to propose 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 propose to be zero dollars for CY 2025. For the amount of payment for a medical device, the separate payment amount will be determined by subtracting from the hospital's charges for the device, adjusted to cost, the portion of the otherwise applicable Medicare OPD fee schedule amount associated with the medical device, which as previously discussed, we propose to be zero dollars for CY 2025. These separate payment amounts will all be 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. Our proposed implementation of this payment limitation is discussed in further detail below. Given this statutory requirement, we propose to pay 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 more information on the drug packaging threshold, see section V.B.1.a of this proposed rule, and section II.A.b of this proposed rule for further information on C-APC packaging. We propose that non-opioid treatments for pain relief would not be subject to the threshold packaging policy in section V.B.1.a. of the proposed rule (88 FR 49676) and would also be separately paid when used during a comprehensive APC (C-APC) procedure in the HOPD setting.

e. 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.

For the non-opioid products that are currently billed under the OPPS, we conducted a claims analysis of CY 2023 OPPS claims, which are the claims available for CY 2025

rulemaking, and found that approximately 90 percent of the utilization, on average, for these non-opioid products is focused in the top five most frequently performed services for each product. Given this, we believe that using the top five services would provide a representative estimate for purposes of the payment limitation. As illustrated in Table 85, we propose to use the top five services by volume associated with a drug, biological, or medical device, to determine the volume-weighted payment rate per claim and the 18 percent payment limitation specified by statute, based on the most recent claims data available. This payment limitation approach is also generally consistent with the comments received in response to the comment solicitation in the CY 2024 OPPS/ASC proposed rule (88 FR 49767 through 49769). For example, in response to the CY 2024 comment solicitation, several commenters supported CMS establishing a payment limitation for each non-opioid treatment item based on a volume-weighted OPPS payment rate for the top five services that package the item into their payment rate.

We propose to apply the 18 percent payment limitation per date of service billed, rather than per HCPCS dosage unit. This is due to the fact that there are typically multiple HCPCS dosage units (also called billing units) of each drug or biological billed per claim. Thus, the total units of a drug billed on a date of service is more reflective of the cost of the drug in that encounter. The amount of drug or biological used during an encounter, represented by a date of service for purposes of this proposal, will impact whether the separate payment for the drug or biological exceeds the payment limitation required by statute. Meaning, the same drug or biological may or may not be subject to the payment limitation depending on the amount of drug used. For example, a drug is paid \$1 per 1 mg (per billing unit) and has a payment limitation set at \$100 based on 18 percent of the volume weighted average of the payment of the top 5 services associated with the use of the drug. If 50 mg (50 billing units) of this drug were to be billed during one patient encounter or one date of service, then \$50 would be paid. The payment limitation would not apply as the payment for the drug did not exceed the payment limitation of

\$100. If 200 mg (200 billing units) of that same drug were to be billed during one patient encounter or one date of service, then the \$200 payment would be limited to \$100. In this case the payment limitation would apply as the payment for the drug exceeded the payment limitation of \$100. We propose to apply this payment limitation to the date of service billed as the payment limitation applies to the total amount of separate payment, rather than the HCPCS dosage unit payment, which may only represent a small fraction of the total amount of payment.

We propose to create new status indicators for non-opioid drugs and devices to implement this payment limitation. Under the OPPS, non-opioid drugs and biologicals under this policy would be assigned a status indicator of K1, while non-opioid devices would be assigned a status indicator of H1. Further discussion of these new status indicators can be found in section X1.A of this proposed rule.

As discussed in section XIII.B.6.b. of this proposed rule, we propose to modify the descriptor of ASC payment indicator “L6” – “New Technology Intraocular Lens (NTIOL); special payment” to “Special payment; New Technology Intraocular Lens (NTIOL) or qualifying non-opioid devices” and propose to assign qualifying non-opioid medical devices to this payment indicator to operationalize payment of these devices. We propose to assign qualifying drugs and biologicals to existing payment indicator “K2.” 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 2025 update.

We have presented our proposed payment limitation calculations for qualifying non-opioid products in Table 85. We welcome public comment on the methodology used to determine the payment limitation.

d. 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 are soliciting comment on the

best approach for determining a payment limitation, as required by section 1833(t)(16)(G)(iii) of the Act. As discussed in the CY 2024 OPPTS/ASC final rule with comment period (88 FR 81953), CMS could utilize the services with which a product would be expected to be furnished and would typically be packaged absent this policy, based on expected clinical use patterns. Determining the service, or group of services, to use to calculate the payment limitation could be accomplished through engagement with interested parties and a review by CMS Medical Officers and clinical staff. Absent engagement from interested parties, CMS could determine the service, or group of services, to use to calculate the payment limitation based on expected clinical use patterns. CMS could then adjust the services that are used to calculate the payment limitation as claims data becomes available in subsequent years. We welcome comments on how to set a payment limitation for a product for which we do not have claims data on which to base a payment limitation. The product is described by HCPCS code C98X4 (ON-Q Pump). We solicit comment on the top 5 procedures performed with this product, and the HCPCS code that describes the procedure, in order to calculate a volume weighted payment limitation for this device for CY 2025.

We anticipate 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.

e. Qualifying Products

The following tables (Tables 84 and 85) list the non-opioid alternatives of which we are aware that we propose would receive separate payment as a non-opioid pain management drug or device under section 4135 criteria for CY 2025. With respect to one medical device, Table 84 also includes references to literature previously submitted to CMS, which CMS has reviewed and based on that review, has determined that the device shows 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. Based on this determination, we propose the device listed in Table 84 is eligible for separate payment.

In general, CMS routinely receives comments from readers of the proposed rule with detailed rationale as to why and how a particular drug, biological, medical device, or other item or service should be paid in their view. We are soliciting comment on whether there are any additional drugs, biologicals, or medical devices that meet the statutory requirements outlined in 1833(t)(16)(G) and 1833(i)(10). As discussed in this section, there are specific requirements with respect to FDA approval that must be met in order for the product to qualify for separate payment.. For medical devices, the statute also requires that the device 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. Interested parties that believe that a product not addressed in this proposed rule meets the statutory requirements should submit information during the comment period that indicates that such product meets the statutory eligibility requirements. If CMS determines that such product(s) does in fact meet the statutory eligibility requirements, we would finalize separate payment for that product in the CY 2025 OPPS/ASC final rule with comment period. For drugs and biological products not addressed in this 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 2025. For medical devices not addressed in this 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, then CMS will not finalize separate payment for such device for CY 2025.

TABLE 84: PROPOSED LIST OF QUALIFYING PRODUCTS FOR SEPARATE PAYMENT UNDER SECTION 4135 OF THE CAA, 2023

Brand Name	HCPCS Code	Long Descriptor	Meets Requirements
Exparel	C9290	Injection, bupivacaine liposome, 1mg	Yes ¹⁰⁶
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	Yes ¹⁰⁷
Dextenza	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	Yes ¹⁰⁸
Xaracoll	C9089	Bupivacaine, collagen-matrix implant, 1 mg	Yes ¹⁰⁹
Zynrelef	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	Yes. ¹¹⁰ Effective April 1, 2025
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg	Yes ¹¹¹
ON-Q Pump	C98X4	Elastomeric infusion pump, non-opioid pain management delivery system, including catheter and other system component(s)	Yes ^{112,113}

¹⁰⁶ Exparel. FDA Package Insert. November 2023.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022496s0511bl.pdf

¹⁰⁷ Omidria. FDA Package Insert. December 2017.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s0061bl.pdf

¹⁰⁸ Dextenza. FDA Package Insert. October 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s0071bl.pdf

¹⁰⁹ Xaracoll. FDA Package Insert. August 2020.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209511s0001bl.pdf

¹¹⁰ Zynrelef. FDA Package Insert. January 2024.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211988s0131bl.pdf

¹¹¹ Ketorolac tromethamine Injection. FDA Package Insert. May 2014.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/074802s0381bl.pdf

¹¹² On-Q Pump. FDA 510K. February 2019. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181360.pdf

¹¹³ 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>

TABLE 85: PROPOSED LIST OF QUALIFYING PRODUCTS AND PROPOSED PAYMENT LIMITATION DETERMINATIONS UNDER SECTION 4135 OF THE CAA, 2023

Non-Opioid Drug	HCPCS Code for Primary Procedure	Total Units in CY 2025 data (CY 2023 claims)	Proportion of Top 5	CY 2025 Procedure Payment Rate	18% of the CY 2025 Procedure Payment Rate	Payment Limitation Applied Per Date of Service Volume Weighted Average of 18% of Procedure Payment Rate	Separate Payment Rate (Per Billing Unit)*
Zynrelef (C9088)	27447	9,385	36.25%	\$13,048.08	2,348.65	\$1,206.16	\$0.73
	73560	6,471	24.99%	\$86.88	15.64		
	27130	3,831	14.80%	\$13,048.08	2,348.65		
	96361	3,256	12.58%	\$42.37	7.63		
	86900	2,947	11.38%	\$116.11	20.90		
Xaracoll (C9089)	49505	347	47.02%	\$3,541.93	637.55	\$388.53	\$0.85
	88307	106	14.36%	\$324.11	58.34		
	88302	99	13.41%	\$24.96	4.49		
	88304	95	12.87%	\$50.14	9.03		
	49507	91	12.33%	\$3,541.93	637.55		
Exparel (C9290)	27447	33,513	24.01%	\$13,048.08	2,348.65	\$583.29	\$1.41
	96361	27,739	19.88%	\$42.37	7.63		
	88307	26,224	18.79%	\$324.11	58.34		
	86900	26,117	18.71%	\$116.11	20.90		
	73560	25,968	18.61%	\$86.88	15.64		
Dextenza (J1096)	66984	4,553	46.57%	\$2,159.44	388.70	\$386.39	\$117.01
	68841	4,349	44.48%	\$2,114.22	380.56		
	66982	564	5.77%	\$2,159.44	388.70		
	66991	174	1.78%	\$4,250.50	765.09		
	92499	137	1.40%	\$24.96	4.49		
Omidria (J1097)	66984	8,885	79.76%	\$2,159.44	388.70	\$383.59	\$97.12
	66982	1,256	11.28%	\$2,159.44	388.70		
	68841	393	3.53%	\$2,114.22	380.56		
	92499	370	3.32%	\$24.96	4.49		
	66991	235	2.11%	\$4,250.50	765.09		
Ketorolac tromethamine Injection (J1885)	96375	659,685	28.34%	\$42.37	7.63	\$22.82	\$0.702
	96361	489,948	21.05%	\$42.37	7.63		
	96374	451,076	19.38%	\$206.57	37.18		
	96372	395,425	16.99%	\$67.47	12.14		
	99284	331,342	14.24%	\$381.61	68.69		

*We note the payment rates for drugs and biologicals are subject to our standard quarterly drug pricing updates; therefore, the payment rate is the payment rate available as of April 1, 2024, and may not be the same payment rate available throughout CY 2025.

Conforming proposed regulation text changes can be found at 42 CFR 416.174 for the ASC payment system and § 419.43 for the OPPTS. We propose revisions to § 419.174(a) to establish the eligibility for non-opioid pain management drugs and biologicals, and by adding modifications to subparagraphs (1), (2), and (3) to outline drug and biological FDA approval requirements, the exclusion of drugs and biologicals with pass-through status, and the requirement that the drug or biological has payment that is packaged. We propose new § 419.174(b) to establish the eligibility for non-opioid pain management medical devices, which includes new subparagraphs (1), (2), (3), and (4). These new subparagraphs describe medical device FDA requirements, medical device clinical trial or peer-reviewed journal requirements, the exclusion of medical devices with pass-through status, and the requirement that the medical device has payment that is packaged. New paragraph (c) describes the payment amounts for qualifying drugs and biologicals in subparagraph (1) and medical devices in subparagraph (2), as well as the payment limitation for drugs, biologicals, and medical devices in subparagraph (3). Similarly, we also propose new 419.43(k), which contains payment for non-opioid pain management drugs and biologicals. Specifically, new paragraph (1) outlines the eligibility for separate payment for non-opioid pain management drugs and biologicals, with new subparagraphs outlining (i) the drug or biological's required FDA status, (ii) the drug or biological's pass-through status, and (iii) the drug or biological's packaged status. We also propose to add new paragraph 419.43(k)(2), which contains payment for non-opioid pain management medical devices. Specifically, new paragraph (2) outlines the eligibility for separate payment for non-opioid pain management medical devices, with new subparagraphs outlining (i) the medical device's required FDA status, (ii) the medical device clinical trial or peer-reviewed journal requirements, (iii) the medical device's pass-through status, and (iv) the medical device's packaged status. New 419.43(k)(3) describes the separate payment amount for qualifying non-opioid treatments for pain relief. Specifically, subparagraph (i) sets the separate payment amount for a qualifying drug or biological, subparagraph (ii) sets the separate payment amount for a

qualifying medical device, and subparagraph (iii) sets the payment limitation for drugs, biologicals, and medical devices.

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 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 2025

We did not receive any requests for review to establish a new NTIOL class for CY 2025 by March 1, 2024, the due date published in the CY 2024 OPPTS/ASC final rule with comment period (88 FR 81956).

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 2025.

H. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007, ASC final rule (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 OPPTS 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)).

We note that we consider the term “expenditures” in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

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 (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 results 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 provides 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>). The pre-floor pre-reclassified IPPS hospital wage indexes for CY 2024 do not reflect OMB's new area delineations and, because the ASC wage indexes are the pre-floor and pre-reclassified IPPS hospital wages indexes, the CY 2024 ASC wage indexes do not reflect the most recent OMB changes. As discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36139 through 36150), we proposed 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, we propose 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 adopting the revised CBSA delineations from the 2010 Census data which were issued by OMB on July 15, 2015 through OMB Bulletin No. 15-01, for ASCs in counties that would see a decline in their ASC wage index for CY 2015, we adopted a blended wage index of 50 percent of the CY 2014 wage index value and 50 percent of the CY 2015 wage index value (79 FR 66937). However, we note that other Medicare payment systems incorporate a policy of capping year-to-year wage index decreases for each facility at 5 percent of the previous year's wage index value (89 FR 23431 through 23433). We believe such a policy would also be appropriate

for the ASC payment system as we transition to the CBSA delineations based on the 2020 Census data. As discussed in the IPPS/LTCH FY 2025 proposed rule, the 5-percent cap 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 (89 FR 36150). Therefore, for CY 2025, we propose to incorporate the new OMB delineations into the CY 2025 ASC wage indexes and propose to apply a 5-percent cap on wage index decreases at the county level (or county-equivalent level) and the ASC wage index of that county would apply to all ASCs physically located in that county. We note that this 5-percent cap is applied in a budget neutral manner. The 5-percent cap reduces the wage index scalar for a calendar year which, in turn, will reduce the ASC conversion factor and the payment rates for covered ASC services in counties that are not affected by the 5-percent cap on wage index decreases. Further, we are soliciting comments on whether we should extend this policy after CY 2025 and permanently adopt a budget-neutral 5-percent cap on year-to-year wage index decreases.

The proposed CY 2025 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 Nos. 23-01) including replacing the eight counties with the county-equivalent planning regions of Connecticut. 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 2025, we

are applying a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville, GA) and in CBSA 35 (Rural North Dakota).

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2025 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.

Where the estimated ASC expenditures for an upcoming year are higher than the estimated ASC expenditures for the current year, the ASC weight scalar is reduced, in order to bring the estimated ASC expenditures in line with the expenditures for the baseline year. This frequently results in ASC relative payment weights for surgical procedures that are lower than the OPPS relative payment weights for the same procedures for the upcoming year. Therefore, over time, even if procedures performed in the HOPD and ASC receive the same update factor under the OPPS and ASC payment system, payment rates under the ASC payment system would increase at a lower rate than payment for the same procedures performed in the HOPD as a result of applying the ASC weight scalar to ensure budget neutrality.

As discussed in section II.A.1.a of this proposed rule, we are using the CY 2023 claims data to be consistent with the OPPS claims data for this proposed rule. Consistent with our established policy, we propose to scale the CY 2025 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 2023, we propose to compare the estimated total payment using the CY 2024 ASC relative payment weights with the estimated total payment using the CY 2025 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2024 and CY 2025.

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. We estimated in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72094) that the impact on CY 2023 estimated total payments from our finalized CY 2023 ASC complexity adjustment codes would be \$5 million in spending and we finalized our proposal to incorporate this \$5 million in estimated CY 2023 total payments for the budget neutrality calculation. Based on CY 2023 utilization data, we now estimate that the actual amount of spending on the new CY 2023 ASC complexity adjustment codes for CY 2023 was \$24 million. We estimate that there will not be an additional increase in ASC spending related to our newly proposed ASC complexity adjustment codes for CY 2025.

Additionally, as discussed in Section XIII.E of this proposed rule, 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.e of this proposed rule, for qualifying nonopioid products, we propose to apply the 18 percent payment limitation on the volume weighted payment average of the top 5 services

associated with the use of the qualifying nonopioid product. Currently, four of these qualifying nonopioid products are separately payable without the 18 percent payment limitation – HCPCS Codes C9089 (Bupivacaine implant, 1 mg), C9290 (Inj, bupivacaine liposome), J1096 (Dexametha oph insert 0.1 mg), and J1097 (Phenylep ketorolac oph soln). Therefore, to maintain budget neutrality, we must estimate the total anticipated reduction as a result of the 18 percent payment limitation required by Section 4135 of the CAA, 2023. Using CY 2023 utilization for these four drugs and CY 2024 ASC payment rates, we anticipate that the 18 percent payment limitation will reduce CY 2025 ASC expenditures by approximately \$9 million. Therefore, we are reducing estimated CY 2025 total payments by \$9 million in our weight scalar calculation as a result of Section 4135 of the CAA, 2023.

We propose to use the ratio of estimated CY 2024 to estimated CY 2025 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2025. The proposed CY 2025 ASC weight scalar is 0.876. We note that 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). An ASC weight scalar rounded to the nearest ten thousandth is highly sensitive to spending changes and can require the costly reissuance of new ASC payment rates from only very minor payment rate changes within the ASC Payment System, such as a revised PFS conversion factor as a result of Congressional action. Therefore, for CY 2025 and subsequent calendar years, we propose to set the ASC weight scalar rounded to the nearest thousandth. Consistent with historical practice, we propose to scale, using this method, 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 would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

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 2023 claims data to model our budget neutrality adjustment for CY 2025.

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 2025, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2023 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2025 ASC wage indexes. Specifically, holding CY 2023 ASC utilization, service-mix, and the proposed CY 2025 national payment rates after application of the weight scalar constant, we

calculated the total adjusted payment using the CY 2024 ASC wage indexes and the total adjusted payment using the proposed CY 2025 ASC wage indexes which included our proposed 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 2024 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2025 ASC wage indexes and applied the resulting ratio of 0.9958 (the proposed CY 2025 ASC wage index budget neutrality adjustment) to the CY 2024 ASC conversion factor to calculate the proposed CY 2025 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 2025 was projected to be 0.4 percentage point, as published in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36204) based on IGI's 2023 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 OPPTS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized a policy to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we would assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a productivity-adjusted hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. The most recent available full year of claims data to assess the expected migration applying the productivity-adjusted hospital market basket update during the interim period would fall within the period from CY 2019 through CY 2022. However, the impact of the COVID-19 PHE on health care utilization, in particular in CY 2020, 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 is 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 need 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, that is, through CY 2024 and CY 2025. We believed hospital outpatient and ASC utilization data from CYs 2023 and 2024 will enable us to more accurately analyze whether the application of the productivity-adjusted 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) and (iv), which establish the annual update to the ASC conversion factor, to reflect this 2-year extension. We also revised

our regulations at § 416.171(a)(2)(vi) and (vii), which establish the 2.0 percentage point reduction for ASCs that fail to meet the standards for reporting ASC quality measures, and § 416.171(a)(2)(viii)(B) and (C), which establish the productivity adjustment, to reflect this 2-year extension.

For CY 2025, we propose to utilize the proposed hospital market basket percentage increase of 3.0 percent reduced by the proposed productivity adjustment of 0.4 percentage point, resulting in a proposed productivity-adjusted hospital market basket update of 2.6 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to apply a proposed 2.6 percent productivity-adjusted hospital market basket update factor to the CY 2024 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2025 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 productivity-adjusted 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 3.0 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then reduced by the proposed 0.4 percentage point productivity adjustment. Therefore, we propose to apply a 0.6 percent productivity-adjusted hospital market basket update factor to the CY 2024 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 2025 ASC update for the CY 2025 OPPS/ASC final rule with comment period.

For CY 2025, we propose to adjust the CY 2024 ASC conversion factor (\$53.514) by the proposed wage index budget neutrality factor of 0.9958 in addition to the proposed productivity-adjusted hospital market basket update of 2.6 percent discussed previously, which results in a proposed CY 2025 ASC conversion factor of \$54.675 (a 2.2 percent increase) for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we propose to adjust the CY 2024 ASC conversion factor (\$53.514) by the proposed wage index budget neutrality factor of 0.9958 in addition to the proposed quality reporting/productivity-adjusted hospital market basket update of 0.2 percent discussed previously, which results in a proposed CY 2025 ASC conversion factor of \$53.609 for ASCs not meeting the quality reporting requirements.

3. Display of the Proposed CY 2025 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 2025 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 proposed 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 2025 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.

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).

The values displayed in the column titled “Proposed CY 2025 Payment Weight” are the proposed relative payment weights for each of the listed services for CY 2025. 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 2025 payment rate displayed in the “Proposed CY 2025 Payment Rate” column, each ASC payment weight in the “Proposed CY 2025 Payment Weight” column was multiplied by the proposed CY 2025 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 2025 ASC conversion factor uses the proposed CY 2025 productivity-adjusted hospital market basket update factor of 2.6 percent (which is equal to the proposed inpatient hospital market basket percentage increase of 3.0 percent reduced by the proposed productivity adjustment of 0.4 percentage point).

In Addendum BB, there are no relative payment weights displayed in the “Proposed CY 2025 Payment Weight” column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The “Proposed CY 2025 Payment” column displays the proposed CY 2025 national unadjusted ASC payment rates for all items and services. The proposed CY 2025 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.

Addendum EE to this proposed rule provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2025.

Addendum FF to this proposed rule displays the OPSS 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 2025 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. CMS Commitment to Advancing Health Equity Using Quality Measurement

We are committed to advancing health equity and improving health outcomes through our quality reporting programs. The CMS Framework for Health Equity acknowledges that “addressing health and healthcare disparities and achieving health equity should underpin efforts to focus attention and drive action on our nation’s top health priorities.” CMS defines health equity as “the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual

orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.”¹¹⁴

Significant and persistent disparities in health care outcomes exist in the United States (U.S.). Belonging to a racial or ethnic minority group, living with a disability, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, living in a rural area, or being near or below the poverty level are often associated with worse health outcomes.^{115,116,117} Health disparities manifest primarily as worse health outcomes in populations where access to care is inequitable.^{118,119} Such differences persist across geography and healthcare settings irrespective of improvements in quality of care over time.^{120,121} Inequities in the social determinants of health affecting these groups are interrelated and influence a wide range of health and quality of life outcomes and risks.¹²²

Inequities related to the social determinants of health may affect health-related social needs (HRSNs). HRSNs are individual-level, adverse social conditions that negatively impact an individual’s health or healthcare and are associated with worse health outcomes and increased

¹¹⁴ Centers for Medicare & Medicaid Services. (2022). CMS Framework for Health Equity 2022-2032. Available at: <https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf>.

¹¹⁵ Polyakova M, Udalova V, Kocks G, Genadek K, Finlay K, Finkelstein AN. (2021). Racial Disparities in Excess All-Cause Mortality During The Early COVID-19 Pandemic Varied Substantially Across States. *Health Affairs*, 40(2), 307-316. <https://doi.org/10.1377/hlthaff.2020.02142>.

¹¹⁶ Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. Available at: <https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf>.

¹¹⁷ Heslin KC, Hall JE. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID-19–Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. *MMWR Morbidity Mortality Weekly Report*, 70(5), 149. <http://dx.doi.org/10.15585/mmwr.mm7005a1>.

¹¹⁸ The Physicians Foundation. (2020). Survey of America’s Patients, Part Three. Available at: <https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf>.

¹¹⁹ Office of the Assistant Secretary for Planning and Evaluation. (2020). Report to Congress: Social Risk Factors and Performance Under Medicare’s Value-Based Purchasing Program (Second of Two Reports). Available at: <https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress>.

¹²⁰ Ibid.

¹²¹ Khullar D, Schpero WL, Bond AM, Qian Y, Casalino LP. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA*, 324(10), 975-983. <https://jamanetwork.com/journals/jama/fullarticle/2770410>.

¹²² Office of Disease Prevention and Health Promotion. (2021). Healthy People 2020: Disparities. Available at: <https://wayback.archive-it.org/5774/20220414003754/https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities>.

healthcare utilization.¹²³ While HRSNs account for 50 to 70 percent of health outcomes, the mechanisms by which this connection emerges are complex and multifaceted.^{124,125} Growing evidence demonstrates that specific HRSNs are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality-based payment programs.^{126,127} The persistent interactions among individuals' HRSNs, medical providers' practices and behaviors, and community resources significantly impact healthcare access, quality, and costs, as described in the CMS Equity Plan for Improving Quality in Medicare.^{128,129} Assessment of HRSNs is an essential mechanism for capturing the interaction between social, community, and environmental factors associated with health status and health outcomes.^{130,131} Studies indicate that healthcare facility leadership can positively influence culture for better quality, patient outcomes, and experience of care.^{132,133,134}

¹²³ Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: <https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion>.

¹²⁴ Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: <https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/>.

¹²⁵ The Physicians Foundation. (2021). Viewpoints: Social Determinants of Health. Available at: <https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf>.

¹²⁶ Zhang Y, Li J, Yu J, Braun RT, Casalino LP. (2021), Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open*, 4(6), e2113212. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780864>.

¹²⁷ Khullar D, Schpero WL, Bond AM, Qian Y, Casalino LP (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA*, 324(10), 975–983. <https://doi.org/10.1001/jama.2020.13129>.

¹²⁸ Centers for Medicare & Medicaid Services. (2021). Paving the Way to Equity: A Progress Report. Available at: <https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf>.

¹²⁹ Centers for Medicare & Medicaid Services Office of Minority Health. (2021). The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMSEquityPlanforMedicare_090615.pdf.

¹³⁰ Alley DE, Asomugha CN, Conway PH, Sanghavi DM. (2016). Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. *New England Journal of Medicine*, 374(1), 8-11. Available at: <https://www.nejm.org/doi/10.1056/NEJMp1512532>.

¹³¹ Centers for Disease Control and Prevention. (July 2020). CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/community/CDC-Strategy.pdf>.

¹³² We use the term “healthcare facility” to refer to hospital outpatient departments (HOPDs), rural emergency hospitals (REHs), and ambulatory surgical centers (ASCs) collectively.

¹³³ Smith SA, Yount N, Sorra J. (2017). Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. *BMC Health Services Research*, 17(1), 143. <https://doi.org/10.1186/s12913-017-2078-6>.

¹³⁴ Bradley EH, Brewster AL, McNatt Z, et al. (2018). How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. *BMJ Quality & Safety*, 27(3), 218-225. <https://qualitysafety.bmj.com/content/27/3/218>.

We are committed to supporting healthcare facility leadership in building a culture of equity that focuses on eliminating health disparities to provide patients with high quality healthcare through the collection and public reporting of health equity focused measures, including in outpatient care settings.¹³⁵

Health equity quality measurement supports the Meaningful Measures 2.0 goal to “Leverage Quality Measures to Promote Equity and Close Gaps in Care” as well as the objective to “commit to a patient-centered approach in quality measure and value-based incentives programs.” Additionally, under the CMS National Quality Strategy, adoption of health equity quality measures would support addressing the quality priority to “advance health equity and whole-person care” by employing a uniform approach for gathering, reporting, and analyzing health equity data across CMS quality programs.¹³⁶

1. Proposal to Adopt the Hospital Commitment to Health Equity (HCHE) Measure for the Hospital Outpatient Quality Reporting (OQR) and Rural Emergency Hospital Quality Reporting (REHQR) Programs and the Facility Commitment to Health Equity (FCHE) Measure for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination or Program Determination.¹³⁷

a. Background

¹³⁵ Smith SA, Yount N, Sorra J. (2017). Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. *BMC Health Services Research*, 17(1), 143. <https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-017-2078-6>.

¹³⁶ Centers for Medicare & Medicaid Services. (2024). CMS National Quality Strategy. Centers for Medicare and Medicaid Services. Available at: <https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy>.

¹³⁷ We use the phrase “payment determination” for the Hospital OQR and ASCQR Programs to represent our assessment of whether the 2-percentage point reduction in payment for failing to meet program requirements is warranted. We use the phrase “program determination” for the REHQR Program to represent our assessment of compliance with program requirements for an applicable year because the REHQR Program does not include an associated payment adjustment.

Strong and committed leadership from healthcare facility management is essential in shifting organizational culture to reduce health disparities and reach health equity goals.¹³⁸ The Agency for Healthcare Research and Quality and The Joint Commission identified that healthcare facility leadership plays an important role in promoting a culture of quality and safety.^{139,140} The Institute of Healthcare Improvement's research shows that health equity must be a priority championed by leadership teams to improve both patient access to needed healthcare services and outcomes among disadvantaged populations.¹⁴¹ Based upon these findings, we believe that healthcare facility leadership is instrumental in setting specific, measurable, attainable, realistic, and time-based (SMART) goals to assess progress towards achieving equity priorities and ensuring high-quality care is equally accessible to all individuals.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25592 and 25593), we sought public comment on potential future efforts to address health equity in the Hospital Inpatient Quality Reporting (IQR) Program, particularly the inclusion of a structural measure to assess the degree of hospital leadership commitment to collecting and monitoring health equity performance data. We specifically sought feedback on (1) conceptual and measurement priorities to facilitate organizational efforts to improve health equity; and (2) an appropriate measure regarding organizational commitment to health equity and accessibility for individuals with intellectual and developmental disabilities. In response, we received support for the development and implementation of a health equity structural measure. We also received comments expressing concerns about such a health equity structural measure. We refer readers

¹³⁸ Bradley EH, Brewster AL, McNatt Z, Linnander EL, Cherlin E, Fosburgh H, Ting HH, Curry LA.(2018). How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. *BMJ Quality & Safety*, 27(3), 218-225. <https://pubmed.ncbi.nlm.nih.gov/29101290/>.

¹³⁹ Agency for Healthcare Research and Quality. (September 2019). Leadership Role in Improving Patient Safety. Patient Safety Network. Available at: <https://psnet.ahrq.gov/primer/leadership-role-improving-safety>.

¹⁴⁰ Joint Commission on Accreditation of Healthcare Organizations. (June 2021). The essential role of leadership in developing a safety of culture. *Sentinel Event Alert*. (57), 1–8. <https://www.jointcommission.org/-/media/tjc/newsletters/sea-57-safety-culture-and-leadership-final3.pdf>.

¹⁴¹ Mate KS, Wyatt R. (2017). Health Equity Must Be a Strategic Priority. *NEJM Catalyst*. Available at: <https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556>.

to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45414 through 45416) for summaries of the comments we received related to this solicitation.

We considered this feedback with the intent that future health equity measures would align across the Medicare quality reporting programs, including the Hospital OQR, REHQR, and ASCQR Programs, to ensure equitable care across both inpatient and outpatient settings to the greatest extent possible within facilities and hospitals participating in Medicare. In addition, we believe that measuring leadership commitment to health equity should not be limited to the inpatient hospital setting but should cover the continuum of care as patients seek and receive care at various care settings.

We initially developed the HCHE and FCHE measures for use in the Hospital IQR and Inpatient Psychiatric Facility Quality Reporting (IPFQR) Programs, respectively, with the expectation of expansion into other Medicare quality reporting programs. The HCHE and FCHE measures are attestation-based structural measures that assess hospitals' and facilities' commitment to health equity across the following five domains adapted from the CMS Office of Minority Health's "Building an Organizational Response to Health Disparities" framework: equity as a strategic priority, data calculation, data analysis, quality improvement, and leadership engagement.¹⁴² These measures are intended to encourage hospitals and facilities to analyze their data to understand how factors, including race, ethnicity, and the social determinants of health can contribute to the delivery of more equitable care.¹⁴³

We believe these domains provide actionable focus areas for the assessment of healthcare facility leadership commitment because they are foundational to incentivizing hospitals and facilities to collect and utilize data to identify critical equity gaps, implement plans to address those gaps, and ensure that resources are dedicated toward healthcare equity initiatives. We also

¹⁴² Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf>.

¹⁴³ We note that the term "hospital" includes HOPDs and REHs for the purposes of this measure.

believe these measures support hospitals and facilities in quality improvement, promote efficient and effective use of resources, and leverage available data.

Adoption of these measures in the Hospital OQR, REHQR, and ASCQR Programs would support our efforts to align measures across CMS programs, including the Hospital Inpatient Quality Reporting (IQR) Program (87 FR 49191 through 49201), Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program (88 FR 51100 through 51107), PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (88 FR 59204 through 59210), and End-Stage Renal Disease Quality Incentive Program (ESRD QIP) (88 FR 76437 through 76446). We believe that alignment across the quality reporting programs is important to ensure that health equity, which impacts patients regardless of where they receive their care, is addressed in every healthcare delivery setting. Adopting these measures across quality reporting programs would incentivize quality reporting entities to collect and utilize data to identify critical equity gaps, implement plans to address said gaps, and ensure that resources are dedicated toward addressing health equity initiatives.

b. Overview of the Measures

The HCHE and FCHE measures assess a hospital’s or facility’s commitment to health equity by using equity-focused organizational domains aimed at advancing health equity for all patients, including but not limited to those in racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. Table 86 and Table 87 describe the five attestation domains and their elements for the HCHE and FCHE measures, respectively.

**TABLE 86: HOSPITAL COMMITMENT TO HEALTH EQUITY MEASURE
ATTESTATION DOMAINS**

Attestation	Elements: Select all that apply (Note: Affirmative attestation of all elements within a domain would be required for the hospital to receive a point for the domain in the numerator)
	Domain 1: Equity is a Strategic Priority

Hospital commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your hospital has a strategic plan for advancing health equity and that it includes all the following elements.	(A) Our hospital strategic plan identifies priority populations who currently experience health disparities. (B) Our hospital strategic plan identifies health equity goals and discrete action steps to achieving these goals. (C) Our hospital strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our hospital strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a hospital is an important step in identifying and eliminating health disparities. Please attest that your hospital engages in the following activities.	(A) Our hospital collects demographic information (such as self-reported race, national origin, primary language, and ethnicity data), and/or social determinant of health information on the majority of our patients. (B) Our hospital has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our hospital inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using a certified EHR technology.
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your hospital engages in the following activities.	(A) Our hospital stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on hospital performance dashboards.
Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care has not been delivered equitably to all patients. Engagement in quality improvement activities can improve quality of care for all patients.	(A) Our hospital participates in local, regional, or national quality improvement activities focused on reducing health disparities.
Domain 5: Leadership Engagement	
Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your hospital engages in the following activities.	(A) Our senior leadership, including chief executives and the entire board of trustees, annually reviews our strategic plan for achieving health equity. (B) Our senior leadership, including chief executives and the entire board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

TABLE 87: FACILITY COMMITMENT TO HEALTH EQUITY MEASURE

ATTESTATION DOMAINS

Attestation	Elements: Select all that apply
	(Note: Affirmative attestation of all elements within a domain would be required for the facility to receive a point for the domain in the numerator)
	Domain 1: Equity is a Strategic Priority

<p>Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your facility has a strategic plan for advancing health equity and that it includes all the following elements.</p>	<p>(A) Our facility strategic plan identifies priority populations who currently experience health disparities. (B) Our facility strategic plan identifies health equity goals and discrete action steps to achieving these goals. (C) Our facility strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our facility strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.</p>
<p>Domain 2: Data Collection</p>	
<p>Collecting valid and reliable demographic and social determinant of health data on patients served in a facility is an important step in identifying and eliminating health disparities. Please attest that your facility engages in the following activities.</p>	<p>(A) Our facility collects demographic information (such as self-reported race, national origin primary language and ethnicity data), and/or social determinant of health information on the majority of our patients. (B) Our facility has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using an EHR technology.</p>
<p>Domain 3: Data Analysis</p>	
<p>Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your facility engages in the following activities.</p>	<p>(A) Our facility stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on facility performance dashboards.</p>
<p>Domain 4: Quality Improvement</p>	
<p>Health disparities are evidence that high-quality care has not been delivered equitably to all patients. Engagement in quality improvement activities can improve quality of care for all patients.</p>	<p>(A) Our facility participates in local, regional, or national quality improvement activities focused on reducing health disparities.</p>
<p>Domain 5: Leadership Engagement</p>	
<p>Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your facility engages in the following activities.</p>	<p>(A) Our facility senior leadership, such as chief executives and the entire facility board of trustees, annually reviews our strategic plan for achieving health equity. (B) Our facility senior leadership, such as chief executives and the entire facility board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.</p>

The HCHE measure is currently used in the Hospital IQR and PCHQR Programs. As further discussed below, we propose to adopt the HCHE measure for the Hospital OQR and REHQR Programs. The FCHE measure is currently used in the IPFQR Program and ESRD QIP. As further discussed below, we propose to adopt the FCHE measure for the ASCQR Program.

We note that there are two measure specification variations between the HCHE and FCHE measures, as reflected in Tables 86 and 87. First, Table 86 references hospitals (such as HOPDs and REHs) in connection with HCHE; Table 87 references facilities (such as ASCs,

which are not hospitals) in connection with FCHE. Second, Domain 2C of the HCHE measure requires hospitals to use a certified electronic health record (EHR) technology (CEHRT)¹⁴⁴ in order to attest “yes”; Domain 2C of the FCHE measure requires facilities to use EHR technology, but does not require the use of CEHRT, in order to attest “yes.” We recognize that ASCs have governance structures and operational circumstances that are distinct from hospitals. We also recognize that many non-hospital facilities, including ASCs, have not adopted CEHRT, but may use some EHR technology,¹⁴⁵ justifying this variation in Domain 2C between the HCHE and FCHE measures.¹⁴⁶

c. Pre-Rulemaking Measure Review

As required under section 1890A of the Act, the Consensus-Based Entity (CBE), currently Battelle, established the Partnership for Quality Measurement (PQM), comprised of clinicians, patients, measure experts, and health information technology specialists, to participate in the pre-rulemaking process and the measure endorsement process and provide input on the selection of quality and efficiency measures. 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 PQM for the purpose of providing multi-stakeholder input to the Secretary on the selection of quality and efficiency measures under consideration for use in

¹⁴⁴ CEHRT refers to the certified health IT requirements established by CMS and the Office of the National Coordinator for Health Information Technology (ONC). ONC health IT certification criteria referenced in the CEHRT definition can be found at 45 CFR 170.315. Please refer to the following for more details on CEHRT requirements: <https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs/certified-ehr-technology>. Please refer to the Measure Calculation section for more details on CEHRT and the HCHE Measure.

¹⁴⁵ We define the term “EHR technology” as ONC’s definition for Electronic Health Record, “a real-time patient health record with access to evidence-based decision support tools that can be used to aid clinicians in decision making. The EHR can automate and streamline a clinician’s workflow, ensuring that all clinical information is communicated. It can also prevent delays in response that result in gaps in care. The EHR can also support the collection of data for uses other than clinical care, such as billing, quality management, outcome reporting, and public health disease surveillance and reporting,” at <https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/glossary>.

¹⁴⁶ Taira A. (June 2021). ASCA Survey Shows Mixed Usage of EHR among ASCs. ASC Focus. Available at: <https://www.ascfocus.org/ascfocus/content/articles-content/articles/2021/digital-debut/asca-survey-shows-mixed-usage-of-ehr-among-ascs>.

certain Medicare quality programs, including the Hospital OQR, REHQR, and ASCQR Programs. More details regarding the PRMR process may be found in the PQM Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review, including details of the measure review processes in Chapter 3.¹⁴⁷

As part of the PRMR process, the Hospital Recommendation Group reviewed and voted on the HCHE and FCHE measures during their meeting on January 18 and 19, 2024.^{148,149} The voting results of the HCHE measure for the Hospital OQR and REHQR Programs were “recommend with conditions,” and the voting results of the FCHE measure were “recommended without conditions” for the ASCQR Program. The conditions for the HCHE measure for the Hospital OQR and REHQR Programs were: (1) obtaining CBE endorsement; (2) additional specificity around attestation requirements; and (3) ongoing data collection for further measure testing, particularly with regard to smaller entities.¹⁵⁰ We have taken these conditions into account, as follows, and are proposing both of these measures for adoption. We discuss CBE endorsement in section XIV.B.1.d below.

Regarding the condition to provide additional specificity around attestation requirements, we note that these domains were developed based on the recommendations from a technical expert panel (TEP) that informed our initial selection and development of this measure.¹⁵¹ We also addressed this concern during the January 18-19, 2024 PRMR meeting by sharing that there

¹⁴⁷ Partnership for Quality Measurement. (September 2023). Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review. Available at: https://p4qm.org/sites/default/files/2023-09/Guidebook-of-Policies-and-Procedures-for-Pre-Rulemaking-Measure-Review-%28PRMR%29-and-Measure-Set-Review-%28MSR%29-Final_0.pdf.

¹⁴⁸ Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf>.

¹⁴⁹ Partnership for Quality Measurement. Pre-Rulemaking Measure Review Measures Under Consideration: 2023 Recommendations Report. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-2023-MUC-Recommendations-Report-Final.pdf>.

¹⁵⁰ Ibid.

¹⁵¹ Centers for Medicare & Medicaid Services. (February 2022). Summary of Technical Expert Panel (TEP) Meeting #1, November 16, 2021: Health Equity Quality Measurement, Hospital Commitment to Health Equity Measure. Available at: <https://mmshub.cms.gov/sites/default/files/HealthEquityQualityMeasurementTEP1SumReport.pdf>.

are accompanying guidance documents available to provide information and examples of qualifying activities for the HCHE measure (which can also be applied to the FCHE measure).^{152,153}

With respect to the condition related to ongoing data collection for further measure testing due to concerns that smaller entities may face challenges regarding data collection and analysis, we reiterate that HCHE is an attestation measure only in Hospital OQR, a pay-for-reporting program, and REHQR, a program with no associated payment adjustment.¹⁵⁴ While we acknowledge the limitations in testing structural measures, we believe this measure captures useful information regarding providers' commitment to promoting health equity to inform patient choice. We have therefore considered the Hospital Recommendation Group's concerns and determined that they are adequately addressed.

d. CBE Endorsement

Section 1833(t)(17)(C)(i) of the Act provides that the Hospital OQR Program, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities (not necessarily the CBE). Under section 1833(i)(7)(B) of the Act, this requirement at section 1833(t)(17)(C) applies to the ASCQR Program except as the Secretary may otherwise provide. For the Hospital OQR Program and ASCQR Program, we note that section 1833(t)(17) of the Act does not require that each measure we adopt for these programs be CBE-endorsed (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

¹⁵² Centers for Medicare & Medicaid Services (January 2024). Attestation Guidance for the Hospital Commitment to Health Equity Measure (v 1.2). Available at: https://qualitynet.cms.gov/files/659c609eca7fd3001b35edab?filename=AttstGdnceHCHEMeas_v1.2.pdf.

¹⁵³ Centers for Medicare & Medicaid Services (January 2024). Frequently Asked Questions Hospital Commitment to Health Equity, HIQR. Available at: https://qualitynet.cms.gov/files/659c60afd4b704001df0af51?filename=FAQ_HCHE_HIQR.pdf.

¹⁵⁴ Partnership for Quality Measurement. (2023). 2023 PRMR Final MUC Recommendation Spreadsheet. Available at: <https://p4qm.org/PRMR>.

Section 1833(t)(17)(C)(i) of the Act also requires measures developed for the Hospital OQR Program to reflect consensus among affected parties. Under section 1833(i)(7)(B) of the Act, this requirement also applies to the ASCQR Program except as the Secretary may otherwise provide. 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 (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

For the REHQR Program, section 1861(kkk)(7)(C)(i) of the Act generally requires that quality measures specified by the Secretary for the REHQR Program be endorsed by a CBE; however, section 1861(kkk)(7)(C)(ii) of the Act provides an exception to the general CBE-endorsement requirement, stating that in the case of a specified area or medical topic determined appropriate by the Secretary for which a measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and therefore we believe the exception in section 1861(kkk)(7)(C)(ii) of the Act applies for purposes of this measure for the REHQR Program.

At this time, we find no other feasible and practicable measures set forth by a national consensus building entity on the topic of a hospital's or facility's leadership commitment to health equity. While we recognize the value of measures undergoing CBE endorsement review and prefer to use endorsed measures, there are currently no CBE-endorsed measures that address hospital or facility commitment to health equity. Given the urgency of achieving health equity, it is important to implement this measure as soon as possible. As previously noted, the HCHE measure was developed based on the consensus of a TEP whose recommendations

informed the initial selection, development, and emphasis of the importance of this measure and subsequently the FCHE measure, which, as noted in section XIV.B.1.b above, is a similar measure with only two measure specification variations to accommodate setting-specific realities with regards to CEHRT adoption.¹⁵⁵ We will consider submitting the HCHE and FCHE measures to the CBE for endorsement in the future.

e. Measure Calculation

The proposed HCHE and FCHE measures each consist of the same five attestation-based domains as shown in Table 86 and Table 87, respectively, subject to variations noted above.

The numerator of both the HCHE and FCHE measures would capture the total number of domains to which the hospital or facility is able to attest affirmatively, up to a maximum of five domains. We propose that a hospital or facility would only receive a point for a domain if it attested “yes” to all of the elements within that domain. We would not accept an attestation whereby a hospital or facility attests “yes” to some, but not all, of the elements; in the event a hospital or facility would not be able to attest “yes” to one or more elements within a domain, or the entirety of a domain, they would respond “no.” For example, for Domain 1, if the hospital or facility’s strategic plan meets elements (A) and (B), but not (C) and (D) of Domain 1, then the hospital or facility would not be able to affirmatively attest “yes” and would receive zero points for Domain 1.

The denominator of both the HCHE and FCHE measures would constitute a total of five points (that is, one point per domain).

¹⁵⁵ Centers for Medicare & Medicaid Services. (February, 2022). Summary of Technical Expert Panel (TEP) Meeting # 1 November 16, 2021: Health Equity Quality Measurement Hospital Commitment to Health Equity Measure. Available at: <https://mmshub.cms.gov/sites/default/files/HealthEquityQualityMeasurementTEP1SumReport.pdf>.

We also refer readers to the measure specifications, available on our QualityNet website.¹⁵⁶

As noted above, Domain 2C of the HCHE measure requires the use of CEHRT, while Domain 2C of the FCHE measure requires the use of EHR technology, which is not required to be certified by ONC in accordance with ONC's requirements. We made this distinction because we recognize that many non-hospital facilities, including ASCs, currently have not adopted CEHRT and instead use non-certified EHR technology,¹⁵⁷ while a majority of hospitals have adopted CEHRT.¹⁵⁸ Although REHs are a new Medicare provider type, the majority of REH-eligible facilities, as noted in the CY 2024 OPPTS/ASC final rule (88 FR 82069), have met requirements for the reporting of electronic clinical quality measures (eCQMs), which require CEHRT, under the Medicare Promoting Interoperability Program.

f. Data Submission Requirements

We propose to require hospitals and ASCs to submit their yes/no attestation responses on these structural measures in all three programs by an annual deadline using the CMS-designated information system (currently, the Hospital Quality Reporting (HQR) system) consistent with the data submission requirements of these measures in the Hospital IQR, IPFQR and PCHQR Programs. We refer readers to sections XV.E.2.a, XVI.E.3.b, and XVII.E.2.a of this proposed rule for additional details regarding data submission deadlines for web-based measure reporting such as the HCHE and FCHE measures for the Hospital OQR, REHQR, and ASCQR Programs, respectively.

¹⁵⁶ The proposed Hospital OQR and REHQR Program measure specifications can be found at <https://qualitynet.cms.gov/outpatient/oqr/proposedmeasures>. The proposed ASCQR Program measure specifications can be found at <https://qualitynet.cms.gov/asc/ascqr/proposedmeasures>.

¹⁵⁷ Taira A. (June 2021). ASCA Survey Shows Mixed Usage of EHR among ASCs. ASC Focus. Available at: <https://www.ascfocus.org/ascfocus/content/articles-content/articles/2021/digital-debut/asca-survey-shows-mixed-usage-of-ehr-among-asc>.

¹⁵⁸ Office of the National Coordinator for Health Information Technology. (2023). National Trends in Hospital and Physician Adoption of Electronic Health Records. Available at: <https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records>.

We invite public comment on our proposal to adopt the HCHE measure for the Hospital OQR Program beginning with the CY 2025 reporting period/CY 2027 payment determination, to adopt the HCHE measure for the REHQR Program beginning with the CY 2025 reporting period/CY 2027 program determination, and to adopt the FCHE measure for the ASCQR Program beginning with the CY 2025 reporting period/CY 2027 payment determination.

2. Proposal to Adopt the Screening for Social Drivers of Health (SDOH) Measure for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs Beginning with Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting for the CY 2026 Reporting Period/CY 2028 Payment or Program Determination

a. Background

SDOH is an umbrella term that refers to community-level factors that impact health and well-being, while HRSNs are social and economic needs that individuals experience that affect their ability to maintain their health and well-being.¹⁵⁹ Consistent screening of patients for potential HRSNs helps healthcare facilities identify individuals who have historically been underserved by the healthcare system and could support ongoing quality improvement initiatives at the population level by providing data to stratify patient risk and organizational performance to address SDOH.^{160,161} While widespread interest exists in addressing SDOH at community, state, and national levels and in supporting HRSNs for patients who experience one or more HRSNs, action is inconsistent, with 92 percent of hospitals screening for one or more of the five

¹⁵⁹ Assistant Secretary for Planning and Evaluation. (November 2023). Call to Action: Addressing Health-Related Social Needs in Communities Across the Nation. Available at: <https://aspe.hhs.gov/sites/default/files/documents/3e2f6140d0087435cc6832bf8cf32618/hhs-call-to-action-health-related-social-needs.pdf>.

¹⁶⁰ Assistant Secretary for Planning and Evaluation. (September 2022). Reflections Accompanying a Report on Addressing Social Drivers of Health: Evaluating Area-level Indices. Available at: <https://aspe.hhs.gov/sites/default/files/documents/474a62378abf941f20b3eaa74ca5721c/Area-level-Indices-ASPE-Reflections.pdf>.

¹⁶¹ American Hospital Association. (December 2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. Available at: https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.

HRSNs listed in Table 88 but only 24 percent of hospitals screening for all five of these HRSNs.¹⁶² Additionally, pilot studies screening for HRSNs have been conducted in the HOPD and ASC settings, with clinicians and staff agreeing that HRSN data are important and relevant to collect in these settings to improve patient care and communication as well as to connect patients with social-related services.^{163,164} We believe that it is essential for healthcare facilities to screen for patient-level HRSN data to support the improvement of patient outcomes and their identified social needs.

In 2017, the CMS Center for Medicare and Medicaid Innovation (CMMI) launched the Accountable Health Communities (AHC) Model, which tested whether systematically identifying and addressing the HRSNs of Medicare and Medicaid beneficiaries through screening, referral, and community navigation services impacted their health outcomes and related healthcare utilization and costs.^{165,166} Evaluation of the AHC Model's standard 10-item AHC Health-Related Social Needs Screening Tool (AHC HRSN Screening Tool) found a reduction in emergency department (ED) visits among Medicaid and Medicare fee-for-service (FFS) beneficiaries.¹⁶⁷

Under the AHC Model, the following five core domains were selected to screen for HRSNs among Medicare and Medicaid beneficiaries: (1) food insecurity; (2) housing instability;

¹⁶² Frazee TK, Brewster AL, Lewis VA, Beidler LB, Murray GF, Colla, CH. (2019). Prevalence of Screening for Food Insecurity, Housing Instability, Utility Needs, Transportation Needs, and Interpersonal Violence by US Physician Practices and Hospitals. *JAMA Network Open*, 2(9), e1911514. <https://doi.org/10.1001/jamanetworkopen.2019.11514>.

¹⁶³ Berkowitz RL, Bui L, Shen Z, Pressman A, Moreno M, Brown S, Nilon, A Miller-Rosales, Azar KM. (2021). Evaluation of a social determinants of health screening questionnaire and workflow pilot within an adult ambulatory clinic. *BMC Family Practice*, 22(1), 256. <https://doi.org/10.1186/s12875-021-01598-3>.

¹⁶⁴ Schickedanz A, Hamity C, Rogers A, Sharp AL, Jackson A. (2019). Clinician Experiences and Attitudes Regarding Screening for Social Determinants of Health in a Large Integrated Health System. *Medical Care*, 57, S197–S201. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6721844/>.

¹⁶⁵ Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>.

¹⁶⁶ Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model. Available at: <https://www.cms.gov/priorities/innovation/innovation-models/ahcm>.

¹⁶⁷ Centers for Medicare & Medicaid Services. (2023). Accountable Health Communities (AHC) Model Evaluation: Second Evaluation Report. CMS Innovation Center. Available at: <https://www.cms.gov/priorities/innovation/data-and-reports/2023/ahc-second-eval-rpt>.

(3) transportation needs; (4) utility difficulties; and (5) interpersonal safety. These domains were chosen based upon literature review and expert consensus utilizing the following criteria:

(1) availability of high-quality scientific evidence linking a given HRSN to adverse health outcomes and increased healthcare utilization, including hospitalizations and associated costs;

(2) ability for a given HRSN to be screened and identified prior to discharge, be addressed by community-based services, and potentially improve healthcare outcomes, including reduced readmissions; and (3) evidence that a given HRSN is not systematically addressed by healthcare providers.¹⁶⁸ In addition to established evidence of their association with health status, risk, and outcomes, these five domains were selected for the AHC Model because they can be assessed across the broadest spectrum of individuals in a variety of settings.¹⁶⁹

TABLE 88: THE FIVE CORE HRSN DOMAINS SCREENED UNDER THE AHC MODEL

Domain	Description
Food Insecurity	Food insecurity is defined as limited or uncertain access to adequate quality and quantity of food at the household level. It is associated with diminished mental and physical health and increased risk for chronic conditions. ¹⁷⁰ Individuals experiencing food insecurity often have inadequate access to healthier food options which can impede self-management of chronic diseases like diabetes and heart disease, and require individuals to make personal trade-offs between food purchases and medical needs, including prescription medication refills and preventive health services. ^{171,172} Food insecurity is associated with high-cost healthcare utilization including emergency department (ED) visits and outpatient visits. ^{173,174}

¹⁶⁸ Billioux A, Verlander, K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). <https://doi.org/10.31478/201705b>.

¹⁶⁹ Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model. Available at: <https://innovation.cms.gov/innovation-models/ahcm>.

¹⁷⁰ Berkowitz SA, Seligman HK, Meigs JB, Basu S. (2018). Food Insecurity, Healthcare Utilization, and High Cost: A Longitudinal Cohort Study. *The American Journal of Managed Care*, 24(9), 399–404. <http://www.ncbi.nlm.nih.gov/pmc/articles/pmc6426124/>.

¹⁷¹ Seligman HK, Berkowitz, SA. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. *Annual Review of Public Health*, 40(1), 319–337. <https://www.annualreviews.org/doi/10.1146/annurev-publhealth-040218-044132>.

¹⁷² National Academies of Sciences, Engineering, and Medicine. (2006). Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: <https://nap.nationalacademies.org/catalog/23285/executive-summary-cost-benefit-analysis-of-providing-non-emergency-medical-transportation>.

¹⁷³ Berkowitz SA, Seligman HK, Meigs JB, Basu S. (2018). Food Insecurity, Healthcare Utilization, and High Cost: A Longitudinal Cohort Study. *The American Journal of Managed Care*, 24(9), 399–404. <http://www.ncbi.nlm.nih.gov/pmc/articles/pmc6426124/>.

¹⁷⁴ Dean EB, French MT, Mortensen, K. (2020). Food insecurity, health care utilization, and health care expenditures. *Health Services Research*, 55(S2), 883–893. Available at: <https://doi.org/10.1111/1475-6773.13283>.

Housing Instability	Housing instability encompasses multiple conditions ranging from inability to pay rent or mortgage, frequent changes in residence including temporary stays with friends and relatives, living in crowded conditions, and actual lack of sheltered housing in which an individual does not have a personal residence. ¹⁷⁵ Population surveys consistently show that people from some racial and ethnic minority groups constitute the largest proportion of the U.S. population experiencing housing instability. ¹⁷⁶ Housing instability is associated with higher rates of chronic illnesses, injuries, and complications and more frequent utilization of high-cost healthcare services. ¹⁷⁷
Transportation Needs	Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living. ¹⁷⁸ Groups disproportionately affected include older adults (aged >65 years), people with lower incomes, people with impaired mobility, residents of rural areas, and people from some racial and ethnic minority groups. Transportation needs contribute to postponement of routine medical care and preventive services which ultimately lead to chronic illness exacerbation and more frequent utilization of high-cost healthcare services. ^{179,180} Patients with serious mental illness often lack access to transportation with many Medicaid eligible patients relying on Medicaid's non-emergency medical transportation (NEMT) to access needed healthcare, though this does not provide access to transportation to other aspects of daily living. ¹⁸¹
Utility Difficulties	Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity. ¹⁸² Specifically, interventions that increase or maintain access to such services have been associated with individual and population-level health improvements. ¹⁸³
Interpersonal Safety	Interpersonal safety affects individuals across the lifespan, from birth to old age, and is directly linked to mental and physical health. Assessment for this domain includes

¹⁷⁵ Hill-Briggs, F. (2020). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*, 44(1), 258–279. <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

¹⁷⁶ Henry M, de Sousa T, Roddey C, Gayen S, Bednar T, Abt Associates. (January 2021). The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness. U.S. Department of Housing and Urban Development. Available at: <https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf>.

¹⁷⁷ Baxter A, Tweed E, Katikireddi S, Thomson H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. *Journal of Epidemiology and Community Health*, 73; 379–387. <https://doi.org/10.1136/jech-2018-210981>.

¹⁷⁸ Centers for Medicare and Medicaid Services. (2023) Addressing Transportation Barriers: A User Case in Leveraging the Value-Based Insurance Design (VBID) Model. Available at: <https://www.cms.gov/priorities/innovation/innovation-models/vbid>.

¹⁷⁹ Billieux A, Verlander, K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). <https://doi.org/10.31478/201705b>.

¹⁸⁰ Shier G, Ginsburg M, Howell J, Volland P, Golden R. (2013). Strong Social Support Services, Such as Transportation And Help For Caregivers, Can Lead To Lower Health Care Use And Costs. *Health Affairs*, 32(3), 544–551. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2012.0170>.

¹⁸¹ National Alliance on Mental Illness. Medicaid: Non-Emergency Medical Transportation (NEMT). Available at: <https://www.nami.org/Advocacy/Policy-Priorities/Supporting-Community-Inclusion-and-Non-Discrimination/Medicaid-Non-Emergency-Medical-Transportation>.

¹⁸² Baxter A, Tweed E, Katikireddi S, Thomson H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. *Journal of Epidemiology and Community Health*, 73; 379–387. <https://doi.org/10.1136/jech-2018-210981>.

¹⁸³ Wright BJ, Vartanian KB, Li HF, Royal N, Matson JK (2016). Formerly Homeless People Had Lower Overall Health Care Expenditures After Moving into Supportive Housing. *Health Affairs*, 35(1), 20–27. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0393>.

screening for exposure to intimate partner violence, child abuse, and elder abuse. ¹⁸⁴ Exposure to violence and social isolation are reflective of individual-level social relations and living conditions that are directly associated with injury, psychological distress, and death in all age groups. ¹⁸⁵
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These five evidence-based HRSN domains described in Table 88 informed our development of the Screening for SDOH and Screen Positive Rate for SDOH measures. We used these five HRSN domains to inform the development of the SDOH measure we propose to adopt in this proposed rule because the AHC Model’s HRSN Screening Tool allows healthcare facilities to quickly screen for patients’ core health-related social needs and was designed to work in a variety of clinical settings, making it ideal for implementing across quality reporting programs, including the Hospital OQR, REHQR, and ASCQR Programs, with minimal burden to healthcare facilities.¹⁸⁶

We recognize that patient interaction with the healthcare system may be limited by setting. For example, a patient receiving care in an HOPD, REH, or ASC may not have recently received care in an acute care hospital paid under IPPS, inpatient psychiatric facility cancer hospital, or dialysis facility, and therefore would not have the opportunity to benefit from being screened for SDOHs despite this measure’s prior adoption in other quality programs. By adopting aligned Screening for SDOH measures within the Hospital OQR, REHQR, and ASCQR Programs, we expect to increase the likelihood that these settings will screen patients and provide contextualized care and any necessary relevant referrals to address their patient’s needs.

¹⁸⁴ Billioux A, Verlander K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). <https://doi.org/10.31478/201705b>.

¹⁸⁵ Henry M, de Sousa T, Roddey C, Gayen S, Bednar T, Abt Associates. (January 2021). The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness. U.S. Department of Housing and Urban Development. Available at: <https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf>.

¹⁸⁶ Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>.

Screening for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety in HOPDs, REHs, and ASCs can help identify and provide appropriate referrals for patients who may benefit from greater support in one or more of those areas.

Adoption of the Screening for SDOH measure in the Hospital OQR, REHQR, and ASCQR Programs would continue to support our priority of identifying risk factors for inadequate health care access and adverse health outcomes among patients.

b. Measure Overview

The Screening for SDOH measure is a process measure that assesses the total number of patients, who were 18 years or older on the date of service, screened for social risk factors (specifically, the five HRSNs of food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) as they receive care from a HOPD, REH, or ASC.

c. Pre-Rulemaking Measure Review

As part of the PRMR process, the Hospital Recommendation Group reviewed and voted on the Screening for SDOH measure during their meeting on January 18 and 19, 2024.¹⁸⁷ The Hospital Recommendation Group “recommended with conditions” the Screening for SDOH measure for all three programs (that is, the Hospital OQR, REHQR, and ASCQR Programs).

The committee recommended a condition specific to the Hospital OQR Program, which was to allow hospitals to report this measure one time each year for both the Hospital IQR Program and Hospital OQR Program if applicable.¹⁸⁸ We note that we considered allowing hospitals to report this measure jointly for the Hospital IQR and Hospital OQR Programs (if applicable); however, as the patient populations represented by the programs are different, as is the measure calculation due to this difference in the denominator, we propose to require a separate data submission for each program. More importantly, patients and consumers would

¹⁸⁷ The Screening for SDOH measure is identified on the MUC List as MUC2023-156.

¹⁸⁸ Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf>.

likely find useful Compare tool information on screening rates separated for inpatient and outpatient departments of the same hospital.

d. CBE Endorsement

Section 1833(t)(17)(C)(i) of the Act provides that the Hospital OQR Program, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities (not necessarily the CBE). Under section 1833(i)(7)(B) of the Act, this requirement at section 1833(t)(17)(C) applies to the ASCQR Program except as the Secretary may otherwise provide. For the Hospital OQR Program and ASCQR Program, we note that section 1833(t)(17) of the Act does not require that each measure we adopt for these programs be CBE-endorsed (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

Section 1833(t)(17)(C)(i) of the Act also requires measures developed for the Hospital OQR Program to reflect consensus among affected parties. Under section 1833(i)(7)(B), this requirement also applies to the ASCQR Program except as the Secretary may otherwise provide. 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 (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

For the REHQR Program, section 1861(kkk)(7)(C)(i) of the Act generally requires that quality measures specified by the Secretary for the REHQR Program be endorsed by a CBE; however, section 1861(kkk)(7)(C)(ii) of the Act provides an exception to the general CBE-endorsement requirement, stating that in the case of a specified area or medical topic determined appropriate by the Secretary for which a measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed

or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and therefore we believe the exception in section 1861(kkk)(7)(C)(ii) of the Act applies for purposes of this measure for the REHQR Program.

At this time, we find no other feasible and practicable measures set forth by a national consensus building entity on the topic of screening for SDOH. While we recognize the value of measures undergoing CBE endorsement review and prefer to use endorsed measures, there are currently no CBE-endorsed measures that address screening for SDOH in the outpatient setting. Given the urgency of achieving health equity, it is important to implement this measure as soon as possible. We note that the five domains for which patients would be screened were chosen based upon literature review and expert consensus, and that these five domains informed development of the Screening for SDOH measure. We will consider submitting the Screening for SDOH measure to the CBE for endorsement in the future.

e. Data Sources

For data collection of the Screening for SDOH measure, we propose that healthcare facilities would use a self-selected screening tool to collect these data. We propose to allow healthcare facilities to select their screening tool to reduce burden and in recognition of the fact that some healthcare facilities may already be screening their patients for HRSNs. If a healthcare facility is not already doing so, many screening tools for HRSNs already exist. While we acknowledge the potential benefits of requiring all healthcare facilities to use the same screening instrument or a prescribed set of standards around the number or types of screening questions used, we also recognize the benefits of providing healthcare facilities with flexibility to customize screening and data collection to their patient populations and individual needs.

One example of a screening tool that healthcare facilities could consider using is the AHC HRSN Screening Tool, which providers used in the AHC Model to screen for HRSNs in

their Medicare, Medicaid, and dually eligible beneficiary populations.¹⁸⁹ We have tested the AHC HRSN Screening Tool across many care delivery sites in diverse geographic locations and determined that it demonstrates evidence of both reliability and validity.¹⁹⁰ The AHC HRSN Screening Tool can be implemented in a variety of healthcare settings, including HOPDs, REHs, and ASCs. While the AHC Model focused on HRSNs among community-dwelling Medicare and Medicaid beneficiaries, the AHC HRSN Screening Tool can be used to screen patients with any insurance status or type, including commercially insured and uninsured individuals. The AHC HRSN Screening Tool has broad applicability in settings outside of the AHC Model as it screens for a range of five HRSN domains while also being concise, limited to only ten questions. We believe this promotes manageable integration into clinical workflow settings and provides greater accessibility and application to diverse patient populations.^{191,192}

For additional screening tools for healthcare facilities to consider using to collect data for this proposed Screening for SDOH measure, we refer readers to evidence-based resources like the Social Interventions Research and Evaluation Network (SIREN) website, for example, which provides comprehensive information about the most widely used HRSN screening tools.^{193,194} SIREN contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions.

We also encourage healthcare facilities to consider digital standardized screening tools.

¹⁸⁹ Centers for Medicare and Medicaid Services. The Accountable Health Communities Health-Related Social Needs Screening Tool. Available at: <https://www.cms.gov/priorities/innovation/files/worksheets/ahcm-screeningtool.pdf>.

¹⁹⁰ Centers for Medicare and Medicaid Services. (2023). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: <https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion>.

¹⁹¹ Ibid.

¹⁹² Billieux A, Verlander, K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). <https://doi.org/10.31478/201705b>.

¹⁹³ Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: <https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison>.

¹⁹⁴ The Social Interventions Research and Evaluation Network (SIREN) at University of California San Francisco was launched in the spring of 2016 to synthesize, disseminate, and catalyze research on SDOH and healthcare delivery.

We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49207 through 49208), where we discuss how the use of certified health information technology (IT), including but not limited to CEHRT,¹⁹⁵ can support capture of HRSN information in a standardized, interoperable fashion. We also encourage healthcare facilities to learn about the United States Core Data for Interoperability (USCDI) standard used in certified health IT and how this standard can support interoperable exchange of health and HRSN assessment data.¹⁹⁶

In alignment with the Hospital IQR Program, we propose that HOPDs, REHs, and ASCs could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported, in lieu of re-screening a patient within the reporting period. In addition, if this information has been captured in the EHR in another outpatient setting or the inpatient setting during the same reporting period, we propose that the HOPD, REH, and ASC could use that information for purposes of reporting the measure in lieu of screening the patient. We intend to monitor and evaluate the measure screening requirements, including frequency, in these outpatient settings to ensure balance between quality of care for patients and facility burden.

f. Measure Calculation

The Screening for SDOH measure is calculated as a percentage equal to the numerator over the denominator. The numerator is defined as the number of patients admitted to an HOPD, REH, or ASC, who are 18 years or older on the date of admission and are screened for all five HRSNs described in Table 88 during their receipt of services in the HOPD, REH, or ASC, as applicable.¹⁹⁷ The denominator is defined as the number of patients who are admitted to a

¹⁹⁵ CEHRT refers to certified health IT requirements defined by CMS for certain programs which incorporate health IT certification criteria established by the Office of the National Coordinator for Health Information Technology (ONC) at 45 CFR 170.315.

¹⁹⁶ Office of the National Coordinator for Health IT (ONC). United States Core Data for Interoperability. Available at: <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>.

¹⁹⁷ The term “admitted patients” appears in the measure specifications and MUC documentation and is intended to refer to a person who receives ambulatory care in these designated settings.

HOPD, REH, or ASC, as applicable, and who are 18 years or older.

The measure excludes patients who: (1) opt-out of screening; or (2) are themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf.

g. Data Submission and Reporting

We propose to allow healthcare facilities to voluntarily submit to CMS aggregate data for this measure for the CY 2025 reporting period and then to require mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination. Specifically, we propose that healthcare facilities would aggregate data they collect for the numerator and the denominator to CMS (as described in section XIV.B.2.f of this proposed rule), and that they would not be required to submit patient-level data. We propose to require aggregate data because we believe patient-level reporting is unnecessary and would cause undue burden due to the transfer of large quantities of data. However, in the future, we may consider requiring the reporting of patient-level information. This measure aims to encourage healthcare facilities to screen for and identify HRSNs in order to identify and address social needs among their patient populations.

We also propose that healthcare facilities would be required to submit data on this measure annually using the CMS-designated information system (currently, the HQR system) consistent with the data submission requirements for this measure in the Hospital IQR, IPFQR and PCHQR Programs. We refer readers to sections XV.E.2.a, XVI.E.3.b, and XVII.E.2.a of this proposed rule for additional details regarding data submission using the CMS-designated information system in the Hospital OQR, REHQR, and ASC Programs, respectively.

We propose to adopt this measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination. We propose to begin with one year of voluntary reporting to provide a transition period for healthcare facilities to select and integrate

screening tools into their clinical workflow processes.

We invite public comment on our proposal to adopt the Screening for SDOH measure for the Hospital OQR, REHQR, and ASCQR Programs beginning with voluntary reporting for the CY 2025 reporting period, and to require mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination, as described above.

3. Proposal to Adopt the Screen Positive Rate for Social Drivers of Health (SDOH) Measure for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs Beginning with Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning with the CY 2026 Reporting Period/CY 2028 Payment or Program Determination

a. Background

In the outpatient setting, we encourage systematic screening of patients' HRSNs to identify patient needs and support improvements in health outcomes. While the Screening for SDOH measure (discussed previously in section XIV.B.2 of this proposed rule) identifies individuals with HRSNs, the Screen Positive Rate for SDOH measure estimates the magnitude of these needs for a healthcare facility's patient population served. We believe the adoption of the Screen Positive Rate for SDOH measure would encourage healthcare facilities to track the prevalence of specific HRSNs among patients over time and use the data to stratify risk as part of quality performance improvement efforts.

We propose that healthcare facilities would be required to report the Screen Positive Rate for SDOH measure as the rate of patients who screened positive for each of the five core HRSNs domains discussed in Table 88: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.¹⁹⁸

¹⁹⁸ Billieux A, Verlander, K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). <https://doi.org/10.31478/201705b>.

b. Measure Overview

While the Screening for SDOH measure (discussed in section XIV.B.2) enables identification of individuals with HRSNs, the Screen Positive Rate for SDOH measure would allow healthcare facilities to capture the magnitude of these needs by requiring healthcare facilities to report the rates of patients who screened positive for each of the five core HRSNs. The Screen Positive Rate for SDOH is a process measure that provides information on the percent of patients receiving care at an HOPD, REH, or ASC, who were 18 years or older on the date of service, who were screened for all five HRSNs described in Table 88, and who screened positive for one or more of those HRSNs. Healthcare facilities would report this measure as five separate rates, one for each of the HRSNs: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. This measure is not intended for comparison of screen positive rates of HRSNs between healthcare facilities but is rather to provide transparency in the delivery of care and actionable information to healthcare facilities on the unmet needs among their patients.

c. Pre-Rulemaking Measure Review

As part of the PRMR process, the Hospital Recommendation Group reviewed and voted on the Screen Positive Rate for SDOH measure¹⁹⁹ during their meeting on January 18 and 19, 2024.^{200,201} The committee did not reach the 75 percent vote required to reach a consensus as to its recommendation for the Screen Positive Rate for SDOH measure for the Hospital OQR, REHQR, or ASCQR Programs. The committee expressed a concern about ambiguity in the interpretation of data from the Screen Positive Rate for SDOH measure as well as expectations regarding healthcare facilities. We acknowledge that a high score could be interpreted in different ways but that the objective of this measure is to incentivize collection of these data to

¹⁹⁹ The Screen Positive Rate for SDOH measure is identified on the MUC List as MUC2023-171.

²⁰⁰ Centers for Medicare & Medicaid Services. List of Measures Under Consideration for December 1, 2023. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

help identify patient needs and where resources constraints exist. The committee also discussed a condition specific to the Hospital OQR Program, which was to allow hospitals to report this measure one time each year for both the Hospital IQR Program and Hospital OQR Program.²⁰²

We note that we considered allowing hospitals to report this measure jointly for the Hospital IQR and Hospital OQR Programs (if applicable); however, as the patient-populations represented by the programs are different, as is the measure calculation due to this difference in the denominator, we propose to require a separate data submission for each program.

Further, we have identified the implementation of this measure in the Hospital OQR, REHQR, and ASCQR Programs as an important way to address the health equity measurement gap. We also believe that the information collected from this measure can help HOPDs, REHs, and ASCs understand SDOH needs in their patient population and to devise appropriate interventions. On this basis, we propose this measure for adoption for all three of our programs.

d. CBE Endorsement

As discussed in section XIV.B.2.d, we find no other feasible and practicable measures set forth by a national consensus building entity on the topic of screening for SDOH. While we recognize the value of measures undergoing CBE endorsement review and prefer to use endorsed measures, there are currently no CBE-endorsed measures that address screening for SDOH in the outpatient setting. Given the urgency of achieving health equity, it is important to implement this measure as soon as possible. We note that the five domains for which patients would be screened were chosen based upon literature review and expert consensus, and that these five domains informed development of the Screen Positive Rate for SDOH measure. We

²⁰¹ Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: <https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf>.

²⁰² Partnership for Quality Measurement. (2023). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf>.

will consider submitting the Screen Positive Rate for SDOH measure to the CBE for endorsement in the future.

e. Data Sources

The data sources for this measure are as described for the Screening for SDOH measure found in section XIV.B.2.e of this proposed rule.

f. Measure Calculation

The Screen Positive Rate for SDOH measure is calculated with a numerator and denominator. The numerator is defined as the number of patients receiving care at an HOPD, REH, or ASC who are 18 years or older on the date of admission, who were screened for all five HRSNs described in Table 88, and who screen positive for having a need in one or more of those HRSNs (calculated separately). The denominator is defined as the number of patients receiving care at the HOPD, REH, or ASC who are 18 years or older on the date of admission and are screened for all five HRSNs during their care.

The results of this measure are calculated and reported as five separate rates—one for each HRSN, each calculated with the same denominator. The measure excludes patients who: (1) opt-out of screening; or (2) are themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf.

g. Data Submission and Reporting

While this measure would require healthcare facilities to collect patient-level data on their patients' SDOH screening results, consistent with the Screening for SDOH measure, we propose to adopt this measure as an aggregate measure. Specifically, we propose that healthcare facilities would be required to submit aggregated data representing the total numerator results for each of the five screening areas and the total number of patients screened for all five of the HRSNs. We propose to require aggregate data because we believe it is unnecessary for healthcare facilities to submit data collected at the patient level as this would cause undue burden due to the transfer of large quantities of data. However, in the future, we may consider the

reporting of patient-level information. This measure aims to encourage healthcare facilities to screen for and identify HRSNs as it is most important for healthcare facilities to collect this HRSN data to address social needs among their patient populations.

Healthcare facilities would be required to submit information via a CMS-designated information system (currently the HQR system) consistent with the prior adoption of this measure in the Hospital IQR, IPFQR and PCHQR Programs. We refer readers to sections XV.E.2.a, XVI.E.3.b, and XVII.E.2.a of this proposed rule for additional details regarding data submission using the CMS-designated information system in the Hospital OQR, REHQR, and ASC Programs, respectively.

We note that we considered requiring hospitals to report this measure jointly for the Hospital IQR and Hospital OQR Programs; that is, requiring hospitals to submit once under both programs rather than submitting data twice in the HQR system. However, as the populations represented by the programs are different, resulting in different calculations of the measure denominator under each program, we propose to require a separate data submission for each program.

We propose to adopt this Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination to be consistent with the Screening for SDOH measure. Similar to the Screening for SDOH measure, a voluntary period would allow time for healthcare facilities to select and integrate screening tools into their clinical workflow processes and gain experience with both measures before measure results are publicly displayed on the Compare tool.

We invite public comment on our proposal to adopt the Screen Positive Rate for SDOH measure for the Hospital OQR, REHQR, and ASCQR Programs beginning with voluntary reporting on this measure for the CY 2025 reporting period followed by mandatory reporting

beginning with the CY 2026 reporting period/CY 2028 payment or program determination, as described above.

C. Proposal to Modify the Immediate Measure Removal Policy for the Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs Beginning with CY 2025

In the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60634 through 60635) and the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66967 through 66968), we finalized a process for immediate removal of Hospital OQR and ASCQR Program measures, respectively, based on evidence that the continued use of a measure as specified raises patient safety concerns. We refer readers to our regulations at 42 CFR 419.46(i)(2) for the Hospital OQR Program and 42 CFR 416.320(b) for the ACSQR Program for the codification of these immediate measure removal policies.

When there is evidence that continued use of a measure potentially raises patient safety concerns, we believe that immediate action should be taken to discontinue collection of the measure to not encourage potentially harmful practices. We also believe that seeking public input on the removal of such measures increases the public's voice in decision-making and increases transparency. We noted this in the CY 2024 OPPTS/ASC final rule (88 FR 82052), where we finalized an immediate measure suspension policy for the REHQR Program in lieu of an immediate measure removal policy. The REHQR Program's immediate measure suspension policy more appropriately provides that, in cases where we believe that a measure raises patient safety concerns, we will suspend the measure's use in the program, instead of immediately removing the measure, until its potential removal undergoes the standard rulemaking process (88 FR 82052).

We believe that our rationale for finalizing the immediate measure suspension policy in the REHQR Program (88 FR 82052) also applies to the Hospital OQR and ASCQR Programs. On this basis, we propose to modify the immediate measure removal policies in the Hospital

OQR and ASCQR Programs so that they are more appropriately referred to as immediate measure suspension policies beginning with CY 2025.

Under this proposed immediate measure suspension policy in the Hospital OQR or ASCQR Programs, in cases where we determine there is evidence that the collection and reporting of a measure raises potential patient safety concerns, we would suspend the measure from the program (as applicable) until potential removal can be proposed through the rulemaking process. We will notify the healthcare facility (HOPDs or ASCs, as applicable) and the public of the decision to suspend the measure through standard communication channels, including, but not limited to, program-specific listservs and program guidance currently housed on a CMS-designated website. We would then address the suspension and propose policies regarding any such suspended measure in the next feasible rulemaking cycle.

We also propose to revise the Hospital OQR Program regulatory text at § 419.46(i)(2) and the ASCQR Program regulatory text at § 416.320(b) to codify the immediate measure suspension policy. We further propose to clarify the standard for immediate measure suspension in these regulatory texts by revising references to patient safety concerns raised by “continued use of a measure as specified” to patient safety concerns raised by “collection and reporting activities related to a quality measure”.

We invite public comment on these proposals.

XV. Hospital Outpatient Quality Reporting (OQR) Program

A. Background and Statutory Authority

The Hospital Outpatient Quality Reporting (OQR) Program is a pay-for-reporting program intended to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency, and ensure accountability of 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 OPPTS/ASC Payment System final rule (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program, as well as program requirements codified at 42 CFR 419.46, and to the CY 2024 OPPTS/ASC final rule for information regarding the program’s regulatory history (88 FR 81961 through 82012).

1. Previously Finalized Program Measure Set Beginning With the CY 2027 Payment Determination

Table 89 summarizes the previously finalized Hospital OQR Program measures beginning with the CY 2027 payment determination:

TABLE 89: PREVIOUSLY FINALIZED HOSPITAL OQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION

CBE #	Measure Name
None	Abdomen Computed Tomography (CT) – Use of Contrast Material
3490	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Breast Cancer Screening Recall Rates
None†	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
None†	Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among Health Care Personnel (HCP)
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Excessive Radiation eCQM)**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
0661	Head 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
None†	MRI Lumbar Spine for Low Back Pain
None†	Median Time from ED Arrival to ED Departure for Discharged ED Patients
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) <ul style="list-style-type: none"> • About Facilities and Staff • Communication About Procedure • Preparation for Discharge and Recovery • Overall Rating of Facility • Recommendation of Facility

**TABLE 89: PREVIOUSLY FINALIZED HOSPITAL OQR PROGRAM MEASURE
SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION**

CBE #	Measure Name
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO-PM)***
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

†Measure is no longer endorsed by the Consensus Based Entity (CBE) but was endorsed previously.

*This measure is voluntary.

**This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination, as discussed in the CY 2024 OPSS/ASC final rule (88 FR 81988 through 81992).

***This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination, as discussed in the CY 2024 OPSS/ASC final rule (88 FR 81984 through 81986).

B. Program Measure Set Policies

1. Measure Retention

We refer readers to § 419.46(i)(1) and the CY 2013 OPSS/ASC final rule (77 FR 68471) for our policies regarding measure retention.

We are not proposing any changes to these policies in this proposed rule.

2. Measure Suspension or Removal

We refer readers to §§ 419.46(i)(2) and (3) and the CY 2013 OPSS/ASC final rule (77 FR 68472 and 68473) for our program policies regarding: (1) general measure removal, suspension, and replacement; and (2) immediate measure removal.

We refer readers to section XIV.C of this proposed rule for our cross-program proposal to modify the immediate removal policy for adopted Hospital OQR Program measures.

3. Measure Adoption

We refer readers to the CY 2024 OPSS/ASC final rule (88 FR 81973) for a discussion of the statutory requirements and our considerations for adopting quality measures under the Hospital OQR Program.

We are not proposing any changes to these policies in this proposed rule.

C. Program Measure Proposals

1. Proposed New Measures for the Hospital OQR Program Measure Set

a. Proposals to Adopt Health Equity Measures in the Hospital OQR Program

We refer readers to sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively, of this proposed rule for our cross-program proposals to adopt the following measures in the Hospital OQR Program: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

b. Proposal 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 2026 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination

(1) Background

Recent studies have shown that compared to inpatient settings, outpatient settings are associated with worse patient understanding and lower patient activation (that is, an individual's understanding, competence, and willingness to participate in care decisions during their

recovery), indicating an area for quality of care improvement.^{203,204,205} One study found that providers in the inpatient setting provided more complete discharge instructions and end-of-visit summaries to patients when compared to providers in the ambulatory setting, including continuing medication names and instructions (96 percent vs. 40 percent), new medication names and instructions (99 percent vs. 29 percent), and pending diagnostic test names and instructions (90 percent vs. 61 percent).²⁰⁶ A lack of understanding of recovery information²⁰⁷ and other aspects of health literacy have been linked to poor adherence to treatment, decreased patient safety, increased return to the emergency department (ED), lower levels of patient satisfaction, and disproportionate effects on patients with limited English proficiency and patients over age 65, who face additional barriers and recovery issues after their receipt of a hospital outpatient service.^{208,209} Reduced patient engagement and a deficiency in detailed discharge information in the inpatient setting were also associated with a higher risk of readmissions to an inpatient setting.²¹⁰ Research indicates that information that is simpler to read and more complete has been associated with fewer follow-up calls to providers as well as less frequent hospital readmissions.^{211,212}

²⁰³ Kang E, Gillespie BM, Tobiano G, et al. (2018). Discharge education delivered to general surgical patients in their management of recovery post discharge: A systematic mixed studies review. *Int J Nurs Stud.* 87:1-13. <https://doi.org/10.1016/j.ijnurstu.2018.07.004>.

²⁰⁴ Hoek AE, Anker SCP, van Beeck EF, et al. (2020). Patient Discharge Instructions in the Emergency Department and Their Effects on Comprehension and Recall of Discharge Instructions: A Systematic Review and Meta-analysis. *Ann Emerg Med.* 75(3):435-444. <https://doi.org/10.1016/j.annemergmed.2019.06.008>.

²⁰⁵ Downey E, Olds DM. (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>.

²⁰⁶ Ibid.

²⁰⁷ We use the term “recovery information” to mean the clinical care instructions provided to patients or their caregivers after the completion of surgery or a non-surgical procedure.

²⁰⁸ 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/bmjopen-2021-001419>.

²⁰⁹ 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 Issues, The Joint Commission Journal on Quality and Patient Safety, 47(12):775-782. <https://doi.org/10.1016/j.jcjq.2021.08.013>.

²¹⁰ Erlang AS, Schjødt K, Linde JKS, Jensen AL. (2021). An observational study of older patients' experiences of involvement in discharge planning. *Geriatr Nurs* 42(4):855-862. <http://doi.org/10.1016/j.gerinurse.2021.04.002>

²¹¹ 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>.

²¹² Mitchell JP. (2015). Association of provider communication and discharge instructions on lower readmissions. *J Healthc Qual.*, 37(1):33-40. <https://doi.org/10.1097/01.JHQ.0000460126.88382.13>.

(2) Measure Overview

The Information Transfer PRO–PM aims to assess the level of clear, personalized recovery information provided to patients aged 18-years or older who had surgery or a procedure at an HOPD. The measure reports the average score of a patient’s ratings on a three-domain, 9-item survey²¹³ to evaluate the clarity of the clinical information patients are given before, during, and after an outpatient surgery or procedure. The survey covers three domains for patients or their caregivers to rate the clarity of information received regarding their post-discharge²¹⁴ recovery: applicability to patient needs, medication, and daily activities. The applicability to patient needs domain assesses whether the recovery information considered a patient's health needs and personal circumstances. The medications domain examines the clarity of medication information provided, specifically guidance on taking new medications, potential side effects, and discontinuing medication. The daily activities domain assesses the clarity of guidelines around diet, physical activity, returning to work, and driving. Results from the survey provide hospitals with patient reported outcome (PRO) data designed to assess communication efforts and enable hospitals to reduce the risk of patient harm that may occur if the patient does not fully understand the recovery information.

This measure addresses the priority area stated in our Meaningful Measures Framework of adopting high-quality measures that focus on person-centered care.²¹⁵ Additionally, the Information Transfer PRO–PM supports the National Quality Strategy goal of equity and engagement by engaging individuals to become partners in their care and ensuring that

²¹³ 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>.

²¹⁴ The term “discharge” appears in the measure specifications and is intended to refer to the transition of a patient from the outpatient hospital setting to home or next level of care.

²¹⁵ Centers for Medicare & Medicaid Services. (2024). Meaningful Measures 2.0. Available at: <https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-20> .

individuals and caregivers have the information needed to make the best choices for their health.²¹⁶

Pilot testing conducted by the measure developer in 26 HOPDs in five states demonstrated that the measure is reliable and meaningful.^{217,218} The measure developer assessed reliability of the measure using the Cronbach alpha score²¹⁹ to determine whether the nine survey questions reliably measured the same underlying characteristic; that is, the clarity and applicability of recovery instructions. The Cronbach alpha score, which compares the amount of shared variance, or covariance, among the instrument items to the total variance, indicated that the survey items are reliable because they reflect a high level of covariance relative to the total variance.²²⁰ Additionally, the measure developer 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 facility specific errors to determine the extent to which variance in facility scores can be attributed to variance in actual performance.²²¹ To assess meaningfulness, the measure developer asked members of a Patient and Family Engagement (PFE) Work Group and a Technical Expert Panel (TEP) to vote on the measure's ability to distinguish between good and poor quality of care at measured facilities.^{222,223} All of the patients from the PFE Work Group and 80% of the TEP panel members who participated in the vote agreed that the measure could

²¹⁶ Centers for Medicare & Medicaid Services. (2024). CMS Quality Strategy. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>.

²¹⁷ Partnership for Quality Measurement. (2024). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf>.

²¹⁸ Partnership for Quality Measurement. Submission Tool and Repository Measure Database. <https://p4qm.org/measures/4210>.

²¹⁹ 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. www.doi.org/10.5116/ijme.4dfb.8dfd

²²⁰ *Ibid.*

²²¹ Partnership for Quality Measurement. Submission Tool and Repository Measure Database. <https://p4qm.org/measures/4210>.

²²² Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf>.

²²³ See also <https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/measure-methodology>

distinguish between good and poor quality of care.²²⁴ We refer readers to <https://p4qm.org/measures/4210> for more information about the feasibility, scientific acceptability, meaningfulness, and validity of the Information Transfer PRO–PM.

As previously stated in the CY 2024 OPPI/ASC final rule (88 FR 81985), while we acknowledge that PRO–PMs require providers to integrate data collection into clinical information systems, this integration provides an important opportunity for patient-reported outcomes to inform clinical decision-making and benefits patients by engaging them in discussions about potential outcomes. The testing of this measure by the measure developer, which included interviews with clinicians, nurses, quality improvement officers, and data administrators in HOPDs, indicated that the increased burden on HOPDs would be minimal because the data would be collected and reported electronically by administrative staff and quality officers engaged in data sharing activities, outside of the clinical workflow, before being integrated into a clinical information system. Additionally, testing indicated that the increased burden on respondents would be minimal and contribute minimally to patient survey fatigue because the survey is easily understood and consists of only nine questions administered electronically,²²⁵ presenting a low burden for completion.

(3) Pre-Rulemaking Measure Review

Under the PRMR process, the Hospital Recommendation Group reviewed and voted on the Information Transfer PRO–PM²²⁶ during their meeting on January 18-19, 2024.²²⁷ The voting results for the Information Transfer PRO–PM measure for the Hospital OQR Program were “recommend with conditions”. The condition was that the survey be administered at the time of

²²⁴ *Ibid.*

²²⁵ Examples of survey administration and collection include email, text, and patient information portals. These examples are not exhaustive. By leaving the method of survey administration and collection to the HOPD, we allow facilities the flexibility to choose the most appropriate method for their current infrastructure and patient base.

²²⁶ The Information Transfer PRO–PM is identified on the MUC List as MUC2023-17.

²²⁷ Partnership for Quality Measurement. (2024). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf>.

the surgery or procedure so there is no conflict with other measured pain and function outcomes to improve response rates.²²⁸ We have taken into account the condition to administer the survey at the time of the surgery or procedure; however, we have determined that allowing time after the surgery or procedure before administration of the survey is important to limit the possibility that the patient's responses are influenced by time-dependent variables related to proximity to the surgery or procedure, such as medications that could affect comprehension, fatigue, or acute pain. In addition, administering the survey more than one day but less than seven days post-procedure mitigates overlap of the initial administration and survey reminder of the OAS CAHPS, which is administered on the first day post-procedure and then followed up at 14 days.²²⁹

(4) CBE Endorsement

We submitted the Information Transfer PRO–PM to the CBE for endorsement review in the Fall 2023 cycle (CBE #4210), and the CBE endorsed the measure on March 18, 2024.²³⁰

(5) Data Collection, Submission, and Reporting

(a) Data Collection

(i) Data Sources

We propose that the Information Transfer PRO–PM would be calculated based on PRO data collected by HOPDs directly or through their authorized third-party vendors through a web-based survey instrument distributed to patients or their caregivers.

We also propose that the survey would be administered two-to-seven days post-procedure or surgery, based on evidence that the most common time period for patients to be delivered a

²²⁸ *Ibid.*

²²⁹ Centers for Medicare and Medicaid Services. Schedule of OAS CAHPS Contact Attempts by Survey Mode. Available at: https://oascahps.org/ScheduleOASCAHPSContactAttempts_7-20-21.pdf.

²³⁰ Partnership for Quality Measurement. Submission Tool and Repository Measure Database. <https://p4qm.org/measures/4210>.

survey is within 0-48 hours post-procedure or surgery at a HOPD (n=6),^{231,232,233,234,235,236} while other time periods include within two weeks post-procedure or surgery (n=4),^{237,238,239,240} one week post-procedure or surgery, (n=3)^{241,242,243} or 90 days post-procedure or surgery (n=1).²⁴⁴ We propose that the survey would be administered not less than two days post-procedure or surgery because we have determined, as discussed above, that allowing time after the surgery or procedure before administration of the survey will limit the possibility that the patient's responses are influenced by time-dependent variables related to proximity to the surgery or procedure, such as medications that could affect comprehension, fatigue, or acute pain. We propose that the survey would be administered no later than seven days post-procedure or surgery because this timeframe may be more appropriate for patient reporting of specific events than

²³¹ Engel KG, Buckley BA, Forth VE, et al. (2012). Patient understanding of emergency department discharge instructions: where are knowledge deficits greatest? *Acad Emerg Med.* 19(9):E1035-1044.

²³² Engel KG, Heisler M, Smith DM, Robinson CH, Forman JH, Ubel PA. (2009). Patient comprehension of emergency department care and instructions: are patients aware of when they do not understand? *Ann Emerg Med.* 53(4):454-461 e415.

²³³ Erlang AS, Schjodt K, Linde JKS, Jensen AL. (2021). An observational study of older patients' experiences of involvement in discharge planning. *Geriatr Nurs.* 42(4):855-862.

²³⁴ Lin MJ, Tirosh AG, Landry A. (2015). Examining patient comprehension of emergency department discharge instructions: Who says they understand when they do not? *Intern Emerg Med.* 10(8):993-1002.

²³⁵ Makaryus AN, Friedman EA. (2005). Patients' understanding of their treatment plans and diagnosis at discharge. *Mayo Clin Proc.* 80(8):991-994.

²³⁶ Hastings S, Stechuchak K, Oddone E, et al. (2012). Older veterans and emergency department discharge information. *BMJ Qual Saf.* 21(10):835-842.

²³⁷ Clarke C, Friedman SM, Shi K, Arenovich T, Monzon J, Culligan C. (2005). Emergency department discharge instructions comprehension and compliance study. *CJEM.* 7(1):5-11.

²³⁸ Henderson A, Zernike W. A study of the impact of discharge information for surgical patients. (2001). *J Adv Nurs.* 35(3):435-441.

²³⁹ Karliner LS, Auerbach A, Napoles A, Schillinger D, Nickleach D, Perez-Stable EJ. (2012). Language barriers and understanding of hospital discharge instructions. *Med Care.* 50(4):283-289.

²⁴⁰ Makaryus AN, Friedman EA. (2005). Patients' understanding of their treatment plans and diagnosis at discharge. *Mayo Clin PRac.* 80(8):991-994.

²⁴¹ Albrecht JS, Gruber-Baldini AL, Hirshon JM, et al. (2014). Hospital discharge instructions: comprehension and compliance among older adults. *J Gen Intern Med.* 29(11):1491-1498.

²⁴² Coleman EA, Chugh A, Williams MV, et al. (2013). Understanding and execution of discharge instructions. *AM J Med Qual.* 28(5):383-391.

²⁴³ Flacker J, Park W, Sims A. (2007). Hospital discharge information and older patients; do they get what they need? *J Hosp Med.* 2(5):291-296.

²⁴⁴ Hastings SN, Barrett A, Weinberger M, et al. (2011). Older patients' understanding of emergency department discharge information and its relationship with adverse outcomes. *J Patient Saf.* 7(1):19-25.

longer time periods.^{245,246} In pilot testing, patients were sent a reminder to complete the survey seven days after receipt. The survey remained open until pilot testing was completed, with the mean length of time between the procedure date to the survey response date being 65 days, or approximately two months. We are therefore proposing a 65-day window for patient response.

The survey has been tested and reliability determined in English and Spanish, and the survey can be completed using a translator, proxy, or caregiver.

(ii) Measure Specifications

The measure numerator is the sum of all individual scores a HOPD receives from eligible respondents, which could be patients or caregivers. Individual scores are calculated using a top-box approach; each individual score is calculated for each respondent by taking the sum of items for which the respondent gave the most positive response (“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).²⁴⁷

The measure denominator is the total number of patients 18-years or older who had a procedure or surgery in an HOPD, left the HOPD alive, and responded to the survey.^{248,249} Only fully completed surveys are included in the measure calculation.

The intent of the measure is to encourage HOPDs to provide individualized recovery instructions regardless of the patient’s unique characteristics; therefore, there is no need for risk-

²⁴⁵ Stull, D, Leidy, N, Parasuraman, B, et al. (2009). Optimal recall periods for patient-reported outcomes: Challenges and potential solutions. *Current medical research and opinion*. 25. 929-42. www.doi.org/10.1185/03007990902774765.

²⁴⁶ Peasgood T, Caruana JM, Mukuria C. (2023). Systematic Review of the Effect of a One-Day Versus Seven-Day Recall Duration on Patient Reported Outcome Measures (PROMs). *Patient*. 16(3):201-221. www.doi.org/10.1007/s40271-022-00611-w.

²⁴⁷ Partnership for Quality Measurement. Submission Tool and Repository Measure Database. <https://p4qm.org/measures/4210>.

²⁴⁸ Surveys could be completed by patient or a caregiver.

²⁴⁹ Partnership for Quality Measurement. Submission Tool and Repository Measure Database. <https://p4qm.org/measures/4210>.

adjustment. For additional details regarding the measure specifications, we refer readers to our QualityNet website.²⁵⁰

(b) Data Submission and Reporting

We propose to adopt the Information Transfer PRO–PM as a voluntary measure for the CY 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination. We would utilize the voluntary period to monitor the implementation and operationalization of the measure.

We refer readers to section XV.E.2.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. Proposed Measure Removals from the Hospital OQR Program Measure Set

a. Proposal to Remove the MRI Lumbar Spine for Low Back Pain Measure Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2009 OPPS/ASC final rule (73 FR 68766), we adopted the MRI Lumbar Spine for Low Back Pain measure beginning with the CY 2010 payment determination. This claims-based measure evaluates the percentage of magnetic resonance imaging (MRI) of the lumbar spine studies for low back pain performed in the outpatient setting where conservative therapy was not attempted prior to the MRI. The MRI Lumbar Spine for Low Back Pain measure was initially endorsed by a consensus-based entity (CBE) in 2008, but endorsement of this measure was removed in 2017 because the measure developer did not submit the measure for review during its designated measure endorsement maintenance cycle.

²⁵⁰ The proposed OQR Program measure specifications can be found at <https://qualitynet.cms.gov/outpatient/oqr/proposedmeasures>.

When we adopted this measure for the Hospital OQR Program, we cited growing concerns about the overuse of imaging services and evidence that a substantial portion of MRIs for low back pain does not lead to any modification of therapy based on MRI results, especially when performed on the first visit prior to any attempt to diagnose or treat the patient through more conservative means (73 FR 68764). Since then, our internal analyses have shown that the measure has maintained stable national performance (excluding the CY 2022 performance period impacted by our COVID–19 exception policies) and low average volumes, indicating limited reliability and capacity to improve the quality of care for patients with reported low back pain. A study in the *Journal of the American College of Radiology* found that documentation of conditions that fall into the exclusion criteria of the measure increased after implementation, resulting in smaller patient populations and indicating that the measure may not translate to improvement of imaging appropriateness.²⁵¹ Other studies have shown that the MRI Lumbar Spine for Low Back Pain measure has not correlated with improved outcomes.^{252,253,254} The latest findings are consistent with responses to a 2020 request for public comment where commenters expressed concerns regarding measure exclusion conditions, imaging modalities, measure validity, and measure usability. In response to that request for public comments, commenters also stated that an unintended consequence of using this measure may be delayed diagnoses.²⁵⁵

Based on these findings, this measure meets the criteria that we have adopted for measure removal Factor 2 (that is, performance or improvement on a measure does not result in better

²⁵¹ Flug JA and Lind KE. (2017). Public Reporting of MRI of the Lumbar Spine for Low Back Pain and Changes in Clinical Documentation, *Journal of the American College of Radiology* (14)12: 1545-1551. <https://doi.org/10.1016/j.jacr.2017.07.012>.

²⁵² Blackmore CC. (2019). The Relationship Between Medicare Outpatient Efficiency Measure OP8 and Lumbar MRI Utilization, *Journal of the American College of Radiology* 16(3): 276-281. <https://doi.org/10.1016/j.jacr.2018.10.026>.

²⁵³ Lind KE and Flug JA. (2019). Sociodemographic Variation in the Use of Conservative Therapy Before MRI of the Lumbar Spine for Low Back Pain in the Era of Public Reporting, *Journal of the American College of Radiology* 16(4): 560-569. <https://doi.org/10.1016/j.jacr.2018.12.047>.

²⁵⁴ Martin BI and Jarvik JG. (2015). The Medicare Outpatient Imaging Efficiency Measure for Low Back Pain (“OP-8”), *Radiology* 276(1). <https://doi.org/10.1148/radiol.2015150648>.

²⁵⁵ *Ibid.*

patient outcomes), as codified under § 419.46(i)(3)(i)(B). Therefore, we propose to remove the MRI Lumbar Spine for Low Back Pain measure from the Hospital OQR Program beginning with the CY 2025 reporting period/CY 2027 payment determination.

We invite public comment on this proposal, including feedback on other potential measures that may better address unnecessary imaging, which we will consider for adoption into the Hospital OQR Program in future rulemaking.

b. Proposal to Remove the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery Measure Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2011 OPPI/ASC final rule (75 FR 72079 and 72080), we adopted the claims-based Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2012 payment determination. This measure calculates the percentage of stress echocardiography, single photon emission computed tomography myocardial perfusion imaging (SPECT MPI), stress magnetic resonance imaging (MRI), or computed coronary tomography angiography (CCTA) performed at each facility in the 30 days prior to an ambulatory non-cardiac, low-risk surgery performed at any location, and was endorsed by a CBE in 2011. Endorsement was removed in 2021 after the measure developer did not submit the measure for review during its designated measure endorsement maintenance cycle.

We adopted the measure for the Hospital OQR measure set, in part, to address an area of patient safety related to one of the most common imaging services in the Medicare population at the time, as we believed inappropriate use could increase the patient's risk of cancer, contribute no benefit to the quality of care, and result in the unnecessary waste of services (75 FR 72076). In response to commenter concerns regarding the infrequent occurrence of low-risk non-cardiac surgeries, and whether this measure may assess significant differences in the provision of imaging tests and their impact on the quality of care provided, we stated our belief at the time

that the measure could identify outlier practice patterns and encourage HOPDs to improve their quality of care.

Our routine monitoring and evaluation shows that the range of cases per HOPD varies greatly (that is, from one to over 1,300 cases), posing limitations when assessing and interpreting comparative performance trends over time.²⁵⁶ In addition, while there was a slight average performance score improvement from payment determination years CY 2020 to 2024 (despite the COVID-19 pandemic and the larger pool of reporters) of about one percent (4.7 percent and 3.6, respectively), the variation between the 10th and 25th percentiles of performance is not statistically distinguishable, indicating the measure may not provide meaningful data for informing consumers about quality of care for this service in HOPDs. Furthermore, at a 3.5 percent average overall rate for this measure for the CY 2024 payment determination year, there is little room for national performance on this measure to show significant improvement as lower rates are better for this measure.

Based on these findings, this measure meets the criteria for measure removal Factor 2 (that is, performance or improvement on a measure does not result in better patient outcomes), as codified under § 419.46(i)(3)(i)(B). Therefore, we propose to remove the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2025 reporting period/CY 2027 payment determination.

We invite public comment on this proposal, including feedback on other potential measures that may better address unnecessary imaging, which we will consider for adoption into the Hospital OQR Program in future rulemaking.

²⁵⁶ *Ibid.*

3. Summary of Proposed Program Measure Set Updates

a. Proposed Program Measure Set Beginning With the CY 2027 Payment Determination

Table 90 summarizes the newly proposed Hospital OQR Program measure set beginning with the CY 2027 payment determination, which would remove the two imaging efficiency measures discussed above and add the three cross-program health equity measures discussed in sections XV.C.2.a, XV.C.2.b, and XIV.B, respectively, of this proposed rule.

TABLE 90: PROPOSED UPDATED HOSPITAL OQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION

CBE #	Measure Name
None	Abdomen CT – Use of Contrast Material
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Breast Cancer Screening Recall Rates
None†	Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among HCP
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
0661	Head CT or 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	Hospital Commitment to Health Equity***
None†	Left Without Being Seen
None†	Median Time from ED Arrival to ED Departure for Discharged ED Patients
None	OAS CAHPS <ul style="list-style-type: none"> • About Facilities and Staff • Communication About Procedure • Preparation for Discharge and Recovery • Overall Rating of Facility • Recommendation of Facility
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM)****
None	Screening for Social Drivers of Health*****
None	Screen Positive Rate for Social Drivers of Health*****
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

†Measure is no longer endorsed by the CBE but was endorsed previously.

*This measure is voluntary.

**This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination, as discussed in the CY 2024 OPPS/ASC final rule (81988 FR through 81992).

***In this proposed rule, we propose to adopt this measure beginning with the CY 2025 reporting period/ CY 2027 payment determination, as discussed in section XIV.B.1 of this proposed rule.

****This measure begins with voluntary reporting for the CY 2025 reporting period, 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 81984 through 81986).

*****In this proposed rule, we propose to adopt this measure beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, as discussed in sections XIV.B.2 and XIV.B.3 of this proposed rule.

b. Proposed Program Measure Set Updates Beginning With the CY 2031 Payment

Determination

Table 91 summarizes the newly proposed Hospital OQR Program measure set for the CY 2031 payment determination, which would remove the two imaging efficiency measures, discussed in sections XV.C.2.a and XV.C.2.b of this proposed rule; add the Information Transfer PRO-PM, discussed in section XV.C.1.b of this proposed rule; and add the three cross-program health equity measures, discussed in sections XIV.B.1, XIV.B.2, and XIV.B.3 of this proposed rule.

TABLE 91: PROPOSED UPDATED HOSPITAL OQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2031 PAYMENT DETERMINATION

CBE #	Measure Name
None	Abdomen CT – Use of Contrast Material
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Breast Cancer Screening Recall Rates
None†	Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among HCP
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
0661	Head CT or 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	Hospital Commitment to Health Equity**
None†	Left Without Being Seen
None†	Median Time from ED Arrival to ED Departure for Discharged ED Patients
None	OAS CAHPS <ul style="list-style-type: none"> • About Facilities and Staff • Communication About Procedure • Preparation for Discharge and Recovery • Overall Rating of Facility • Recommendation of Facility
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)
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO-PM)
None	Screening for Social Drivers of Health***
None	Screen Positive Rate for Social Drivers of Health***
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

†Measure is no longer endorsed by the CBE but was endorsed previously.

*This measure is voluntary.

**In this proposed rule, we propose to adopt this measure beginning with the CY 2025 reporting period/ CY 2027 payment determination, as discussed in section XIV.B.1 of this proposed rule.

***In this proposed rule, we propose to adopt this measure beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment

determination, as discussed in sections XIV.B.2 and XIV.B.3 of this proposed rule.

D. Administrative Requirements

We refer readers to § 419.46(b) and (c) and the CYs 2014, 2016, and 2019 OPPTS/ASC final rules (78 FR 75108 through 75109, 80 FR 70519, and 83 FR 59103 through 59104, respectively) for our policies regarding program participation requirements and withdrawal from the program.

We are not proposing any changes to these policies in this proposed rule.

E. Form, Manner, and Timing of Data Submission

1. General Data Submission Policy

We refer readers to § 419.46(d) and the CY 2023 OPPTS/ASC final rule (87 FR 72110 through 72112) for our general program policies regarding: (1) submission of data under the Hospital OQR Program generally; (2) review and correction of submitted data; and (3) extraordinary circumstance exception requests (ECE) for data submission.

We also refer readers to the CYs 2019 and 2022 OPPTS/ASC final rules (83 FR 59104 through 59105 and 86 FR 63861, respectively) for details regarding our maintenance of technical specifications. We maintain measure technical specification manuals (referred to as Specifications Manuals) that can be found on the CMS website at: <https://qualitynet.cms.gov/outpatient/specifications-manuals>.

We are not proposing any changes to these policies in this proposed rule.

2. Measure Specific Data Submission and Reporting Requirements

We refer readers to the CYs 2014, 2016, 2022, 2023, and 2024 OPPTS/ASC final rules (77 FR 68484; 80 FR 70521, 87 FR 72110 through 72112; 78 FR 75097 through 75100; and 88 FR 82004 through 82006, respectively) for information regarding our claims-based, web-based, eCQM, chart-abstracted, PRO-PM, and survey-based data submission and reporting requirements.

a. Web-Based Measures

(1) CMS-Designated Information System and Proposal for Data Submission for the Hospital Commitment to Health Equity (HCHE), Screening for Social Drivers of Health (SDOH), and Screen Positive Rate for SDOH Measures

We refer readers to the CY 2014 OPPTS/ASC final rule (78 FR 75112 through 75115), the CY 2016 OPPTS/ASC final rule (80 FR 70521), and the CMS website, currently available at <https://qualitynet.cms.gov>, for a discussion of the requirements for measure data submitted via the Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal). The HQR System safeguards protected health information in compliance with the HIPAA Privacy and Security Rules (45 CFR part 160 and 45 CFR part 164, Subparts A, C, and E).

In section XIV.B.1, XIV.B.2, and XIV.B.3 of this proposed rule, we proposed adoption of:

(1) the Hospital Commitment to Health Equity measure, beginning with the CY 2025 reporting period/CY 2027 payment determination;

(2) the Screening for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and

(3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

Consistent with our established data submission requirements (80 FR 70521 and 70522), we propose that HOPDs would be required to submit all of the data required to calculate each of these three measures annually using a CMS-approved, web-based, data collection tool available within the HQR System starting January 1 through and including May 15 in the year prior to the applicable payment determination year. For the Hospital OQR Program, the performance period (which we refer to as the CY reporting period) for each of these measures on which data is

submitted using a web-based tool would be January 1 through and including December 31 of the year that is 2 years prior to the applicable payment determination year; and the data submission period would be January 1 through and including May 15 in the calendar year immediately following the CY reporting period and immediately prior to applicable payment determination year. For example, for the CY 2025 reporting period/2027 payment determination, the data submission period would be January 1, 2026, through and including May 15, 2026, covering the performance period of January 1, 2025, through and including December 31, 2025. Pursuant to § 419.46(d)(4), a review and corrections period runs concurrently with the data submission period. During this timeframe, HOPDs would be able to enter, review, and correct data submitted for these measures.

We invite public comment on this proposal.

(2) National Healthcare Safety Network (NHSN)

We refer readers to the CY 2014 OPPI/ASC final rule (78 FR 75097 through 75100) for a discussion of the previously finalized requirements for measure data submitted via the Centers for Disease Control and Prevention NHSN website.

We are not proposing any changes to these policies in this proposed rule.

b. Electronic Clinical Quality Measures (eCQMs) and Proposal to Require Electronic Health Record (EHR) Technology to Be Certified to All eCQMs Available to Report Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2024 Medicare Physician Fee Schedule (PFS) final rule (88 FR 79307 through 79312), we finalized revisions to the definition of certified electronic health record technology (CEHRT) for the Medicare Promoting Interoperability Program at 42 CFR 495.4 and for the Quality Payment Program at 42 CFR 414.1305. Specifically, we added a reference to the “Base EHR definition,” which ONC proposed in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) proposed rule (88 FR 23759, 23905). We finalized these revisions to ensure, if

the HTI–1 proposals were finalized, the “Base EHR definition” would be applicable for the CEHRT definitions going forward (88 FR 79309 through 79312).²⁵⁷ ONC subsequently finalized a definition of “Base EHR” in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing final rule (89 FR 1192, 1298).

We also finalized the replacement of references to the “2015 Edition health IT certification criteria” with “ONC health IT certification criteria,” and the addition of the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. We finalized the proposal to specify that EHR technology must meet ONC’s health IT certification criteria “as adopted and updated in 45 CFR 170.315” to qualify as CEHRT (88 FR 79553). These revisions, finalized in the CY 2024 PFS final rule, are consistent with the policy subsequently finalized in ONC’s HTI–1 final rule, which appeared in the Federal Register on January 9, 2024 (89 FR 1205 through 1210). For additional background and information on this update, we refer readers to the discussion in the CY 2024 PFS final rule on this topic (88 FR 79307 through 79312).

In the CY 2022 OPPI/ASC final rule (86 FR 63868 and 63869), we adopted a requirement for hospitals to utilize certified technology updated to be consistent with the 2015 Edition Cures Update for reporting eCQMs under the Hospital OQR Program, beginning with the CY 2023 reporting period/CY 2025 payment determination. However, we did not finalize a requirement that the EHR technology used for eCQM reporting must be certified to all eCQMs (that is, tested and validated on each individual eCQM) in the Hospital OQR Program.

The Hospital IQR Program and the Medicare Promoting Interoperability Program require EHRs to be certified to all available eCQMs in the programs. We finalized this policy for the Hospital IQR Program in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38393) for the FY

²⁵⁷ Revisions to the CEHRT definition are intended to incorporate ONC’s approach of discontinuing references to yearly editions. For additional background, we refer readers to HTI-1 proposed rule (88 FR 23759).

2019 and FY 2020 payment determination years, and we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42505 through 42506) that this policy would continue beginning with the CY 2020 reporting period/FY 2022 payment determination. For the Medicare Promoting Interoperability Program, we finalized this policy in the FY 2018 and FY 2019 IPPS/LTCH PPS final rules for CYs 2018 and 2019, respectively (82 FR 38483 through 38485 and 83 FR 41671 through 41672, respectively). We also finalized the continuation of this requirement in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42600 and 42601) for CY 2020 and subsequent years. When EHRs are certified to all available eCQMs in a program measure set, hospitals are able to accurately capture and report data for these measures. For this reason, and to align the Hospital OQR Program's eCQM certification requirements with the Hospital IQR Program and Medicare Promoting Interoperability Program clinical quality measure electronic submission requirements for eligible hospitals, we propose that beginning with the CY 2025 reporting period/CY 2027 payment determination, a HOPD using EHR technology certified to the ONC health IT certification criteria would be required to have its EHR technology certified to all eCQMs that are available to report under the Hospital OQR Program to meet reporting requirements for the Hospital OQR Program.

We further propose that for the CY 2025 reporting period/CY 2027 payment determination and subsequent years, HOPDs would additionally be required to use the most recent version of the eCQM electronic measure specifications for the designated reporting period available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: <https://ecqi.healthit.gov/>. We noted in the CY 2021 OPSS/ASC final rule (86 FR 63861) that we would generally update the measure specifications on an annual basis to align with current clinical guidelines and code systems.

Our proposal to require that EHRs be certified to all available eCQMs would promote more accurate electronic quality reporting by incentivizing HOPDs to have their EHR and other health information technology (IT) vendors test all available eCQMs and offer reporting modules

with certified eCQMs. Through this requirement, we expect greater certainty for hospitals that their EHR systems are capable of accurately calculating the eCQMs reported to CMS under the Hospital OQR Program because the EHR technology would be up to date and tested on each eCQM. Additionally, we anticipate this requirement would help reduce burden for hospitals by potentially reducing the frequency of needing to consult with their EHR and other health IT vendors to troubleshoot implementation or reporting issues.

Finally, we propose to revise regulatory text at § 419.46 to add a new section (j) to codify submission requirements for eCQMs under the Hospital OQR Program. Under this proposal, we would codify in § 419.46(j)(1) the requirement for hospitals to utilize certified technology updated to be consistent with ONC's health IT certification criteria, as adopted and updated in 45 CFR 170.315, for reporting eCQMs under the Hospital OQR Program. We propose to codify in § 419.46(j)(2) the requirement that the EHR technology used for eCQM reporting must be certified to all eCQMs (that is, tested and validated on each individual eCQM) available to report under the Hospital OQR Program. We also propose to codify in § 419.46(j)(3) the requirement that hospitals 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 invite public comment on these proposals.

c. Patient-Reported Outcome-Based Performance Measures (PRO-PMs)

(1) Proposal for Data Submission of PRO-PM Data

In the CY 2024 OPSS/ASC final rule (88 FR 82006) we finalized that for the Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA) PRO-PM, hospitals must use the HQR system for data submission 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. We propose that hospitals must use the HQR system for data submission for any PRO-PM that we adopt for the Hospital OQR Program measure set. HOPDs 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, XML) and a manual data entry option, allowing HOPDs additional flexibility in data submission.

We invite public comment on this proposal.

(2) Proposal for Data Submission and Reporting Requirements for 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)

In section XV.C.1.b of this proposed rule, we discuss the proposed adoption of the Information Transfer PRO–PM beginning with voluntary reporting for the CY 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination. We propose that the performance period on which data is submitted would be January 1 through and including December 31 of the year that is two years prior to the applicable payment determination year. We propose to require HOPDs to submit their Information Transfer PRO–PM data between the period starting January 1st through and including May 15 of the year prior to the applicable payment determination year. 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. We propose to require HOPDs to offer all patients meeting the measure's denominator specifications the opportunity to complete the survey. Additionally, we propose a minimum random sample size of 300 completed surveys to ensure the reliability of the measure, 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.^{258,259} HOPDs that are unable to collect 300 completed surveys will not be able to perform random sampling, and would instead be required to submit data on survey responses from all completed surveys received.

We invite public comment on these proposals.

F. Public Reporting of Measure Data

1. General Policy

We refer readers to the CY 2024 OPPS/ASC final rules (88 FR 81995 and 81996) for our previously finalized policies regarding public display of quality measures.

2. Proposal to Publicly Report the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients - Psychiatric/Mental Health Patients Strata on Care Compare

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72086) where we adopted the Median Time from ED Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure beginning with CY 2013 payment determination. The Median Time for Discharged ED Patients measure is a chart-abstracted measure that evaluates the time from ED arrival to departure, also known as ED throughput time. The measure data are stratified into four separate calculations: a) Median Time for Discharged ED Patients – Overall Rate; b) Median Time for Discharged ED Patients – Reporting Measure, which excludes psychiatric/mental health and transfer patients; c) Median Time for Discharged ED Patients – Psychiatric/Mental Health Patients, which includes information only for psychiatric/mental health patients; and d) Median Time for Discharged ED Patients – Transfer Patients, which includes information only for patients transferred from the ED.

²⁵⁸Ahmad, H., & Halim, H. (2017). Determining Sample Size for Research Activities. *Selangor Business Review*, 2(1), 20-34. Retrieved from <https://sbr.journals.unisel.edu.my/ojs/index.php/sbr/article/view/12>

²⁵⁹Voorhis, 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.

In the CY 2024 OPPTS/ASC final rule (88 FR 81995 and 81996), we finalized that data for three measure strata (that is, the Overall Rate, Reporting Measure, and Transfer Patients strata) would be publicly reported both on data.medicare.gov in downloadable data files and on Care Compare (or subsequent CMS-designated websites). Data for the Psychiatric/Mental Health Patients stratum are not currently publicly reported on the Care Compare site, though these data are published on data.medicare.gov in downloadable data files (82 FR 59438). In the CY 2018 OPPTS/ASC final rule (82 FR 52576 through 52578), we summarized commenters' concerns that delays in ED discharge of mental health patients may be influenced, in part, by the availability of community resources. In response, we stated that we would take additional time for further consideration prior to displaying this subset of data on Care Compare. We have considered commenters' concern that factors outside of an HOPD's control may influence ED throughput for psychiatric/mental health patients; however, it is our understanding that many hospitals face such concerns, and that timely care is a critical aspect of quality of care. We also stated in the CY 2024 OPPTS/ASC final rule (88 FR 82061) in the context of adopting this measure for the REHQR Program that the public reporting of these data on Care Compare could help patients and their caregivers identify which facilities are performing better than others despite potential challenges, and drive quality improvement efforts.

Our routine monitoring and evaluation of the CY 2024 performance period for this measure has shown a median ED throughput time of 4.7 hours for psychiatric/mental health patients compared to 2.6 hours for non-psychiatric/mental health patients, suggesting this is an area that may benefit from additional quality improvement efforts. Data from the Median Time for Discharged ED Patients – Psychiatric/Mental Health Patients will be useful for patients choosing a care location, as well as researchers and hospital staff as they attempt to address health disparities and improve the timeliness of care for mental health patients. Since the data required for public reporting are already collected and submitted by participating HOPDs, publicly reporting this stratification would not create additional hospital burden.

For these reasons, we propose to make data for the Psychiatric/Mental Health Patients stratification available on Care Compare, including data that were previously published on data.medicare.gov but not displayed on the Care Compare site, beginning in CY 2025.

We invite public comment on this proposal.

G. Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2025 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:

$$\text{Full Conversion Factor} = \text{Baseline OPPS conversion factor} * (1 + \text{OPD update factor})$$
$$\text{Reduced Conversion Factor} = \text{Baseline OPPS conversion factor} * (1 + \text{OPD update factor} - 0.02)$$
$$\text{Reporting Ratio} = \text{Reduced Conversion Factor} / \text{Full Conversion Factor}$$

Which is equivalent to:

$$\text{Reporting Ratio} = (1 + \text{OPD Update factor} - 0.02) / (1 + \text{OPD update factor})$$

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 2025

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 2025 annual payment update factor. For the CY 2025 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of \$89.379, 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 \$87.636. 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 also propose to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For CY 2025, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of \$89.379, equaled a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of \$87.636.

XVI. Rural Emergency Hospital Quality Reporting (REHQR) Program

A. Background and Statutory Authority

The Rural Emergency Hospital Quality Reporting (REHQR) Program’s overarching goals are to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency, ensure accountability, and safeguard the accessibility of hospitals in rural settings.

Section 1861(kkk)(7)(A) of the Social Security Act (the Act) provides that the Secretary shall establish quality measurement reporting requirements for Rural Emergency Hospitals (REHs), which may include the use of a small number of claims-based outcomes measures or

surveys of patients with respect to their experience in the REH. In selecting measures for quality reporting, section 1861(kkk)(7)(C)(iii) provides that the Secretary shall take into consideration ways to account for REHs that lack sufficient case volume to ensure that the performance rates for such measures are reliable. Although section 1861(kkk)(7)(C)(i) of the Act requires that measures 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, section 1861(kkk)(7)(C)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In addition, section 1861(kkk)(7)(D) of the Act provides that the Secretary shall establish procedures for making data submitted by REHs for the REHQR Program available to the public, following the opportunity for the REH to review and submit corrections on such data, with such data to be posted on a CMS website as determined appropriate by the Secretary. Beginning with 2023 (or each year beginning on or after the date that is one year after one or more measures are first specified), section 1861(kkk)(7)(B)(ii) of the Act requires REHs to submit quality measure data to the Secretary “in a form and manner, and at a time, specified by the Secretary.”

We refer readers to section XVI of the CY 2024 OPSS/ASC final rule (88 FR 82046 through 82076) for an overview of the REHQR Program, which includes a more detailed discussion of the statutory history and program requirements codified at 42 CFR 419.95.

1. Previously Finalized Program Measure Sets

We refer readers to the CY 2024 OPSS/ASC final rule (88 FR 82066 through 82067) for more information regarding the previously finalized REHQR Program measure set beginning with the CY 2024 reporting period.

Table 92 below summarizes the previously finalized REHQR Program measure set and

initial reporting periods with program determinations beginning with the CY 2026 program determination.²⁶⁰

TABLE 92: PREVIOUSLY FINALIZED REHQR PROGRAM MEASURE SET AND INITIAL REPORTING PERIODS BEGINNING WITH THE CY 2026 PROGRAM DETERMINATION

CBE #	Measure Name	Initial Reporting Periods	Initial Program Determination Affected
None	Abdomen Computed Tomography (CT) – Use of Contrast Material	January 1, 2024 – December 31, 2024	CY 2026
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients		
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery		
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	January 1, 2024 – December 31, 2026	CY 2028

B. Program Measure Set Policies: Retention, Suspension or Removal, Modification, and Adoption

We refer readers to § 419.95(e) and the CY 2024 OPPTS/ASC final rule (88 FR 82051 through 82053) for our program policies regarding measure retention, and immediate and general measure suspension and removal, and to § 419.95(d) and the CY 2024 OPPTS/ASC final rule (88 FR 82054) for our program policies regarding modifications to previously adopted measures.

We further refer readers to the CY 2024 OPPTS/ASC final rule (88 FR 82047 through 82051) for a discussion of our considerations for adopting quality measures under the REHQR Program, and to section XIV.B.1.c of this proposed rule for information regarding the pre-rulemaking process.

We are not proposing any changes to these policies in this proposed rule.

²⁶⁰ We are using the phrase “Program Determination” for the REHQR Program to represent our assessment of compliance with program requirements for an applicable year because the REHQR Program does not include an associated payment adjustment.

C. Program Measure Proposals

1. Proposal to Adopt Health Equity Quality Measures in the REHQR Program

We refer readers to sections XIV.B.1, XIV.B.2, and XIV.B.3 of this proposed rule for our cross-program proposals to adopt the following measures in the REHQR Program: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 program determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination.

Under the REHQR Program's statutory requirement under section 1861(kkk)(7)(C)(iii) of the Act to consider the impact of low case volumes, we note that once mandatory reporting begins, the measure specifications require all patients to be screened and thus we do not believe the Screening for SDOH measure or the Screen Positive Rate for SDOH measure would suffer from low case volumes. In addition, as stated in the CY 2024 OPPTS/ASC final rule (88 FR 82066), CMS does not report measures publicly unless it achieves sufficient case volumes to allow for public reporting of the collected data.

2. Proposal to Modify the Reporting Period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure Beginning With the CY 2027 Program Determination

In the CY 2024 OPPTS/ASC final rule, we adopted the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure in the REHQR Program with a one-year reporting period beginning with the CY 2024 reporting period (88 FR 82064 through 82066).

This measure is calculated from Part A and Part B Medicare administrative claims data for Medicare FFS beneficiaries with an outpatient same-day surgical procedure excluding eye surgeries and colonoscopies (except colonoscopy with biopsy). Colonoscopies are excluded from this measure as these procedures are examined separately on their own. Eye surgeries are excluded because they are performed in high volume and are generally perceived as being “low risk.” As stated in the CY 2024 OPPS/ASC final rule (88 FR 82064), this measure makes unplanned patient hospital visits (ED visits, observation stays, or unplanned inpatient admissions) after surgery more visible to providers and patients through publicly reporting scores.

As we noted in the CY 2024 OPPS/ASC final rule (88 FR 82064), we believe this measure could also encourage providers to engage in quality improvement activities to reduce these visits by providing feedback to hospitals and providers. This measure meets the National Quality Strategy goals of embedding quality into the care journey and promoting safety,²⁶¹ and we expect that the measure would promote improvement in patient care over time (88 FR 82064 through 82065).

We have continued to monitor and evaluate the reporting patterns of hospitals that have converted to REH status and have found that under the Hospital OQR Program, a limited number of current REHs are able to publicly report on this measure as specified based on case threshold minimums. Therefore, in consideration of our statutory obligation to consider ways to account for low case volumes and to publicly report on quality-of-care metrics for REHs, we propose to increase the reporting period from one year to two years beginning with the CY 2027 program determination.

²⁶¹ CMS, What is the CMS National Quality Strategy?. Available at: <https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy>.

Under this proposal, the previously finalized one-year data collection period for the CY 2026 program determination would remain the same (that is, encounters from January 1, 2024 through December 31, 2024), and then beginning with the CY 2027 program determination, the reporting period would be supplemented with data from the prior calendar year. For example, for the CY 2027 program determination, the reporting period would comprise data from CYs 2024 and 2025 (that is, encounters from January 1, 2024 through December 31, 2025). We note that, as stated in the CY 2024 OPPTS/ASC final rule (88 FR 82066), CMS does not report measures publicly unless it achieves sufficient case volumes to allow for public reporting of the collected data.

TABLE 93: COMPARISON OF 1-YEAR AND 2-YEAR REPORTING PERIODS FOR THE RISK-STANDARDIZED HOSPITAL VISITS WITHIN 7 DAYS AFTER OUTPATIENT SURGERY MEASURE FOR REHS

Data Time Period	REHs with at least 1 Denominator Case	REHs Meeting the Threshold for Public Reporting*	Total Eligible Surgical Cases	Total Number Patients with Visits
Risk-Standardized Hospital Visits Within 7 Days After Outpatient Surgery Measure				
One-Year Reporting Period				
Jan 1, 2020 - Dec 31, 2020	6	1	120	7
Jan 1, 2021 - Dec 31, 2021	7	1	207	14
Jan 1, 2022 - Dec 31, 2022	8	1	225	19
Proposed Two-Year Reporting Period				
Jan 1, 2020 - Dec 31, 2021	7	4	327	21
Jan 1, 2021 - Dec 31, 2022	8	3	432	33
Jan 1, 2022 - Dec 31, 2023	8	4	552	40

*30 or more eligible surgical cases are required to meet the Risk-Standardized Hospital Visits Within 7 Days After Outpatient Surgery measure’s threshold to establish reliability for public reporting.

As seen in Table 93, the longer reporting period of two years would facilitate greater case volumes for this measure and, subsequently, a larger portion of REHs would have data that could be reported publicly as more REHs attain the Risk-Standardized Hospital Visits Within 7 Days After Outpatient Surgery measure’s minimum case threshold for reliability of 30 surgical cases. In addition, REHs reporting on the measure with two years of data would have more eligible patients to assess; this increase in eligible cases would reduce the error estimate, making the confidence interval narrower, that is, increasing the reliability of the calculated measure. We

refer readers to the CY 2019 OPPTS/ASC final rule (83 FR 59106 through 59107) where we finalized a similar policy to extend the reporting period of the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure in the Hospital OQR Program from two to three years.

Under this proposal, there would be no gap in public reporting nor delay in providing REHs with data for quality improvement efforts. As this is a claims-based measure, REHs would not have any additional reporting burden associated with a longer reporting period.

We invite public comment on this proposal.

3. Summary of Proposed Program Measure Set Updates

a. Proposed Program Measure Set Beginning With the CY 2027 Program Determination

Table 94 summarizes the proposed updated REHQR Program measure set and reporting periods beginning with the CY 2027 program determination.

Specifically, Table 94 includes the previously finalized measure set with updates to reflect the proposed extension of the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure beginning with the CY 2027 program determination, and the three proposed new cross-program health equity measures as detailed in sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively, of this proposed rule:

TABLE 94: PROPOSED UPDATED REHQR PROGRAM MEASURE SET AND REPORTING PERIODS BEGINNING WITH THE CY 2027 PROGRAM DETERMINATION

CBE #	Measure Name	Reporting Period	Program Determination
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	January 1, 2024 – December 31, 2026	CY 2028
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery*	January 1, 2024 – December 31, 2025	CY 2027
None	Abdomen Computed Tomography (CT) – Use of Contrast Material	January 1, 2025 – December 31, 2025	
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients		
None	Hospital Commitment to Health Equity (HCHE)**		
None	Screening for Social Drivers of Health (SDOH)***		
None	Screen Positive Rate for SDOH***		

*We propose that this measure would have an extended reporting period beginning with the CY 2027 program determination, as discussed in section XVI.C.2 of this proposed rule.

**We propose that this measure would be mandatory beginning with the CY 2025 reporting period/CY 2027

program determination, as discussed in section XIV.B.1 of this proposed rule.

***We propose that this measure would begin with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination, as discussed in sections XIV.B.2 and XIV.B.3 of this proposed rule.

b. Proposed Program Measure Set Beginning With the CY 2028 Program Determination

Table 95 summarizes the proposed updated REHQR Program measure set and reporting periods beginning with the CY 2028 program determination.

Specifically, Table 95 includes the previously finalized measure set with updates to reflect the proposed extension of the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure beginning with the CY 2028 program determination, and the three proposed new cross-program health equity measures as detailed in sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively, of this proposed rule:

TABLE 95: PROPOSED UPDATED REHQR PROGRAM MEASURE SET AND REPORTING PERIODS BEGINNING WITH THE CY 2028 PROGRAM DETERMINATION

CBE #	Measure Name	Reporting Period	Program Determination
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	January 1, 2024 – December 31, 2026	CY 2028
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery*	January 1, 2025 – December 31, 2026	
None	Abdomen Computed Tomography (CT) – Use of Contrast Material	January 1, 2026 – December 31, 2026	
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients		
None	Hospital Commitment to Health Equity (HCHE)**		
None	Screening for Social Drivers of Health (SDOH)***		
None	Screen Positive Rate for SDOH***		

*We propose that this measure would have an extended reporting period beginning with the CY 2027 program determination, as discussed in section XVI.C.2 of this proposed rule.

**We propose that this measure would be mandatory beginning with the CY 2025 reporting period/CY 2027 program determination, as discussed in section XIV.B.1 of this proposed rule.

***We propose that this measure would begin with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination, as discussed in sections XIV.B.2 and XIV.B.3 of this proposed rule.

D. Administrative Requirements

We refer readers to § 419.95(b) and the CY 2024 OPPTS/ASC final rule (88 FR 82074) for our policies regarding administrative requirements previously finalized for the REHQR Program.

We are not proposing any changes to these policies in this proposed rule.

E. Form, Manner, and Timing of Data Submission

1. General Policy

We refer readers to § 419.95(c) and § 419.95(g) and the CY 2024 OPPI/ASC final rule (88 FR 82074 through 82076) for our general policies regarding: (1) submission of data under the REHQ Program generally; (2) review and correction of submitted data; and (3) extraordinary circumstance exception (ECE) requests for data submission.

We are not proposing any changes to these policies in this proposed rule.

2. Proposed Data Submission Policy Following Conversion to REH Status

As we have implemented these general policies and some hospitals have converted to REH status, we believe that it is necessary to specify when a hospital that converts to REH status is required to report data to the REHQ Program. Thus, we propose that an REH must begin submitting data to the REHQ Program on the first day of the quarter following the date that a hospital has been designated as converted to an REH in accordance with the process outlined in section 1861(kkk) of the Act.

We invite public comment on this proposal.

3. Measure-Specific Data Submission and Reporting Requirements

a. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the CY 2024 OPPI/ASC final rule (88 FR 82074 through 82075) for information regarding chart-abstracted data submission and reporting requirements.

We are not proposing any changes to these policies in this proposed rule.

b. Proposal for the HCHE, Screening for SDOH, and Screen Positive Rate for SDOH Measures' Data Submission Requirements and Reporting Requirements

To align with the Hospital OQR (80 FR 70521 through 70522) and ASCQR (81 FR 79821 through 79822) Programs, we propose a web-based submission policy where REHs would submit data for applicable measures once annually using a CMS-approved, web-based, data collection tool available within the Hospital Quality Reporting (HQR) System. In

alignment with the Hospital OQR and ASCQR Programs, REHs would submit data during the period of January 1 to May 15 in the year prior to the affected program determination year. For example, for the CY 2025 reporting period/CY 2027 program determination, the data submission period would be January 1, 2026, to May 15, 2026, covering the performance period of January 1, 2025, to December 31, 2025. Under the review and corrections period provided at § 419.95(c)(3), REHs would be able to enter, review, and correct data submitted during the data submission period.

These policies would apply to web-based measures adopted by the REHQR program, including the following three measures proposed for adoption in this year's rule:

- The HCHE measure, beginning with the CY 2025 reporting period/CY 2027 program determination;
- The Screening for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination; and
- The Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination.

We refer readers to sections XIV.B.1, XIV.B.2, and XIV.B.3 for additional information on the HCHE, Screening for SDOH, and Screen Positive Rate for SDOH measures.

We invite public comment on this proposal.

c. Data Submission Requirements for Claims-Based Measure Data

In addition, we refer readers to section XVI.C.2 of this proposed rule where we discuss our proposal to modify the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure beginning with the CY 2027 program determination. This claims-based measure would continue to be reported in accordance with other claims-based measures, as previously finalized in the CY 2024 OPSS/ASC final rule (88 FR 85075).

We are not proposing any changes to these policies in this proposed rule.

F. Public Reporting of Measure Data

We refer readers to § 419.95(f) and the CY 2024 OPPTS/ASC final rule (88 FR 82071 through 82074) for our program policy regarding the public reporting of quality data.

We are not proposing any changes to these policies in this proposed rule.

XVII. Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background and Statutory Authority

The Ambulatory Surgical Center Quality Reporting (ASCQR) Program is a pay-for-reporting program intended to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency, and ensure accountability of 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 that 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. Sections 1833(t)(17)(B) through (E) of the Act generally govern the development and replacement of quality measures, the form and manner of submission of data to CMS, and procedures for making the data submitted to CMS available to the public.

We refer readers to the CY 2012 OPPTS/ASC final rule (76 FR 74492 through 74494) for a detailed discussion of the program's statutory authority, as well as program requirements

codified at 42 CFR part 416, subpart H (§ 416.300 through § 416.330), and the CY 2024 OPPS/ASC final rule (88 FR 82012) for information regarding the program’s regulatory history.

1. Previously Finalized Program Measure Sets

We refer readers to the CY 2024 OPPS/ASC final rule (88 FR 82038) for additional information regarding the previously finalized ASCQR Program measure set beginning with the CY 2027 payment determination.

a. Previously Finalized Measure Set Beginning With the CY 2027 Payment Determination

Table 96 summarizes the previously finalized ASCQR Program measures beginning with the CY 2027 payment determination.

TABLE 96: PREVIOUSLY FINALIZED ASCQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION

CBE #	Measure Name
None†	All-Cause Hospital Transfer/Admission
None†	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery)*
3636	COVID–19 Vaccination Coverage Among Health Care Personnel (HCP)
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at ASCs
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
3470	Hospital Visits After Orthopedic Ambulatory Surgical Center (ASC) Procedures
3366	Hospital Visits After Urology ASC Procedures
None	Normothermia Outcome
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)
	<ul style="list-style-type: none"> • About Facilities and Staff • Communication About Procedure • Overall Rating of Facility • Preparation for Discharge and Recovery • Recommendation of Facility
None†	Patient Burn
None†	Patient Fall
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the ASC Setting**
None	Unplanned Anterior Vitrectomy
None†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

†Measure is no longer endorsed by Consensus Based Entity (CBE) but was endorsed previously.

*This measure is voluntary.

**This measure begins with voluntary reporting for the CY 2025 reporting period, 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 82033 through 82036).

b. Previously Finalized Measure Set Beginning With the CY 2031 Payment Determination

Table 97 summarizes the previously finalized ASCQR Program measures beginning with the CY 2031 payment determination.

TABLE 97: PREVIOUSLY FINALIZED ASCQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2031 PAYMENT DETERMINATION

CBE #	Measure Name
None†	All-Cause Hospital Transfer/Admission
None†	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery)*
3636	COVID–19 Vaccination Coverage Among Health Care Personnel (HCP)
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at ASCs
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
3470	Hospital Visits After Orthopedic ASC Procedures
3366	Hospital Visits After Urology ASC Procedures
None	Normothermia Outcome
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)
	<ul style="list-style-type: none"> • About Facilities and Staff • Communication About Procedure • Overall Rating of Facility • Preparation for Discharge and Recovery • Recommendation of Facility
None†	Patient Burn
None†	Patient Fall
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the ASC Setting
None	Unplanned Anterior Vitrectomy
None†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

†Measure is no longer endorsed by the CBE but was endorsed previously.

*This measure is voluntary.

B. Program Measure Set Policies

1. Measure Retention

We refer readers to § 416.320 and the CY 2012 OPPTS/ASC final rule (76 FR 74504) for our policies regarding measure retention.

We are not proposing any changes to these policies in this proposed rule.

2. Measure Suspension or Removal

We refer readers to § 416.320 and the CY 2019 OPPTS/ASC final rule (83 FR 59111 through 59115) for our program policies regarding: (1) general measure removal, suspension, or replacement; and (2) immediate measure removal.

We refer readers to section XIV.C of this proposed rule for our cross-program proposal to modify the immediate measure removal policy for quality measures for the ASCQR Program.

3. Measure Modification

We refer readers to § 416.325 and the CY 2016 OPPS/ASC final rule (80 FR 70531) for our program policies regarding modifications to previously adopted measures.

We are not proposing any changes to these policies in this proposed rule.

4. Measure Adoption

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68493 and 68494) for details regarding program priorities we consider for quality measure selection.

We are not proposing any changes to these policies in this proposed rule.

C. Program Measure Proposals

1. Proposal to Adopt Health Equity Quality Measures in the ASCQR Program

We refer readers to sections XIV.B.1, XIV.B.2, and XIV.B.3 of this proposed rule for our cross-program proposals to adopt the following measures in the ASCQR Program: (1) the Facility Commitment to Health Equity (FCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

2. Summary of Proposed Program Measure Set Updates

a. Proposed Program Measure Set Beginning With the CY 2027 Payment Determination

Table 98 summarizes the proposed updated ASCQR Program measure set beginning with the CY 2027 payment determination.

Specifically, Table 98 includes the previously finalized measure set and the three proposed new cross-program health equity measures, as detailed in sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively, of this proposed rule.

TABLE 98: PROPOSED UPDATED ASCQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION

CBE #	Measure Name
None†	All-Cause Hospital Transfer/Admission
None†	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery)*
3636	COVID–19 Vaccination Coverage Among Health Care Personnel (HCP)
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Facility Commitment to Health Equity (FCHE)***
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at ASCs
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
3470	Hospital Visits After Orthopedic Ambulatory Surgical Center (ASC) Procedures
3366	Hospital Visits After Urology ASC Procedures
None	Normothermia Outcome
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)
	<ul style="list-style-type: none"> • About Facilities and Staff • Communication About Procedure • Overall Rating of Facility • Preparation for Discharge and Recovery • Recommendation of Facility
None†	Patient Burn
None†	Patient Fall
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the ASC Setting**
None	Screening for Social Drivers of Health (SDOH)****
None	Screen Positive for Social Drivers of Health (SDOH)****
None	Unplanned Anterior Vitrectomy
None†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

†Measure is no longer endorsed by the CBE but was endorsed previously.

*This measure is voluntary.

**This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination, as discussed in the CY 2024 OPSS/ASC final rule (88 FR 82033 through 82036).

***We propose that this measure would be mandatory beginning with the CY 2025 Reporting Period/CY 2027 payment determination, as discussed in section XIV.B.1 of this proposed rule.

****We propose that this measure would begin with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, as discussed in sections XIV.B.2 and XIV.B.3 of this proposed rule.

b. Proposed Program Measure Set Beginning With the CY 2031 Payment Determination

Table 99 summarizes the proposed updated ASCQR Program measure set beginning with the CY 2031 payment determination.

Specifically, Table 99 includes the previously finalized measure set and the three proposed new cross-program health equity measures, as detailed in sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively, of this proposed rule.

TABLE 99: PROPOSED UPDATED ASCQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2031 PAYMENT DETERMINATIONP

CBE #	Measure Name
None†	All-Cause Hospital Transfer/Admission
None†	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery)*
3636	COVID–19 Vaccination Coverage Among Health Care Personnel (HCP)
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Facility Commitment to Health Equity (FCHE)**
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (ASCs)
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
3470	Hospital Visits After Orthopedic ASC Procedures
3366	Hospital Visits After Urology ASC Procedures
None	Normothermia Outcome
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)
	<ul style="list-style-type: none"> • About Facilities and Staff • Communication About Procedure • Overall Rating of Facility • Preparation for Discharge and Recovery • Recommendation of Facility
None†	Patient Burn
None†	Patient Fall
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the ASC Setting
None	Screening for Social Drivers of Health (SDOH)***
None	Screen Positive for Social Drivers of Health (SDOH)***
None	Unplanned Anterior Vitrectomy
None†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

†Measure is no longer endorsed by the CBE but was endorsed previously.

*We note that this measure is voluntary.

**We propose that this measure would be mandatory beginning with the CY 2025 Reporting Period/CY 2027 payment determination, as discussed in section XIV.B.1 of this proposed rule.

***We propose that this measure would begin with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, as discussed in sections XIV.B.2 and XIV.B.3 of this proposed rule.

D. Administrative Requirements

We refer readers to § 416.305 and the CY 2016 OPPS/ASC final rule (80 FR 70533 and 70534) for our program policies regarding participation and withdrawal requirements.

We are not proposing any changes to these policies in this proposed rule.

E. Form, Manner, and Timing of Data Submission

1. General Policy

We refer readers to § 416.310 and the CYs 2017, 2018, and 2021 OPPS/ASC final rules (81 FR 79824 and 79825; 82 FR 59472 through 59475; and 85 FR 86191 and 86192, respectively) for our general program policies regarding: (1) submission of data under the ASCQR Program generally; (2) review and correction of submitted data; and (3) extraordinary circumstance exception (ECE) requests for data submission.

We are not proposing any changes to these policies in this proposed rule.

We also refer readers to the CY 2016 OPPS/ASC final rule (80 FR 70531) for details regarding submission requirements for previously adopted ASCQR Program measures in the ASCQR Program Specifications Manual.

2. Measure-Specific Data Submission and Reporting Requirements

We refer readers to § 416.310 and the CYs 2016, 2022, and 2024 OPPS/ASC final rules (80 FR 70534 through 70536; 86 FR 63905 through 63909; and 88 FR 82041 through 82045, respectively) for information regarding our claims-based, survey-based, and PRO-PM data submission and reporting requirements.

a. Web-Based Measures

(1) CMS-Designated Information System and Proposal for Data Submission for the Facility Commitment to Health Equity (FCHE), Screening for Social Drivers of Health (SDOH), and Screen Positive Rate for SDOH Measures

We refer readers to § 416.310(c)(1), the CY 2017 OPPS/ASC final rule (81 FR 79821 and 79822), the CY 2018 OPPS/ASC final rule (82 FR 59473), and the CY 2024 final rule (88 FR 82039 and 82040) for details regarding submission of web-based data via a CMS-designated information system (currently the Hospital Quality Reporting (HQR) System).

In sections XIV.B.1, XIV.B.2, and XIV.B.3 of this proposed rule, we propose the adoption of:

(1) the FCHE measure, beginning with the CY 2025 reporting period/CY 2027 payment determination;

(2) the Screening for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and

(3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

Consistent with our established data submission requirements (81 FR 79821 and 79822; 82 FR 59473; 88 FR 82039 and 82040), we propose that ASCs would be required to submit all of the data required to calculate each of these three measures annually using a CMS-approved, web-based, data collection tool available within the HQR System starting January 1 through and including May 15 in the year prior to the applicable payment determination year. For the ASCQR Program, the performance period (which we refer to as the CY reporting period) for each measure on which data is submitted using a web-based tool would be January 1 through and including December 31 of the year that is two years prior to the applicable payment determination year; and the data submission period would be January 1 through and including May 15 in the calendar year immediately following the CY reporting period and immediately prior to applicable payment determination year. For example, for the CY 2025 reporting period/2027 payment determination, the data submission period would be January 1, 2026, through and including May 15, 2026, covering the performance period of January 1, 2025, through and including December 31, 2025. Pursuant to § 416.310(c)(1)(iii), a review and corrections period runs concurrently with the data submission period. During this timeframe, ASCs would be able to enter, review, and correct data submitted during the data submission period.

We invite public comment on this proposal.

(2) National Health Safety Network (NHSN)

We refer readers to § 416.310(c)(2) and the CY 2014 OPPS/ASC final rule (78 FR 75139 and 75140) for our policies regarding submission of web-based data via the Center for Disease Control and Prevention's NHSN.

We are not proposing any changes to these policies in this proposed rule.

F. Public Reporting of Measure Data

We refer readers to § 416.315 and the CY 2018 OPPS/ASC final rule (82 FR 59472) for our program policies regarding public reporting of quality data.

We are not proposing any changes to these policies in this proposed rule.

G. Request for Information (RFI) - Development of Frameworks for Specialty Focused Reporting and Minimum Case Number for Required Reporting

The ASCQR Program promotes informed patient decision-making regarding clinical care across ASC procedures through a robust set of quality measures, data on which the ASCQR Program publicly reports as discussed in section XVII.F of this proposed rule. The ASCQR Program's current measure set captures clinical quality across all ASCs, including specialty clinical procedures performed only by a subset of ASCs. Thus, a portion of the ASCQR Program measure set only applies to an ASC if it performs those specialty procedures. Currently, ASCs are required to attest if they do not have cases for a given measure, increasing reporting burden.

We seek to ensure the most meaningful measures apply to each facility, as requiring an ASC to report on measures minimally relevant to their patient population increases burden with minimum benefit. Therefore, we are seeking comment on two potential future frameworks which would achieve the following outcomes: (1) the addition of case minimums for specialty measure reporting; (2) the removal of the zero case attestation requirement for specialty measures to decrease reporting burden; and (3) the verification of individual measure case counts using claims data to determine which specialty measures would potentially be required for

reporting for individual ASCs. Verifying case counts using claims data would allow us to confirm that individual ASCs are reporting on measures meeting or surpassing case minimums.

Under these potential frameworks, we are considering revising the data reporting requirements for the ASCQR Program to only require that ASCs report data to CMS on quality measures that are related to their medical interventions, policies, processes, and procedures, or can be abstracted from claims. These potential frameworks would require ASCs to report measures generally applicable to all ASCQR Program participants and relevant specialty-specific measures, defined as those which evaluate performance on certain specialty clinical procedures performed only by a subset of ASCs.

The current ASCQR Program measure set has seven generally applicable measures for which reporting would be required in both frameworks for all ASCs: four patient safety measures (Patient Burn; Patient Fall; Wrong Site, Wrong Patient, Wrong Procedure, Wrong Implant; All-Cause Hospital Transfer Admission), one general surgery measure (Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers), one vaccination measure (COVID-19 Vaccination Coverage Among Health Care Personnel), and one patient experience of care survey measure (OAS CAHPS). In addition, we have proposed in this proposed rule to adopt three new generally applicable measures (FCHE, Screening for SDOH, and Screen Positive Rate for SDOH), which ASCs would also be required to report if finalized.

The specialties addressed by the current ASCQR Program measure set, and the related specialty-specific measures, are described in Table 100. Under our first potential framework, the “Specialty-Select” framework, all ASCs would be required to report all specialty-specific, claims-based measures (currently, four) because these measures are not administratively burdensome to ASCs. Additionally, ASCs would also be required to select a specified number of the remaining non-claims-based specialty-specific measures (currently, four) to report if those

measures are applicable to that ASC. We would define the number of non-claims-based specialty-specific measures that ASCs would be required to report in future rulemaking.

To determine if a non-claims-based specialty-specific measure is applicable to an ASC, we are considering the implementation of a case threshold minimum which we would specify in future rulemaking, for each measure. We would determine if case threshold minimums, defined as the number of cases for a specific measure that must be met or exceeded to potentially require reporting, have been met using claims data. Once an ASC met the measure's case threshold minimum, that measure would become available for that ASC to select to meet reporting requirements. We note that reporting claims-based specialty-specific measures would be required regardless of whether the case threshold minimum is met. In this RFI we are seeking comment on the number of non-claims-based specialty-specific measures that ASCs should be required to report and what the appropriate threshold for the case threshold minimum should be.

We are considering the use of Medicare Fee-for-Service (FFS) and Medicare Advantage claim volume data to determine which non-claims-based specialty-specific measures have met the specified case threshold minimum (that is, claims information would indicate an ASC was performing sufficient case volumes in a specialty area). We note that this threshold would be independent from our "Minimum case volume for program participation" policy, which exempts ASCs with fewer than 240 total Medicare claims per year from participating in the ASCQR Program, in the manner specified at § 416.305(c). The case threshold minimum discussed in this RFI would be applied to individual non-claims-based specialty-specific measures for ASCs required to participate in the ASCQR Program.

For example, if we decide that each ASC must select three out of the four available non-claims-based specialty-specific measures to report, and an ASC surpasses the specified case threshold minimum for all four non-claims-based specialty-specific measures, the ASC would then choose three out of the four non-claims-based specialty-specific measures to report. If an ASC surpasses the specified case threshold minimum for only one or two non-claims-based

specialty-specific measures, the ASC will no longer have a choice, and must report all measures meeting the case threshold minimum. If an ASC does not meet the case threshold minimum for any non-claims-based specialty-specific measures, reporting for any of these measures would be voluntary. Under such a framework, ASCs could not utilize the claims-based measures to meet Specialty-Select reporting requirements nor could ASCs opt-out of reporting these measures. ASCs which do not have one or more cases for a given measure would no longer be required to provide an attestation of having zero cases.

TABLE 100: CURRENT SPECIALTY-SPECIFIC ASCQR PROGRAM MEASURES

Specialty	Measure	Current Reporting Requirement	Data Source
Ophthalmology	Unplanned Anterior Vitrectomy	Mandatory	Patient Medical Records
Ophthalmology	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery)	Voluntary	Patient Reported Data and Surveys
Surgical	Normothermia Outcome	Mandatory	Patient Medical Records
Surgical	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO– PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM)	Voluntary through CY 2027 reporting period; Mandatory beginning with CY 2028 reporting period	Patient Reported Data and Surveys
Surgical	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures	Mandatory	Medicare Claims
Gastroenterology	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Mandatory	Medicare Claims
Gastroenterology	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	Mandatory	Medicare Claims
Urology	Hospital Visits after Urology Ambulatory Surgical Center Procedures	Mandatory	Medicare Claims

Four of these measures are not claims-based and, under this potential framework, would not be applicable or required for all ASCs to report, but would rather be available for selection upon meeting a specified case threshold minimum:

- Unplanned Anterior Vitrectomy;

- Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery) (voluntary);
- Normothermia Outcome; and
- Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO– PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM).

We acknowledge that currently there are few non-claims-based specialty-specific measures from which to choose to report. However, we are interested to learn if such a framework with both mandatory measures applicable to all ASCs and selectable, specialty-specific measures could lay the groundwork for providing higher quality data to patients while ensuring ASCs are not reporting data on measures that are minimally relevant, if not irrelevant, to their patient population.

Regarding this Specialty-Select framework, we are requesting comment on the following questions:

- Given that ASCs would still be required to report claims-based specialty-specific measures, as these measures are not administratively burdensome to ASCs, and there are currently only four non-claims-based specialty-specific quality measures in the ASCQR Program data set, how many non-claims-based specialty-specific measures should we require ASCs select to report?
- Are there specialty-specific measures that commenters would recommend for development and adoption in the ASCQR Program measure set to create a more robust selection?
- How should we determine what non-claims-based specialty-specific measures would be eligible for a given ASC to select toward meeting reporting requirements? In other words, how can we determine if an ASC meets the minimum case number for a given measure, which would allow the ASC to choose that measure to meet reporting requirements?

As an alternative to the Specialty-Select framework discussed previously, we are considering requiring reporting for all non-claims-based specialty-specific measures for which case counts reach a specified case threshold minimum. This case threshold minimum would not apply to claims-based specialty-specific measures, as their reporting would be mandatory since these measures are not administratively burdensome to ASCs. Under this alternative framework, mandatory data reporting for non-claims-based specialty-specific measures would occur only if an ASC met established case threshold minimums. For example, if an ASC has 30 or more qualifying patients for the measure during the applicable reporting period, which is the current minimum case threshold required for public reporting for some measures, the ASC would be required to submit data for these measures. Likewise, if an ASC has fewer than 30 patients for the measure, data reporting on the measure would be voluntary. This framework could be termed a Specialty Threshold framework and would differ from the previously discussed Specialty-Select framework as an ASC would be required to report on all non-claims-based specialty-specific measures for which the ASC reaches the case threshold minimum.

Regarding both the Specialty Threshold framework and the Specialty-Select framework, we are requesting comment on the following questions:

- Would use of Medicare Fee-for-Service (FFS) claim volume be sufficient for determining minimum case volumes?
- Should Medicare Advantage claim volume or service data be included when determining case volume thresholds for reporting a measure?
- Do commenters recommend any processes that could be followed or analyses we could conduct to determine case minimums?

We invite public comment on both the Specialty-Select framework and the alternative Specialty Threshold framework for potential inclusion in the ASCQR Program.

H. 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 2025, 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 is the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023), which was extended an additional two years (through CY 2025) in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81960). 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 the proposed rule, which are available via the Internet on the CMS website): “A2,” “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 2024 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 2025 reporting period/CY 2027 payment determination and for subsequent years.

XVIII. Medicaid Clinic Services Four Walls Exceptions

A. Background

Under section 1902(a)(10) of the Act, States may offer certain Medicaid benefits, at State option, to categorically needy and medically needy Medicaid beneficiaries, as described in that section of the statute. Clinic services are one of these optional benefit categories.

Section 1905(a)(9) of the Act, as amended by section 4105 of part 1 of subtitle B of title IV of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87, Pub. L. 110-203), defines clinic services as services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, including such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling

or does not have a fixed home or mailing address (hereinafter referred to as “individuals who are unhoused”).^{262,263}

The regulation implementing section 1905(a)(9) of the Act, 42 CFR 440.90, includes certain conditions and limitations on Medicaid coverage of clinic services. Specifically, § 440.90 defines clinic services as preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients.²⁶⁴ Section 440.90 further provides that clinic services include two types of services furnished to outpatients, listed at § 440.90(a) and (b). The first type of services included in the benefit, under § 440.90(a), is services furnished at the clinic (hereinafter referred to as the “four walls” requirement) by or under the direction of a physician or dentist. Section 440.90(b) implements the statutory language providing that clinic services also include services furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who is unhoused. In section 4320 of the State Medicaid Manual, we explained that if a State elects to cover clinic services, the State may choose the type of clinics or clinic services that are covered.²⁶⁵

²⁶² Pub. L. 100-203, enacted December 22, 1987, 100 Stat. 1330, 1330-147, <https://www.congress.gov/100/statute/STATUTE-101/STATUTE-101-Pg1330.pdf>.

²⁶³ This document contains links to non-United States Government websites. We are providing these links because they contain additional information relevant to the topic(s) discussed in this document or that otherwise may be useful to the reader. We cannot attest to the accuracy of information provided on the cited third-party websites or any other linked third-party site. We are providing these links for reference only; linking to a non-United States Government website does not constitute an endorsement by CMS, HHS, or any of their employees of the sponsors or the information and/or any products presented on the website. Also, please be aware that the privacy protections generally provided by United States Government websites do not apply to third-party sites.

²⁶⁴ An outpatient is defined at 42 CFR § 440.2 as a patient of an organized medical facility, or distinct part of that facility who is expected by the facility to receive and who does receive professional services for less than a 24-hour period regardless of the hour of admission, whether or not a bed is used, or whether or not the patient remains in the facility past midnight.

²⁶⁵ U.S. Department of Health and Human Services, Health Care Financing Administration (HCFA), *The State Medicaid Manual*, Manual, (Baltimore, MD, 1985), Section 4320, <https://www.cms.gov/regulations-and-guidance/guidance/manuals/paper-based-manuals-items/cms021927>.

We added § 440.90(b) in 1991, after Congress added the language about services furnished outside the clinic to individuals who are unhoused to section 1905(a)(9) of the Act in OBRA '87.²⁶⁶ In the preamble to that rule, we explained that clinic services have always been limited to people who go to the clinic (or a satellite location) and get the services onsite, and that the exception added by OBRA '87 represents an exception to the general coverage requirement for services to be furnished on the premises of the clinic. Further, we explained our view that Congress ratified the requirement that other clinic services must be furnished onsite by establishing an explicit exception to the requirement that clinic services be furnished onsite in order to be covered. CMS has long interpreted the exception to the four walls requirement at § 440.90(b) to be mandatory for States that opt to cover the clinic services benefit. We reiterated CMS's longstanding interpretation that section 1905(a)(9) of the Act and § 440.90 establish a four walls requirement in a frequently asked questions document that we published on January 18, 2017 (hereinafter referred to as "the January 18, 2017 FAQ"), to supplement State Health Official letter number 16-002, Federal Funding for Services "Received Through" an IHS/Tribal Facility and Furnished to Medicaid-Eligible American Indians and Alaska Natives.^{267,268}

The Medicaid clinic services benefit is distinct from the Medicaid federally qualified health center (FQHC) services benefit and the Medicaid rural health clinic (RHC) services benefit. The Medicaid FQHC services benefit is defined at section 1905(a)(2)(C) of the Act, and

²⁶⁶ Medicare and Medicaid Programs; OBRA '87 Conforming Amendments, 56 FR 8832, 8835 (March 1, 1991) (hereinafter referred to as the 1991 rule). https://archives.federalregister.gov/issue_slice/1991/3/1/8829-8854.pdf.

²⁶⁷ CMS, *Federal Funding for Services "Received Through" an IHS/Tribal Facility and Furnished to Medicaid-Eligible American Indians and Alaska Natives*, State Health Official Letter (SHO) #16-002, (Baltimore, MD, 2016), <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/sho022616.pdf>.

²⁶⁸ CMS, *Frequently-Asked Questions (FAQs) Federal Funding for Services "Received Through" an IHS/Tribal Facility and Furnished to Medicaid Eligible American Indians and Alaska Natives (SHO #16-002)*, FAQ, (Baltimore, MD, 2017), <https://www.medicaid.gov/media/40241> .

FQHCs and FQHC services are further defined at section 1905(l)(2) of the Act. The Medicaid RHC services benefit is defined at section 1905(a)(2)(B) of the Act, and RHCs and RHC services are further defined at section 1905(l)(1) of the Act. Unlike the clinic services benefit, which is an optional benefit for States, the FQHC and RHC benefits are mandatory for categorically needy Medicaid beneficiaries under section 1902(a)(10) of the Act. In addition, there is no Federal four walls requirement under the Medicaid FQHC or RHC services benefits, unlike the clinic services benefit. Federal Medicaid law does not prevent States from covering Medicaid FQHC and RHC services provided outside of the four walls of an FQHC or RHC.²⁶⁹

On January 28, 2021, the President signed Executive Order (E.O.) 14009, “Strengthening Medicaid and the Affordable Care Act,” which established the policy objective to protect and strengthen Medicaid and the Affordable Care Act and to make high-quality health care accessible and affordable for every American, and directed executive departments and agencies to review existing regulations, orders, guidance documents, and policies to determine whether such agency actions are inconsistent with this policy.²⁷⁰ As part of this review of existing policies, E.O. 14009 directed Federal agencies to consider whether to suspend, revise, or rescind agency actions considered inconsistent with this objective. On April 5, 2022, E.O. 14070, “Continuing to Strengthen Americans’ Access to Affordable, Quality Health Coverage,” directed Federal agencies with responsibilities related to Americans’ access to health coverage to review agency actions to identify ways to continue to expand the availability of affordable health

²⁶⁹ We note that the Consolidated Appropriations Act, 2024, Division G, Title I, Section 209 (P.L. 118-42) amended section 1905 of the Act to establish a certified community behavioral health clinic (CCBHC) services benefit effective March 9, 2024. The CCBHC services benefit is distinct from the clinic services benefit and there is no four walls requirement for the CCBHC services benefit under Federal Medicaid law.

²⁷⁰ Exec. Order No. 14009, 86 Fed. Reg. 7793 (Jan. 28, 2021). See, <https://www.Federalregister.gov/documents/2021/02/02/2021-02252/strengthening-medicaid-and-the-affordable-care-act>.

coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage.²⁷¹

On November 6, 2000, President Clinton signed E.O. 13175, “Consultation and Coordination With Indian Tribal Governments,” which recognizes the unique legal relationship between the United States and Indian Tribal governments and, to strengthen this government-to-government relationship and support tribal sovereignty and self-determination, charges all executive departments and agencies with engaging in meaningful and timely consultation with Tribal officials in the development of Federal policies that have Tribal implications.²⁷² On January 26, 2021, President Biden issued a “Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships,” which reaffirms E.O. 13175’s directive to engage in regular, meaningful, and robust consultation with Tribal officials in the development of Federal policies that have Tribal implications.²⁷³

Consistent with E.O. 13175, CMS issued a Tribal Consultation policy in 2011 and updated it in 2015 for the purpose of building meaningful relationships with Indian Tribes and to establish a clear, concise and mutually acceptable process through which consultation can take place between CMS and Tribes.^{274,275} As one of its core principles, the policy provides that, because Congress amended titles XVIII and XIX of the Act to authorize Indian Health Service

²⁷¹ Exec. Order No. 14070, 87 Fed. Reg. 20689 (Apr. 8, 2021). See, <https://www.Federalregister.gov/documents/2022/04/08/2022-07716/continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage>.

²⁷² Exec. Order No. 13175, 65 Fed. Reg. 67249 (Nov. 6, 2000). See, <https://www.Federalregister.gov/documents/2000/11/09/00-29003/consultation-and-coordination-with-indian-tribal-governments>.

²⁷³ President Joseph R. Biden to Heads of Executive Departments and Agencies, memorandum, “Tribal Consultation and Strengthening Nation-to-Nation Relationships,” January 26, 2021, Presidential Actions, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/26/memorandum-on-tribal-consultation-and-strengthening-nation-to-nation-relationships/>.

²⁷⁴ CMS, “Tribal Consultation,” CMS.gov, September 6, 2023, <https://www.cms.gov/training-education/partner-outreach-resources/american-indian-alaska-native/tribal-consultation>.

²⁷⁵ CMS, *Tribal Consultation Policy*, Policy, (Washington, DC, 2015), <https://www.cms.gov/outreach-and-education/american-indian-alaska-native/aian/downloads/cmstribalconsultationpolicy2015.pdf>.

(IHS) and Tribal health programs to bill Medicare and Medicaid, “[t]he involvement of Indian tribes in the development of CMS policy is crucial for mutual understanding and development of culturally appropriate approaches to improve greater access to CMS programs for American Indians and Alaska Natives (AI/ANs), to enhance health care resources to IHS and tribal health programs, and to contribute to overall improved health outcomes for American Indians.” As part of its government-to-government relationship with the Tribes, CMS has engaged in meaningful consultation with Tribes and Tribal leaders, the CMS Tribal Technical Advisory Group (TTAG), and the HHS Secretary’s Tribal Advisory Committee (STAC) regarding concerns about the impact that the four walls requirement could have on IHS/Tribal clinics and AI/AN beneficiaries’ access to health care when a grace period currently in place for IHS/Tribal clinics (as discussed below) ends. As part of this consultation, Tribes requested a permanent exemption from the four walls requirement for IHS/Tribal clinics. In the development of this proposed rule, we have taken into consideration comments and feedback received during Tribal consultation.

IHS, a Federal agency within the Department of Health and Human Services, is responsible for furnishing comprehensive, culturally appropriate health services to, as of April 2024, almost 2.8 million AI/ANs who are eligible for services from IHS, per regulations at 42 CFR part 136, as well as other individuals whom IHS or Tribes are authorized to serve under 25 U.S.C. 1680c.²⁷⁶ IHS’s provision of health services to its beneficiaries stems from the special government-to-government relationship between the Federal government and Indian Tribes. The Federal government’s relationship with Tribes is based on Article I, section 8 of the Constitution, and has been given form and substance by numerous treaties, statutes, Supreme Court decisions, and Executive Orders. The IHS delivery system includes hospitals and clinics that are owned and operated by IHS, owned by IHS and Tribally-operated as authorized by the Indian Self-

²⁷⁶ IHS, *Indian Health Service Health Equity Report, Fact Sheet*, (2024), https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/factsheets/IHS_Health_Equity_Report_FactSheet_2024.pdf.

Determination and Education Assistance Act (ISDEAA, Pub. L. 93-638 (as amended)), or owned and operated by Tribes and Tribal organizations as authorized by the ISDEAA.²⁷⁷ We refer to these three kinds of facilities in our discussions of the proposed amendments to § 440.90 as “IHS/Tribal facilities” or, when referring to circumstances where these facilities operate as Medicaid clinic services providers, “IHS/Tribal clinics.”²⁷⁸ Section 1911 of the Act and implementing regulations at § 431.110 provide that a facility of IHS, whether operated by IHS or by a Tribe or Tribal organization (CMS has interpreted similar language in section 1905(b) of the Act to refer to all three kinds of IHS/Tribal facilities described above),²⁷⁹ may participate in the Medicaid program subject to the conditions and requirements generally applicable under Title XIX of the Act. Many IHS/Tribal facilities are covered and paid as clinic services providers in the Medicaid program. Under section 1903(a)(1) of the Act, the Federal government is required to match State expenditures for medical assistance at the Federal Medical Assistance Percentage (FMAP), which is defined at section 1905(b) of the Act to be 100 percent for State expenditures for Medicaid-covered services received through an IHS facility whether operated by IHS or by a Tribe or Tribal organization (which, again, CMS has interpreted to refer to all three kinds of IHS/Tribal facilities described above). Under CMS’s longstanding interpretation of section 1905(b) of the Act, this 100 percent FMAP is available only for State expenditures on services received through an IHS/Tribal facility (such as a clinic) by AI/AN Medicaid beneficiaries. State expenditures on services furnished by an IHS/Tribal facility to other individuals are not

²⁷⁷ HCFA and IHS, “Memorandum of Agreement Between the Indian Health Services and the Health Care Financing Administration,” Memorandum of Agreement, December 19, 1996, <https://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/LTSS-TA-Center/pdf/memorandum-of-agreement.pdf>.

²⁷⁸ Although Urban Indian Organizations that operate under Title V of the Indian Health Care Improvement Act are also part of the IHS delivery system, for purposes of our discussions of the proposed amendments to § 440.90, the terms IHS/Tribal facility and IHS/Tribal clinic do not include a facility operated by an Urban Indian Organization.

²⁷⁹ HCFA and IHS, Memorandum of Agreement.

matched by the Federal government at 100 percent, but rather at the State's regularly applicable FMAP rate.

As part of our Center for Medicaid & CHIP Services (CMCS) Mental Health and Substance Use Disorder Action Plan published in July 2023, we are pursuing strategies to increase access to prevention and treatment, engagement in care, and improve quality of care for beneficiaries with behavioral health disorders.²⁸⁰ Behavioral health disorders include both substance use disorders and mental health disorders. Medicaid plays a crucial role in financing health care for individuals with behavioral health disorders and is the largest payer of behavioral health services.²⁸¹ There are no Federal requirements for States to cover services furnished by behavioral health clinics or any specific types of behavioral health clinics under the clinic services benefit. However, we are aware that approximately 16 States cover services provided by behavioral health clinics of varying types under the clinic services benefit, such as Community Mental Health Centers certified under the Medicare Conditions of Participation at 42 CFR part 485 Subpart J, substance use disorder clinics, or mental health clinics.

We released a framework for advancing health care in rural, Tribal, and geographically isolated communities in November 2022.²⁸² Our framework focuses on six priorities, including expanding access to comprehensive health care coverage, benefits, and services and supports to individuals who live in these communities. Medicaid plays an important role in financing health care in rural areas, as nearly a quarter of individuals under age 65 who live in rural areas are

²⁸⁰ CMS, *Mental Health and Substance Use Disorder Action Plan*, (2023), Action Plan, <https://www.medicaid.gov/medicaid/benefits/downloads/cmcs-mntl-helth-substnce-disrdr-actn-plan.pdf>.

²⁸¹ Guth, Madeline, Heather Saunders, Lauren Niles, Angela Bergefurd, Kathleen Gifford, and Roxanne Kennedy Published. 2023. "How Do States Deliver, Administer, and Integrate Behavioral Health Care? Findings from a Survey of State Medicaid Programs." KFF. May 25, 2023. <https://www.kff.org/mental-health/issue-brief/how-do-states-deliver-administer-and-integrate-behavioral-health-care-findings-from-a-survey-of-state-medicaid-programs/>.

²⁸² CMS, *CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities*, (2022), Framework, <https://www.cms.gov/files/document/cms-geographic-framework.pdf>.

covered by Medicaid. Importantly, Medicaid also provides critical access to care for individuals in rural areas who are older or disabled, as more than one in five residents of rural areas (approximately 22 percent) are dually enrolled in Medicaid and Medicare.²⁸³ There are no Federal requirements under the clinic services benefit governing how States should provide coverage of services furnished specifically by clinics located in rural areas under that benefit—the Federal requirements that apply generally to that benefit, including the four walls requirement, also apply to services furnished by clinics in rural areas. A State may cover Medicaid clinic services provided by various types of clinics located in rural areas, such as primary care clinics, behavioral health clinics, surgical clinics, and other types of clinics. As noted earlier in this section of the proposed rule, the Medicaid RHC services benefit is different from the Medicaid clinic services benefit and does not include a four walls requirement under Federal Medicaid law; thus, facilities that qualify as RHCs under Federal Medicaid law could provide Medicaid services under the RHC services benefit, including outside of the four walls.

Section 1902(a)(30)(A) of the Act requires that Medicaid payments for services be consistent with efficiency, economy, and quality of care, and be sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Under this requirement, States generally have significant latitude in setting payment methodologies and rates for covered services, and there is no specific payment methodology required for clinic services, although regulations at § 447.321 require the application of upper payment limits for clinics that are not IHS/Tribal clinics. States generally pay for clinic services via a facility rate. They typically adopt, as the payment rate for Medicaid clinic services furnished by IHS/Tribal clinics, the Outpatient per Visit Rate (excluding Medicare) that IHS establishes for services

²⁸³ Medicaid and CHIP Payment and Access Commission (MACPAC), *Medicaid and Rural Health*, Issue Brief, (Washington, DC, 2021), 1, <https://www.macpac.gov/wp-content/uploads/2021/04/Medicaid-and-Rural-Health.pdf>.

provided by IHS facilities to Medicaid beneficiaries and for certain other Federal programs. This rate, and a set of three other rates for Medicare outpatient visits and certain inpatient services, are frequently referred to collectively as the IHS all-inclusive rates (AIRs), and therefore this IHS Outpatient per Visit Rate (excluding Medicare) is hereinafter referred to as the “AIR.”²⁸⁴ In contrast, States generally pay for Medicaid benefits provided by individual practitioners, such as the physician services benefit, at a professional fee schedule rate under the Medicaid State plan.

As we noted in the January 18, 2017 FAQ, CMS recognized in 2017 that IHS/Tribal clinics were providing services outside of the four walls, including to individuals to whom the existing statutory and regulatory exception does not apply, and that States were paying for these services at the clinic services rate (which in all or nearly all cases is the AIR). In the January 18, 2017 FAQ, we announced a 4-year grace period to January 30, 2021, to allow States time to come into compliance with the four walls requirement for IHS/Tribal clinics. On January 15, 2021, due to the COVID-19 Public Health Emergency (PHE), CMS issued a CMCS Informational Bulletin (CIB) announcing an extension of the four walls grace period to October 31, 2021. CMS issued subsequent CIBs on October 4, 2021 and September 8, 2023, announcing further extensions of the grace period to nine months from when the COVID-19 PHE ended, and February 11, 2025, respectively.²⁸⁵

²⁸⁴ IHS establishes the AIRs under the authority in sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 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.*). IHS calculates AIRs on an annual basis and the rates are then published in the Federal Register. The AIRs are based on annual cost report analysis prepared by IHS’s contractor. IHS reviews the cost report analysis and upon completion of the review, IHS submits recommended rates to the Office of Management and Budget (OMB) for final approval through HHS and CMS. Upon approval by OMB, the approved rates are published in the Federal Register. See <https://www.ihs.gov/BusinessOffice/reimbursement-rates/>. Calendar year 2024 rates and additional information can be found in the Federal Register published December 19, 2023 (88 FR 87789): <https://www.Federalregister.gov/documents/2023/12/19/2023-27815/reimbursement-rates-for-calendar-year-2024>.

²⁸⁵ CMS, *Further Extension of Grace Period Related to the “Four Walls” Requirement under 42 CFR 440.90 for Indian Health Service and Tribal Facilities to February 11, 2025*, CMCS Informational Bulletin, (Baltimore, MD, 2023), <https://www.medicaid.gov/sites/default/files/2023-09/cib090823.pdf>.

Since the release of the January 18, 2017 FAQ and throughout the grace period, we have heard from Tribes, the CMS TTAG, and the HHS STAC, that the four walls requirement will create barriers in access to care for Medicaid beneficiaries who receive care from IHS/Tribal clinics after the grace period expires. Tribes, the TTAG, and the STAC have asked CMS to eliminate the four walls requirement for IHS/Tribal clinics. In addition to these requests, CMS has received a handful of other requests from States to allow exceptions to the four walls requirements for clinics that serve vulnerable populations. For example, we received one section 1115 demonstration request to cover clinic services outside of the four walls for behavioral health clinics, under which the State sought to use the requested section 1115 demonstration authority to improve access to and retention in behavioral health treatment. In addition, we received inquiries from States seeking to cover, under the clinic services benefit, mobile crisis services provided by behavioral health clinics to individuals experiencing a behavioral health crisis, but we advised those States that we could not approve coverage of mobile crisis services under the clinic services benefit due to the four walls requirement.

This proposed rule aims to address the concerns we have heard from Tribes, the TTAG, the STAC, States, and other interested parties. It aims to fulfill E.O.s 14009 and 14070 by helping States to strengthen and improve access to clinic services. It also helps to fulfill E.O. 13175 by recognizing the United States' unique legal relationship with Tribes and by responding to advice and input received from Tribes through consultation. In addition, we believe this proposed rule is consistent with our strategies, goals, and objectives to advance health equity and improve health care access for Tribal, behavioral health, and rural populations as described in our CMCS Mental Health and Substance Use Disorder Action Plan and CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities.

Consistent with our statutory authority at section 1905(a)(9) of the Act, we propose to add three exceptions to the four walls requirement at § 440.90, for the reasons set forth in

section XVIII.B of this proposed rule. First, we propose to add an exception for clinic services furnished by IHS/Tribal clinics. Second, we propose to add an exception for clinic services furnished by a clinic that is primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health and substance-use disorders. Third, we propose to add an exception for clinic services furnished by a clinic located in a rural area (and that is not an RHC, which could already provide services covered under a separate Medicaid benefit). We propose to make the exception for clinic services furnished by IHS/Tribal clinics a mandatory component of the clinic benefit and to make the exceptions for clinic services furnished by behavioral health clinics and clinics located in rural areas optional for States.

B. Provisions of the Proposed Regulations

As explained in section XVIII.A of this proposed rule, we previously interpreted section 1905(a)(9) of the Act to limit Medicaid clinic services to services furnished within the four walls of the clinic, except only for services furnished by clinic personnel to individuals who are unhoused. We continue to believe that because Congress added only one specific reference to services furnished outside the clinic to the statute in OBRA '87, it generally ratified our prior interpretation of the four walls requirement. Thus, we continue to believe that the statute authorizes neither broad exceptions to the four walls requirement that have no relationship to the current exception nor a complete elimination of the four walls requirement. However, we are now reinterpreting section 1905(a)(9) of the Act as permitting additional exceptions to the four walls requirements for populations served by clinics if those populations have similar health care access issues to individuals who are unhoused. When Congress added the exception to the statute, it introduced the exception with the word “including” (OBRA '87). We interpret the word “including” in the statute as not precluding additional exceptions to the four walls requirement, so long as any additional exception is similar to the exception for individuals who are unhoused. Had Congress wanted to limit the clinic benefit to only services provided within the four walls and services provided outside the four walls to the unhoused, it could have written

a narrower exception instead of using “including” as it did when adding the exception to section 1905(a)(9) of the Act. As discussed in the Congressional record for OBRA ’87 in H.R. Rep. 100-391, Congress amended section 1905(a)(9) of the Act to create an exception to the four walls requirement for individuals who are unhoused to address access concerns for a population that has unmet health needs, distrusts mainstream providers, and has difficulty accessing care when providers are unable to meet them where they are located.²⁸⁶ We believe that adding exceptions to the four walls requirement for populations with similar needs and barriers to access as individuals who are unhoused is consistent with the statutory text and purpose of the initial exception.

In developing the proposed exceptions, we considered the characteristics of the unhoused population that is targeted by the current statutory and regulatory exception. According to data from the Department of Housing and Urban Development (HUD), 21 percent of individuals who are unhoused reported having a serious mental illness while 16 percent reported having a substance use disorder.²⁸⁷ Individuals who are unhoused often lack transportation to access health care and cite this lack of transportation as a barrier to managing their health.^{288,289} In many cases, individuals who are unhoused distrust providers due to perceptions of disrespect and discrimination.²⁹⁰ Individuals who are unhoused also experience much poorer health outcomes than those who are housed; for example, nearly two thirds of individuals who are unhoused

²⁸⁶ H.R. Rep. No. 100-391, at 523 (1987), reprinted in 1987 U.S.C.C.A.N. 2313-1, 2313-343.

²⁸⁷ U.S. Department of Housing and Urban Development (HUD), *HUD 2022 Continuum of Care Homeless Assistance Programs Homeless Populations and Subpopulations*, Summary Report, (Washington, DC, 2022), https://files.hudexchange.info/reports/published/CoC_PopSub_NatlTerrDC_2022.pdf.

²⁸⁸ Yale University, “Barrier to Care,” Hypertension Awareness & Prevention Program at Yale, accessed March 15, 2024, <https://happy.sites.yale.edu/barriers-care>.

²⁸⁹ Murphy, Erin Roark. 2019. “Transportation and Homelessness: A Systematic Review.” *Journal of Social Distress and the Homeless* 28 (2): 1-10. <https://doi.org/10.1080/10530789.2019.1582202>.

²⁹⁰ Becker, Jenna N., and Karen J. Foli. 2021. “Health-Seeking Behaviours in the Homeless Population: A Concept Analysis.” *Health & Social Care in the Community* 30 (2). <https://doi.org/10.1111/hsc.13499>.

experience clinically significant dental problems and are four times as likely to visit an emergency department.^{291,292} A recent study found that when controlling for demographic and geographic differences, an individual who is unhoused is three and one half times more likely to experience early mortality than an individual who is housed.²⁹³ As indicated earlier in this section of the proposed rule, we believe that providing additional exceptions to the clinic services four walls requirement for populations with similar needs and barriers to access as individuals who are unhoused is consistent with the statute.

The exceptions outlined in this proposed rule follow four criteria that mirror the needs and barriers to access experienced by individuals who are unhoused:

- The population experiences high rates of behavioral health diagnoses or difficulty accessing behavioral health services;
- The population experiences issues accessing services due to lack of transportation;
- The population experiences a historical mistrust of the health care system; and
- The population experiences high rates of poor health outcomes and mortality.

By authorizing additional clinic services to be furnished outside of the four walls, the proposed exceptions are expected to improve access to care for the populations targeted by the exceptions. The exceptions would authorize States to pay the facility-based clinic services payment rates (such as the AIR for IHS/Tribal clinics) for the excepted services. Currently, due

²⁹¹ Baggett, Travis P., James J. O'Connell, Daniel E. Singer, and Nancy A. Rigotti. 2010. "The Unmet Health Care Needs of Homeless Adults: A National Study." *American Journal of Public Health* 100 (7): 1326-33. <https://doi.org/10.2105/ajph.2009.180109>.

²⁹² Lin, Wen-Chieh, Monica Bharel, Jianying Zhang, Elizabeth O'Connell, and Robin E. Clark. 2015. "Frequent Emergency Department Visits and Hospitalizations among Homeless People with Medicaid: Implications for Medicaid Expansion." *American Journal of Public Health* 105 (S5): S716-22. <https://doi.org/10.2105/ajph.2015.302693>.

²⁹³ Logani, Ilina, Bruce Meyer, and Angela Wyse. 2023. *The Mortality of the US Homeless Population*. BF Becker Friedman Institute for Economics at UChicago. The University of Chicago. March 27, 2023. <https://bfi.uchicago.edu/insight/research-summary/the-mortality-of-the-us-homeless-population/>.

to the four walls requirement, States can cover and pay for services that are provided by clinic personnel outside the four walls—but that do not fit within the exception at § 440.90(b)—only under Medicaid practitioner services benefits, such as physician services, rehabilitative services, or other licensed practitioner services—not under the clinic services benefit.

It is CMS’s understanding that State payment rates for these Medicaid practitioner services benefits are generally lower than the facility-based payment rates that States establish or adopt for Medicaid clinic services (such as the facility-based payment rate under the AIR, in the case of IHS/Tribal clinics), because the facility-based payment rates typically account for more overhead costs. While it is CMS’s understanding that States generally pay lower rates for Medicaid practitioner services than they do for Medicaid facility-based services, it should be noted that States generally have the flexibility to increase practitioner services payment rates. States must also comply with section 1902(a)(30)(A) of the Act, which requires States to assure that payments are consistent with efficiency, economy, and quality of care, and are sufficient to enlist enough providers so that care and services are available under the Medicaid State plan at least to the extent that such care and services are available to the general population in the geographic area.

Creating the exceptions could thus result in higher payments to providers for the excepted services. Studies of Medicaid payment rates have found that provider willingness to furnish services may be greater in States that pay providers at higher rates.^{294,295} Further, practitioners may be reluctant to provide home-based care when paid under a professional fee schedule rate,

²⁹⁴ Candon, Molly, Stephen Zuckerman, Douglas Wissoker, Brendan Saloner, Genevieve M. Kenney, Karin Rhodes, and Daniel Polsky. 2018. “Declining Medicaid Fees and Primary Care Appointment Availability for New Medicaid Patients.” *JAMA Internal Medicine* 178 (1): 145. <https://doi.org/10.1001/jamainternmed.2017.6302>.

²⁹⁵ Holgash, Kayla, and Martha Heberlein. 2019. *Physician Acceptance of New Medicaid Patients: What Matters and What Doesn’t*. Health Affairs Blog (blog). April 19, 2019. <https://www.healthaffairs.org/content/forefront/physician-acceptance-new-medicaid-patients-matters-and-doesn-t>.

since travel expenses and time are often not factored into the payment rate.²⁹⁶ As this evidence suggests, higher payment rates for services are more likely to incentivize providers to furnish those services. Because the proposal would authorize payment at the generally higher facility-based clinic services payment rates for the excepted services, we believe that it would incentivize providers to provide these services, and thereby meet these beneficiaries where they are located, which for reasons further discussed below, will help to ensure access to necessary care.

We considered whether this change in interpretation could burden States, beneficiaries, providers, or others who have relied on our current interpretation. Based on our current awareness of how States implement the Medicaid clinic services benefit, we do not anticipate that our proposal would create burdens for Medicaid clinic services providers or Medicaid beneficiaries, and we have considered the possible burden for State Medicaid programs in developing the proposal. We invite comments on whether our proposal might create any burdens for States, beneficiaries, providers, or other interested parties.

1. IHS/Tribal Clinics

In response to advice and input received through Tribal consultation, we propose to add a new paragraph (c) to § 440.90 to add an exception to the four walls requirement for IHS/Tribal clinics, to authorize payment for clinic services provided outside the four walls by IHS/Tribal clinic personnel. This exception would be mandatory for all States that opt to cover the Medicaid clinic services benefit. We refer in the proposed regulation text to clinics that are facilities of the IHS, whether operated by IHS or by a Tribe or Tribal organization as authorized by the ISDEAA, to make clear that this exception applies only to IHS/Tribal clinics. The proposed regulatory language identifying the facilities that would be subject to the exception is

²⁹⁶ Klein, Sarah, Martha Hostetter, and Douglas McCarthy. 2017. *An Overview of Home-Based Primary Care: Learning from the Field*. The Commonwealth Fund. The Commonwealth Fund. June 7, 2017. <https://www.commonwealthfund.org/publications/issue-briefs/2017/jun/overview-home-based-primary-care-learning-field>.

consistent with our longstanding interpretation of the language used in sections 1905(b) and 1911 of the Act, and would mean clinics that are owned and operated by IHS, clinics that are owned by IHS and Tribally-operated as authorized by the ISDEAA, or clinics that are owned and operated by Tribes and Tribal organizations as authorized by the ISDEAA.²⁹⁷

Under section 1903(a)(1) of the Act, as discussed earlier, the Federal government is required to match State expenditures for medical assistance at the Federal Medical Assistance Percentage (FMAP), which is defined at section 1905(b) of the Act to be 100 percent for State expenditures for Medicaid-covered services received through an IHS facility whether operated by IHS or by a Tribe or Tribal organization (which, again, CMS has interpreted to refer to all three kinds of IHS/Tribal facilities described above). Under CMS's longstanding interpretation of section 1905(b) of the Act, this 100 percent FMAP is available only for State expenditures on services received through an IHS/Tribal facility (such as a clinic) by AI/AN Medicaid beneficiaries. State expenditures on services furnished by an IHS/Tribal facility to other Medicaid beneficiaries are not matched by the Federal government at 100 percent, but rather at the otherwise applicable FMAP, and this would continue to apply for services provided outside the four walls of a clinic.

We are not proposing to include facilities operated by urban Indian organizations (UIOs) in this proposed exception, because it is our understanding that many of those facilities currently participate in Medicaid as providers of the Medicaid FQHC services benefit, not as providers of the clinic services benefit. Because Medicaid FQHC services are not subject to a four walls requirement under Federal Medicaid law, we believe that UIOs are unlikely to need the proposed exception. UIO facilities that provide Medicaid clinic services might qualify as behavioral health clinics or clinics in rural areas and be exempt from the four walls requirement under one of the two optional exceptions discussed below.

²⁹⁷ HCFA and IHS, Memorandum of Agreement.

This exception would apply to any Medicaid beneficiary who receives services from the IHS/Tribal clinic. Under IHS authorities, these clinics serve Medicaid beneficiaries who are eligible to receive services from the IHS/Tribal clinic under IHS regulations at 42 CFR part 136, and also may serve other Medicaid beneficiaries under 25 U.S.C. 1680c. As mentioned in section XVIII.A of this proposed rule, all services covered under the clinic services benefit must be furnished by or under the direction of a physician, so we propose to include language in this exception specifying that services subject to the exception would have to be furnished under the direction of a physician to make that requirement clear.

We propose this exception based on advice and input received through Tribal consultation and because the population served by IHS/Tribal clinics, which is predominately AI/AN, tends to meet the criteria CMS has identified that warrant an exception from the four walls requirement (for example, high rates of behavioral health needs, lack of accessible transportation, mistrust of the health care system, and high rates of morbidity and poor health outcomes).

AI/ANs experience high rates of behavioral health diagnoses. In particular, the opioid crisis plaguing many communities is especially acute in Tribal communities.²⁹⁸ As reported by the Centers for Disease Control and Prevention (CDC), AI/ANs have the highest rate of drug overdose compared to other U.S. populations, and they experienced a 39 percent increase in overdoses between 2019 and 2020.²⁹⁹

Many AI/ANs also experience difficulties accessing services due to lack of transportation. Tribal lands encompass about 56 million acres nationwide, including 145,000

²⁹⁸ Tipps, Robin T., Gregory T. Buzzard, and John A. McDougall. 2018. "The Opioid Epidemic in Indian Country." *The Journal of Law, Medicine & Ethics* 46 (2): 422-36. <https://doi.org/10.1177/1073110518782950>.

²⁹⁹ Centers for Disease Control and Prevention (CDC), "Drug Overdose Prevention in Tribal Communities," CDC, May 2, 2024, https://www.cdc.gov/overdose-prevention/health-equity/tribal-communities.html?CDC_AAref_Val=https://www.cdc.gov/drugoverdose/health-equity/tribal.html.

miles of roads.³⁰⁰ Roads in Tribal communities are typically rudimentary and in poor condition. For example, about 70 percent of Tribal roads across the country are unpaved compared to 45 percent of all rural roads.^{301,302} Because Tribal communities are often located in rural or remote areas covering vast distances, providers can be extremely far away from their patients. For example, it is common for AI/ANs to have to travel between 60 and 90 miles one-way for health care appointments.³⁰³ Many AI/ANs also do not have reliable personal transportation. The rate of AI/ANs without a personal vehicle is more than double that of individuals in other rural areas.³⁰⁴ Per a recent CDC report, approximately 17.1 percent of AI/ANs lack reliable transportation, the highest rate compared to other U.S. populations, and this is a barrier to accessing health care.³⁰⁵ Many AI/ANs have a profound mistrust of the Federal government and mainstream providers based on trauma from a long history of harmful U.S. Tribal policies, such as removal of AI/ANs from homelands and Tribal community structures, bans on cultural practices and language, forced relocation to reservations, abusive boarding school practices, and other destructive policies. AI/AN health disparities are the visible, lingering result of these harmful policies.³⁰⁶

Furthermore, AI/ANs face poorer health outcomes than all other adults on average and have the lowest life expectancy compared to other U.S. populations. For example, AI/ANs have

³⁰⁰ Congressional Research Service (CRS), *Highways and Highway Safety on Indian Lands*, CRS Report, (Washington, DC, 2016), https://www.everycrsreport.com/files/20160202_R44359_38af583fdef681edc7b5d4daeeeb5bc506a4f919.pdf.

³⁰¹ Id.

³⁰² CRS, *Rural Highways*, CRS Report, (Washington, DC, 2018), <https://crsreports.congress.gov/product/pdf/R/R45250>.

³⁰³ Government Accountability Office (GAO), *Indian Health Service: Health Care Services Are Not Always Available to Native Americans*, GAO-05-789, (Washington, DC, 2005), <https://www.gao.gov/assets/gao-05-789.pdf>.

³⁰⁴ CRS, *Tribal Highway and Public Transportation Programs*, In Focus, (Washington, DC, 2022), <https://crsreports.congress.gov/product/pdf/IF/IF12129>.

³⁰⁵ CDC, National Center for Health Statistics (NCHS), *Lack of Reliable Transportation for Daily Living Among Adults: United States, 2022*, by Amanda E. Ng, Dzifa Adjaye-Gbewonyo, and James Dahlhamer, NCHS Data Brief No. 490, (Hyattsville, MD, 2024), <https://dx.doi.org/10.15620/cdc:135611>.

³⁰⁶ U.S. Commission Civil Rights, *Broken Promises: Continuing Federal Funding Shortfall for Native Americans*, Briefing Report, (Washington, DC, 2018), <https://www.usccr.gov/files/pubs/2018/12-20-Broken-Promises.pdf>.

higher rates of obesity, heart disease, and diabetes than other adults in the U.S. population on average.³⁰⁷ The CDC's Provisional Life Expectancy Estimates for 2021 found a severe drop in life expectancy for AI/ANs—decreasing by 6.6 years from 2019 to 2021.³⁰⁸ Not only do AI/ANs, on average, die younger than all other Americans, but this disparity is worsening at an alarming rate. AI/AN life expectancy today is the same as it was for the average American in 1944.³⁰⁹

This evidence indicates that an exception to the four walls requirement is warranted for IHS/Tribal clinics because the individuals served by these clinics are more likely than those in other groups to meet a higher number of the four criteria we described in this proposed rule. Through Tribal Consultation, Tribal leaders indicated that IHS/Tribal clinics need the flexibility to provide services to AI/ANs where they are located due to their high levels of behavioral health diagnoses, challenges accessing services due to lack of transportation and appropriate infrastructure, historic mistrust of the Federal government and the health care system, and poor health outcomes.

As explained below, we propose that behavioral health clinics and clinics in rural areas would serve as a proxy for their patient populations, instead of limiting the exception for behavioral health clinics to patients with behavioral health disorders or limiting the exception for clinics in rural areas to patients residing in rural areas. We proposed this approach because we believe that these clinics serve predominantly patients with behavioral health disorders or who live in rural areas (as applicable), and to reduce the operational burden of implementing these

³⁰⁷ MACPAC, *Medicaid's Role in Health Care for American Indians and Alaska Natives*, Issue Brief, (Washington, DC, 2021), <https://www.macpac.gov/wp-content/uploads/2021/02/Medicoids-Role-in-Health-Care-for-American-Indians-and-Alaska-Natives.pdf>.

³⁰⁸ CDC, NCHS, *Provisional Life Expectancy Estimates for 2021*, by Elizabeth Arias, Betzaida Tejada-Vera, Kenneth D. Kochanek, and Farida B. Ahmad, Vital Statistics Rapid Release Report No. 23, (Hyattsville, MD, 2022), <https://dx.doi.org/10.15620/cdc:118999>.

³⁰⁹ IHS, "Disparities," Indian Health Services, October 2019, <https://www.ihs.gov/newsroom/factsheets/disparities/>.

exceptions. Similar to the proposed exceptions for behavioral health clinics and clinics in rural areas, we are also proposing that the IHS/Tribal clinics would be a proxy for their patient population, but for somewhat different reasons. The operational burden that the proposed proxy approach would address for behavioral health clinics and clinics in rural areas would not be as much of an issue for IHS/Tribal clinics, because the entire patient population of an IHS/Tribal clinic is likely to meet some or all of the four criteria described in this proposed rule. For that same reason, a proxy approach would be appropriate for these clinics. These clinics serve a clearly identifiable group of Medicaid beneficiaries under IHS statutes and regulations: Medicaid beneficiaries whom IHS/Tribal clinics serve under 42 CFR part 136 or other Medicaid beneficiaries whom these clinics may serve under 25 U.S.C. 1680c. As discussed above, the population served by IHS/Tribal clinics, which is predominately AI/AN, is more likely than other groups to meet a higher number of the criteria identified in this proposed rule as warranting an exception.

2. Behavioral Health Clinics

We propose to add a new paragraph (d) to § 440.90 to authorize an exception to the four walls requirement for clinic services provided outside the four walls by personnel of behavioral health clinics. This exception would not be mandatory in States that opt to cover the clinic services benefit but could be implemented as a State option. Specifically, we propose an exception for clinics that are primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health disorders and substance use disorders. We note that this proposed exception would include any clinic services furnished outside of the four walls by a behavioral health clinic, including non-behavioral clinic services such as physical health services.

This proposed exception would include behavioral clinic types that are recognized nationally, such as Community Mental Health Centers, and other behavioral health clinics organized in a State. We recognize that the types of behavioral health clinics within a State may

vary, so we are not proposing to limit this exception to specific types of behavioral health clinics. However, to be considered a behavioral health clinic under this proposed exception, the clinic would have to be primarily organized to treat outpatients with behavioral health disorders regardless of the patient mix of the clinic. For example, if a State has established separate licensure or certification requirements for mental health clinics and primary care clinics, under which primary care clinics are licensed to treat outpatients for a range of services beyond the treatment of behavioral health disorders, then we would consider a mental health clinic in that State to be primarily organized to treat outpatients with behavioral health disorders but would not consider a primary care clinic in that State to be primarily organized to treat such outpatients. We recognize that there may be other means by which a State determines that a clinic is primarily organized to treat outpatients with behavioral health disorders (that is, other than through licensure or certification), including behavioral health accreditation by accrediting organizations, such as The Joint Commission, or based on the organizing documents of the clinic, such as a business charter. If this proposal is finalized as described, States that choose to adopt this exception would describe the types of behavioral health clinics such exception applies to in their Medicaid State plan. Just like our proposed exception for IHS/Tribal clinics, we propose to include language in this exception specifying that services subject to the exception would have to be furnished under the direction of a physician.

Per 2022 data from the Substance Abuse and Mental Health Services Administration (SAMHSA), approximately 94.7 percent of adults nationwide with a substance use disorder did not seek substance use treatment and nearly half of adults nationwide with a mental health disorder did not receive mental health treatment, which suggests that this population may have

difficulty accessing behavioral health services.³¹⁰ Lack of transportation and geographic distance from behavioral health services are often cited in research as barriers to behavioral health treatment.³¹¹ One study of transportation-disadvantaged adults found that nearly half of adults nationwide who lacked medical transportation were diagnosed with depression or another mental health disorder.³¹² Studies have found that individuals with behavioral health disorders often report negative experiences with providers and stigmatizing attitudes from providers are common, which can lead to a mistrust of the health care system and forgone care.³¹³ Finally, research has found that individuals with a severe mental illness or substance use disorder experience worse health outcomes and increased risk of premature mortality, with one recent study finding individuals with a severe mental illness or substance use disorder experiencing a shorter life span than comparable individuals by an average of 6 years.³¹⁴

State-specific circumstances may affect the degree to which a State's population of individuals with behavioral health disorders meets the four criteria described in this proposed rule. The Health Resources and Services Administration (HRSA), in coordination with State

³¹⁰ Substance Abuse and Mental Health Services Administration (SAMHSA), *Key substance use and mental health indicators in the United States: Results from the 2022 National Survey on Drug Use and Health*, HHS Publication No. PEP23-07-01-006, NSDUH Series H-58, (Rockville, MD, 2023), <https://www.samhsa.gov/data/report/2022-nsduh-annual-national-report>.

³¹¹ Priester, Mary Ann, Teri Browne, Aidyn Iachini, Stephanie Clone, Dana DeHart, and Kristen D. Seay. 2016. "Treatment Access Barriers and Disparities among Individuals with Co-Occurring Mental Health and Substance Use Disorders: An Integrative Literature Review." *Journal of Substance Abuse Treatment* 61 (61): 47-59. <https://doi.org/10.1016/j.jsat.2015.09.006>.

³¹² Wallace, Richard J, Paul Hughes-Cromwick, Hillary J Mull, and Snehamay Khasnabis. 2005. "Access to Health Care and Nonemergency Medical Transportation: Two Missing Links." *Transportation Research Record* 1924 (January): 76-84. <https://doi.org/10.3141/1924-10>.

³¹³ Knaak, Stephanie, Ed Mantler, and Andrew Szeto. 2017. "Mental Illness-Related Stigma in Healthcare." *Healthcare Management Forum* 30 (2): 111-16. <https://doi.org/10.1177/0840470416679413>.

³¹⁴ Iturralde, Esti, Natalie Slama, Andrea H. Kline-Simon, Kelly C. Young-Wolff, Don Mordecai, and Stacy A. Sterling. 2021. "Premature Mortality Associated with Severe Mental Illness or Substance Use Disorder in an Integrated Health Care System." *General Hospital Psychiatry* 68 (January): 1-6. <https://doi.org/10.1016/j.genhosppsych.2020.11.002>.

primary care offices, designates as Health Professional Shortage Areas (HPSAs)³¹⁵ areas experiencing a shortage in primary care, dental care, or mental health care providers for a whole geographic area, a specific population within a geographic area, and facilities that serve these areas. HRSA publishes data for each State on the percent of need met for primary care, dental care, and mental health providers, with a lower percentage indicating a lower availability of providers. It should be noted that the types of mental health providers counted in HPSAs are set in regulation, and based on the regulations, HRSA allows State Primary Care Offices to choose whether to count: psychiatrists only, core mental health professionals (psychiatrists, clinical psychologists, clinical social workers, psychiatric nurse specialists, and marriage and family therapists), or a combination of all types. As of December 31, 2023, there is significant variation among States in the percent of need met for mental health care, with a low of 9 percent and a high of 63 percent.³¹⁶ This variation in availability of mental health care providers may suggest that populations of individuals with behavioral health disorders in some States may have greater difficulty accessing behavioral health services or accessing transportation to a behavioral health provider than those populations in other States. There may also be significant variability between States with regard to behavioral health outcomes and mortality. For example, in 2021 the age-adjusted drug overdose mortality rate by State had significant variation, from a low of 11 per 100,000 to a high of 90 per 100,000.³¹⁷ These differences between populations of individuals with behavioral health disorders in different States may suggest that the degree to which a State's population of individuals with behavioral health disorders meets the four criteria may be variable.

³¹⁵ Health Resources & Services Administration (HRSA), "What is Shortage Designation?" HRSA Health Workforce, June 2023, <https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation>.

³¹⁶ HRSA, Designated Health Professional Shortage Areas Statistics, Designated HPSA Quarterly Summary, (Rockville, MD, 2024), <https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport>.

³¹⁷ CDC, NCHS, "Drug Overdose Mortality by State," CDC, March 1, 2022, https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm.

This evidence indicates that an exception to the clinic services four walls requirement could be warranted, based on State-specific circumstances, for clinics that are primarily organized for the care and treatment of outpatients with a behavioral health disorder, as these clinics might primarily serve a patient population that may be more likely than other groups to meet more of the four criteria we described in this proposed rule. The evidence also suggests that this patient population is less likely to meet as many of the criteria as consistently nationwide as patients served by IHS/Tribal clinics. Under the proposal, a State could determine that individuals with a behavioral health disorder in that State should be engaged by behavioral health clinic personnel where they are located due to their challenges accessing services, including lack of transportation and geographic distance from services, historic mistrust and stigmatization in the health care system, and poor health outcomes.

We considered proposing that, to qualify for this proposed exception, clinic services would have to be provided specifically to individuals with a behavioral health disorder, in addition to being provided by personnel of a behavioral health clinic. However, we believe that such a requirement would be too operationally burdensome and that instead behavioral health clinics can serve as a proxy for a population that generally consists of individuals with a behavioral health disorder. We recognize there may be circumstances in which a behavioral health clinic furnishes services to an individual who does not have a behavioral health disorder, but it is our understanding that behavioral health clinics generally serve a patient population that consists primarily of individuals with behavioral health disorders (including individuals with a formal behavioral health disorder diagnosis and those with an undiagnosed behavioral health disorder). Thus, these clinics can serve as a proxy for a patient population that is more likely to have such a disorder—and thus, that includes people who are more likely to meet more of the four criteria. In addition, we believe that requiring clinics or States to verify that a clinic patient has a behavioral health disorder and to deny coverage of Medicaid clinic services provided outside the four walls if the patient does not, would be too operationally burdensome. For

example, an individual might experience or present their behavioral health symptoms in an uncommon way, an individual might be misdiagnosed, or an individual might be experiencing a crisis where services are needed urgently and verifying that they have a behavioral health disorder might delay needed care. Because we believe that behavioral health clinics can serve as a proxy for individuals with behavioral health disorders, and because we do not want to make this exception too operationally burdensome, we are not proposing that to qualify for the proposed exception, clinic services must be provided by a behavioral health clinic specifically to an individual with a behavioral health disorder.

3. Clinics Located in Rural Areas

We propose to add a new paragraph (e) to § 440.90 to authorize an exception to the four walls requirement for clinic services provided outside the four walls by personnel of clinics located in rural areas, but that are not RHCs as referenced in section 1905(a)(2)(B) of the Act and § 440.20(b). This exception would not be mandatory in States that opt to cover the clinic services benefit, but could be implemented at State option. Just like our proposed exception for IHS/Tribal clinics and behavioral health clinics, we propose to include language in this exception specifying that services subject to the exception would have to be under the direction of a physician.

Per SAMHSA data, rates of mental illness and substance use disorders are similar in rural and urban areas.³¹⁸ However, individuals in rural areas with a mental illness or substance use disorder are less likely to receive treatment than individuals in urban areas due to more limited access to providers, as rural areas are more likely to lack trained and specialized behavioral health providers.³¹⁹ For example, in 2021 the number of psychologists per 100,000 people in

³¹⁸ SAMHSA, "2022 NSDUH Detailed Tables," SAMHSA, November 13, 2023, <https://www.samhsa.gov/data/report/2022-nsduh-detailed-tables>.

³¹⁹ Morales, Dawn A., Crystal L. Barksdale, and Andrea C. Beckel-Mitchener. 2020. "A Call to Action to Address Rural Mental Health Disparities." *Journal of Clinical and Translational Science* 4 (5): 1-20. <https://doi.org/10.1017/cts.2020.42>.

rural counties was less than half of the number in urban counties.³²⁰ A recent study found that rural individuals on average are 22 percent less likely than urban individuals to utilize primary and specialty clinic services.³²¹ Studies have found that lack of transportation and distance to providers is a common barrier to rural individuals accessing health care services.³²² Furthermore, a recent Government Accountability Office (GAO) report found that rural individuals need to travel 40 miles on average to access specialty services.³²³ With regards to mistrust of the health care system, research has found that rural individuals have historically mistrusted the health care at higher rates, and that some of this mistrust comes from a perception that the health care system prioritizes urban communities over rural communities.³²⁴ Per the CDC, rural individuals are at greater risk of poor health outcomes as they tend to be older and sicker than urban individuals.³²⁵ Finally, according to a CDC National Center for Health Statistics (NCHS) study, age-adjusted mortality rates are higher for rural individuals, with the mortality gap increasing since 1999 between rural and urban individuals.³²⁶

³²⁰ WWAMI Rural Health Research Center, University of Washington. *Changes in the Supply and Rural-Urban Distribution of Psychologists in the U.S., 2014-2021*. 2022. https://familymedicine.uw.edu/rhrc/wp-content/uploads/sites/4/2022/10/RHRC_DBOCT2022_PSYCHOLOGIST_Andrilla.pdf

³²¹ Nuako, Akua, Jingxia Liu, Giang Pham, Nina Smock, Aimee James, Timothy Baker, Laura Bierut, Graham Colditz, and Li-Shiun Chen. 2022. "Quantifying Rural Disparity in Healthcare Utilization in the United States: Analysis of a Large Midwestern Healthcare System." Edited by Nickolas D. Zaller. *PLOS ONE* 17 (2): e0263718. <https://doi.org/10.1371/journal.pone.0263718>.

³²² Arcury, Thomas A., John S. Preisser, Wilbert M. Gesler, and James M. Powers. 2005. "Access to Transportation and Health Care Utilization in a Rural Region." *The Journal of Rural Health* 21 (1): 31-38. <https://doi.org/10.1111/j.1748-0361.2005.tb00059.x>.

³²³ GAO, *Rural Hospital Closures*, GAO-21-93, (Washington, DC, 2020), <https://www.gao.gov/assets/gao-21-93.pdf>.

³²⁴ Lister, Jamey J., and Paul J. Joudrey. 2022. "Rural Mistrust of Public Health Interventions in the United States: A Call for Taking the Long View to Improve Adoption." *The Journal of Rural Health* 39 (1): 18-20. <https://doi.org/10.1111/jrh.12684>.

³²⁵ CDC, "About Rural Health," CDC, May 16, 2024, https://www.cdc.gov/rural-health/php/about/?CDC_AAref_Val=https://www.cdc.gov/ruralhealth/about.html.

³²⁶ CDC, NCHS, *Trends in death rates in urban and rural areas: United States, 1999-2019*, by Sally C. Curtin and Merianne Rose Spencer, NCHS Data Brief No. 417, (Hyattsville, MD, 2021), <https://dx.doi.org/10.15620/cdc:109049>.

State-specific circumstances may affect the degree to which a State’s population of individuals in rural areas meets the four criteria described in this proposed rule. A study found that 21 percent of adults without access to a vehicle or public transit reported skipping needed medical care compared to only 9 percent who did not own a vehicle but had access to public transit.³²⁷ According to a Federal Highway Administration publication, just under 90 percent of passenger trips in rural areas occur in personal vehicles.³²⁸ For the rural individuals who lack access to a personal vehicle, public transit is generally less available, with an approximate 40 percent of rural individuals living in an area without public transit.³²⁹ However, some States establish rural public transit systems that guarantee service coverage to all residents.³³⁰ This variation between States in their rural populations’ access to public transit may suggest that the degree to which a State’s rural population is able to access transportation to medical services may differ from State to State. There may also be significant variability between States with regards to health outcomes and mortality. For example, a CDC report found that the percentage of excess mortality from heart disease in rural counties varied significantly between States in the northeast and the south with a 13 percent excess rate for the northeast States and 56 percent for the southern States.³³¹ These differences between State populations of individuals in rural areas

³²⁷ Smith, Laura Berrie, Michael Karpman, Dulce Gonzalez, and Sarah Morriss, “More than One in Five Adults with Limited Public Transit Access Forgo Health Care Because of Transportation Barriers,” Robert Wood Johnson Foundation, April 26, 2023, <https://www.rwjf.org/en/insights/our-research/2023/04/more-than-one-in-five-adults-with-limited-public-transit-access-forgo-healthcare-because-of-transportation-barriers.html>.

³²⁸ U.S. Department of Transportation (DOT), Federal Highway Administration (FHWA), *Chapter 11: Rural America, Status of the Nation's Highways, Bridges, and Transit Conditions and Performance Report*, 24th Edition (Washington, DC, 2021), <https://www.fhwa.dot.gov/policy/24cpr/pdf/Chapter11.pdf>.

³²⁹ Id.

³³⁰ Id.

³³¹ CDC, *Potentially Excess Deaths from the Five Leading Cause of Death in Metropolitan and Nonmetropolitan Counties - United States, 2010-2017*, by Macarena C. Garcia, Lauren M. Rossen, Brigham Bastian, Mark Faul, Nicole F. Dowling, Cheryll C. Thomas, Linda Schieb, Yuling Hong, Paula W. Yoon, and Michael F. Iademarco, *Morbidity and Mortality Weekly Report* Vol. 68, No. 10, (Atlanta, GA, 2019), <https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6810a1-H.pdf>.

may suggest that the degree to which a State's rural population meets the four criteria may be variable.

This evidence indicates that an exception to the clinic services four walls requirement could be warranted, based on State-specific circumstances, for services furnished by clinics located in rural areas that are not RHCs, as these clinics might primarily serve a patient population that may be more likely than other groups to meet more of the four criteria we identified in this proposed rule. The evidence also suggests that this patient population is less likely to meet as many of the criteria as consistently nationwide as patients served by IHS/Tribal clinics. Under the proposal, a State could determine that individuals who reside in rural areas in that State should be engaged where they are located by personnel of a clinic located in a rural area, due to their challenges accessing behavioral health services, overall health care access challenges stemming from lack of transportation and distance from providers, historic mistrust of the health care system, and poor health outcomes. We note that clinics located in rural areas providing optional services as authorized under sections 1902(a)(10) and 1905(a)(9) of the Act and 42 CFR 440.90 are distinct from RHCs providing mandatory services as authorized under sections 1902(a)(10) and 1905(a)(2)(B) of the Act and 42 CFR 440.20(b). RHC services are a separate Medicaid benefit provided by a type of facility that is referenced in section 1905(a)(2)(B) of the Act and 42 CFR 440.20(b), and a four walls requirement does not apply to that benefit under Federal Medicaid law.

We considered proposing that, to qualify for this proposed exception, clinic services would have to be provided specifically to individuals who reside in rural areas, in addition to being provided by personnel of a clinic located in a rural area. However, we believe clinics located in rural areas can serve as a proxy for a population that generally consists of individuals who reside in rural areas, and that such a requirement would be too operationally burdensome. We recognize there may be circumstances in which a clinic located in a rural area furnishes services to an individual who does not reside in a rural area, but it is our understanding that

clinics located in rural areas generally serve a patient population that consists primarily of individuals who reside in rural areas. Thus, these clinics can serve as a proxy for a patient population that is more likely to reside in a rural area—and thus, that includes people who are more likely to meet more of the four criteria. In addition, we believe that requiring clinics or States to verify that a clinic patient lives in a rural area, and to deny coverage of Medicaid clinic services provided outside the four walls if the patient does not, would be too operationally burdensome. For example, an individual’s address might change frequently, an individual might refuse to provide their address, or the clinic might be located in a rural area that borders a non-rural area. Because we believe that clinics located in rural areas can serve as a proxy for individuals who reside in rural areas, and because we do not want to make this exception too operationally burdensome, we are not proposing that to qualify for the proposed exception, clinic services must be provided by a clinic located in a rural area specifically to an individual who resides in a rural area.

We have not included a definition of “rural” in proposed rule text, but are considering defining that term in the final rule and are considering various approaches to doing so, on which we seek comment. There are many Federal and State definitions of rural for various programs, and no single definition precisely identifies all rural areas. The Rural Health Information Hub provides a non-official tool that could be used to help identify if a specific location is considered a rural location based on various definitions.³³² Some rural definitions may categorize areas that are generally recognized as suburban as rural, while other definitions may classify sparsely populated remote areas as urban. For example, the population residing in rural areas identified by a more limited rural definition may more closely meet more of the four criteria identified in this proposed rule than the population residing in rural areas identified under a broader

³³² “Am I Rural? – Tool,” Rural Health Information Hub, accessed May 7, 2024, <https://www.ruralhealthinfo.org/am-i-rural>. This tool is not official and should not be relied upon as a formal Federal determination that a location is rural.

definition. Definitions of rural adopted and used by Federal governmental agencies for programmatic purposes include the definition used by the Census Bureau, the definition used by the Office of Management and Budget (OMB), and the definition used by HRSA's Federal Office of Rural Health Policy (FORHP).^{333,334} In addition, we believe that State-level variations may also affect whether certain ways of defining rural are appropriate in specific States. States may have their own definitions of rural under State law or regulation for various programmatic purposes, such as definitions adopted by State primary care offices or State Offices of Rural Health.

Under any definition of rural, the specific areas identified as rural may change over time and that would have a direct impact on the scope of clinics eligible for this proposed four walls exception. For example, areas identified as rural under the Census definition may change after the decennial census, which may result in some clinics no longer being located in rural areas under that updated definition.

We considered the following approaches to defining rural: adopting one of the commonly used definitions of rural adopted by the Federal governmental agencies referenced above, permitting a State to adopt a definition of rural that is adopted and used by a Federal governmental agency for programmatic purposes, permitting a State to adopt a definition of rural that is adopted and used by a State governmental agency with a role in setting State rural health policy, or not adopting any definition of rural.

We note that the research, data, and reports cited earlier in this section do not all use the same definition of rural, and for four of the citations it is unclear what definition of rural was

³³³ HRSA, "Defining Rural Population," Health Resources & Services Administration, January 2024, <https://www.hrsa.gov/rural-health/about-us/what-is-rural>.

³³⁴ Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 86 Fed. Reg. 2418 (January 12, 2021). See, <https://www.federalregister.gov/documents/2021/01/12/2021-00443/response-to-comments-on-revised-geographic-eligibility-for-federal-office-of-rural-health-policy>.

used. The SAMHSA data, the study on primary and specialty care utilization, and NCHS study use the OMB definition while the CDC health outcomes research uses the Census Bureau definition and the GAO report uses the FORHP definition of rural.

If we adopt a Federal definition, we would finalize in rulemaking that for the purposes of this exception rural is defined as the definition of rural adopted or used by the Census Bureau, OMB, or FORHP (we would adopt only one of these definitions). The benefits to adopting a Federal definition include that the definition would be consistent for all States electing to implement the exception and all clinics located in rural areas in such States. However, if we adopted a specific Federal definition of rural then States could not consider the variation in which their rural populations under different rural definitions meet the four criteria we describe in this proposed rule. In addition, CMS does not directly control any of these Federal definitions, so if we adopt a specific Federal definition then future rulemaking might be necessary to align our rule with another Federal agency's changes to that Federal definition.

The Census Bureau does not specifically define rural but considers any area that is not urban as rural. An urban area must meet certain density standards and contain at least 2,000 housing units or at least 5,000 people. There are 2,644 urban areas defined by the Census Bureau following the 2020 Census. Over 80 percent of the Census-defined urban areas (2,134 urban areas) have populations of less than 50,000 people while the remaining 19 percent (510 urban areas) have populations of 50,000 people or more.³³⁵ Following the 2020 Census, the Census Bureau does not sub-categorize urban areas as Urbanized Areas or Urban Clusters.³³⁶ If we adopted the Census Bureau definition, then we would finalize in rulemaking that a rural area

³³⁵ Census Bureau, "Urban and Rural," United States Census Bureau, September 2023, <https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html>.

³³⁶ Urban Area Criteria for the 2020 Census-Final Criteria, 87 Fed. Reg. 16706 (Mar. 24, 2022). See, <https://www.federalregister.gov/documents/2022/03/24/2022-06180/urban-area-criteria-for-the-2020-census-final-criteria>.

is defined as an area identified by the Census Bureau in “Urban Area Criteria for the 2020 Census-Final Criteria,” 87 FR 16706 as not being an urban area. The advantage to the Census Bureau definition of rural is that it is a widely recognized definition, which may make it an easier definition to implement for purposes of an exception to the clinic services four walls requirement, if this proposed rule is finalized. A disadvantage to the Census Bureau definition is that the Census Bureau’s urban area boundaries do not follow other administrative units, such as county or municipality borders, and may be complex to operationalize. The Census Bureau provides TIGERweb Decennial online mapping tools for urban area boundaries at <https://tigerweb.geo.census.gov/> that may be helpful for interested parties considering what it would mean for CMS to finalize a rule that defines rural according to the U.S. Census Bureau’s definition. The CDC research on health outcomes we cite elsewhere in this section used the Census Bureau definition, which demonstrates that this definition can be linked to the four criteria described in this proposed rule. However, the Census Bureau definition is broad, and some policy experts point out that the definition classifies many suburban areas as rural while also classifying towns and small cities with populations of less than 50,000 people as non-rural.³³⁷

OMB also does not specifically define rural, but designates areas as metropolitan, micropolitan, or neither (also known as noncore).³³⁸ A metropolitan area consists of an urban core of 50,000 or more individuals, a micropolitan area consists of an urban core of 10,000 to 49,999 individuals, and all other areas are considered neither. Areas that are micropolitan or neither are considered rural while metropolitan areas are considered urban.³³⁹ If we adopted the

³³⁷ Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 85 Fed. Reg. 59806 (Oct. 23, 2020). See, <https://www.federalregister.gov/documents/2020/09/23/2020-20971/revised-geographic-eligibility-for-federal-office-of-rural-health-policy-grants>.

³³⁸ 2020 Standards for Delineating Core Based Statistical Areas, 86 Fed. Reg. 37770 (July 16, 2021). See, <https://www.federalregister.gov/documents/2021/07/16/2021-15159/2020-standards-for-delineating-core-based-statistical-areas>.

³³⁹ HRSA, Defining Rural Population.

OMB definition, then we would finalize in regulation text that a rural area is defined as an area not identified as metropolitan by OMB, as described in “2020 Standards for Delineating Core Based Statistical Areas,”^{86 FR 37770}. Like the Census Bureau definition of rural, the OMB definition is a widely recognized definition that may be an easier definition to implement for purposes of an exception to the clinic services four walls requirement, if this proposed rule is finalized. For example, the study on primary and specialty care utilization and the NCHS study on mortality we cite elsewhere in this section use the OMB definition, which demonstrates that this definition can be linked to the four criteria described in this proposed rule. In addition, the NCHS Urban-Rural Classification Scheme for Counties follows the OMB definition of rural and is widely used in health research.³⁴⁰ However, the OMB definition is considered by some policy experts to be too narrow as areas OMB defines as metropolitan include areas that are often considered to be rural, like for example the Grand Canyon.³⁴¹

The last Federal definition of rural we are considering is the FORHP definition, which consists of all non-metropolitan counties, all metropolitan census tracts with Rural-Urban Commuting Area (RUCA) codes four through ten, large area census tracts of at least 400 square miles in area with population density of 35 or less per square mile with RUCA codes two to three, and all outlying metropolitan counties without an Urbanized Area.^{342,343} If we adopted the FORHP definition, then we would finalize in regulation text that a rural area is defined as an area identified as rural by FORHP, as described in “Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants,” 86 FR 2418. We recognize that the FORHP definition uses terminology that has not yet been updated to align with the latest Census

³⁴⁰ CDC, NCHS, “NCHS Urban-Rural Classification Scheme for Counties,” CDC, June 1, 2017, https://www.cdc.gov/nchs/data_access/urban_rural.htm.

³⁴¹ Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 85 Fed. Reg. 59806 (Oct. 23, 2020).

³⁴² Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 86 FR 2418 (January 12, 2021).

³⁴³ HRSA, Defining Rural Population.

Bureau terminology, that is, FORHP currently refers to urbanized area, but we are still considering the FORHP definition, as is, based on its wide use and the benefits described in this paragraph. We note that FORHP is proposing to update the FORHP definition to incorporate the U.S. Department of Agriculture's Economic Research Service (ERS) Road Ruggedness Scale (RRS) measure of rugged terrain into the existing definition, specifically for census tracts of at least 20 square miles in area in metro counties with RRS 5 and RUCA code 2 or 3. In addition, if finalized, the update will align the FORHP definition's use of Census Bureau terminology with the current Census Bureau definition.³⁴⁴ If this proposed update to the FORHP definition is finalized, we would then consider the updated FORHP definition for the final rule over the existing FORHP definition. The advantage to the FORHP definition is that it is more precise, as it is narrower than the Census Bureau definition and broader than the OMB definition. In addition, as described elsewhere in this section, the GAO report that identified rural individuals needing to travel 40 miles on average to access specialty care used the FORHP definition in effect at the time of the report, which demonstrates that this definition can be linked to the four criteria we describe in this proposed rule. However, some have criticized the FORHP definition for excluding some areas that used to be considered rural while others consider the definition to be too expansive.³⁴⁵

Instead of specifying a uniform definition of rural nationwide for this exception, we are also considering allowing States to adopt a definition of rural that has been adopted by a Federal governmental agency. If we permit States to adopt a definition of rural that is adopted by a Federal governmental agency for programmatic purposes, then we would finalize in regulation

³⁴⁴ Proposed Inclusion of Terrain Factors in the Definition of Rural Area for Federal Office of Rural Health Policy Grants, 89 FR 32451 (April 26, 2024). See, <https://www.federalregister.gov/documents/2024/04/26/2024-08931/proposed-inclusion-of-terrain-factors-in-the-definition-of-rural-area-for-federal-office-of-rural>.

³⁴⁵ Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 86 FR 2418 (January 12, 2021).

text that a rural area is defined by the State based upon a reasonable definition adopted by a Federal governmental agency for programmatic purposes. We would not specifically list out the Federal definitions of rural that we consider reasonable in the regulation text. In addition to the Census, OMB, and FORHP definitions, we would consider rural definitions developed by the U.S. Department of Agriculture's Economic Research Service (ERS) to be reasonable definitions for a State to select if we adopt this option in the final rule (this would include RUCAs, Rural-Urban Continuum Codes, Urban-Influence Codes, and Frontier and Remote Area Codes).³⁴⁶ We did not consider adopting any of the ERS definitions as one of the Federal definitions we are considering (as described above) because it is our understanding that the ERS definitions are less commonly used on their own (that is, not in conjunction with other Federal definitions) in identifying rural areas in health care. However, the ERS definitions could be used by States if we opt to permit States to identify a Federal definition. While we do not believe that any of the ERS definitions should be adopted as one definition for all States to follow, if we provide States with the flexibility to adopt a Federal definition, then we want to ensure that we are not too prescriptive in the definitions they may choose from. It is possible that a State could determine that one of the ERS definitions better captures the population of rural individuals that meets the four criteria described in this proposed rule. Under such an approach, States that elect this exception would identify the specific Federal definition of rural (that is, Census Bureau, OMB, FORHP definition, or one of the ERS definitions) they are adopting in their State plan and attest that the selected definition best captures the population of rural individuals that meets more of the four criteria described in this proposal. The benefits to this approach include that each State can consider which Federal definition of rural best captures the population of rural individuals that meet more of the four criteria described in this proposed rule for that State (and States would

³⁴⁶ U.S. Department of Agriculture (USDA), Economic Research Services (ERS), "Rural Classifications," USDA, September 8, 2023, <https://www.ers.usda.gov/topics/rural-economy-population/rural-classifications/>.

attest to this in their State plan), while also being required to adopt a rural definition commonly accepted as a legitimate definition for programmatic purposes at the national level. Requiring the State to attest that the selected Federal definition best captures the population of rural individuals that meets more of the four criteria would help to ensure that there is an explanation for any variations in the definitions selected by different states. However, even if the variations in the definitions chosen by different States can be explained, it might burden or cause confusion for some beneficiaries if the States that elect this exception have different definitions of rural. For example, a beneficiary that moves from a State that has adopted this exception with a broader definition of rural to another State that has adopted the exception but has a narrower definition of rural might lose access to clinic services provided outside of the four walls. In addition, if we finalize this proposal, clinics that operate in different States that have adopted this exception might find it confusing or burdensome to track each such State's definition of rural.

If we permit States to adopt a definition of rural that is adopted by a State governmental agency with a role in setting State rural health policy, then we would finalize in regulation text that a rural area is defined by the State based upon a rural definition adopted by a State governmental agency with a role in setting State rural health policy. Under such an approach, a State that elects this exception would describe in its State plan the specific definition of rural that it is adopting, attest that this definition has been adopted by a State governmental agency with a role in setting State rural health policy (such as a State primary care office or State Office of Rural Health), and attest that the selected definition best captures the population of rural individuals that meets more of the four criteria described in this proposal. The benefits to this approach include that States may consider a State definition of rural that best identifies the population of rural individuals that meet more of the four criteria described in this proposed rule, and attest to in their State plan that the definition does so. Requiring the State to attest that the selected definition best captures the population of rural individuals that meets more of the four criteria would help to ensure that there is an explanation for any variations in the definitions

selected by different States. In addition, under this approach to defining rural, the State would adopt a rural definition commonly accepted and used to manage State programs, which thus may be a more familiar definition to providers and be easier for a State to implement since that definition is also used for other health policy purposes in that State. However, even if the variations in the definitions chosen by different States can be explained, it might burden or cause confusion for some beneficiaries if the States that elect this exception have different definitions of rural. For example, a beneficiary that moves from a State that has adopted this exception with a broader definition of rural to another State that has adopted the exception but has a narrower definition of rural may lose access to clinic services provided outside of the four walls. In addition, if we finalize this proposal, clinics that operate in different States that have adopted this exception might find it confusing or burdensome to track each such State's definition of rural.

Finally, if we choose not to define rural in the final rule, then we would finalize proposed regulation text with no definition of rural. Under this approach, a State that elects this exception would choose any definition of rural that can be linked to the four criteria we describe in this proposed rule and meets its program needs, but would not identify the definition in the State plan or submit it to CMS for review and approval. We would require and finalize in rule text that the State would publish its rural definition on a web site maintained by the State that is accessible to the public. The benefits to not adopting a definition of rural under the final rule would include that States can consider which definition of rural best captures the population of rural individuals that meets more of the four criteria described in this proposed rule. This approach also recognizes that States may have the best information and data to determine the definition of rural that best meets their operational needs. However, under this approach CMS would not be reviewing State definitions of rural, and a State might adopt a definition of rural that could be considered to be overly broad or overly narrow. For example, a State might adopt a definition of rural that encompasses large urban areas, such as a populous city. As we stated earlier in this section of the proposed rule, we are aware that there are many definitions of rural, so the other

approaches we are considering could potentially leave out reasonable definitions of rural, although we are not currently aware of any such reasonable definitions. We invite comment on which approach to defining rural we should adopt if the rule is finalized.

4. Additional Four Walls Considerations

We propose that the proposed exception to the four walls requirement for IHS/Tribal clinics would be a mandatory component of the clinic services benefit for States electing to cover that benefit. We propose that the proposed exceptions for behavioral health clinics and clinics located in rural areas would be optional for States covering that benefit. In addition, we propose to codify in regulation text our longstanding interpretation (discussed in section XVIII.A of this proposed rule) that existing § 440.90(a) and (b) are mandatory components of the clinic services benefit for States that elect to cover that benefit. Finally, we propose to delete the word “eligible” from existing regulation text at § 440.90(b) because there is no Federal authority for States to provide Medicaid-covered services to individuals who are ineligible for Medicaid, so we believe it is unnecessary to specify that the individuals who would receive services under this exception are eligible.

We propose to make the exception for IHS/Tribal clinics mandatory because the population served by IHS/Tribal clinics more consistently meets the four criteria described above, both within and across States, than the populations targeted by the optional exceptions, especially given the degree of State variability in whether the populations targeted by the optional exceptions meet those criteria. Further, Medicaid is the largest source of third-party payment for services billed by IHS facilities, accounting for nearly two-thirds of health coverage payments to these facilities.³⁴⁷ Given the significant role of Medicaid as a payer for IHS/Tribal

³⁴⁷ Assistant Secretary of Planning and Evaluation (ASPE), *How Increased Funding Can Advance the Mission of the Indian Health Service to Improve Health Outcomes for American Indians and Alaska Natives*, Report No. HP-2022-21, (Washington, DC, 2022), <https://aspe.hhs.gov/sites/default/files/documents/1b5d32824c31e113a2df43170c45ac15/aspe-ihs-funding-disparities-report.pdf>.

clinic services, any reduction in the Medicaid payments IHS/Tribal clinics receive for services (such as a reduction in payment from the AIR to a professional services rate for services furnished outside the four walls by the clinic) might uniquely burden IHS/Tribal clinics. These clinics might need to curtail their available services, or no longer provide services outside the four walls, which could significantly impede their ability to serve their patients. For these reasons, we propose a mandatory exception to the clinic services four walls requirement for IHS/Tribal clinics.

In contrast to the exception for IHS/Tribal clinics, we believe that the exceptions for behavioral health clinics and clinics located in rural areas should be optional because there may be geographic variability in the degree to which the populations served by these clinics meet the four criteria we described above, and thus there may be State-specific variation in the degree to which these populations have the four characteristics described in this proposed rule. For example, the populations served by behavioral health clinics and clinics located in rural areas may not as consistently face transportation challenges nationwide, to the extent that Tribal populations do. In addition, it is our understanding that Medicaid funding is less often the largest source of payment for behavioral health clinics and clinics located in rural areas, compared to IHS/Tribal clinics. We believe it best to let each State assess the degree to which these two exceptions might be warranted based on the State's specific circumstances. In making this assessment, each State should consider the degree to which individuals located in rural areas of the State and/or individuals with behavioral health disorders in the State meet the four criteria described in this proposed rule. We solicit comment on the arguments made in this proposed rule in support of the mandatory and optional exceptions, and on whether the optional exceptions should also be mandatory for States opting to cover the clinic services benefit.

If we finalize this proposed rule as proposed, then upon the effective date of the final rule, services qualifying for the exception for IHS/Tribal clinics must be paid for as Medicaid clinic services in States that opt to cover that benefit. Accordingly, we would require States that

cover the clinic services benefit to submit a State plan amendment (SPA), as applicable, to attest to coverage of IHS/Tribal clinic services under the exception. Similarly, if we finalize this proposed rule as proposed, then no earlier than the effective date of a SPA or SPAs implementing one or both of the optional exceptions, services provided outside the four walls under the exceptions may be paid for as Medicaid clinic services. Under any of the exceptions, the excepted services could be paid for using a facility-based Medicaid clinic services payment methodology, which for most IHS/Tribal clinics is the AIR.

We are not proposing any additional exceptions to the clinic services four walls requirement. It is our understanding that other populations are better able than those targeted by the proposed exceptions to access services through Medicaid benefits to which a four walls requirement does not apply under Federal Medicaid law (for example, FQHC services, RHC services, outpatient hospital services, etc.). As described in section XVIII.A of this proposed rule, States have considerable discretion regarding the types of clinics they opt to cover under the clinic services benefit. There are no specific Federal Medicaid credentialing requirements, such as licensure or certification, for providers of the Medicaid clinic services benefit like there are for other Medicaid facility State plan benefits, such as hospitals and nursing facilities. This leads to considerable variability in the types of clinics providing services that a State may cover under the clinic services benefit. We invite comment on whether there are additional populations that are likely to meet the four criteria described in this proposed rule and that have no alternative access to services through Medicaid benefits not subject to a four walls requirement under Federal Medicaid law, and on whether there are additional types of clinics that might serve as a proxy for such a population.

XIX. Changes to the Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process

The CMS Interoperability and Prior Authorization final rule (89 FR 8758) (Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and

Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children’s Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program) creates, improves, or shortens prior authorization timeframes for certain payers such as Medicare Advantage organizations and applicable integrated plans, CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities to respond to prior authorization requests for covered items and services, excluding drugs (89 FR 8878). The final rule requires impacted payers (excluding Qualified Health Plan issuers on the Federally-Facilitated Exchanges) to send prior authorization decisions as expeditiously as the enrollee’s health condition requires or as the beneficiary’s health condition requires but no later than 72 hours for expedited (that is, urgent) requests and 7 calendar days for standard (that is, non-urgent) requests.

As part of the CY 2020 OPPS/ASC final rule with comment period (84 FR 61446 through 61456), CMS established a nationwide prior authorization process and requirements for certain OPD services. OPD providers must submit to the Medicare Administrative Contractor (MAC) a prior authorization request for any service on the list of outpatient department services that require prior authorization. CMS currently requires prior authorization for the following services: blepharoplasty, rhinoplasty, botulinum toxin injections, panniculectomy, vein ablation, cervical fusion with disc removal, implanted spinal neurostimulators, and facet joint interventions. Upon receipt of the prior authorization request, the MAC should review it and issue a decision within specific timeframes, which are listed in the regulation text at § 419.82(d)(1)(iii) and § 419.82(d)(2). These timeframes ensure providers receive timely responses and beneficiaries get appropriate care. While Medicare FFS is not an impacted payer under the CMS Interoperability and Prior Authorization final rule, we propose to align our

Medicare FFS prior authorization review timeframe for standard review requests for hospital outpatient department services with the timeframe in this final rule. This change would not only streamline the prior authorization processes so that they are the same across payers but would also help to reduce provider burden by having the same timeframe and reducing the potential for delays in care by decreasing the time beneficiaries and providers wait for prior authorization decisions on standard requests in FFS Medicare. We propose to change the current review timeframe for provisionally affirmed or non-affirmed standard review requests for these services from 10-business days to 7-calendar days in § 419.82(d)(1)(iii). For example, if a standard request is submitted on a Tuesday, June 2, under the new timeframe, a decision must be rendered by the next Monday, June 8, whereas under the old timeframe, the decision must be rendered by Monday, June 15.

We are still considering the impact of aligning our expedited review decision timeframe with the expedited review decision timeframe in the CMS Interoperability and Prior Authorization final rule because, depending on when the expedited request is submitted, it may take longer for OPD provider to receive a decision using the 72-hour timeframe than our current expedited timeframe of 2-business days. The goal of changing the standard review timeframe is not only to align the timeframe across the prior authorization programs but also to reduce the time beneficiaries wait to access the care they need. Since changing the expedited review decision timeframe from 2-business days to 72 hours would not reduce beneficiaries' wait time in all circumstances, we are not proposing to conform that timeframe with the one in the CMS Interoperability and Prior Authorization final rule at this time, but we may address this issue in future rulemaking.

XX. Provisions Related to Medicaid and the Children's Health Insurance Program (CHIP)

A. Continuous Eligibility in Medicaid and CHIP (42 CFR 435.926 and 457.342)

Continuous eligibility (CE) provides important coverage protections for low-income children who are eligible for Medicaid or CHIP. Research indicates that children who are

disenrolled from coverage for all or part of a year are more likely to have fair or poor health status compared to children who have health coverage continuously throughout the year.³⁴⁸ CE, in those States that have adopted it, has shown to reduce financial barriers to accessing health care for low-income families, promote health equity, and provide States with better tools to hold health plans (where applicable) accountable for quality care and improved health outcomes.³⁴⁹ CE policies may also be beneficial to States, as they may result in reduced administrative burden on State agencies associated with repeated eligibility reviews and re-enrollments following a gap in coverage.³⁵⁰

Prior to January 1, 2024, States had the option to provide up to 12 months of continuous coverage to children under age 19 enrolled in Medicaid or CHIP, regardless of changes in circumstances that otherwise would impact their eligibility for these programs. This option has been available to State Medicaid programs under section 1902(e)(12) of the Act and Federal regulations at § 435.926 and to States' separate CHIP programs through Federal regulations at § 457.342. Under this option, States had the option to elect an age limit under age 19 and/or CE periods shorter than 12 months. However, except for the limited exceptions defined in the regulations, states could not terminate the coverage of children during a CE period.

Section 5112 of Title V, subtitle B of the Consolidated Appropriations Act, 2023 (CAA, 2023) amended section 1902(e)(12) of the Act to make the previously optional CE policy a requirement under the state plan or waiver of the state plan for children enrolled in Medicaid. The CAA, 2023 also added a new paragraph (K) to section 2107(e)(1) of the Act, incorporating

³⁴⁸ Brantley, E., & Ku, L. (2022). Continuous eligibility for Medicaid associated with improved child health outcomes. *Medical Care Research and Review*, 79(3), 404-413.

³⁴⁹ Park, E., Alker, J., & Corcoran, A. (2020). Jeopardizing a Sound Investment: Why Short-Term Cuts to Medicaid Coverage During Pregnancy and Childhood Could Result in Long-Term Harm. Retrieved from: <https://www.commonwealthfund.org/publications/issue-briefs/2020/dec/short-term-cuts-medicaid-long-term-harm>

³⁵⁰ Georgetown University. (2021). Advancing Health Equity for Children and Adults with a Critical Tool: Medicaid and Children's Health Insurance Program Continuous Coverage. Retrieved from <https://ccf.georgetown.edu/wp-content/uploads/2021/10/continuity-of-coverage-final.pdf>

by reference Medicaid's CE policy into CHIP. Thus, effective January 1, 2024, States are required to provide a 12-month period of CE that offers continuous coverage to children under the age of 19 in Medicaid and CHIP, with limited exceptions.

The existing Medicaid continuous eligibility regulation includes three exceptions that were unaffected by the CAA, 2023, and that would not be altered by this proposed rule. These exceptions permit States to terminate coverage for children during a CE period if the child or child's representative requests a voluntary termination of eligibility; the agency determines that eligibility was erroneously granted at the most recent determination, redetermination, or renewal of eligibility because of agency error or fraud, abuse, or perjury attributed to the child or the child's representative; or the child is deceased. The CAA, 2023 amended section 1902(e)(12) of the Act to make the CE option mandatory for state Medicaid programs, but it did not foreclose these existing exceptions that CMS had already promulgated pursuant to section 1902(e)(12), which are important to maintain program integrity. We described our intention to retain these exceptions in CMS State Health Official (SHO) Letter #23-004, Section 5112 Requirement for all States to Provide Continuous Eligibility to Children in Medicaid and CHIP under the Consolidated Appropriations Act, 2023, which was issued on September 29, 2023. We do not propose any changes to these exceptions in this proposed rule.

We propose to update the Medicaid regulations at § 435.926 to conform to changes to the CE policy effectuated by the CAA, 2023 amendments to section 1902(e)(12) of the Act, which are incorporated by cross reference into the CHIP regulations at § 457.342(a). Specifically, as required by section 5112 of the CAA, 2023, and under our authority under section 2101(a) of the Act to "initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner," and at section 2107(e)(1)(K) of the Act (cross-referencing section 1902(e)(12) of the Act as amended by CAA, 2023 relating to continuous eligibility), we propose to revise § 435.926(b) to specify that a state must provide CE for the specified period. We also propose to revise § 435.926(b)(1) to remove the option to limit

CE to an age younger than 19. We further propose to revise § 435.926(c)(1) to remove the option to limit CE to a period of time of less than 12 months. Finally, we propose to revise § 435.926(d)(1) to remove the option of ending a CE period for a person when they reach the state-specified maximum age, as now all States must provide CE to children until they reach age 19.

Prior to January 1, 2024, States also had the option under § 457.342(b) to disenroll children from a separate CHIP for failure to pay required premiums or enrollment fees required under the state plan, subject to the disenrollment protections afforded under section 2103(e)(3)(C) of the Act (related to premium grace periods) and § 457.570 (related to other disenrollment protections). The CAA, 2023, changed the statutory authority for the CE period in the CHIP statute, requiring that CE “shall” apply to CHIP “in the same manner” as it does to Medicaid. The Medicaid continuous eligibility regulation at § 435.926 never contained an exception permitting States to terminate coverage for failure to pay premiums or enrollment fees, so after the CAA, 2023, the CHIP CE period also could not contain this exception.

Therefore, under the above-mentioned authority in section 2101(a) of the Act to enable States to provide child health assistance in an effective and efficient manner and in section 2107(e)(1) of the Act as amended by CAA, 2023 relating to continuous eligibility, we propose to remove the option in § 457.342(b) to disenroll children from separate CHIP coverage for failure to pay required premiums or enrollment fees during a continuous eligibility period. This change will not preclude States from disenrolling children with an unpaid premium balance at the end of their 12-month CE period, provided the state has followed the premium grace period requirements of section 2103(e)(3)(C) of the Act. Under section 2103(e)(3)(C)(ii) of the Act, the State must provide the child with a grace period of “at least 30 days from the beginning of a new coverage period to make premium payments before the individual’s coverage” may be terminated. Section 2103(e)(3)(C)(ii)(II) of the Act defines “new coverage period” as “the month immediately following the last month for which the premium has been paid.” If a child

does not pay a premium in a given month during the CE period, the grace period extends from that month until the 12-month CE period expires. Section 2103(e)(3)(C)(ii) of the Act also requires the State to provide notice no later than 7 days after the first day of the grace period (typically 7 days after the premium payment was due) that failure to make a premium payment within the grace period will result in termination of coverage and when such termination will be effective.

Although current paragraph (b) of § 457.342, which includes a reference to enrollment fees, would be eliminated, the collection of enrollment fees, as referenced in §§ 457.10 and 457.510, would remain an option to States. States would maintain the option to require payment of an enrollment fee prior to initial enrollment. States will also continue to have the option to require payment of the first month's premium prior to enrolling a child who is determined eligible at application and to require payment of the first month's premium or re-enrollment fee prior to re-enrolling a child into a new CE period, if the child is determined eligible at renewal.

XXI. Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals

A. Background and Statutory Authority

CMS has broad statutory authority to establish health and safety regulations, which includes the authority to establish requirements that protect the health and safety of pregnant, postpartum, and birthing patients. Several statutes applicable to specific provider and supplier types explicitly give CMS the authority to enact regulations that the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in an institution, while others give CMS the authority to prescribe regulations as may be necessary to carry out the administration of the program.

Sections 1861(e)(1) through (8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the

Secretary finds necessary in the interest of the health and safety of individuals furnished services in the institution. Under this authority, the Secretary has established regulatory requirements that a hospital must meet to participate in Medicare at 42 CFR part 482, Conditions of Participation (CoPs) for Hospitals. Section 1905(a) of the Act provides that Medicaid payments from States may be applied to hospital services. Under regulations at 42 CFR 440.10(a)(3)(iii) and 42 CFR 440.20(a)(3)(ii), hospitals are required to meet the Medicare CoPs in order to participate in Medicaid.

Sections 1820 and 1861(mm) of the Act, as amended by section 4201 of the Balanced Budget Act (BBA) of 1997, replaced the EACH/RPCH program with the Medicare Rural Hospital Flexibility Program (MRHFP), under which a qualifying facility can be designated and certified as a critical access hospital (CAH). CAHs participating in the MRHFP must meet the conditions for designation specified in the statute under section 1820(c)(2)(B) of the Act, and to be certified must also meet other criteria the Secretary may require, under section 1820(e)(3) of the Act. Under this authority, the Secretary has established regulatory requirements that a CAH must meet to participate in Medicare at 42 CFR part 485, subpart F.

The CoPs for hospitals and CAHs are organized according to the types of services a hospital or CAH may offer, and include specific, process-oriented requirements for each hospital or CAH service or department. The purposes of these CoPs are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals and CAHs. In accordance with Section 1864 of the Act, State surveyors assess hospital and CAH compliance with the conditions as part of the process of determining whether a hospital qualifies for a provider agreement under Medicare. However, under section 1865 of the Act, hospitals and CAHs can elect to be reviewed instead by private accrediting organizations approved by CMS as having standards that meet or exceed the applicable Medicare standards and survey procedures comparable to those CMS requires for State survey agencies.

1. The U.S. Maternal Health Crisis

The U.S. is currently facing a maternal health crisis which has not only led to a maternal mortality rate that is amongst the highest in high-income countries, but also disproportionately affects racial and ethnic minorities. In 2022, the most recent year for which there is data, there were 22 maternal deaths for every 100,000 live births in the U.S. which is more than double the rate for most other high-income countries. For example, in 2022, Canada, France, the United Kingdom, Germany, and Japan had maternal death rates of 8.6 deaths per 100,000 live births or lower.³⁵¹ In the U.S. in 2021, 1,205 women were identified as having died while pregnant or within 42 days after pregnancy ended. In 2022, 817 women were identified as having died in this manner.^{352,353} Over 80 percent of pregnancy-related deaths are considered preventable.³⁵⁴ Approximately 13 percent of all pregnancy-related deaths (deaths during and up to one year after pregnancy) occur at the time of delivery, and nearly 12 percent occur between 1 and 6 days after the end of pregnancy.

Native Hawaiian and Pacific Islander women, Black women, and American Indian/Alaska Native (AI/AN) women are two to four times more likely to suffer a pregnancy-related death than non-Hispanic White women.³⁵⁵ Black and AI/AN women experience severe maternal morbidity rates that are more than two times higher than their White

³⁵¹ Munira Gunja et al., *Insights into the U.S. Maternal Mortality Crisis: An International Comparison* (Commonwealth Fund, June 2024).
<https://doi.org/10.26099/cthn-st75>

³⁵² <https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2022/maternal-mortality-rates-2022.pdf>

³⁵³ <https://stacks.cdc.gov/view/cdc/103855>

³⁵⁴ <https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc.html>

³⁵⁵ <https://www.cms.gov/files/document/maternal-health-may-2022.pdf>

counterparts.^{356,357} Systemic societal barriers, including a patient's social determinants of health, have meant that these individuals experience a greater share of these poor maternal health outcomes.^{358,359,360}

Pregnant women who live in rural communities face a higher risk for severe maternal morbidity and have about 60 percent higher risk of pregnancy-related deaths and are more likely to die before, during, or the year after delivery than those living in urban settings.^{361,362} Pregnant women with disabilities receive lower quality maternity care, experience a higher risk of pregnancy and birth-related complications, and are eleven times more likely to experience maternal death than people without disabilities.^{363,364}

³⁵⁶ Centers for Disease Control and Prevention. Pregnancy Mortality Surveillance System. Available at: <https://www.cdc.gov/maternal-mortality/php/pregnancy-mortality-surveillance/index.html/> Accessed June 5th, 2024. .

³⁵⁷ <https://www.commonwealthfund.org/publications/issue-briefs/2021/oct/severe-maternal-morbidity-united-states-primer#:~:text=Approximately%20140%20of%2010%2C000%20women,severe%20maternal%20morbidity%20every%20year>

³⁵⁸ <https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf>

³⁵⁹ Taylor, J., Novoa, C., Hamm, K., & Phadke, S. (2021, December 3). Eliminating Racial Disparities in Maternal and Infant Mortality. Center for American Progress. <https://www.americanprogress.org/article/eliminating-racialdisparities-maternal-infant-mortality/>.

³⁶⁰ Hoffman KM, Trawalter S, Axt JR, Oliver MN. Racial bias in pain assessment and treatment recommendations, and false beliefs about biological differences between blacks and whites. *Proc Natl Acad Sci U S A*. 2016;113(16):4296-4301. doi:10.1073/pnas.1516047113 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4843483/>.

³⁶¹ White House Fact Sheet: Vice President Kamala Harris Announces Call to Action to Reduce Maternal Mortality and Morbidity. <https://www.whitehouse.gov/briefing-room/statementsreleases/2021/12/07/fact-sheet-vice-presidentkamala-harris-announces-call-to-action-to-reducematernal-mortality-and-morbidity/>.

³⁶² Kozhimannil, K. B., Interrante, J. D., Henning-Smith, C., & Admon, L. K. (2019). Rural-urban differences in severe maternal morbidity and mortality in the US, 2007–15. *Health affairs*, 38(12), 2077-2085. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.00805>

³⁶³ Gleason JL, Grewal J, Chen Z, Cernich AN, Grantz KL. Risk of Adverse Maternal Outcomes in Pregnant Women With Disabilities. *JAMA Netw Open*. 2021;4(12):e2138414. doi:10.1001/jamanetworkopen.2021.38414.

³⁶⁴ Willi Horner-Johnson et.al, Perinatal Health Risks and Outcomes Among US Women With Self-Reported Disability, 41 *Health Aff*. 2011 (September. 2022), <https://doi.org/10.1377/hlthaff.2022.00497>.

2. Efforts to Improve Maternal Health

CMS has undertaken various efforts to improve the state of maternal health care. In 2023, CMS launched the first ever “Birthing-Friendly” designation icon on CMS’ Care Compare online tool.³⁶⁵ To earn the designation, hospitals and health systems report their progress on our Maternal Morbidity Structural Measure to the Hospital Inpatient Quality Reporting (IQR) Program. The measure determines whether a hospital or health system has participated in a Statewide or national perinatal quality improvement collaborative program and implemented evidence-based quality interventions in hospital settings to improve maternal health, such as maternal safety bundles. Maternal safety bundles have demonstrated success in driving improvements, particularly with regards to obstetric hemorrhage, severe hypertension in pregnancy, and nonmedically indicated Cesarean deliveries.^{366,367,368} Hospitals and health professionals also have access to evidence-based best practices for determining the risk of obstetric hemorrhage and hypertension and for managing patients with these complications (including in an emergency setting). However, these best practices are not universally utilized nor incorporated into facilities’ standards of care.³⁶⁹

We also published the quality, safety, and oversight memorandum (QSO–22–05-Hospitals) which encourages hospitals to consider the implementation of evidence-based best practices for the management of obstetric emergencies, along with interventions to address other key contributors to maternal health disparities, and to support the delivery of equitable, high-

³⁶⁵ <https://data.cms.gov/provider-data/birthing-friendly-hospitals-and-health-systems>

³⁶⁶ Jennifer A. Callaghan-Koru et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. *Obstet Gynecol* 2019; 134:109-19.

³⁶⁷ Elliott K. Main et al. Reduction of severe maternal morbidity from hemorrhage using a state perinatal quality collaborative. *Am J Obstet Gynecol* 2017;216(3); 298.e1-298.e11.

³⁶⁸ Patricia Lee King et al. Reducing time to treatment for severe maternal hypertension through statewide quality improvement. *Am J Obstet Gynecol* 2018; 218:S4.

³⁶⁹ Jennifer A. Callaghan-Koru et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. *Obstet Gynecol* 2019; 134:109-19.

quality care for all pregnant and postpartum individuals.³⁷⁰ Facilities can implement these best practices voluntarily as part of a hospital's QAPI program (§ 482.21), which requires that hospitals develop, implement, and maintain an effective, ongoing, hospital wide, datadriven quality assessment and performance improvement program.

We have taken several steps to better understand the impacts of the maternal health crisis and the potential need for revisions to the CoPs to protect the health and safety of pregnant and postpartum women. In the FY 2023 IPPS/LTCH PPS final rule, we published responses to a maternal health RFI that solicited feedback on a wide range of maternal health issues and opportunities for CMS to improve maternal health care (87 FR 49290 through 49292). Some commenters were concerned that failure to comply with any new CoP could result in the loss of Medicare certification and that access to obstetrical care would be negatively impacted, potentially exacerbating rates of maternal morbidity/mortality and disparities in obstetrical care. Other commenters supported the creation of a CoP specifically for labor and delivery, to establish minimum health and safety standards across participating hospitals.

We conducted a literature review on maternal health with a focus on obstetric (OB) services delivery, staff training, and best practices for maternal health and safety to help inform the proposals in this rule. We also held a series of listening sessions with industry stakeholders, patient advocacy groups, and health care professionals on ways the CoPs can be revised to improve maternal health care outcomes and reduce disparities. We received valuable feedback from stakeholders regarding establishing an OB services CoP, staff training and the importance of providing culturally competent care. Some groups also highlighted the value of recommendations from Maternal Mortality Review Committees (MMRCs). Other stakeholders cautioned on being overly specific (that is, certain diseases) in the CoPs and encouraged CMS to instead leverage existing regulations text or quality metrics rather than create new CoPs.

³⁷⁰ <https://www.cms.gov/files/document/qso-22-05-hospitals.pdf>

Finally, we issued a request for information (RFI) in the FY 2025 Inpatient Prospective Payment System (IPPS) proposed rule (89 FR 36498 through 36502) to gather stakeholder feedback on several options for establishing an obstetrical services CoP for participating hospitals, CAHs, and rural emergency hospitals (REHs) and other detailed questions.

Request for Information on Obstetrical Services Standards for Hospitals, CAHs, and REHs: Summary and Responses to Public Comments

In May 2024, we published a Request for Information (RFI) on Obstetrical Services Standards for hospitals, CAHs, and REHs in the FY 2024 Hospital IPPS proposed rule (89 FR 35934). We solicited public comments on developing targeted baseline health and safety standards for obstetrical services. We received comments from a variety of parties interested in addressing obstetrical care including advocacy groups, industry associations, state health departments, labor unions, and professional organizations. Commenters supportive of CoPs for obstetrical care services noted that establishing CoPs for obstetrical care would enhance the quality and safety of maternal care and provide the opportunity to standardize services across various healthcare settings. These commenters also stated that obstetrical services CoPs regarding organization and staffing would promote multidisciplinary, team-based care with specialists, such as cardiologists, maternal fetal medicine practitioners, primary care physicians, and adult congenital heart disease specialists, among others providing care to pregnant women. Other commenters stated that establishing obstetrical training standards for hospital/CAH non-OB units can help to mitigate the impact of OB unit closures on maternal health outcomes and also supported staff training on respectful care, cultural competency, trauma-informed care, and nondiscrimination. Some commenters supported requiring facilities to report directly to the Maternal Mortality Review Committee (MMRC) and others supported specific transfer protocol requirements.

Other commenters expressed concerns regarding establishing CoPs for obstetrical care services for a variety of reasons including the current regulatory environment related to

obstetrical and gynecological services, conflicting regulations between the State and Federal requirements, insufficient clinical evidence, impact on access, regulatory burden, accelerating closures, potential redundancy with CMS' quality measurement programs, severity of consequences for not meeting CoP requirements, and unintended consequences. One commenter stated that existing CoPs provide adequate protection for patients and was concerned that more requirements specific to obstetrical services may lead to overlapping, conflicting or otherwise confusing requirements that may negatively impact care, while others believed that an obstetrical services CoP would not address the main drivers of maternal morbidity and mortality.

After analyzing the issue of high rates of maternal mortality and morbidity in the U.S. receiving feedback from various stakeholders on improving maternal health care, and reviewing available resources and current requirements, we believe that it is necessary to establish new requirements for the provision of obstetrical services to protect the health and safety of pregnant, birthing, and post-partum patients. Currently, there are no baseline care requirements for hospitals and CAHs that are specific to maternal-child services (that is, labor and delivery, prenatal and post-partum care, and care for newborn infants, alternately referred to in this discussion as obstetrical services, obstetrics, maternal health, or maternity care). In addition to obstetrical units, care for pregnant and postpartum patients may also occur in other parts of facilities such as other inpatient units, emergency departments, hospital outpatient departments, as well as in facilities without obstetrical units and/or emergency services. Such care may occur before, during, or after delivery. Based on the issues regarding the delivery of maternity care referenced, we propose a new OB services CoP, including proposed requirements for the organization, staffing, and delivery of OB services and staff training. We also propose revisions to the current hospital and CAH QAPI, hospital and CAH emergency services requirements, and hospital discharge planning requirements specific to OB services. We also solicit comments on whether these proposed requirements should also apply to REHs.

B. Provisions of the Proposed Regulations

1. Organization, Staffing, and Delivery of Services (§ 482.59 and § 485.649)

a. Background

The Hospital CoPs at 42 CFR 482.51 through 482.58 include requirements for optional services that hospitals are not required by law to provide but may elect to offer to their patients. If a hospital provides an optional service to its patients, the hospital must comply with the requirements of the CoP specific to that service. The hospital CoPs include requirements for optional services such as surgery (§ 482.51), anesthesia (§ 482.52), outpatient services (§ 482.54), emergency services (§ 482.55), and other health care services. CAHs may also opt to provide certain services to its patients. CoPs for the provision of optional CAH services such as surgeries, inpatient psychiatric services, and inpatient rehabilitation services have been established at § 485.639, §485.647(a)(1) and § 485.647(a)(2), respectively. Outside of an emergency department (ED), hospitals and CAHs may also offer obstetrical services to their patients. Currently, there are no baseline requirements for the organization, staffing, and delivery of such OB services in hospitals and CAHs.

Several accrediting bodies and professional medical specialty societies including the American College of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), and The Center for Improvement in Healthcare Quality (CIHQ), have discussed recommendations for standards of practice for OB staffing and organization within a hospital care setting. For example, ACOG and SMFM have developed a system that defines four different levels of maternal care that range from least complex care to the most complex care and they have recommended the obstetrical care providers and services, as well as the capabilities and equipment, that should be available at each level based on the patient's need.³⁷¹ They

³⁷¹ <https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2019/08/levels-of-maternal-care>

recommend that an OB-GYN physician be present onsite 24 hours a day, 7 days a week (24/7), within the two highest facility levels that can treat complex maternal medical conditions (levels III and IV). Within a level II facility, which can treat moderate-to-high-risk maternal medical conditions, ACOG and SMFM suggest that such facility retain a family physician with an OB fellowship or equivalent training can be present in place of an OB-GYN physician. Lastly, they recommend a certified nurse-midwife (CNM), certified midwife (CM), or family physician accompanied by a qualified registered nurse (RN) should be present 24/7 within the lowest level facility that provides basic care for low-risk, uncomplicated conditions (level I).³⁷² ACOG and SMFM also recommend appropriately trained and qualified RNs, along with a formally trained nursing leadership team with maternal care experience for hospitals and CAHs providing maternal care.³⁷³

CIHQ has recommended that an OB-GYN physician with advanced cardiovascular life support and neonatal resuscitation training should always be present at a facility providing emergency OB services.³⁷⁴ They also recommend that OB services be organized to allow for effective communication, collaboration, and coordination of care between the emergency services program and inpatient maternal/child services.³⁷⁵

We understand that State law regarding OB staffing varies, and some States have enacted laws and regulations regarding OB services organizational standards and require levels of maternal care designation. We believe that proposing standards for obstetrical services ensures that all Medicare and Medicaid participating hospitals and CAHs that offer these services are held to a consistent set of requirements, supports high-quality maternity care and protects the health and safety of patients. Therefore, we believe it is necessary to propose CoPs specific to

³⁷² <https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2019/08/levels-of-maternal-care>

³⁷³ <https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2019/08/levels-of-maternal-care>

³⁷⁴ <https://cihq.org/acc-default-hospitals.asp>

³⁷⁵ <https://cihq.org/acc-default-hospitals.asp>

obstetrical services for hospital and CAH CoPs, similar to the current requirements for optional services provided in these facilities.

b. Proposals

We propose at new sections § 482.59 and § 485.649 new CoPs for hospitals and CAHs offering obstetrical services outside of an ED. Specifically, we propose to require that if a hospital or a CAH offers obstetrical services, the services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for physical and behavioral (inclusive of both mental health and substance use disorders) health care of pregnant, birthing, and postpartum patients. If outpatient obstetrical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered. Nationally recognized acceptable standards of practice may be based on medical professional society and/or accrediting organization standards. While these CoPs would not require adherence to a specific organization's guideline or recommendations, we expect that facilities would be able to articulate their standards and the source(s) and to demonstrate that their standards are based on evidence and nationally recognized sources. This overarching requirement for obstetric services is consistent with other hospital and CAH CoPs and is foundational to ensuring high-quality safe care.

At new subsections § 482.59(a) and § 485.649(a), we further propose that the organization of the obstetrical services be appropriate to the scope of services offered by the facility and integrated with other departments of the facility. For example, in order to provide high quality and safe care, a labor and delivery unit needs to ensure good communication and collaboration with services such as laboratory, surgical services, and anesthesia services as applicable. At § 482.59(a)(1) and § 485.649(a)(1), we propose that the OB patient care units (that is, labor rooms, delivery rooms, including rooms for operative delivery, and post-partum/recovery rooms whether combined or separate) be supervised by an individual with the necessary education and training, and specify that that person should be an experienced

registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy. This individual is typically responsible for a variety of activities important to patient safety, such as overseeing staff, training, overall patient care, and supporting communications within the unit and across the facility. Given the importance of the role, ensuring appropriate training and education is imperative.

At § 482.59(a)(2) and § 485.649(a)(2), we propose that obstetrical privileges be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner. The obstetrical service must maintain a roster of practitioners specifying the privileges of each practitioner. While a variety of practitioners may deliver a wide range of obstetric services and perform a wide range of procedures, not every practitioner can provide all services nor perform every procedure. All hospitals are already required, at § 482.22(c)(6), to have medical staff bylaws that include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. This process ensures that practitioners have the necessary education, training, and experience to provide safe, effective care and safely perform specific procedures. This proposed CoP provides additional specificity for an obstetrics service. Such an approach is consistent with existing hospital optional services CoPs, such as surgical services at § 482.51(a)(4) and, given existing requirements, adds little additional burden. The proposed obstetric services CoPs at § 482.59(a)(2) and § 485.649(a)(2) also recognize that practitioners other than physicians are important to delivering obstetric services and we considered them when developing these provisions. We remind hospitals that existing CoPs allow for the privileging and credentialing of practitioners other than physicians, including nurse midwives (§ 482.12(a) and (c); § 482.22). Specifically, the hospital regulations at § 482.12(c) permit licensed practitioners (for example, nurse practitioners, nurse midwives, etc.), as allowed by the State, to admit patients to a hospital. CMS does not require that these practitioners be employed by, under the supervision of, or associated with, a Doctor of Medicine (MD) or doctor of osteopathic medicine (DO) unless

required by State law, regulations, or facility policy. A hospital is not precluded from credentialing and granting privileges to practitioners not listed under § 482.12(c)(1). Additionally, if not otherwise prohibited by State law, a hospital may elect to include these practitioners (such as advanced practice providers, including advanced practice registered nurses, clinical nurse specialists, physician assistants, and nurse midwives) as part of their medical staff. Moreover, the hospital CoPs prohibit a hospital from granting staff membership or professional privileges in the hospital solely upon certification, fellowship, or membership in a specialty body or society. (§ 482.12(a)(7)). In States that permit nurse midwives to admit patients (in accordance with hospital policy and practitioner privileges), per statute (section 1861(e)(4) of the Act) CMS requires only Medicare patients of a nurse midwife to be under the care of an MD or DO (§ 482.12(c)(2)). CMS does not require Medicaid nor other non-Medicare patients admitted by a nurse midwife to be under the care of an MD or DO.³⁷⁶ For CAHs, CMS does not have the authority to remove the physician oversight requirement for inpatients at § 485.631(b)(1)(iv), as this is a statutory requirement and the physician oversight requirement for outpatients at § 485.631(b)(1)(v) is only applicable if required by State law.

At new subsections § 482.59(b) and § 485.649(b), “Delivery of services”, we propose to require that OB services must be consistent with the needs and resources of the facility. Policies governing obstetrical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety. We additionally propose at paragraphs § 482.59 (b)(1) and § 485.649(b)(1) that labor and delivery room suites have certain basic resuscitation equipment readily available, including a call-in-system, cardiac monitor, and fetal doppler or monitor. We believe a basic set of equipment should be in place for all obstetric services to ensure efficient, effective delivery of care as well as timely response to emergency

³⁷⁶ Quality Safety & Oversight Memorandum QSO-23-22-Hospital, September 21, 2123. <https://www.cms.gov/files/document/qso-23-22-hospital.pdf> Accessed April 23 2024.

situations. However, we recognize that different facilities offer different levels of service. We welcome public comment on what is an appropriate minimum set of equipment for all hospitals offering obstetric services.

Furthermore, at § 482.59 (b)(2) and § 485.649(b)(2) we propose that the service ensure that it has protocols, consistent with evidence-based, nationally recognized guidelines, as well as readily available provisions (that is, necessary supplies and equipment on the unit or in close proximity and easily accessed by unit personnel) for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the facility's QAPI program. While this requirement does not require any specific items, we would expect provisions to include equipment, in addition to the equipment required under § 482.59 (b)(1) and § 485.649(b)(1), supplies, blood, and medication used in treating emergency cases. Examples of such emergency equipment or supplies could include: resuscitator, defibrillator, aspirator, and airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, nasogastric tubes, IV therapy supplies, suction machine, and defibrillator. Emergency medications could include analgesics, local anesthetics, anti-arrhythmics, cardiac glycosides, antihypertensives, antiepileptics, uterotonics, anticoagulants, antifibrinolytics, electrolytes and replacement solutions. As discussed in section XXI.B.2 of this proposed rule, obstetric readiness is a concern in avoiding preventable maternal morbidity and mortality. Provisions and protocols, as we propose to require, are one step towards addressing those concerns and improving perinatal outcomes.

We solicit public comments on these proposals, including whether these proposed requirements should be applicable to REHs.

2. Training for Obstetrical Staff in Hospitals and CAHs (§§ 482.59(c), 485.649(c))

a. Background

Given the worsening maternal health crisis as discussed in XXI.A.1.a of this proposed rule and research indicating that over 80 percent of pregnancy-related deaths in the U.S. are

preventable, CMS is committed to ensuring that all Medicare and Medicaid participating hospitals and CAHs offering obstetrical services are held to a consistent standard of high-quality maternity care and patient health and safety. Currently, the CoPs for hospitals and CAHs include no baseline requirements for the training of obstetrical staff.

The majority of hospitals participate in the Medicare program through deemed status with an accrediting organization.³⁷⁷ These accrediting organizations may have additional requirements that exceed the Medicare CoP requirements as part of their CMS- approved deeming program. For example, The Joint Commission (TJC) requires education on the provision of care, treatment, and services standards for maternal safety for all staff and providers who treat pregnant/postpartum patients. Specifically, TJC requires training on the hospital's evidence-based severe hypertension/preeclampsia and hemorrhage procedures.³⁷⁸ The TJC standards also require that hospitals use in-situ training and drills that include multidisciplinary teams.³⁷⁹

Despite the requirements of accrediting organizations, several organizations have determined that in their view, obstetrical readiness for hospitals with obstetrical services is suboptimal.^{380,381,382} Additionally, the lack of standardized approaches to emergency OB care may contribute to poor maternal health outcomes.^{383,384} Variation in processes of care is problematic

³⁷⁷ <https://www.jointcommission.org/resources/news-and-multimedia/fact-sheets/facts-about-hospital-accreditation/>

³⁷⁸ <https://www.jointcommission.org/standards/r3-report/r3-report-issue-24-pc-standards-for-maternal-safety/>

³⁷⁹ <https://www.jointcommission.org/-/media/tjc/documents/standards/r3-reports/r3-issue-24-maternal-12-7-2021.pdf>

³⁸⁰ <https://www.acog.org/news/news-articles/2022/01/commitment-to-action-eliminating-preventable-maternal-mortality>

³⁸¹ https://rhrc.umn.edu/wp-content/uploads/2021/09/UMN-emOB-Training-Needed_11.12.20_508.pdf

³⁸²

<https://www.cdcfoundation.org/sites/default/files/files/ReportfromNineMMRCs.pdf>

³⁸³ Jennifer A. Callaghan-Koru et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. *Obstet Gynecol* 2019;134:109-19.

³⁸⁴ <https://www.acpjournals.org/doi/10.7326/M19-3258>

because it may lead to increased rates of error.³⁸⁵ Appropriate training, best practice protocols (such as recognizing early warning signs of hemorrhage, preeclampsia, and other adverse events associated with pregnancy and birth), and appropriate transfer protocols are critical to averting avoidable maternal complications and deaths, establishing and maintaining facilities' obstetrical readiness,³⁸⁶ and ensuring compliance with existing regulations.

Research shows that women with any form of disability are at heightened risk for pregnancy and labor and delivery complications, as well as severe maternal morbidity and mortality, including pre-term birth, hypertensive disorders during pregnancy, gestational diabetes, and cesarean delivery.³⁸⁷ Understanding these risks, and education to help health care practitioners be more comfortable managing care for people with disabilities before, during, and after pregnancy can help ensure patients with disabilities receive safe, high quality OB care.³⁸⁸

Research also indicates that women with limited English proficiency (LEP) are also found to experience disparities in OB care and are at risk for mental health conditions, including post-partum depression and substandard newborn care following neonatal intensive care unit (ICU) discharge due to insufficient patient education by staff.^{389,390} Language-concordant care and awareness among medical providers regarding the use of medical interpreters and materials in

³⁸⁵ <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/clinical-guidelines-and-standardization-of-practice-to-improve-outcomes>

³⁸⁶ <https://saferbirth.org/aim-obstetric-emergency-readiness-resource-kit/>

³⁸⁷ Tarasoff LA, Ravindran S, Malik H, Salaeva D, Brown HK. Maternal disability and risk for pregnancy, delivery, and postpartum complications: a systematic review and meta-analysis. *Am J Obstet Gynecol.* 2020;222(1):27.e1-27.e32. doi: 10.1016/j.ajog.2019.07.01

³⁸⁸ Gleason JL, Grewal J, Chen Z, Cernich AN, Grantz KL. Risk of Adverse Maternal Outcomes in Pregnant Women With Disabilities. *JAMA Netw Open.* 2021 Dec 1;4(12):e2138414. doi: 10.1001/jamanetworkopen.2021.38414. PMID: 34910153; PMCID: PMC8674748. and Smeltzer SC, Mitra M, Long-Bellil L, Iezzoni LI, Smith LD. Obstetric clinicians' experiences and educational preparation for caring for pregnant women with physical disabilities: a qualitative study. *Disabil Health J.* 2018;11(1):8-13. doi: 10.1016/j.dhjo.2017.07.004).

³⁸⁹ Togioka, Brandon & Seligman, Katherine & Delgado Upegui, Carlos. (2022). Limited English proficiency in the labor and delivery unit. *Current Opinion in Anaesthesiology.* 35. 285-291.

³⁹⁰ Sentell, Tetine & Chang, Ann & Ahn, Hyeong Jun & Miyamura, Jill. (2015). Maternal Language and Adverse Birth Outcomes in a Statewide Analysis. *Women & health.* 56.).

diverse languages can improve patient satisfaction, decrease medical errors, and improve patient safety.^{391,392,393}

Studies have shown a direct correlation between the experience of a severe maternal event and the development or exacerbation of a mental health disorder, such as posttraumatic stress disorder (PTSD).³⁹⁴ Posttraumatic stress disorder affects about three to four percent of mothers, with higher rates among some population groups. Perinatal PTSD includes PTSD episodes occurring during pregnancy through one year postpartum. Perinatal PTSD negatively affects physical and mental health, interpersonal relationships, and parenting capacity.³⁹⁵ After a severe event, patients and their families may struggle to understand why an event occurred and how they might have received better information or care throughout the experience, adding to their overall emotional distress.³⁹⁶ These examples highlight the need for new requirements for hospitals that provide obstetrical services.

b. Proposed Requirements for Staff Training for Hospitals and CAHs with OB Services

Given the existing literature and prevalence of health and safety concerns impacting maternal health outcomes (as described earlier in this section), we propose a core set of requirements for hospitals and CAHs offering OB services to protect the health and safety of pregnant, birthing, and postpartum patients. We believe that training of OB services staff on evidence-based best practices and protocols would enhance the quality of care and services provided to pregnant, birthing, and postpartum women and improve patient health and safety.

³⁹¹ Togioka, Brandon & Seligman, Katherine & Delgado Upegui, Carlos. (2022). Limited English proficiency in the labor and delivery unit. *Current Opinion in Anaesthesiology*. 35. 285-291. 10.1097/ACO.0000000000001131.

³⁹² Sentell, Tetine & Chang, Ann & Ahn, Hyeong Jun & Miyamura, Jill. (2015). Maternal Language and Adverse Birth Outcomes in a Statewide Analysis. *Women & health*. 56. 10.1080/03630242.2015.1088114.

³⁹³ <https://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf>

³⁹⁴ <https://www.sciencedirect.com/science/article/pii/S0884217520303166?via%3Dihub>

³⁹⁵ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.01447>

³⁹⁶

<https://www.sciencedirect.com/science/article/pii/S0884217520303166?via%3Dihub>

We therefore propose at new paragraph §§ 482.59(c) and 485.649(c) that hospitals and CAHs with OB services would be required to develop policies and procedures that would ensure that relevant obstetrical services staff would be trained on select topics for improving the delivery of maternal care. We propose at § 482.59(c)(1) and § 485.649(c)(1) training topics would have to reflect the scope and complexity of services offered, including, but not limited to, facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility. Performing critical tasks consistently through standardized practices can reduce errors, especially when fatigue is a factor, and in stressful environments such as the labor and delivery suite or operating room.³⁹⁷ To facilitate improvements in care, the Centers for Disease Control and Prevention (CDC) established perinatal quality collaboratives (PQCs).³⁹⁸ PQCs are state or multistate networks of teams that work to improve the quality of care for mothers and babies by identifying health care processes in need of improvement. In addition, the Health Resource and Services Administration (HRSA) partnered with the Alliance for Innovation on Maternal Health (AIM) to establish patient safety bundles.³⁹⁹ Facilities may participate in local or regional PQCs and implement patient safety bundles. The Institute for Healthcare Improvement defines bundles as, “a small, straightforward set of evidence-based best practices that, when performed collectively and reliably, have been demonstrated to improve patient outcomes.”⁴⁰⁰ Maternal safety bundles, often implemented through PQCs, have demonstrated success in driving improvements, particularly with regards to obstetric hemorrhage, severe hypertension in pregnancy, and non-medically indicated Cesarean

³⁹⁷ <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/clinical-guidelines-and-standardization-of-practice-to-improve-outcomes>

³⁹⁸ <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc.htm>

³⁹⁹ <https://saferbirth.org/about-us/>

⁴⁰⁰ <https://www.ihl.org/insights/what-is-a-bundle>

deliveries.^{401,402,403,404} Other examples of evidence-based trainings topics for obstetrical staff may include education in trauma informed care,^{405 406} cultural competency,^{407,408, 409,410, 411, 412,413,414,415,}

⁴⁰¹ Jennifer A. Callaghan-Koru et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. *Obstet Gynecol* 2019;134:109-19.

⁴⁰² Elliott K. Main et al. Reduction of severe maternal morbidity from hemorrhage using a state perinatal quality collaborative. *Am J Obstet Gynecol* 2017;216(3):298.e1-298.e11.

⁴⁰³ Patricia Lee King et al. Reducing time to treatment for severe maternal hypertension through statewide quality improvement. *Am J Obstet Gynecol* 2018;218:S4.

⁴⁰⁴ <https://www.cms.gov/files/document/qso-22-05-hospitals.pdf>

⁴⁰⁵ https://saferbirth.org/wp-content/uploads/13-FINAL_AIM_OERRK_RESC.pdf

⁴⁰⁶ <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/04/caring-for-patients-who-have-experienced-trauma>

⁴⁰⁷ <https://store.samhsa.gov/sites/default/files/sma16-4931.pdf>

⁴⁰⁸ Effects of Cultural Sensitivity Training on Health Care Provider Attitudes and Patient Outcomes
<https://sigmapubs.onlinelibrary.wiley.com/doi/10.1111/j.1547-5069.2004.04029>.

⁴⁰⁹ Lelutiu-Weinberger, Corina. Implementation and Evaluation of a Pilot Training to Improve Transgender Competency Among Medical Staff in an Urban Clinic

<https://www.liebertpub.com/doi/full/10.1089/trgh.2015.0009>

⁴¹⁰ Rotenberg, Sara et.al. Disability Training for health Workers: A Global Narrative Systematic Review. *Disability and Health Journal* doi: 10.1016/j.dhjo.2021.101260.

⁴¹¹ Cultural Competency: A Systemic Review of Health Care Provider Educational Interventions. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3137284/>

⁴¹² <https://journals.sagepub.com/doi/10.1177/0163278712454137>

⁴¹³ Linda Govere et. Al. How Effective Is Cultural Competence Training of Healthcare Providers on Improving Patient Satisfaction of Minority Groups? A Systematic Review of Literature. <https://doi.org/10.1111/wvn.12176> October 25, 2016.

⁴¹⁴ <https://onlinelibrary.wiley.com/doi/10.1111/j.1745-7599.2009.00406.x>

⁴¹⁵ <https://journals.sagepub.com/doi/10.1177/0163278712454137>

^{416,417,418,419,420,421,422,423,424,425,426} and person-centered care.^{427,428,429,430,431,432,433,434} We also point readers to training resources at CMS' Medicare Learning Network: <https://www.cms.gov/training-education/medicare-learning-network/web-based-training>.

Additionally, at § 482.59(c)(1)(ii) and § 485.649(c)(1)(ii), we propose that hospitals and CAHs that provide OB services use findings from their QAPI programs, as required at § 482.21 and § 485.641, respectively, to inform obstetrical staff training needs and any additions, revisions, or updates to training topics on an ongoing basis. Stratified data can produce meaningful measures that can be used to expose health disparities, develop interventions to reduce them, and monitor performance to ensure interventions aimed at improving care do not have unintended consequences for certain patients and improve patient outcomes.⁴³⁵ Continuous quality improvement depends on a disciplined and well-defined data-driven process that

⁴¹⁶ Santana, Maria. How to Practice Person-Centered Care: A conceptual Framework. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5867327/>.

⁴¹⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3726251/>

⁴¹⁸ <https://pubmed.ncbi.nlm.nih.gov/12013268/>

⁴¹⁹ <https://thinkculturalhealth.hhs.gov/clas>

⁴²⁰ <https://ethnomed.org/>

⁴²¹ <https://minorityhealth.hhs.gov/clas-behavioral-health-implementation-guide>

⁴²² https://minorityhealth.hhs.gov/assets/PDF/Evaluation_of_the_Natn_CLAS_Standards_Toolkit_PR3599_final.508Compliant.pdf

⁴²³ <https://www.cms.gov/about-cms/agency-information/omh/downloads/clas-toolkit-12-7-16.pdf>

⁴²⁴ <https://www.albany.edu/cphce/bridging-gaps-vital-role-cultural-competence-healthcare>.

⁴²⁵ <https://thinkculturalhealth.hhs.gov/resources/presentations/1/fundamentals-of-the-national-standards-for-culturally-and-linguistical>.

⁴²⁶ <https://thinkculturalhealth.hhs.gov/education/maternal-health-care>.

⁴²⁷ An approach to coordinate health care services to better address an individual's physical, mental, behavioral, and social needs (See <https://www.cms.gov/priorities/innovation/key-concepts/person-centered-care>)

⁴²⁸ <https://www.cms.gov/priorities/innovation/key-concepts/person-centered-care>

⁴²⁹ <https://www.hrsa.gov/about/organization/bureaus/ohe/health-literacy/culture-language-and-health-literacy>

⁴³⁰ <https://edit.cms.gov/about-cms/agency-information/omh/downloads/language-access-plan.pdf>

⁴³¹ <https://www.marchofdimes.org/our-work/beyond-labels>

⁴³² <https://www.acog.org/education-and-events/emodules/respectful-care>

⁴³³ <https://www.perinatalqi.org/page/mmtrends>

⁴³⁴ <https://www.cci.training/courses/maternal-mental-health-support-specialist>

⁴³⁵ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0617>

constantly is monitored and improved.⁴³⁶ We note that patient satisfaction and quality measures may be an effective way to measure the success of staff training.

At new paragraph § 482.59(c)(2) and § 485.649(c)(2), we propose to require the governing body to identify and document which staff must complete annual training on the topics identified at § 482.59(c)(1) and § 485.649(c)(1). In addition, we propose at § 482.59(c)(3) and § 485.649(c)(3) to require the hospital and CAH to document in the staff personnel records that the training was successfully completed. Further, at new paragraph § 482.59(c)(4) and § 485.649(c)(4), we propose that the hospital and CAH be able to demonstrate staff knowledge on the topics identified at § 482.59(c)(1) and § 485.649(c)(1), respectively. We are not proposing to require the specific manner or method in which a facility would be required to demonstrate that their staff is knowledgeable and competent in the ways to improve the delivery of maternal care, since this would likely vary based on the training delivery method. There are various ways in which a facility can assess their staff knowledge on ways to improve the delivery of maternal care. Facilities could do so through self-assessments, surveys, or questionnaires administered to their staff. Some examples of how a facility can demonstrate knowledge on these concepts include instructor-led training, computer-based or printed self-learning packets that contain a test to demonstrate their staff person's knowledge. In addition, for those trainings that are instructor-led, a question-and-answer session could follow the training. However the facility chooses to demonstrate this knowledge, we would expect the facility to maintain documentation that the training was completed, and that the facility's staff are knowledgeable of the ways to improve the delivery of maternal care.

We would expect facilities to consider the qualifications of the individuals or organizations that would be conducting the staff training and utilize trainers that are

⁴³⁶ <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/clinical-guidelines-and-standardization-of-practice-to-improve-outcomes>

knowledgeable on the subjects that they are teaching and are qualified to conduct the training. These requirements allow facilities the flexibility to determine the curriculum that would be used to train their staff on evidence-based best practices and protocols to improve the delivery of maternal care and other training topics as identified by the facilities' QAPI program. We would expect facilities to provide high quality training that is consistent with and tailored to the staff's expected role, with the goal of improving maternal health outcomes. We acknowledge that many hospitals and CAHs may have already implemented these practices and that those practices may satisfy this proposed requirement. Of note, these required staff trainings are in addition to the education and training necessary for a clinician to administer care within the scope of their practice or for a staff member to perform their job.

While there is, as noted above, ample objective research demonstrating the need for such requirements, we are also asking the public for any additional data, detailed analysis, academic studies, or any other information on the link between the proposed requirements and patient health and safety. We solicit public comment on these proposals, including whether these proposed staff training requirements should be applicable to REHs. We also seek public comment on whether CMS should require specific training on person-centered care, trauma-informed care, cultural competency, and/or other topics as part of the evidence-based training.

3. Quality Assessment and Performance Improvement (QAPI) Program (§ 482.21; § 485.641)

a. Background

i. Existing QAPI CoP Requirements

Medicare-participating hospitals and CAHs are required by CMS regulations to engage in quality activities to improve patient care and outcomes and to facilitate efficient and effective operations under the QAPI program standards (42 CFR 482.21; 42 CFR 485.641). Specifically, the QAPI standards are a data-driven and proactive approach to continuous quality improvement, with the end goal of improving the overall quality of care and services delivered to patients. The governing body is required to be involved in the QAPI program by ensuring that the program

reflects the complexity of the facility's organization and services.⁴³⁷ These data and measures remain with the facility; there is no requirement to transmit QAPI data to CMS or other Federal entities.

ii. Data Analysis and Stratification

In executing these QAPI requirements, hospitals and CAHs (including those with OB services) use patient population data to identify, reduce, and eliminate unfavorable patient health and safety outcomes, while identifying opportunities for improvement. As such, CMS considers QAPI a critical tool for improving facilities' maternal health outcomes amid the ongoing maternal health crisis. For while existing QAPI regulations (§ 482.21; § 485.641) require facilities to "develop, implement, and maintain an effective, ongoing, facility-wide, data-driven" QAPI program that focuses on "indicators related to improved health outcomes and the prevention and reduction of medical errors," existing regulations do not require that hospitals focus on addressing the worsening public health crises such as the U.S. maternal health crisis.

Moreover, in performing their data analysis, facilities may aggregate patient data in such a way that masks health outcome differences among patient subpopulations.⁴³⁸ Existing QAPI standards do not require that facilities monitor for or address health disparities, or otherwise analyze or stratify QAPI data by patient subpopulations. Yet, research has repeatedly shown the important role of data collection and analysis by patient subgroup within health care facilities in order to improve patient care consistently across patient populations.^{439,440,441, 442, 443} Specifically, analysis by patient subgroup can produce meaningful measures that can be used to expose health

⁴³⁷ RNHCIs (at § 403.732), ASCs (at § 416.43), hospices (at § 418.58), hospitals (at § 482.21), transplant programs (at § 482.96), LTC facilities (at § 483.75), HHAs (at § 484.65), CAHs (at § 485.641), CMHCs (at § 485.917), OPOs (at § 486.348), and ESRD dialysis facilities (at § 494.110)

⁴³⁸ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0617>

⁴³⁹ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0617>

⁴⁴⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3861327/>

⁴⁴¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6259664/>

⁴⁴² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7647227/>

⁴⁴³ <https://pubmed.ncbi.nlm.nih.gov/16567608/>

disparities, develop interventions to reduce them, and monitor performance to ensure interventions to improve care do not have unintended consequences for certain patients.^{444, 445}

However, such data practices are not universally applied by hospitals.⁴⁴⁶ The persistent maternal health crisis and well-documented correlations between certain patient demographics and maternal health outcomes as discussed at length in section XXI.A.1 of this proposed rule, strongly indicate that the absence of analyses by diverse subpopulations among obstetrical patients likely serves as a barrier to facilities' effectiveness in achieving performance improvement in maternal health outcomes. Therefore, we believe requiring QAPI analyses of maternal health data, quality indicators, and outcomes by diverse subpopulations served by a facility would support facilities in establishing structures to assess and improve health and safety conditions on an ongoing basis, thereby promoting access and high-quality care for all pregnant, birthing, and postpartum patients.

iii. Maternal Mortality Review Committees

Initially created in the 1930s to combat high rates of maternal mortality in the U.S.,⁴⁴⁷ Maternal Mortality Review Committees (MMRCs) are multi-disciplinary teams that work at the State or local level to engage stakeholders, comprehensively review deaths that occur during or within a year of pregnancy (pregnancy-related deaths), and develop recommendations aimed at preventing future pregnancy-related deaths.^{448,449} As of April 2024, MMRCs exist in 47 States and often function under the authority of State health and safety codes.^{450,451,452} MMRC composition varies but can consist of individuals with training in public health, obstetrics and gynecology, maternal-fetal medicine, nursing, midwifery, forensic pathology, behavioral health

⁴⁴⁴ <https://www.nejm.org/doi/full/10.1056/NEJMp1911700>

⁴⁴⁵ <https://www.nejm.org/doi/full/10.1056/NEJMp1911700>

⁴⁴⁶ <https://ifdhe.aha.org/benchmarking-study-us-hospitals-surveys>

⁴⁴⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6511983/>

⁴⁴⁸ <https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/index.html>

⁴⁴⁹ <https://doi.org/10.1097/AOG.0000000000002417>

⁴⁵⁰ <https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/index.html>

⁴⁵¹ <https://doi.org/10.1097/AOG.0000000000002417>

⁴⁵² <https://www.guttmacher.org/state-policy/explore/maternal-mortality-review-committees>

professionals, patient advocacy groups, and community-based organizations to determine cause of death, preventability of death, and relationship to pregnancy.^{453,454} Specifically, as of 2021, all existing MMRCs included representation from State public health agencies as well as provider groups (inclusive of hospitals, hospital organizations, State health professional chapters, State medical societies, etc.). Twenty-one out of forty-four (21/44; 47.7 percent) included representation from State Medicaid agencies, 20/44 (45.5 percent) included State behavioral health agencies, 18/44 (40.9 percent) included a violence prevention agency, and 27/44 (61.4 percent) included community-based organizations.⁴⁵⁵ Among provider groups, 28/44 (63.6 percent) of existing MMRCs included social workers; 12/44 (27.3 percent) included doulas and 14/44 (31.8 percent) substance use counselors.⁴⁵⁶ MMRCs may use a variety of data sources including: birth and death certificate data, prenatal care records, hospital records, autopsy reports, and social services records in their review process.⁴⁵⁷ Yet such data reporting and sharing is dependent upon State requirements and often voluntary for health care facilities.^{458,459} MMRCs generally disseminate annual or biennial reports reflecting their findings.

In FY 2023, CDC supported MMRC initiatives through cooperative agreements in 44 States and 2 territories via its Enhancing Reviews and Surveillance to Eliminate Maternal Mortality (ERASE MM) Program.⁴⁶⁰ Other sources of funding include the Federally-funded and State-administered Title V Maternal and Child Health (MCH) Services Block Grants, State

⁴⁵³ <https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/index.html>

⁴⁵⁴ <https://doi.org/10.1097/AOG.0000000000002417>

⁴⁵⁵ <https://nashp.org/state-tracker/state-maternal-mortality-review-committee-membership-and-recommendations/>

⁴⁵⁶ <https://nashp.org/state-tracker/state-maternal-mortality-review-committee-membership-and-recommendations/>

⁴⁵⁷ <https://www.cdcfoundation.org/sites/default/files/upload/pdf/MMRIARepor.pdf>

⁴⁵⁸ <https://www.cdcfoundation.org/sites/default/files/upload/pdf/MMRIARepor.pdf>

⁴⁵⁹ <https://www.gutmacher.org/state-policy/explore/maternal-mortality-review-committees>

⁴⁶⁰ <https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/index.html>

government appropriations, non-governmental grants, philanthropic contributions, and dedicated initiative funds.⁴⁶¹

Despite their pivotal role, MMRCs encounter various challenges, including resource constraints, funding challenges, data accessibility issues (including timeliness of data), operational authority, and limited to no ability to directly implement or enforce their recommendations.^{462,463,464} Moreover while, policies in 36 States and the District of Columbia legally require MMRCs to operate and review pregnancy associated deaths, only 10 States and the District of Columbia mandate the consideration of health disparities during MMRCs' review despite the widening maternal health disparities described in section XXI.A.1 of this proposed rule.^{465,466} Moreover, thirteen States require that MMRC membership reflect and/or consider the jurisdiction's demographic composition (for example, geographic, racial, socioeconomic status, communities most affected) when selecting Committee members.⁴⁶⁷

Stakeholders highlight the need for improved hospital engagement in data standardization and data collection as part of a comprehensive strategy to reduce rates of maternal mortality. Collaborative and consistent reporting at the hospital level directly impacts the quality and timeliness of MMRCs' work, as well as informs targeted recommendations and next steps within facilities. Specifically, Perinatal Quality Collaboratives (PQC) are a central method for how MMRCs' recommendations are implemented. PQCs are State or regional networks working to improve maternal and infant quality of care by identifying possible improvements in health care processes and leveraging the best available methods to enact changes expeditiously.⁴⁶⁸ As of

⁴⁶¹ <https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/index.html>

⁴⁶² <https://doi.org/10.1097/AOG.0000000000002417>

⁴⁶³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6511983/>

⁴⁶⁴ <https://www.cdc.gov/reproductivehealth/maternal-mortality/preventing-pregnancy-related-deaths/state-strategies.html>

⁴⁶⁵ <https://www.guttmacher.org/state-policy/explore/maternal-mortality-review-committees>

⁴⁶⁶ <https://pubmed.ncbi.nlm.nih.gov/31499056/>

⁴⁶⁷ <https://www.guttmacher.org/state-policy/explore/maternal-mortality-review-committees>

⁴⁶⁸ <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc.htm>

April 2024, there are 49 State-based PQCs, of which 36 are funded by the CDC.⁴⁶⁹ Through Federal grants and cooperative agreements with the CDC⁴⁷⁰ and/or funding and support from State and local governments, PQCs have achieved notable improvements in maternal health and safety, including in severe pregnancy complications.⁴⁷¹ Of note, participation in State or national Perinatal Quality Improvement (QI) Collaborative is a part of CMS’ “birthing friendly” hospital designation for hospitals that provide high quality maternal care.⁴⁷²

As an example of the collaboration between MMRCs and PQCs, the State of California demonstrates the impact that high quality hospital data collection and reporting can have in supporting MMRCs’ work and patient care improvements.⁴⁷³ California’s MMRC, known as the California Pregnancy-Associated Mortality Review project (CA-PAMR), was created in 2006 to “identify pregnancy-related deaths, causation, and contributing factors, and then make recommendations on quality improvements to maternity care.” CA-PAMR has consistently reported a pregnancy-related mortality rate below the U.S. rate since 2011.⁴⁷⁴ As mentioned above, California’s approach centers on a collaborative model, wherein CA-PAMR serves as a data collector, evaluator, and recommender, while the California Maternal Quality Care Collaborative (CMQCC; one of California’s PQCs with over 200 hospital members)⁴⁷⁵ works to implement recommendations. This close collaboration has been described as critical to California’s success in reducing maternal mortality.⁴⁷⁶ Specifically, the California Maternal Data Center allows for direct links between hospital reporting and State vital records offices for 95 percent of births, allowing for real time evaluation of perinatal metrics and quality

⁴⁶⁹ <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc-states.html>

⁴⁷⁰ <https://www.cdc.gov/maternal-infant-health/pqc/index.html>

⁴⁷¹ <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc.htm>

⁴⁷² <https://data.cms.gov/provider-data/birthing-friendly-hospitals-and-health-systems>

⁴⁷³ <https://www.cmqcc.org/research/maternal-mortality-review-ca-pamr/ca-pamr-recent-data>

⁴⁷⁴ <https://www.cmqcc.org/research/maternal-mortality-review-ca-pamr/ca-pamr-recent-data>

⁴⁷⁵ <https://www.cmqcc.org/about-cmqcc/member-hospitals>

⁴⁷⁶ <https://www.cmqcc.org/about-cmqcc/what-we-do>

improvement benchmarks.⁴⁷⁷ These comprehensive reporting efforts support the development of evidence-based quality improvement toolkits, which have driven a 65 percent reduction in maternal morbidity between 2006 (the year of CA-PAMR and CMQCC's founding) to 2016 in California in the latest analysis.⁴⁷⁸

b. Proposals

Given the above challenges and examples of success from MMRCs' work, we propose to revise the existing QAPI standards (§482.21; §485.641) for hospitals and CAHs that offer obstetrical services⁴⁷⁹. First, we propose that a hospital or CAH that offers OB services would be required to use its QAPI program to assess and improve health outcomes and disparities among OB patients on an ongoing basis ((§482.21(b); §485.641 (e)(1)). Specifically, the facility at a minimum would have to: (1) analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the facility among OB patients; (2) measure, analyze, and track data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations, and outcomes among OB patients; (3) analyze and prioritize patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained when disparities exist among OB patients; and (4) conduct at least one performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of OB patients annually.

For the analysis required in item (1), hospitals have flexibility in determining the data analysis methodology most appropriate for their patient population and number of cases. For

⁴⁷⁷ <https://www.cmqcc.org/about-cmqcc/what-we-do>

⁴⁷⁸ <https://www.cmqcc.org/who-we-are>

⁴⁷⁹ For purposes of this proposal, CMS considers a facility to "offer obstetrical services" when the facility "[holds itself] out to the public (by name, posted signs, advertising, or other means) as a place that provides care for obstetrical medical conditions." This is similar to how emergency departments are defined in EMTALA (42 CFR 489.24(b)(2) "Dedicated emergency department")

example, hospitals would stratify data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the hospital among OB patients. For items 2 and 3, we expect hospitals will be able to use this data analysis to monitor and assess for the presence of disparities. If disparities are identified, we expect hospitals to prioritize QAPI work to address these areas. For all QAPI work, we remind hospitals that such analysis must comply with HIPAA, while ensuring such subpopulations are not excluded from QAPI efforts based solely on low numbers of patients.

In terms of existing Federal maternal health data and metrics and their relation to this proposal, in August 2022 CMS finalized the adoption of two additional maternal health quality measures to the Hospital IQR program, both of which are electronic clinical quality measures including: (1) a measure of severe obstetric complications (which describes the number of inpatient hospitalizations for patients with severe complications occurring during the delivery hospitalization, such as hemorrhage), and (2) a measure of low-risk Cesarean section rates, which describes the share of patients with low-risk pregnancies who give birth via a Cesarean section. Hospitals may use these maternal health quality metrics to inform their QAPI activities and are an example of how a hospital could comply with this new standard. Hospitals may also choose to utilize CMS' mandatory Health Related Social Needs screening metrics and data to inform maternal health QAPI activities.⁴⁸⁰ Hospitals may also collaborate with their Quality Improvement Organization (QIOs) in this work. We refer readers to the following website which discusses CMS' Action Plan for Maternity Care in greater detail:

<https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf>.

Next, under a new standard for Maternal Health QAPI activities for hospitals (§ 482.21(e)(1)) and CAHs (§485.641(d)(4)(i)), we propose to require that for hospitals and

⁴⁸⁰ <https://www.cms.gov/newsroom/fact-sheets/fy-2023-hospital-inpatient-prospective-payment-system-ipsps-and-long-term-care-hospitals-ltch-pps>

CAHs that offer OB services, leadership must be engaged in the facility's QAPI activities. For purposes of this provision, leadership is defined as facility leadership, obstetrical services leadership, or their designate(s).

Per existing state statutes as applicable, facilities are already required to report data to MMRCs.⁴⁸¹ We therefore propose that if a MMRC is available at the State or local jurisdiction in which the facility was located, hospitals (at § 482.21(e)(2)) and CAHs (at § 485.641(d)(4)(ii)) that offer OB services must have to have a process for incorporating MMRC data and recommendations into the facility's QAPI program. Participation in a PQC or pursuing a QI project based on information from a MMRC are examples of how a facility could comply with this proposal. Of note, facilities can review CDC and state resources to identify the coordinating body and/or existence of MMRC in their state or locality.⁴⁸²

c. Solicitation of Comments

We welcome public comments on the enhancements to the existing QAPI standards for hospitals and CAHs that offer obstetrical services proposed above. Our central goal with these proposals is to improve the health and safety of all pregnant, birthing, and postpartum patients in Medicare-participating hospitals and CAHs, including reducing worsened health outcomes among vulnerable subpopulations, and we invite comment on how effectively these proposals would achieve this goal. We are additionally interested in data, evidence, and experience related to QAPI's impact and role in addressing maternal health disparities as well as any benefits, costs, and unintended consequences of the above policies. We welcome public input from a broad range of commenters, including but not limited to patients, community-based organizations, public health professionals, health care professionals, staff, hospitals, operators, researchers, those representing diverse perspectives (such as those from rural and otherwise underserved

⁴⁸¹ <https://www.cdc.gov/maternal-mortality/php/mmrc/index.html>

⁴⁸² <https://www.cdc.gov/maternal-mortality/php/mmrc/index.html>

communities), those disproportionately providing or engaged in maternal health care for specific populations discussed in this rule such as people experiencing health disparities, social risk factors and mental health conditions and substance use disorder which may lead to stigma, discrimination, and adverse outcomes). We also solicit public comments on the following questions:

- How effectively would these proposals achieve CMS' central goal of improving the health and safety of all pregnant, birthing, and postpartum patients in Medicare-participating hospitals and CAHs, including reducing worsened health outcomes among vulnerable subpopulations?
- To what extent do facilities already stratify, measure, analyze, and track quality data and indicators over time by diverse subpopulations or conduct performance improvement projects focused on reducing maternal health disparities as part of their QAPI activities? What are examples and outcomes of such work to date? What challenges do facilities (including those in rural areas or geographically isolated areas) face in performing such data stratification (for example, administrative recordkeeping processes, information systems, patient willingness to disclose information, and staff time/expertise) and implementing maternal health equity related QAPI projects? How can such challenges be overcome? What is needed for facilities to collect and stratify data by diverse sub-populations?
- What types of data stratifications/subgroups/categories are key to ensuring the health and safety of all pregnant, birthing, and postpartum patient subgroups? How can facilities best ensure their subgroup data collection and analysis reflects the diverse subpopulations served? What is the benefit versus possible unintended consequences of CMS defining and requiring a minimum set of data stratifications/subgroup/categories in facilities' maternal health QAPI program analyses? For example, should facilities be required to, at minimum, collect and stratify data by the subgroups included in MMRIA? How can facilities meaningfully acquire and disseminate subpopulation data in a way that avoids disclosure (that is, protecting individual

privacy and confidentiality of their data), which can lead to increased vulnerability for underserved populations? How should facilities address stratifying small populations?

- How can facilities best involve and/or share the results of the facilities' maternal health equity focused QAPI efforts with patients, their families/caregivers, and community members? What are examples and outcomes of such efforts to date? What gaps and challenges exist?

- Should any of these proposals apply to other types of Medicare-participating facilities besides hospitals and CAHs that offer OB services? For example, should similar requirements apply to REHs? What could be the benefits, challenges, or potential unintended consequences of such policies? How could CMS minimize the burden of any such requirements?

4. Emergency Services Readiness (§ 482.55; § 485.618)

a. Background

In compliance with the EMTALA statute (42 U.S.C. §1395dd) and its implementing regulations (42 CFR §489.24), Medicare-participating hospitals and CAHs with emergency departments must be continually prepared to provide individuals presenting to the emergency department with an appropriate medical screening exam and stabilizing treatment if an emergency medical condition is found or, under certain circumstances, appropriately transfer such individuals to receive stabilizing care at another facility with higher treatment capabilities not available at the originating hospital. Such readiness is essential to the health and safety of emergency services patients, and relies on adequate staff training, provisions, protocols, and supplies.

However, several organizations have reported that that emergency department readiness can be suboptimal, especially for obstetrical, geriatric, and pediatric populations, among others.

483,484,485,486,487, 488 Specific to obstetrical patients, as discussed in section XXI.A.1 of this proposed rule, given the worsening maternal morality crisis and declining access to inpatient and outpatient maternity care in the U.S. in recent years, especially in rural and low-income communities, non-obstetrical professionals working in hospital emergency departments, CAHs, and REHs nationwide may experience a higher acuity and frequency of patients needing OB care, which may result in patients receiving care by staff with less training in obstetrical emergencies. Moreover, pregnant women who live in rural communities, have low income, are members of certain racial/ethnic groups (non-Hispanic Black, American Indian/Alaska Native (AI/AN)), and have disabilities experience disproportionately higher rates of pregnancy-related morbidity and mortality. For some pregnant women, the emergency department may be their first and/or only contact with the health care system during the pregnancy. Hospital emergency departments, CAHs, and REHs must therefore continue to ensure they are prepared to meet the needs of these high-risk patient populations in order to maintain high quality of care and reduce disparate health outcomes. Research shows that additional obstetric training for emergency department staff improves staff competencies (that is, skills, knowledge, comfort, confidence, and effectiveness) in managing obstetric emergencies, supporting improved maternal health and

⁴⁸³ <https://www.acog.org/news/news-articles/2022/01/commitment-to-action-eliminating-preventable-maternal-mortality>

⁴⁸⁴ https://rhrc.umn.edu/wp-content/uploads/2021/09/UMN-emOB-Training-Needed_11.12.20_508.pdf

⁴⁸⁵

<https://www.cdcfoundation.org/sites/default/files/files/ReportfromNineMMRCs.pdf>

⁴⁸⁶ <https://emscimprovement.center/domains/pediatric-readiness-project/>

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<https://publications.aap.org/pediatrics/article/142/5/e20182459/38608/Pediatric-Readiness-in-the-Emergency-Department>

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https://forms.ihi.org/hubfs/Guide%20to%20Recognition%20for%20GEDA%20Sites_FINAL.pdf

safety.^{489,490,491,492,493,494} Similarly, staff training in pediatric readiness^{495,496,497} and geriatric readiness^{498,499,500,501,502} improves staff capabilities in caring for these populations as well as patient health and safety.

While the hospital Emergency Services CoP requires that “there must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility” (§ 482.55(b)(2)), CMS believes clearer expectations surrounding “qualified in emergency care” and maintenance of qualifications (that is, training) would improve facilities’ readiness to care for patients with emergency conditions, enhancing patient health and safety.

b. Proposal

Given CMS’ commitment to ensuring the health and safety of all emergency services

⁴⁸⁹ Burke SM, Schmitt T, Kennedy P, et al. Emergency Medicine Obstetrics and Gynecology: A Case-Based Curriculum for Residents. *MedEdPORTAL*. 2023;19:11330.

⁴⁹⁰ Espey E, Baty G, Rask J, Chungtuycy M, Pereda B, Leeman L. Emergency in the clinic: a simulation curriculum to improve outpatient safety. *Am J Obstet Gynecol*. Dec 2017;217(6):699.e1-699.e13.

⁴⁹¹ Cooper MI, Papanagnou D, Meguerdichian M, Bajaj K. Emergency Obstetrics for the Emergency Medicine Provider. *MedEdPORTAL*. October 13 2016;12:10481.

⁴⁹² Jacobs PJ. Using High-Fidelity Simulation and Video-Assisted Debriefing to Enhance Obstetrical Hemorrhage Mock Code Training. *J Nurses Prof Dev*. Sep/Oct 2017;33(5):234-239.

⁴⁹³ Hopmann P, Varre JS, Duncan G, Devoe WB, Gable BD. Multidisciplinary Simulation of Trauma in Pregnancy with Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Utilization. *Cureus*. December 2022; 14(12): e32820.

⁴⁹⁴ Harrington J, Duncan G, D. Angelo K G. Multidisciplinary Simulation Improves Resident Confidence for Pregnant Patients Requiring Surgical Intervention. *Cureus*. Mar 2022;14(3): e23454.

⁴⁹⁵ <https://pubmed.ncbi.nlm.nih.gov/31444254/>

⁴⁹⁶ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800400>

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<https://publications.aap.org/pediatrics/article/144/3/e20190568/76984/Emergency-Department-Pediatric-Readiness-and>

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<https://www.sciencedirect.com/science/article/pii/S0196064413015527?via%3Dihub>

⁴⁹⁹ <https://onlinelibrary.wiley.com/doi/10.1111/acem.13880>

⁵⁰⁰ <https://onlinelibrary.wiley.com/doi/10.1111/j.1741-6612.2010.00499.x>

⁵⁰¹

<https://www.sciencedirect.com/science/article/pii/S1525861021001961?via%3Dihub>

⁵⁰² <https://pubmed.ncbi.nlm.nih.gov/37389490/>

patients, including OB patients, we propose a new standard entitled “Emergency Services Readiness” within the existing Emergency Services CoP for hospitals (§ 482.55) and CAHs (§ 485.618) to set clear expectations as well as improve facility readiness in caring for emergency services patients, including pregnant, birthing, and postpartum patients. Notably, these requirements would apply to all hospitals and CAHs offering emergency services,⁵⁰³ whether or not a hospital/CAH offers an additional specialty service lines (such as OB services). This is done with the intention of ensuring baseline health, safety, and training standards for the care of patients with emergency conditions.

First for hospitals (§ 482.55(c)) and CAHs (§ 485.618(e)) that offer emergency services, we propose that these facilities would be required to have adequate provisions and protocols to meet the emergency needs of patients in accordance with the complexity and scope of services offered. For protocols, hospitals (§ 482.55(c)(1)) and CAHs (§ 485.618(e)(1)) must have protocols consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions. For example, facilities may utilize national medical professional society, accrediting organization, credentialing body, or other national guidelines to develop appropriate protocols for their emergency services patient populations. While these CoPs would not require adherence to a specific organization’s guideline or recommendations, we expect that facilities would be able to articulate their standards and the source(s) and to demonstrate that their standards are based on evidence and nationally recognized sources. The American College of Emergency Physicians, for instance, has issued multiple guidelines for best practices in managing common and critical emergency conditions and has developed a Geriatric Emergency Department Accreditation Program, which provides best practice standards for this

⁵⁰³ For purposes of this proposal, CMS considers a facility to “offer emergency services” when it meets the definition of “dedicated emergency department” as defined in EMTALA (42 CFR 489.24(b) “Dedicated emergency department”).”

at-risk population.^{504,505} For obstetrical emergencies, the Alliance for Innovation on Maternal Health's (AIM; a partnership between HRSA and American College of Obstetricians and Gynecologists (ACOG) and other stakeholders) has developed resources which include example protocols and training resources for responding to obstetrical hemorrhage, severe hypertension, perinatal mental health conditions, sepsis, substance use disorder, and cardiac conditions, among others.⁵⁰⁶ ACOG has also developed resources for Obstetric Emergencies in Nonobstetric Settings.⁵⁰⁷ Similarly, the HRSA-supported Emergency Medical Services for Children (EMSC) Innovation and Improvement Center has resources for emergency departments seeking to improve "pediatric readiness."⁵⁰⁸ We expect hospitals to be able to identify the source of the nationally recognized and evidence-based guidelines utilized in their protocols.

For hospitals (§ 482.55(c)(3)) and CAHs (§ 485.618(e)(2)) that offer emergency services, applicable emergency services personnel, as determined by the facility, would need to be trained on these protocols and provisions annually. However given the diversity of staff and services offered by hospitals and CAHs, we are not proposing which emergency services staff should be trained. Once staff are identified, hospitals and CAHs would be expected to document that applicable staff have successfully completed such facility-identified training and demonstrate staff knowledge on these topics.

Finally, for hospitals that offer emergency services, we further propose at § 482.55(c)(2) that provisions include equipment, supplies, and medication used in treating emergency cases. Such provisions must be kept at the hospital and be readily available for treating emergency cases. The available provisions must include: (1) drugs, blood and blood products, and biologicals commonly used in life-saving procedures; (2) equipment and supplies commonly

⁵⁰⁴ <https://www.acep.org/patient-care/clinical-policies>

⁵⁰⁵ <https://www.acep.org/geda>

⁵⁰⁶ <https://saferbirth.org/>

⁵⁰⁷ <https://www.acog.org/programs/obstetric-emergencies-in-nonobstetric-settings>

⁵⁰⁸ <https://emscimprovement.center/domains/pediatric-readiness-project/>

used in life-saving procedures; and (3) a call-in-system for each patient in each emergency services treatment area. These supply requirements are similar to existing CAHs (at § 485.618(b) and (c)) and REHs (at § 485.516(c)(2)) supply standards for emergency services, as well as the surgical services CoP supply requirements (§ 482.51(b)(3)). We are not proposing any new emergency services equipment, supplies, or medication requirements for CAHs or REHs. Of note, hospitals have the flexibility to contract for services (§ 482.12(e)), which could include procurement and storage of blood and blood products.

Like CAHs and REHs, hospitals would have flexibility in identifying and determining the type and necessary quantity of drugs, blood products, biologicals, equipment and supplies commonly used in emergency procedures needed to meet the needs of their patients. This CMS proposal does not require facilities to maintain supplies of particular drugs, biologicals, equipment, or supplies or amounts. Rather each facility would be expected to tailor their equipment and supplies to meet the needs of their patient populations, consistent with the needs, services, and resources of the facility. Examples of drugs and biologicals commonly used in life-saving procedures could include analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrhythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions. Supply and equipment commonly used in life-saving procedures could include airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters. Such standards would be consistent with existing CAH (§ 485.618(b) and (c)) and REH (§ 485.516(c)(2)) emergency services standards.

Lastly, the proposed requirement for a call-in-system for each patient in each emergency services treatment area is in line with the surgical services CoP (§ 482.51(b)(3)) and promotes patient safety by ensuring patients have a ready means of notifying staff of any emergencies or concerns.

c. Solicitation of Comments

We welcome public comments on the above enhancements to the existing emergency services standards for hospitals and CAHs. Our goal with this section's proposals is to improve the health and safety of all emergency services patients, including pregnant, birthing, and postpartum patients. We seek comments on how effectively these proposals would achieve this goal. We are additionally interested in data, evidence, and experience related to these proposals as well as any benefits, costs, and unintended consequences of the above policies. We welcome public input from a broad range of commenters, including but not limited to patients, community-based organizations, public health professionals, health care professionals, staff, hospitals, operators, and researchers. Specifically, we solicit public comments on the following questions:

- While REHs do have existing equipment, supply, and medication standards, should the above proposals related to provisions, protocols, and staff training apply to REHs as well?
- What would be the benefits versus burden of such an approach? How could any burdens be mitigated?

5. Transfer Protocols (§ 482.43)

a. Background

The Discharge Planning CoP for hospitals at § 482.43 currently require facilities to have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) in the process. The discharge planning CoP include standards for the discharge planning process, the provision and transmission of the patient's necessary medical information, and discharge to post-acute services. However, the hospital Discharge Planning CoP does not currently include baseline requirements related to patient transfers.

Errors can occur during hospital transfers, including incomplete or inaccurate communication at the time of transfer. This is associated with worse patient outcomes, including

delayed diagnoses, redundant tests, longer length of stays, and increased costs.⁵⁰⁹ Additionally, delays from the time a patient is accepted to another hospital to when they are transferred can be exacerbated by limited bed availability.⁵¹⁰ These delays can prevent patients from receiving the medical care they need in a timely manner. Establishing transfer protocols can enhance patient health and safety by ensuring consistent and thorough communication between healthcare providers, minimize the risks of errors, reduce delays, and ensure that patients receive timely and appropriate care.

Hospitals regularly encounter situations where they may be unable to provide the appropriate level of care to meet the needs of a patient and must transfer the patient to another facility. As noted previously, EMTALA (42 CFR 489.24) requires Medicare-participating hospitals with emergency departments to provide an appropriate medical screening examination to a presenting individual to determine whether an emergency medical condition exists. If the hospital determines that the individual has an emergency medical condition, the hospital must offer stabilizing treatment or, under certain circumstances, appropriately transfer such patients to receive stabilizing care that the originating hospital does not have the capability to provide.⁵¹¹ Roughly 20 percent of patients seen in U.S. emergency departments are admitted to the hospital as inpatients or transferred to a different facility.⁵¹² In 2018, about 2.8 percent of patients were transferred from the ED to another hospital. Lower-volume EDs had the highest transfer rates, at

⁵⁰⁹ Mueller S, Schnipper JL. Physician Perspectives on Interhospital Transfers. *J Patient Safety*. 2019 June; 15(2): 86-89. doi: 10.1097/PTS.0000000000000312

⁵¹⁰ Carroll M, Fanning C, Herrigel DJ, Parikh A, et al. Interhospital Transfer Handoff Practices Among US Tertiary Care Centers: A Descriptive Study. *J. Hosp Med*. 2017 Dec, 11(6): doi:10.1002/jhm.2577

⁵¹¹ <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-489/subpart-B/section-489.24>

⁵¹² American College of Emergency Physicians—ACEP Now (2019). Latest Data Reveal the ED's Role as Hospital Admission Gatekeeper. <https://www.acepnow.com/article/latest-data-reveal-theeds-role-as-hospital-admission-gatekeeper/>.

about 5 percent.⁵¹³ However, hospitals that do not have an emergency department or are otherwise not covered by EMTALA, may also have a need to transfer patients to other facilities to receive needed services. Additionally, patients that are admitted as hospital inpatients may require transfer between facilities to meet the needs of the patient (for example, changing clinical condition, need for specialty and/or higher level of care). It is estimated that each year, patient transfers between acute care hospitals make up approximately 3.5 percent of all hospital inpatient admissions (roughly 1.5 million admissions).⁵¹⁴

Existing CoPs for CAHs and REHs include requirements related to the transfer of patients in the event that the facility is unable to furnish needed services for a patient or the patient requires a higher level of care. For example, the CAH CoPs at § 485.616(a) require CAHs that are members of a rural health network to have an agreement in place with at least one hospital that is also a member of the network for patient transfer. Additionally, the discharge planning requirements at § 485.642(b) require CAHs to discharge, transfer, or refer the patient, where applicable, with all necessary medical information pertaining to the patient's condition. We require similar actions regarding patient transfers for REHs at § 485.538.

Efficient transfers to hospitals that can treat complex conditions and provide higher levels of care is critical for patients that are experiencing obstetrical emergencies or complications, or patients that require immediate post-delivery care. Elements of safe transfer would include: (1) risk identification and determination of conditions necessitating consultation, referral, and transfer; (2) mechanisms and procedures for transfer/transport to a higher-level hospital at all

⁵¹³ American College of Emergency Physicians—ACEP Now (2019). Latest Data Reveal the ED's Role as Hospital Admission Gatekeeper. <https://www.acepnow.com/article/latest-data-reveal-theeds-role-as-hospital-admission-gatekeeper/>.

⁵¹⁴Hernandez-Boussard T, Davies S, McDonald K, Wang NE. Interhospital Facility Transfers in the United States: A Nationwide Outcomes Study. *J Patient Saf.* 2017 Dec;13(4):187-191. doi: 10.1097/PTS.000000000000148. PMID: 25397857; PMCID: PMC4956577.

times; (3) a reliable, accurate, and comprehensive communication system between participating hospitals, hospital personnel, and transport teams.⁵¹⁵

b. Proposals

We believe that comprehensive discharge planning CoP for hospitals, including documented requirements for transfer protocols, will enhance this process and better protect the health and safety needs of all patients, including pregnant, birthing, and postpartum women. Having an established process with identified policies and procedures, and a medical staff that has received training regarding transfer protocols can support hospitals in expediting transfers when necessary. Therefore, we propose revisions to the hospital discharge planning regulations to include requirements for transfer protocols.

We propose at § 482.43(c) to require that hospitals have written policies and procedures for transferring patients under their care. This would be inclusive of hospital inpatients (for example, transfers from the emergency department to inpatient admission, transfers between inpatient units in the same hospital, as well as transfers between inpatient units at different hospitals). This would ensure patients are transferred to the appropriate level of care promptly and without undue delay, in order to meet their needs.

We also propose to require the hospital to provide training to the relevant staff (as determined by the facility) regarding the hospital policies and procedures for transferring patients under its care.

Although we have established requirements for certain facilities regarding patient transfers and propose standards for transfer protocols and training requirements here, in general hospitals are not required to accept or receive patients transferred from other facilities unless the receiving hospital has the capacity to treat the individual (42 CFR 489.24(f)). To ensure that

⁵¹⁵ <https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2019/08/levels-of-maternal-care>

patients receive the care their medical conditions require, we encourage all recipient hospitals to have policies and procedures in place regarding the acceptance of transfers and remind hospitals of their obligations to comply with EMTALA and Federal civil rights laws.⁵¹⁶ EMTALA requires hospitals with emergency departments to provide an appropriate medical screening examination to determine whether an emergency medical condition exists, provide stabilizing treatment if hospital determines that there is an emergency medical condition, and if necessary, to appropriately transfer individuals with an emergency medical condition as needed, whether or not the individual is eligible for Medicare benefits and regardless of ability to pay (42 CFR 489.24(a)). Federal civil rights laws prohibit discrimination based on an individual's race, color, national origin, sex, religion, disability, and age. Further, hospitals that have specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or, with respect to rural areas, regional referral centers) may not refuse to accept from a referring hospital an appropriate transfer of an individual who requires such specialized capabilities or facilities, if the receiving hospital has the capacity to treat the individual (42 CFR 489.24(f)). We solicit comments on these proposals.

We also solicit public comments on the following questions:

- How often should staff be trained in transfer protocols?
- What definitions or criteria exist to determine if a transfer is carried out “promptly and without undue delay”?
- Should hospitals be required to have written policies and procedures outlining their standards and conditions for accepting transfers?

⁵¹⁶ Recipients of Federal financial assistance must comply with Federal civil rights laws, including but not limited to Title VI of the Civil Rights Act of 1964 (45 CFR Part 80), Section 504 of the Rehabilitation Act of 1973 (45 CFR Part 84), The Age Discrimination Act (45 CFR Part 90), and Section 1557 of the Affordable Care Act (45 CFR Part 92).

- Should all hospitals (inclusive of CAHs and REHs) be required to have a documented partnership with another hospital that both provides OB services, as well as has a Medical Fetal Medicine (MFM) specialist available for consultations in urgent situations, if such service(s) are already offered directly by the hospital? What would be the benefits versus burden of such a policy? How could any burden be mitigated?

XXII. Modification to the Hybrid Hospital-Wide All-Cause Readmission and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measures in the Hospital Inpatient Quality Reporting Program

A. Background

We refer readers to the following final rules for detailed discussions of the history of the Hospital IQR Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set:

- The FY 2010 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) final rule (74 FR 43860 through 43861);
- The FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181);
- The FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 61653);
- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 38348);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509);
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959);

- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45360 through 45426);
- The FY 2023 IPPS/LTCH PPS final rule (87 FR 49190 through 49310); and
- The FY 2024 IPPS/LTCH PPS final rule (88 FR 59144 through 59203).

We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations and the FY 2025 IPPS/LTCH PPS proposed rule published on May 2, 2024 (89 FR 36306 through 36341).

B. Proposed Update to the Form, Time, and Manner Requirements for the Hybrid Hospital-Wide All-Cause Readmission (HWR) and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) Measures for the FY 2026 Payment Determination

1. Background of the Hybrid HWR and Hybrid HWM Measures in the Hospital IQR Program

The Hospital IQR Program previously adopted two hybrid measures: (1) the Hybrid Hospital-Wide Readmission (HWR) measure; and (2) the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure. Hybrid measures use more than one data source for measure calculation; specifically for the Hybrid HWR and Hybrid HWM measures, they use core clinical data elements (CCDEs), linking variables, and claims data (80 FR 49698). CCDEs are a set of clinical variables derived from electronic health records (EHRs) that can be used to risk adjust hospital outcome measures (80 FR 49699). Linking variables are administrative data that can be used to link or merge the CCDEs and administrative claims data for measure calculation (80 FR 49703). These measures are designed to enhance risk adjustment of administrative claims-based outcome measures by utilizing patient clinical data captured in EHRs (80 FR 49698).

We initially solicited public comment on the potential future adoption of hybrid measures into the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS final rule adoption (80 FR 49698 through 49704). In subsequent years, we adopted both the Hybrid HWR measure and the Hybrid HWM measure with initial voluntary reporting periods. A discussion of the measure history for both measures follows.

The Hybrid HWR was the first hybrid measure introduced into the Hospital IQR Program. The Hybrid HWR measure is designed to capture all unplanned readmissions that arise from acute clinical events requiring urgent rehospitalization within 30 days of discharge. The measure was adopted in a stepwise fashion starting with voluntary reporting periods. In the FY 2018 IPPS/LTCH PPS final rule, we finalized 6 months of voluntary reporting for the CY 2018 reporting period (82 FR 38350 through 38355). In the FY 2020 IPPS/LTCH PPS final rule, we finalized 2 additional years of voluntary reporting, followed by mandatory reporting impacting the FY 2026 payment determination (84 FR 42465 through 42479). Then, in the FY2024 IPPS/LTCH PPS final rule, we modified the Hybrid HWR measure cohort to include both Medicare fee-for-service (FFS) patients and Medicare Advantage (MA) patients 65 years and older for the FY 2027 payment determination and for subsequent years (88 FR 59161 through 59168).

The Hybrid HWM measure was the second hybrid measure to be adopted into the Hospital IQR Program. The Hybrid HWM measure is an outcome measure that captures the hospital-level, risk-standardized mortality rate (RSMR) of unplanned, all-cause mortality within 30 days of hospital admission for any eligible condition. Similar to the Hybrid HWR measure, we adopted the Hybrid HWM measure in a stepwise fashion, starting with a period of voluntary reporting. We initially adopted the Hybrid HWM measure in the FY 2022 IPPS/LTCH PPS final rule and finalized one voluntary reporting period followed by mandatory reporting impacting the FY 2026 payment determination (86 FR 45365 through 45374). Then in the FY 2024 IPPS/LTCH PPS final rule, we modified the Hybrid HWM measure cohort to include both Medicare fee-for-service (FFS) patients and Medicare Advantage (MA) patients 65 to 94 years old for the FY 2027 payment determination and for subsequent years (88 FR 59161 through 59168).

As previously noted, these hybrid measures use data from claims in combination with CCDEs and linking variables pulled from hospital EHRs. We require that hospitals submit

linking variables on 95 percent of hospital discharges (84 FR 42470; 86 FR 45371). The previously finalized linking variables are: (1) CMS Certification Number; (2) Health and Insurance Claims Number or Medicare Beneficiary Identifier; (3) Date of Birth; (4) Sex; (5) Admission date; and (6) Discharge date (84 FR 42469; 86 FR 45371). The previously finalized CCDEs are vital signs and laboratory results (84 FR 42469; 86 FR 45371). We also previously finalized that hospitals would be required to report CCDEs on 90 percent of discharges in a given reporting period (84 FR 42469; 86 FR 45371). These submission requirements were finalized beginning with mandatory reporting for the FY 2026 payment determination (84 FR 42469 through 42470; 86 FR 45371). We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42465 through 42479) and FY 2022 IPPS/LTCH PPS final rule (86 FR 45365 through 45374) for more information regarding data sources, measure calculation, and risk adjustment requirements. We also refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42506 through 42508), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58941), the CY 2021 PFS final rule (85 FR 84472), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45421) for our previously adopted policies regarding certification, file format, and data submission requirements for hybrid measures in the Hospital IQR Program. For both hybrid measures, hospitals are currently required to submit data for the mandatory reporting period impacting the FY 2026 payment determination, based on performance data from July 1, 2023 through June 30, 2024, by October 1, 2024 (86 FR 45370).

Under our stepwise approach when we adopted the hybrid measures, we finalized that data collected during the voluntary reporting periods would not be publicly reported (84 FR 42470; 86 FR 45371). We also finalized that we would begin public reporting of both hybrid measures' results, beginning with data collected from the July 1, 2023 through June 30, 2024 reporting period, impacting the FY 2026 payment determination (84 FR 42470 through 42471; 86 FR 45371).

2. Proposal to Extend Voluntary Reporting of CCDE and Linking Variable Data for the Hybrid HWR and Hybrid HWM Measures

Based on hospital performance during the most recent voluntary reporting period, it appears that hospitals are unprepared for mandatory reporting of the Hybrid HWR and Hybrid HWM measures. As a part of measure maintenance, we routinely monitor hospital performance on the Hospital IQR Program's measures. We have been closely monitoring the results of voluntary reporting for both hybrid measures, including most recently the results of the second voluntary period for Hybrid HWR and the first voluntary period for Hybrid HWM. During these periods, approximately one-third of IPPS hospitals participated. The data currently indicate that three-fourths of the participating hospitals would not have met the reporting thresholds for the CCDEs and linking variables if the reporting requirement had been mandatory, and accordingly, would have been subject to a one quarter reduction to their annual payment update under the Hospital IQR Program for the given fiscal year.

The hospitals that participated in the voluntary reporting were mostly large, non-rural, non-critical access, and non-safety net. Based on our experience with implementing new types of digital measures, we understand that small and rural hospitals, as well as hospitals with fewer financial resources, may need additional time and flexibility to successfully implement new measure reporting requirements relative to larger, non-rural hospitals (82 FR 38357). We therefore believe the reporting failure rate may have been even higher if all IPPS hospitals participated.

In addition, we received feedback from hospitals (via email and help desk questions) raising various issues with reporting including issues related to CCDE collection timing and clinical workflow, issues with the types of units required for CCDE values, and achievability of the data submission requirement thresholds. We are investigating whether any of these issues or any other issues may be making it difficult for hospitals to meet CCDE and linking variable

thresholds (that is, of 90 percent and 95 percent, respectively, of hospital discharges), and need additional time to analyze and identify the root cause of these challenges.

We appreciate that, in light of the information discussed above, hospitals participating in the Hospital IQR Program may need an additional year to remediate the issues and develop experience with reporting of CCDEs and linking variables before being subject to the associated program payment adjustments for noncompliance. We therefore propose that for the FY 2026 payment determination (based on performance data from July 1, 2023 through June 30, 2024), the submission of CCDEs and linking variables would remain voluntary. We propose that for the FY 2027 payment determination and subsequent years, the submission of CCDEs and linking variables become mandatory.

Under our proposal, a hospital's annual payment determination for FY 2026 would not be affected by the voluntary reporting of CCDEs and linking variables, although we would still evaluate and assess the claims data portion of these measures. The Hybrid HWR and Hybrid HWM measures would be publicly reported based on claims data. This proposal would allow the Hospital IQR Program to publicly display hospital information on these important clinical areas and provide patients with visibility into hospital performance, while providing hospitals with more time to improve reporting on CCDEs and linking variables. Hospitals would continue to receive confidential hospital-specific reports in the Spring as a preview of public reporting. We note that the hospital-specific reports would reflect the CCDEs and linking variables, should hospitals choose to submit them. We continue to evaluate potential changes to the reporting requirements related to CCDEs and linking variables.

We invite public comment on our proposal to continue voluntary reporting of the CCDEs and linking variables for both the Hybrid HWR and Hybrid HWM measures, for the performance period of July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination for the Hospital IQR Program. We specifically request feedback regarding the difficulties hospitals

have in meeting the thresholds and any recommendations hospitals may have based on their experiences reporting on hybrid measures.

XXIII. Individuals Currently or Formerly in the Custody of Penal Authorities

A. Medicare FFS No Legal Obligation to Pay Payment Exclusion and Incarceration (revisions to 42 CFR 411.4)

1. Background

Section 1862(a)(2) of the Act prohibits Medicare payment under Part A or Part B for any expenses incurred for items or services for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services. We refer to this payment exclusion as the "no legal obligation to pay" payment exclusion. The no legal obligation to pay payment exclusion is codified in regulation at § 411.4. The regulatory exclusion includes a general rule at § 411.4(a) that applies to all services (except as provided in § 411.8(b)) and a special condition at § 411.4(b) for services furnished to individuals in custody of penal authorities.

In the 1989 final rule establishing the special condition at § 411.4(b) for services furnished to individuals in custody of penal authorities, we explained that the purpose of § 411.4(b) is to clarify how the no legal obligation to pay payment exclusion applies to services furnished to prisoners (see 54 FR 41716, 41723 (Oct. 11, 1989)) ("1989 final rule"). We explained that prisoners generally have the status of public charges and, as such, have no obligation to pay for the medical care they receive. Consequently, under the statutory no legal obligation to pay payment exclusion, Medicare is prohibited for paying for such care. We noted, however, that in certain circumstances prisoners could have a legal obligation to pay for health care items or services they receive, and in such circumstances, Medicare may pay for the items or services.

As finalized in the 1989 final rule, the special rule at § 411.4(b) specifies the conditions that must be satisfied to establish that a prisoner has a legal obligation to pay for health care items or services, and thus that Medicare may pay for such items or services. Specifically, § 411.4(b) provides that Medicare may pay for services furnished to individuals in custody of police or other penal authorities or in the custody of a government agency under a penal statute only if the following conditions are met: (1) State or local law must require individuals in custody to repay the cost of the medical services they receive while in custody; and (2) the State or local government must enforce the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts.

In 2007, we added a definition of “custody” to the special condition at § 411.4(b) for services furnished to individuals in custody of penal authorities (see 72 FR 47130, 47405 through 47406 (Aug. 22, 2007)) (“2007 final rule”). We noted that CMS would not defer to a particular State or local government’s definition or interpretation of what constitutes “custody.” Instead, we adopted a definition of “custody” that is consistent with how the term has been defined by Federal courts for purposes of the habeas corpus protections of the U.S. Constitution. As finalized, § 411.4(b) provides that individuals who are in custody include, but are not limited to, individuals who are under arrest, incarcerated, imprisoned, escaped from confinement, under supervised release, on medical furlough, required to reside in mental health facilities, required to reside in halfway houses, required to live under home detention, or confined completely or partially in any way under a penal statute or rule. We explained that, under this description, individuals who are on parole, probation, bail, or supervised release may be in custody for purposes of the payment exclusion. We also stressed that individuals who are under supervised release for the purpose of receiving medical services on so-called “medical furlough,” and who are required to return to a State or local government facility after the medical services are

furnished, are considered to be in custody for purposes of the no legal obligation to pay payment exclusion.

In the 2007 final rule, we responded to several commenters who objected to the breadth of the definition of custody that we adopted. The commenters maintained that the policy would place an unreasonable burden on hospitals, because hospitals often have no means of identifying whether an individual is in custody for purposes of § 411.4(b) if the individual is not physically confined in a correctional facility or brought to the hospital by government authorities. Another commenter added that a hospital has no way of knowing whether an individual who is in custody for purposes of § 411.4(b) has a legal obligation to pay for his or her medical care. In response, we stated that hospitals are not required to seek criminal histories or do background checks on all patients being registered. We explained that, if Medicare denies payment because the individual receiving care is in custody of penal authorities, the provider or supplier will be directed to seek payment from the State or local government that has custody of the individual. We concluded that, if the State or local government believes in such circumstances that it is not responsible for the care provided to the individual, it should be prepared to prove to Medicare either that the individual would not be considered to be in custody under Federal habeas corpus law or that the State or local government has no legal obligation to pay for the services because the conditions in § 411.4(b)(1) and (b)(2) are satisfied.

There have been no further revisions to § 411.4 since it was revised in 2007.

2. Proposal

a. Overview of proposed changes

The special condition at § 411.4(b) for services furnished to individuals in custody of penal authorities operates as a rebuttable presumption. The presumption is that individuals who are in custody, as the term is described in §411.4(b), have no legal obligation to pay for health care items or services they receive while in custody; therefore, Medicare is prohibited from paying for such health care items or services under the no legal obligation to pay payment

exclusion. The presumption can be rebutted by a showing that: (1) the State or local government requires individuals in custody to repay the cost of the medical services they receive while in custody; and (2) the State or local government enforces the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts.

We propose to narrow the description of “custody” in § 411.4(b), because, as explained in greater detail below, we no longer believe that certain classes of individuals should be presumed to be in custody for purposes of the no legal obligation to pay payment exclusion. Specifically, we propose to remove individuals who are under supervised release or required to live under home detention from the description of “custody” in § 411.4(b), and we propose to strike the phrase “or confined completely or partially in any way under a penal statute or rule.” We are also seeking comments on a proposal, described in greater detail below, to determine when individuals who are required to reside in halfway houses should be considered to be in custody for purposes of the no legal obligation to pay payment exclusion.

In addition to the proposed changes to the description of “custody,” we are also taking this opportunity to reorganize and renumber the regulation at § 411.4(b). Currently, § 411.4(b) includes both a description of “custody” and a statement of the conditions that must be satisfied for payment to be made under Medicare for items or services furnished to individuals in custody of penal authorities. Our proposed reorganization would separately codify the description of “custody” and the special conditions for payments. Specifically, at proposed §§ 411.4(b)(1)(i) through 411.4(b)(1)(iii), we propose to state the conditions that must be satisfied for Medicare to pay for items or services furnished to an individual in custody of penal authorities; we also propose certain non-substantive edits to the regulatory language adopted from current § 411.4(b). At proposed § 411.4(b)(2), we propose a definition of “penal authority” that would apply

generally to § 411.4(b). At § 411.4(b)(3), we propose a description of “custody” that is narrower in scope than the current description.

In addition to these proposed changes, which are discussed in greater detail below, we are making certain non-substantive edits to § 411.4(a) to align the regulatory text with the statutory no legal obligation to pay payment exclusion at section 1862(a)(2) of the Act. Specifically, where the statute refers to items and services, the current regulation refers only to services; consistent with the statute, we propose to refer to both items and services in the regulatory text. We are also adding a reference to Federally Qualified Health Center services at § 411.4(a) to align with the statute. The regulatory text at § 411.4(a)(2) currently states that no other person or organization has a legal obligation to pay, whereas the statute refers only to a person; we propose to delete “organization” from the regulation because the term “person” includes both natural and non-natural persons, and the term “organization” is therefore superfluous. We also propose to align the parenthetical in § 411.4(a)(2) with the statutory parenthetical and to replace the term “beneficiary” in §§ 411.4(a)(1) and 411.4(a)(2) with “individual,” to align with section 1862(a)(2) of the Act.

We also propose to redesignate the special conditions that are specified in §§ 411.4(b)(1) and 411.4(b)(2) as §§ 411.4(b)(1)(i) through 411.4(b)(1)(iii). Under the proposal, the rebuttable presumption in § 411.4(b)(1) would apply to all items or services furnished to individuals in custody of penal authorities, regardless of who provides the items or services. We are seeking comments on whether the scope of the rebuttable presumption in proposed § 411.4(b)(1) should be limited to items or services furnished by the penal authority or by a third party with which the penal authority has arranged to provide the items or services. Were we to limit the scope of the rebuttable presumption in this way, the rebuttable presumption in proposed § 411.4(b)(1) would not apply to items or services furnished to individuals in custody of penal authorities by third parties who do not have an arrangement or contract with the penal authority to provide the items or services. We are also seeking comments on whether individuals in custody of penal

authorities are permitted to arrange for their own health care with third parties who do not have an agreement with the penal authority to provide the items or services.

Lastly, we propose at proposed § 411.4(b)(3)(v) to clarify that an individual who is required to reside in a mental health facility would only be considered to be in custody under the no legal obligation to pay payment exclusion if the individual is required to reside in such a facility under a penal statute or rule.

b. Description of “custody” – proposed § 411.4(b)(3)

We propose to redesignate the description of “custody” as § 411.4(b)(3), to remove individuals who are on supervised release and home detention from the current description of “custody,” and to strike the phrase “completely or partially in any way under a penal statute or rule.” (We are also seeking comments on a separate proposal for individuals residing in halfway houses; this proposal is discussed below at section c.) Under the proposal, individuals who have been lawfully released from confinement in jail, prison, penitentiary, or similar institution, or released following arrest (that is, the individuals are no longer physically detained by law enforcement or penal authorities) on bail, parole, probation, or home detention would not be presumed to be in custody for purposes of the no legal obligation to pay payment exclusion, even if such individuals are required to return to jail, prison, penitentiary, or similar institution at some later time (for example, due to conviction or failure to satisfy the conditions of their supervised release). However, individuals who are on “medical furlough” or similar arrangements (that is, the individuals are under the control of law enforcement or penal authorities and required to return to jail or prison after medical services have been provided) would still be considered in custody for purposes of § 411.4(b)(3). Given the differences in terminology used by various Federal, State, and local government penal authorities to refer to different levels of control and confinement in the criminal justice system, we are seeking comments on the appropriateness of the terminology in the existing description of “custody” in our regulations and whether additional or different terminology should be incorporated in the description of “custody” at

§ 411.4(b)(3) in the final rule. We are also seeking comment on whether we should explicitly state in regulatory text that individuals on bail, parole, probation, or home confinement are not considered to be in custody for purposes of proposed § 411.4(b).

We propose to narrow the description of custody in § 411.4(b)(3) for several reasons. First, we believe that individuals who have been released from jail or prison on bail, parole, probation, or home detention typically have a legal obligation to pay for the health care items or services they receive. We do not believe that such individuals have the status of public charges, and we do not believe that Federal, State, or local government law enforcement or penal authorities are typically responsible for providing for the health care of such individuals. Therefore, we no longer believe that such individuals (and the providers and suppliers who furnish services to them) should have the burden to prove that the special conditions in existing §§ 411.4(b)(1) and 411.4(b)(2) have been satisfied in order to receive payment from Medicare. We are seeking specific, detailed comments on the circumstances in which individuals who have been released from incarceration on bail, parole, probation, or home detention have a legal obligation to pay for some or all of the health care items or services they receive. We are also seeking comment on what specific health care items or services, if any, are typically furnished by Federal, State, or local governments at no cost to individuals who have been released from jail or prison on bail, parole, probation, or home detention.

We also propose to narrow the description of “custody” in § 411.4(b) to remove barriers to access to Medicare by individuals who are returning to the community after incarceration. According to advocates, confusion about the applicability of the payment exclusion has led individuals released from incarceration to not apply for Medicare, even if they are eligible, or to apply only for Medicaid, because they believe that Medicare will not pay for items or services that they receive under the payment exclusion. Advocates have also maintained that certain providers or suppliers may be hesitant or refuse to treat individuals who are on bail, parole, probation, or home detention because the providers or suppliers believe that Medicare payment is

not available for items or services provided to such individuals. As a result, such individuals may delay or forgo necessary treatment, including treatment for substance use disorders, upon release from incarceration. The proposed changes to the description of “custody” would clarify that Medicare may pay for health care items and services furnished to an individual while on bail, parole, probation, or home detention, provided the individual has a legal obligation to pay for such items or services, without having to prove that the special conditions in § 411.4(b)(1) have been satisfied. (See section XII.2 of this proposed rule for a discussion of proposed modifications to the special enrollment periods (SEP) for formerly incarcerated individuals under §§ 406.27(d) and 407.23(d) that would also increase access to Medicare for individuals returning to the community from incarceration.)

Finally, our proposal to narrow the description of “custody” in § 411.4(b) would bring the Medicare no legal obligation to pay payment exclusion into greater alignment with certain related Social Security and Medicaid provisions. CMS relies on data provided by the Social Security Administration to identify individuals who are in custody of penal authorities. However, under Social Security regulations, individuals who are released from incarceration on parole, probation, or home detention are generally not considered to be confined for purposes of a limitation on payment of certain benefits (see section 202(x)(1) of the Social Security Act (42 USC § 402)), and the Social Security data does not track such individuals. Our proposal to narrow the description of “custody” would improve the alignment between the no legal obligation to pay regulation at § 411.4(b) and the data that is used to help carry out the rule. We note, however, that there would still be substantive differences between the Social Security definition of “confinement” and the proposed description of “custody” at § 411.4(b)(3). Most notably, the Social Security Administration suspends benefits if the individual has been convicted of a criminal offense and sentenced to a period of confinement, and based on that conviction remains confined for more than 30 days. In contrast, under proposed § 411.4(b)(3), an individual is considered to be in custody of penal authorities for purposes of the Medicare no

legal obligation to pay payment exclusion if the individual is under arrest; confined in jail, prison, penitentiary, or similar institution while awaiting trial (that is, the person has not yet been convicted); or confined in jail, prison, penitentiary, or similar institution following conviction for any period of time, including sentences of less than 30 days. We note these differences are a result of Medicare's statutory no legal obligation to pay payment exclusion. Specifically, we believe that individuals who are confined to jail while awaiting trial typically do not have a legal obligation to pay for health care items or services. We seek comments on whether such individuals confined to jail while awaiting trial typically pay for health care items or services they receive or have a legal obligation to do so.

Our proposal to narrow the description of "custody" in § 411.4(b)(3) would also bring the Medicare no legal obligation to pay payment exclusion into closer alignment with Medicaid. Under Medicaid regulations, Federal Financial Participation (FFP) is not available for services provided to individuals who are inmates of public institutions (see § 435.1009), and an "inmate of a public institution is defined generally as "a person living in a public institution" (see § 435.1010). According to Medicaid State Health Official Letter (SHO) # 16-007, however, individuals who are on parole, probation, or home confinement are generally not considered to be inmates for purposes of Medicaid (see SHO # 16-007 (RE: To facilitate successful re-entry for individuals transitioning from incarceration to their communities) (April 28, 2016)). By no longer including such individuals in the Medicare description of "custody" at § 411.4(b)(3), our proposal would improve dually eligible individuals' access to both Medicare and, potentially, Medicaid, including accessing benefits for already-enrolled individual. For example, advocates have shared anecdotally that some Medicaid agencies automatically suspend payment for services to an individual whose Medicare benefits are suspended due to a presumption that the individual is in custody. In addition, according to advocates, some individuals who are recently released from jail or prison on bail, parole, probation, or home detention have only enrolled in Medicaid, because they believe, even where they have a legal obligation to pay, that Medicare

will not pay for their health care under the no legal obligation to pay payment exclusion. Our proposal to narrow the description of “custody” in § 411.4(b)(3) is intended to remove this real or perceived barrier to Medicare access.

We caution that, even if we finalize the proposed modification of the description of “custody” in § 411.4(b)(3), the generally applicable no legal obligation to pay payment exclusion at § 411.4(a) would continue to apply to services furnished to individuals on bail, parole, probation, or home detention in the same way it applies to any other Medicare beneficiary who receives an item or service where there is no legal obligation to pay. The no legal obligation to pay payment exclusion in §411.4(a) is a general rule that is applicable to *all* health care items or services (except Federally qualified health center services and as provided in § 411.8(b)) received by any Medicare beneficiary, regardless of whether the individual is in custody of penal authorities. Nothing in the proposed modification of the special condition at § 411.4(b) would affect the scope of the general rule at § 411.4(a). Thus, if an individual on bail, parole, probation, or home detention has no legal obligation to pay for a health care item or service, the general rule at § 411.4(a) would continue to prohibit Medicare from paying for such a service, regardless of the scope of the description of “custody” in § 411.4(b)(3). For example, if a State or local government requires substance use disorder counseling as a condition of parole, and the State or local government does not charge all parolees for such services, then the parolee has no legal obligation to pay for such service under § 411.4(a); therefore, Medicare is prohibited under § 411.4(a) from paying for the service. We are seeking comments on what types of medically necessary health care items or services, if any, are typically provided at no cost to individuals on parole, probation, or home detention.

c. Halfway houses

According to the National Institute of Justice (NIJ), a research, development, and evaluation agency of the U.S. Department of Justice, the term “halfway house” usually refers to temporary housing, provided in a community-based residential facility, which uses around-the-

clock supervision and offers services to assist with the transition from incarceration to the community (see <https://crimesolutions.ojp.gov/ratedpractices/90#1-0>). The NIJ notes that, although the degree to which services are provided to residents varies significantly among halfway house programs, the following characteristics are common to most halfway houses: (1) constant supervision and daily contact between staff and returning individuals; (2) a requirement for participants to abide by rules (such as curfews and drug testing); and (3) access to employment, education, life skills training, and additional services as needed (such as substance use disorder treatment and counseling).

As the name suggests, halfway houses occupy a middle ground between complete custodial incarceration and unconditional release, and there appears to be wide variation in the degree of control exercised over halfway house residents in various State, local, and Federal facilities. We are therefore soliciting comments on whether halfway house residents typically have a legal obligation to pay for health care items and services, and if so, to what extent (that is, do they have a legal obligation to pay for all or most health care items or services, or only certain items or services) and under what conditions. In particular, we are interested in receiving detailed comments, with examples as appropriate, focusing specifically on the legal obligation that halfway house residents have to pay for the health care items and services they receive.

To provide greater focus for our comment solicitation on halfway houses, we propose regulatory text at § 411.4(b)(3)(vi) that is drawn from the Medicaid payment exclusion rule at § 435.1009. As explained in SHO # 16-007, FFP is available for services furnished to Medicaid-eligible individuals living in halfway houses, provided the following conditions are met: (1) residents are not precluded from working outside the facility in employment available to individuals who are not under justice system supervision; (2) residents can use community resources (libraries, grocery stores, recreation, education, etc.) at will; and (3) residents can seek health care treatment in the broader community to the same or similar extent as other Medicaid enrollees in the state. SHO # 16-007 adds that “at will” is consistent with certain house rule

restrictions and travel limitations, and stipulates that the State Medicaid agency must ensure that the halfway house meets the requirements enumerated above.

Consistent with Medicaid guidance, we propose at § 411.4(b)(3)(vi) to consider an individual to be in custody for purposes of the special condition for payment at § 411.4(b) if the individual is required to reside in a halfway house under any of the following conditions: residents are precluded from working outside the facility in employment that is available to individuals who are not under penal authority supervision; residents may not use community resources (for example, libraries, grocery stores, recreation, or educational institutions) at will; or residents may not seek health care items and services in the broader community to the same or similar extent as individuals who are not under penal authority supervision. Like Medicaid, we would interpret “at will” to be consistent with certain house rule restrictions and travel limitations. Our proposal to align the Medicare no legal obligation to pay payment exclusion at § 411.4(b) with Medicaid guidance would facilitate access to Medicare for dually eligible individuals returning to the community from incarceration and residing in halfway houses.

Consistent with our discussion above regarding bail, parole, probation, and home detention, we note that the general no legal obligation to pay payment exclusion at § 411.4(a) would continue to apply to services furnished to individuals in halfway houses even if those individuals do not meet any of the conditions in proposed § 411.4(b)(3)(vi) and thus are not considered to be in custody for purposes of § 411.4(b). If an individual has no legal obligation to pay for a health care item or service, then Medicare may not pay for the item or service.

We are seeking comments on whether individuals who reside in halfway houses under the conditions described in proposed § 411.4(b)(3)(vi) typically do not have a legal obligation to pay for health care items or services, or whether fewer, other, or additional factors compared to the factors described in the proposal would form a more appropriate basis for a presumption that the individual is in custody and has no legal obligation to pay for health care items or services.

d. Definition of penal authority – proposed § 411.4(b)(2)

As noted above, we propose to reorganize § 411.4(b) to separately codify the special conditions under which payment may be for items or services provided to an individual in custody at §§ 411.4(b)(1)(i) through 411.4(b)(1)(iii) and the description of “custody” at § 411.4(b)(3). We also propose to define “penal authority” at § 411.4(b)(2) as a police department or other law enforcement agency, a government agency operating under a penal statute, or a State, local or Federal jail, prison, penitentiary, or similar institution. We are aware that private contractors in some circumstances may be responsible for operating certain penal institutions or halfway houses, and we are seeking comment on whether such contractors should explicitly be included in the proposed definition of “penal authority.” The proposed definition is intended to be broad enough to include all agencies or institutions that might place or hold an individual in custody, as the term is described at proposed § 411.4(b)(3), regardless of whether the individual has been convicted of a crime. We are aware that the term “penal authority” does not appear to be commonly used outside of the Medicare context. We are seeking comments on whether other terminology would be more appropriate or would align more closely with terms commonly used in the criminal justice system. We are also seeking comments on whether the proposed definition of “penal authority” is too broad or narrow for purposes of the no legal obligation to pay payment exclusion.

B. Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals

1. Background

The Consolidated Appropriations Act, 2021 provided the authority to establish Medicare Part A and B special enrollment periods (SEP) for individuals due to exceptional conditions. In the final rule titled “Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules” which appeared in the **Federal Register** on November 3, 2022 (87 FR 66454), CMS used this authority to establish an SEP for formerly incarcerated individuals. Individuals who use this SEP are able to enroll in Medicare Premium Part A and Part B and avoid potential gaps in

coverage and late enrollment penalties (LEPs). As established in §§ 406.27(d)(1) and 407.23(d)(1), an individual is eligible to enroll in Medicare Parts A and/or B using this SEP so long as they demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Parts A and/or B due to being in custody of penal authorities, and there is a record of release either through discharge documents or data available to the Social Security Administration (SSA). The SEP provisions at §§ 406.27(d) and 407.23(d) incorporate the description of ‘in custody of penal authorities’ from the payment exclusion parameters already established in § 411.4(b). In the November 2022 final rule, we stated that it was important to align the scope of the SEP with the scope of individuals specified in § 411.4(b) as individuals in custody of penal authorities; alignment with § 411.4(b) provides a measure of assurance that individuals who are no longer subject to the payment exclusion are able to enroll in Medicare (Part B and, if necessary, premium Part A). We also noted that we would continue to assess the impact of alignment of the SEP with the scope of the payment exclusion. (87 FR 66464).

2. Proposal

Section 202 of the Act generally provides the basis for SSA to determine an individual’s eligibility for old age, survivors, and disability insurance (OASDI) benefits, also known as social security benefits, under Title II of the Act. For most Medicare beneficiaries, entitlement to Medicare Part A is based on entitlement to OASDI benefits under Title II per section 226 of the Act.⁵¹⁷ In addition, the SSA is responsible for determining entitlement to Part A and eligibility for Part B of Medicare. (See Pub. L. 103-296, sec. 105.) Section 202(x) of the Act suspends payment of OASDI benefits to prisoners, certain other inmates of publicly funded institutions, fugitives, probationers, and parolees, including when an individual is confined in a jail, prison, or other penal institution or correctional facility pursuant to conviction of a criminal offense for a

⁵¹⁷ For more detailed information about entitlement and eligibility for Medicare, please refer to sections 226, 226A, 1818, 1818A, 1836, and 1881A of the Act and 42 CFR Parts 406 and 407.

period of more than 30 days. We propose to amend the SEP at §§ 406.27(d)(1) and 407.23(d)(1) to align the SEP triggering event more closely with the bases on which an individual's OASDI benefit is reinstated or initiated rather than on the scope of the Medicare payment exclusion in § 411.4(b). We believe that these proposed amendments would streamline the administrative process for determining an individual eligible for this SEP and align eligibility for this SEP with an individual's obligation and ability to pay for services that would otherwise be covered by Medicare. Furthermore, we believe that the alignment of this SEP with the initiation or reinstatement of OASDI benefits is appropriate, as it allows a population facing many challenges reintegrating into society to enroll or reenroll in Medicare by having premiums deducted from their OASDI benefits, rather than paying out of pocket.

The proposed amendments to § 411.4(b), discussed in section XXIII.A of this proposed rule, would narrow the list of settings where an individual is presumed to have no obligation to pay for Medicare-covered items and services - and, thus, Medicare is prohibited from paying for those services - because the individual is in custody of a penal authority. The rebuttable presumption at § 411.4(b) provides the individual an opportunity to indicate to CMS that the other entity did not cover certain items or services and ask that Medicare provide payment, but this option is moot if the individual is not able to enroll in Medicare. (See section XXIII.A of this proposed rule for more information about the rebuttable presumption and operation of the payment exclusion.) Under the current version of this SEP, beneficiary advocate groups raised concerns about the possibility for scenarios where an individual is not able to enroll when their items and services could be covered by Medicare, or they are able to enroll (and pay monthly premiums) but Medicare is not able to pay for their services.

In making determinations about the suspension of OASDI benefits due to an individual's incarceration, SSA uses data it collects from jails, prisons, other penal institutions or correctional facilities and certain mental health institutions regarding individuals confined in those and similar institutions for the reasons outlined in section 202(x)(1)(A) of the Act. *See SSA System*

of Records Notice: Prisoner Update Processing System 60-0269, at 64 FR 11076 (Mar. 8, 1999) and updated at 72 FR 69723 (Dec. 10, 2007), 78 FR 40542 (Jul. 5, 2013) and 83 FR 54969 (Nov. 1, 2018). However, information about individuals within the full scope of the current provisions at § 411.4(b), including not only individuals who are confined in certain institutions but also individuals who are under arrest but not yet convicted, on medical furlough, or residing in half-way houses may not be as extensively or reliably available. As a result, making eligibility determinations for the SEP for Formerly Incarcerated Individuals as it is currently drafted is operationally difficult. In addition, the current SEP for Formerly Incarcerated Individuals incorporates the rebuttable presumption that is included in § 411.4(b) for situations where an individual (or healthcare provider seeking to bill Medicare for the services) can demonstrate that state or local law requires individuals to repay the cost of medical services while they are in custody and the state or local government entity enforces the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts. However, SSA does not have a role in administering the Medicare payment exclusion in § 411.4(b). Therefore, there is a high likelihood of potential inconsistency and administrative burden with tying the implementation of the SEP at §§ 406.27(d)(1) and 407.23(d)(1) to the Medicare payment exclusion under § 411.4(b).

Although the proposed changes to § 411.4(b) discussed in section XXIII.A to narrow the scope of the payment exclusion would flow through to §§ 406.27(d) and 407.23(d) without amendment to the SEP parameters, we believe that addressing the rebuttable presumption and potential administration burden is appropriate and will reduce potential confusion.

Further, since the establishment of the SEP in January 2023, we have received feedback that raised concerns about tying SEP eligibility to the Medicare payment definition at § 411.4(b) and how SSA has begun administering the SEP using the data in SSA's systems. We have heard that the SEP eligibility parameters are confusing and potentially prevent or discourage eligible

individuals from accessing the SEP. Conversely, situations may arise in which an individual is enrolled in Medicare using the SEP due to SSA data; however, due to the payment exclusion and limited exceptions for these settings, claims for health care may not be paid even if the specific state or local government does not provide health care in this type of setting.

Under our proposal, we intend that SSA would make a determination of an individual's eligibility to enroll using the Medicare SEP at §§ 406.27(d)(1) and 407.23(d)(1) based on the data SSA collects and keeps in its systems for determining OASDI benefit suspensions and any additional documentation provided by individuals to demonstrate that they have been released from incarceration. By more closely aligning the eligibility criteria for the SEP for Formerly Incarcerated Individuals with the data used by SSA in applying the OASDI benefit suspension requirement in section 202(x)(1)(A) of the Act, we intend that the SEP can be more efficiently and accurately administered. With the proposed revisions, the SEP at §§ 406.27(d) and 407.23(d) will provide an opportunity, beginning January 1, 2025, for an individual to enroll in Medicare if the individual was released from incarceration on or after January 1, 2023, failed to enroll in Medicare (Premium Part A or Part B) due to being incarcerated, and is still within the 12-month SEP described in §§ 406.27(d) and 407.23(d).

Overall, we propose to revise the eligibility requirements at §§ 406.27(d) and 407.23(d), beginning January 1, 2025, to remove the use of a release from the “custody of penal authorities as described in § 411.4(b)” and instead tie the eligibility for this SEP to whether an individual is “released from confinement in a jail, prison, or other penal institution or correctional facility,” which is phrasing that is more consistent with section 202(x)(1)(A)(i) of the Act. However, we are not proposing that a criminal conviction or formal sentencing be required for an individual to have been confined in a jail, prison, or other penal institution or correctional facility because conviction of crime is not required for the payment exclusion in § 411.4(b) to apply. As this differs from the requirements under section 202(x)(1)(A) of the Act, we also solicit comment on what documentation an individual can provide to demonstrate they were confined and released

without conviction to determine eligibility for the SEP for formerly incarcerated individuals under §§ 406.27(d) and 407.23(d). Further, individuals who have escaped confinement are not considered to be “released” from confinement. Under our proposal, both §§ 406.27(d) and 407.23(d) would use the terms “incarcerated” and “incarceration” as a general reference for individuals who meet either standard. This proposed change in the eligibility criteria for the SEP for Formerly Incarcerated Individuals would align more closely with the standards SSA uses to determine whether an individual is within the scope of the limitation on payment of OASDI benefits established by section 202(x)(1)(A)(i) of the Act.

In the rulemaking to adopt and finalize §§ 406.27(d) and 407.23(d), we did not fully contemplate the implications of tying the SEP’s eligibility criteria to the Medicare no legal obligation to pay payment exclusion (which includes a rebuttable presumption). A rebuttable presumption like the one available under the payment exclusion does not work well in enrollment context because although payment can be determined at the service level, an enrollment is either effectuated or not. It may be that for some services, the presumption that the individual has no legal obligation to pay can be rebutted while for other services it is not rebutted based on the scope of the state or local entity’s policies and the individual’s (or the healthcare providers) ability to provide sufficient evidence. However, enrollment in Medicare, including the obligation to pay Medicare premiums, would not vary with the specific service. While the proposed changes to § 411.4(b) would narrow the range of settings in which an individual is presumed to be in custody and another entity is responsible for the individual’s health care coverage, we believe that the proposed revisions to §§ 406.27(d) and 407.23(d) would best address concerns about access to and confusion with the SEP for individuals who have been released from incarceration.

We propose several changes to §§ 406.27(d) and 407.23(d) to significantly align the SEP eligibility criteria, beginning January 1, 2025, with the criteria used by SSA to determine whether an individual is incarcerated. Throughout, our proposed changes are largely to replace

references to an individual being in custody of penal authorities as described in § 411.4(b) with references to an individual's confinement in a jail, prison, or other penal institution or correctional facility. First, we propose to amend the introductory text in paragraph (d) of both §§ 406.27 and 407.23 to state the general rule that there is an SEP for Medicare eligible individuals who are no longer incarcerated after January 1, 2023. We use "incarcerated" and "incarceration" in this introductory language and in paragraph (d)(3), respectively, to include both being in custody of penal authorities as described in § 411.4(b) (and in the proposed revisions to paragraph (d)(1) of each regulation regarding the current scope of the SEP) and being confined as described in our proposed amendments to paragraph (d)(2) of each regulation. Using the term "incarcerated" is consistent with how these regulations were originally established and leads to more streamlined and less repetitive regulation text. We are seeking comments on this proposal, especially its implications for people in halfway houses, to ensure access to the SEP for formerly incarcerated individuals.

Second, we propose to reorganize paragraphs (d)(1) and (d)(2) to establish the rules for eligibility for and the duration of the SEP for releases from incarceration during the periods between (1) January 1, 2023, through December 31, 2024, and (2) on and after January 1, 2025. We propose to revise paragraphs §§ 406.27(d)(1) and 407.23(d)(1) to state the current parameters and duration for the SEP that are applicable to releases after January 1, 2023, and before January 1, 2025. The current eligibility requirements are proposed to be redesignated as paragraph (d)(1)(i) and the current duration of the SEP (from current §§ 406.27(d)(2) and 407.23(d)(2)) are proposed to be redesignated paragraph (d)(1)(ii), with clarifications that the date of release is used as part of the eligibility criteria. At §§ 406.27(d)(2) and 407.23(d)(2) we propose to establish new parameters and duration for the SEP that would be applicable beginning January 1, 2025. Specifically, we propose at new §§ 406.27(d)(2)(i) and 407.23(d)(2)(i) that an individual released for releases that occur on and after January 1, 2025, from confinement in a jail, prison, or other penal institution or correctional facility would be eligible for the SEP. The

existing parameters (currently at §§ 406.27(d)(1) and 407.23(d)(1)) that the individual must demonstrate that they are eligible for Medicare and failed to enroll or reenroll due to being incarcerated and there is a record of release either through discharge documents or data available to SSA would continue to be applicable and are therefore included in proposed §§ 406.27(d)(2)(i) and 407.23(d)(2)(i). At new §§ 406.27(d)(2)(ii) and 407.23(d)(2)(ii), we propose that beginning January 1, 2025, the SEP starts the day an individual is released from incarceration as determined by SSA and ends the last day of the 12th month after the month in which the individual is released. As noted above, individuals who use this SEP are able to enroll in Medicare Premium Part A and Part B without LEPs and this would continue to be the case whether individual uses this SEP before or after January 1, 2025.

Under this proposal, as originally intended with the SEP, individuals will have a clearer understanding for how to access this enrollment opportunity to ensure they do not have any gaps in coverage or any LEPs as they leave incarceration.

3. Technical Corrections

In the November 2022 final rule that established the SEP for formerly incarcerated individuals, we provided at §§ 406.27(d)(3) and 407.23(d)(3) that generally entitlement would begin the first day of the month following the month of enrollment. We also provided that an individual had the option to choose a retroactive entitlement date for a period not to exceed 6 months, provided that the individual pays the monthly premiums for the period of coverage. Upon further examination of the regulations, we have identified a number of technical errors in §§ 406.27(d)(3) and 407.23(d)(3) that we are taking this opportunity to propose to correct.

First, the language in § 407.23(d)(3)(ii) states that the individual has the option to request entitlement retroactive to the *date of release* from incarceration and this implies that coverage could start in the middle of the month. Entitlement for Medicare, regardless of the enrollment period being used or whether entitlement is prospective or retrospective, always begins on the first day of a month. As such, we propose to revise the language above to state that coverage

could begin retroactive to the beginning of the month of release from incarceration. We note that the payment exclusion in § 411.4(b) may continue to apply to any items and services furnished during the period between the first of that month and the actual date of release, provided that the individual or other person has no legal obligation to pay for such services as articulated in § 411.4(a).

Second, in §§ 406.27(d)(3)(ii) and 407.23(d)(3)(ii), we erroneously cited § 406.31 when referencing the requirement for individuals to pay monthly premiums for all periods of coverage. We propose to correct the reference to § 406.31 in § 406.27(d)(3)(ii) with § 406.32(f) and the reference in § 407.23(d)(3)(ii) to § 408.4.

Third, we also stated at § 407.23(d)(3)(ii) that if the individual requests retroactive enrollment and the application is filed within the first 6 months of the SEP, the effective date could be retroactive to the release from incarceration. If the individual requests retroactive enrollment and the application is filed in the last 6 months of the SEP, the coverage effective date could be retroactive to 6 months after the date of release from incarceration. This provision results in the same coverage effective date regardless of when the individual applies during the last six months of the SEP, which we do not think is consistent with our policy goal of providing formerly incarcerated individuals the ability to make the healthcare decisions best suited to their needs and provide them the opportunity to avoid or minimize gaps of coverage (87 FR 66463). We believe the best way to remedy this situation is to link the retroactive period of coverage to the date when the individual applies for Medicare coverage, not when they are released from incarceration. As such, we propose to revise § 407.23(d)(3)(ii) to state that if the individual requests retroactive enrollment and the application is filed in the last 6 months of the SEP, the coverage effective date is retroactive to the 6th month before the month of enrollment. We believe this proposed approach strikes an appropriate balance of reducing gaps in coverage without creating excessive (and potentially costly) retroactive periods of coverage. We also propose to make similar changes at § 406.27(d)(3)(ii) for the sake of consistency and clarity.

XXIV. Overall Hospital Quality Star Rating Modification to Emphasize the Safety of Care

Measure Group: Request for Information (RFI)

A. Summary

We seek public input on potential methodologic modifications regarding the Safety of Care measure group within the Overall Hospital Quality Star Rating published on the provider comparison tool on Medicare.gov (<https://www.medicare.gov/care-compare/>). 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.⁵¹⁸ This Request for Information (RFI) is aimed at gathering broad public input on increasing the Safety of Care measure group's contribution to the Overall Hospital Quality Star Rating. We also note our intention to potentially issue additional RFIs or undertake rulemaking on this topic in the future.

B. Background

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information on Medicare.gov based on publicly available quality measure results reported through CMS' hospital quality measurement programs, by assigning hospitals between one and five 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 interested parties. The Overall Hospital Quality Star Rating was first introduced and

⁵¹⁸ <https://www.cms.gov/files/document/cms-national-quality-strategy-handout.pdf>

reported on our Hospital Compare website in July 2016 (now reported on Medicare.gov) and has been refreshed multiple times, with the most current refresh planned for July 2024.⁵¹⁹

In the CY 2021 OPPS/ASC final rule (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 (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.

C. Current Overall Hospital Quality Star Rating Methodology

Measures reported on the provider comparison tool on Medicare.gov (<https://www.medicare.gov/care-compare/>) 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, and Patient 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 seven general steps. First, the direction of all included measures that indicate better performance with a lower score are reversed to uniformly indicate 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. Second, measures are arranged into measure groups. Each measure group contains a number of publicly reported measures to produce a robust measure group score, which are reflective of differences in hospital quality. Third, the measure group

⁵¹⁹ Placeholder for 2024 Stars QUS

scores are calculated as a simple average of measure scores. Measure group scores are then standardized to a common scale making varying scores comparable. Fourth, the hospital summary score is calculated as a weighted average of measure group scores. Specifically, each measure group score is multiplied by the assigned weight for that group. The weighted measure group scores are then summated to generate the hospital summary score. If a hospital has no measure scores in a group (for example, by not achieving sufficient sample size in any of the measures), the weight is redistributed proportionally across the remaining groups. Fifth, minimum reporting thresholds are applied. To receive a Star Rating, hospitals must report at least three measures in at least three measure groups, one of which must be either the Mortality or Safety of Care measure groups. Sixth, 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 3-measure peer group, a 4-measure peer group, and a 5-measure peer group. Seventh, a clustering algorithm is applied within each peer group to assign hospital summary scores to star ratings so that one star is the lowest and five stars is the highest.

For additional details regarding the 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. Safety of Care in Star Ratings

A foundational commitment of providing healthcare services is to ensure safety, as embedded in the centuries-old Hippocratic Oath, “First, do no harm.” Yet, the landmark reports *To Err is Human* and *Crossing the Quality Chasm* surfaced major deficits in healthcare quality and safety.^{520 521} These reports resulted in widespread awareness of the alarming prevalence of patient harm and, over the past two decades, healthcare facilities implemented various

⁵²⁰ 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).

⁵²¹ Institute of Medicine (US) Committee on Quality of Health Care in America. (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*. National Academies Press (US).

interventions and strategies to improve patient safety, with some documented successes.⁵²² Furthermore, the COVID-19 public health emergency (PHE) strained the healthcare system substantially, introducing new safety risks and negatively impacting patient safety in the normal delivery of care.^{523 524}

Safety gaps and further risks in healthcare delivery were illuminated as a result of the COVID-19 PHE, revealing a lack of resiliency in the healthcare system.^{525 526 527} Therefore, we are increasing efforts to emphasize the importance of patient safety for both patients and healthcare workers. To accomplish these goals, the federal government is taking a multi-pronged inter-Agency approach to improve safety. The Agency for Healthcare Research and Quality (AHRQ) on behalf of the Department of Health & Human Services (HHS) established the National Action Alliance to Advance Patient and Workforce Safety as a public-private collaboration to improve both patient and workforce safety and move towards zero harm in healthcare.⁵²⁸ In September 2023, the President’s Council of Advisors on Science and Technology (PCAST) published the “Report to the President: A Transformational Effort on Patient Safety,” with a call to action to renew “our nation’s commitment to improving patient

⁵²² 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/nhqdr/chartbooks/patientsafety/2019qdr-patient-safety-chartbook.pdf>.

⁵²³ Lastinger LM, Alvarez CR, Kofman A, Konnor RY, Kuhar DT, Nkwata A, Patel PR, Pattabiraman V, Xu SY, Dudeck MA. Continued increases in the incidence of healthcare-associated infection (HAI) during the second year of the coronavirus disease 2019 (COVID-19) pandemic. *Infect Control Hosp Epidemiol*. 2023 Jun;44(6):997-1001. doi: 10.1017/ice.2022.116. Epub 2022 May 20. PMID: 35591782; PMCID: PMC9237489.

⁵²⁴ Patel, PR, Weiner-Lastinger, LM, Dudeck, MA, et al. Impact of COVID-19 pandemic on central-line-associated bloodstream infections during the early months of 2020, National Healthcare Safety Network. *Infect Control Hosp Epidemiol* 2021. doi: 10.1017/ice.2021.108.

⁵²⁵ Agency for Healthcare Research and Quality. (2021). AHRQ PSNet Annual Perspective: Impact of the COVID-19 Pandemic on Patient Safety. <https://psnet.ahrq.gov/perspective/ahrq-psnet-annual-perspective-impact-covid-19-pandemic-patient-safety>.

⁵²⁶ Fleisher, L.A., Schreiber, M.D., Cardo, D., and Srinivasan, M.D. (2022). Health care safety during the pandemic and beyond—building a system that ensures resilience. *N Engl J Med*, 386: 609-611. <https://www.nejm.org/doi/full/10.1056/NEJMp2118285>.

⁵²⁷ Implications of the COVID-19 pandemic for patient safety: a rapid review. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

⁵²⁸ AHRQ. (2023). National Action Alliance To Advance Patient and Workforce Safety. <https://www.ahrq.gov/cpi/about/otherwebsites/action-alliance.html>.

safety.”⁵²⁹ The report put forth a recommendation as part of the call to action to “establish and maintain federal leadership for the improvement of patient safety as a national priority.” We also acknowledged a noticeable decline in patient safety measure scores during the COVID-19 PHE which reinforces the emphasis on patient safety established in several CMS initiatives, including the National Quality Strategy and Universal Foundation.^{530 531} Additionally, hospitals report data on healthcare-associated infection (HAI) measures through a number of CMS quality programs, including the Hospital-Acquired Condition (HAC) Reduction and Hospital Value-Based Purchasing Programs. These programs are designed to improve patient quality of care and safety, as well as reduce complications and mortality, by rewarding hospitals that achieve high scores on measures, including HAI measures, and penalizing those that do not meet or exceed established performance standards.⁵³² However, it is possible in the current Overall Star Rating methodology for a hospital to score very low in the Safety of Care measure group yet still receive a high Star Rating due to their high performance in other measure groups. Therefore, we seek to explore potential adjustments to the Overall Hospital Quality Star Ratings methodology that would greater emphasize the measures within the Safety of Care measure group, in alignment with other CMS and HHS efforts to improve patient safety across all programs.

There are currently eight measures in the Safety of Care measure group, including six HAI measures (HAI-1 – HAI-6), one Complications measure after total hip or total knee replacement (Hip/Knee), and one composite adverse event measure (Patient Safety and Adverse Events Composite (PSI-90)). While this group of measures has been the same since the inception of the Overall Hospital Quality Star Rating, the specific safety measures included may be subject

⁵²⁹ https://www.whitehouse.gov/wp-content/uploads/2023/09/PCAST_Patient-Safety-Report_Sept2023.pdf

⁵³⁰ 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

⁵³¹ <https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation>

⁵³² <https://www.cms.gov/blog/first-do-no-harm>

to change in the future. Measures reported on the provider comparison tool on Medicare.gov (<https://www.medicare.gov/care-compare/>) undergo a rigorous development process which includes extensive measure testing, vetting by interested parties, evaluation by the Consensus-based Entity (currently, Battelle, which convenes the Partnership for Quality Measurement), and undergoing rulemaking for inclusion in CMS programs and public reporting. As such, the Overall Hospital Quality Star Rating methodology uses the measures as required under the CMS programs, with measure scores as reported on Medicare.gov at the time of the Overall Hospital Quality Star Rating calculation. Thus, any measures that are removed or suspended from one of the CMS hospital quality measure programs and not published on Medicare.gov would no longer be included. Similarly, any measures that are added to the CMS programs and displayed on Medicare.gov may be included in the Overall Hospital Quality Star Rating; for example, upcoming measures such as the Severe Obstetric Complication (87 FR 48780), Failure-to-Rescue (89 FR 35934), Hospital Harm-Severe Hypoglycemia (89 FR 35934) and Hospital Harm-Opioid-related Adverse Events (87 FR 48780) measures may be considered for inclusion in the Safety of Care measure group. The assessment presented here is based only on the current group of eight measures as listed above, but the Overall Hospital Quality Star Rating methodology is designed with the flexibility to accommodate such changes in the future.

The current methodology places the highest emphasis on the Safety of Care and Mortality measure groups. First, the measure group weights currently utilized in the Overall Hospital Quality Star Rating methodology are based on CMS policy and interested party feedback. Currently, the Safety of Care, Mortality, Readmission, and Patient Experience measure groups are each weighted 22 percent while the Timely and Effective Care measure group is weighted 12 percent (Table 103). Interested parties generally agreed that outcome measures should have more weight since they represent strong indicators of quality and are most important to patients

in making healthcare decisions. Interested parties and stakeholders broadly considered the current weightings to be acceptable.

The Safety of Care and Mortality groups are further emphasized in the reporting threshold to receive a Star Rating: hospitals must report at least three measures in each of at least three measure groups, one of which must specifically be Safety of Care or Mortality (85 FR 86228). This decision was partially informed by interested party feedback on the relative importance of patient safety and prevention of mortality.

Given the current ongoing efforts to advance patient safety, we investigated options to even further emphasize the patient safety measures in the Overall Hospital Quality Star Rating, above and beyond the emphasis of the current methodology.

We conducted an internal analysis utilizing data from the July 2023 refresh of the Overall Hospital Quality Star Rating to determine correlations between the Safety of Care measure group and performance in the Overall Hospital Quality Star Rating. There were 3,076 hospitals that met the criteria to receive a Star Rating. Among the 3,076 rated hospitals, 2,995 (97 percent) had at least 1 Safety of Care measure and therefore received a Safety of Care group score, while 2,615 (85 percent) had at least 3 Safety of Care measures. Our analysis showed a strong relationship between the Safety of Care measure group and the Star Rating. Hospitals that did well in Safety of Care tended to also do well on the Star Rating; however, there were a few hospitals that performed in the bottom quartile (lowest performing 25 percent) of the Safety of Care measure group that still received a 5-star rating. Of the 3,076 hospitals that received a Star Rating, 658 hospitals with at least three Safety of Care measures scored in the lowest quartile of the Safety of Care measure group and 19 hospitals received a 5-star rating, representing 0.6 percent of all rated hospitals (Table 101). An additional 94 hospitals fell into the lowest quartile of Safety of Care when the analysis was based on hospitals that reported just one or two Safety of Care measures. In general, these hospitals attained 5-star ratings despite poor Safety of Care performance by achieving high performance scores across the other measure groups.

TABLE 101: 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	-5.60, -0.38	658	128	230	184	97	19
All Hospitals	-5.60, 2.12	2615	216	575	733	680	411

We assessed reporting of individual Safety of Care measures and performance in the Safety of Care measure group by various hospital characteristics. We observed significant variation in the number of Safety of Care measures reported across different types of hospitals, typically with fewer measures for hospitals that have generally lower volume and so are less likely to reach sufficient case volume for individual measurements. Specifically: non-teaching hospitals, safety net hospitals⁵³³, critical access hospitals, smaller (< 100 beds) hospitals, rural hospitals, and hospitals not qualifying for Medicare Disproportionate Share Hospital (DSH) payments were likely to report fewer Safety of Care measures compared to teaching, non-safety net-, non-critical access, hospitals with 100+ beds, urban, and DSH-qualifying hospitals (Table 102). There was a broad distribution in performance scores across hospital types; however, certain hospital characteristics appear to be associated with performance on the Safety of Care measure group. For example, smaller hospitals are more likely to fall toward the extremes of the performance score distribution while larger hospitals fall more toward the center, and safety net hospitals tend to fall into lower quartiles than non-safety net hospitals (Table 102).

TABLE 102: Safety Performance of Hospitals by Hospital Characteristics

	Number of Hospitals Reporting Safety of Care Measures	Distribution of Safety of Care Measure Group Scores
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⁵³³ Safety net hospitals are defined as those committed to caring for populations without stable access to care, specifically public hospitals or private hospitals with a Medicaid caseload greater than one standard deviation above their respective state's mean private hospital Medicaid caseload. https://www.cmshospitalchartbook.com/sites/default/files/Pfmc-by-Char_HW-Rdmn_2015.pdf

	N	1 measure	2	3	4+ measures	Q1 Safety	Q2	Q3	Q4
All Hospitals with Safety Score & Star Rating	2995	153 (5.1%)	227 (7.6%)	316 (10.6%)	2299 (76.8%)	752 (25.1%)	757 (25.3%)	816 (27.2%)	670 (22.4%)
Specialty status									
Specialty	941	22 (2.3%)	38 (4.0%)	64 (6.8%)	817 (86.8%)	235 (25.0%)	240 (25.5%)	263 (27.9%)	203 (21.6%)
Non-Specialty	1932	120 (6.2%)	174 (9.0%)	232 (12.0%)	1406 (72.8%)	477 (24.7%)	490 (25.4%)	529 (27.4%)	436 (22.6%)
Teaching Status									
Non-Teaching	1739	135 (7.8%)	194 (11.2%)	267 (15.4%)	1143 (65.7%)	462 (26.6%)	402 (23.1%)	453 (26.0%)	422 (24.3%)
Teaching	1148	8 (0.7%)	20 (1.7%)	34 (3.0%)	1086 (94.6%)	255 (22.2%)	329 (28.7%)	343 (29.9%)	221 (19.3%)
Safety net Status									
Non-safety net	2281	100 (4.4%)	142 (6.2%)	224 (9.8%)	1815 (79.6%)	516 (22.6%)	576 (25.3%)	663 (29.1%)	526 (23.1%)
Safety net	586	42 (7.2%)	70 (11.9%)	71 (12.1%)	403 (68.8%)	194 (33.1%)	154 (26.3%)	129 (22.0%)	109 (18.6%)
Critical Access									
Non-Critical Access	2804	58 (2.1%)	157 (5.6%)	291 (10.4%)	2298 (82.0%)	692 (24.7%)	729 (26.0%)	791 (28.2%)	592 (21.1%)
Critical Access	191	95 (49.7%)	70 (36.6%)	25 (13.1%)	1 (0.5%)	60 (31.4%)	28 (14.7%)	25 (13.1%)	78 (40.8%)
Bed Size									
< 100 beds	951	140 (14.7%)	201 (21.1%)	262 (27.5%)	348 (36.6%)	277 (29.1%)	210 (22.1%)	197 (20.7%)	267 (28.1%)
100+ beds	1922	2 (0.1%)	11 (0.6%)	34 (1.8%)	1875 (97.6%)	435 (22.6%)	520 (27.1%)	595 (31.0%)	372 (19.4%)
Geographic Location									
Urban	1924	25 (1.3%)	43 (2.2%)	120 (6.2%)	1736 (90.2%)	433 (22.5%)	487 (25.3%)	582 (30.2%)	422 (21.9%)
Rural	949	117 (12.3%)	169 (17.8%)	176 (18.5%)	487 (51.3%)	279 (29.4%)	243 (25.6%)	210 (22.1%)	217 (22.9%)
Disproportion ate Share Hospital Status*									
DSH-eligible (DSH_cost >0)	2399	41 (1.7%)	128 (5.3%)	213 (8.9%)	2017 (84.1%)	611 (25.5%)	639 (26.6%)	677 (28.2%)	472 (19.7%)
<i>DSH_cost: 1st Quintile</i>	479	10 (2.1%)	30 (6.3%)	45 (9.4%)	394 (82.3%)	101 (21.1%)	117 (24.4%)	148 (30.9%)	113 (23.6%)

<i>DSH_cost:2ⁿ</i> <i>^d Quintile</i>	489	10 (2.0%)	24 (4.9%)	49 (10.0%)	406 (83.0%)	112 (22.9%)	142 (29.0%)	144 (29.4%)	91 (18.6%)
<i>DSH_cost:3^r</i> <i>^d Quintile</i>	408	16 (3.9%)	55 (13.5%)	83 (20.3%)	254 (62.3%)	124 (30.4%)	101 (24.8%)	96 (23.5%)	87 (21.3%)
<i>DSH_cost:4^t</i> <i>^h Quintile</i>	511	2 (0.4%)	8 (1.6%)	19 (3.7%)	482 (94.3%)	136 (26.6%)	128 (25.0%)	163 (31.9%)	84 (16.4%)
<i>DSH_cost:5^t</i> <i>^h Quintile</i>	512	3 (0.6%)	11 (2.1%)	17 (3.3%)	481 (93.9%)	138 (27.0%)	151 (29.5%)	126 (24.6%)	97 (18.9%)
Non-DSH (DSH_COST =0)	474	101 (21.3%)	84 (17.7%)	83 (17.5%)	206 (43.5%)	101 (21.3%)	91 (19.2%)	115 (24.3%)	167 (35.2%)

E. Potential Future Options to Greater Emphasize Patient Safety in the Overall Hospital

Quality Star Rating

As part of the national commitment to improving patient safety, we seek feedback on whether hospitals that performed in the bottom quartile (lowest-performing 25 percent) in the Safety of Care measure group should be eligible to receive the highest 5-star rating. We are considering modifying the Overall Hospital Quality Star Rating methodology, specifically the Safety of Care measure group, to reinforce our dedication to emphasize patient safety across CMS. In this section we discuss three options identified to modify the Overall Hospital Quality Star Rating methodology.

1. Reweighting the Safety of Care Measure Group

We conducted an internal analysis to explore the impact of modifying the weighting system for measure groups in the Overall Hospital Quality Star Rating utilizing data from the July 2023 refresh. Specifically, we explored increasing the weight assigned to the Safety of Care measure group from the current 22 percent to 30 percent while proportionally reducing the weights assigned to the other measure groups to examine the isolated effect of reweighting while otherwise adhering to the current methodology. The exact weighting values noted in this RFI are not prescriptive and could be adjusted based on interested party feedback to be more easily interpretable (for example, to 30 percent, 20 percent, and 10 percent), however, the results reported reflect this preliminary reweighting scenario that preserves proportionality between the

remaining groups. Current and potential new weights for each measure group are detailed in Table 103.

TABLE 103: Overall Star Ratings Weighting by Group

Group	Star Ratings Weight (w_d)	Potential New Weight
Safety of Care	22%	30%
Mortality	22%	19.7%
Readmission	22%	19.7%
Patient Experience	22%	19.7%
Timely and Effective Care	12%	10.8%

Our analysis showed that by modifying the weight of the Safety of Care measure group to 30 percent, out of 3,076 hospitals, 213 hospitals would receive a higher Star Rating than when using the current weighting, while 233 hospitals would receive a lower Star Rating. Specifically, among the 752 rated hospitals in the lowest quartile of the Safety of Care measure group, 16 hospitals would achieve a higher Star Rating, while 133 hospitals would receive a lower Star Rating; only 3 of the 752 hospitals would receive a 5-star rating. Implementing this option would reduce the number of hospitals that perform poorly in Safety of Care yet still obtain the highest 5-star rating. However, reweighting the Safety of Care measure group would slightly reduce the influence of other measure groups on the Overall Hospital Quality Star Rating.

2. Policy-based 1-Star Reduction for Poor Performance on Safety of Care

We are considering a post hoc policy-based adjustment that would reduce the Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measure scores) by one star. Using 2023 Overall Hospital Quality Star Ratings 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 530 hospitals, out of 3,076 hospitals, receiving a lower Star Rating. This option would emphasize safety through a new standard for all hospitals regardless of their Star Rating. Since the minimum Star Rating is one star, hospitals already getting one star would not get a further star reduction and therefore would effectively be exempt from this policy-based adjustment.

Additionally, some hospitals that perform excellently in all other measure groups except the Safety of Care measure group would still receive a 1-star reduction.

3. Reweighting the Safety of Care measure group combined with a Policy-based Star Rating Cap

We are considering increasing the weight of the Safety of Care measure group to 30 percent (and proportionally reducing the weights assigned to the other measure groups, as described in Table 103) while also applying a policy that would limit hospitals in the lowest quartile of Safety of Care (based on at least three measure scores) to a maximum of four stars out of five. Using 2023 Overall Hospital Quality Star Ratings data, implementing a cap of four stars in the lowest quartile of Safety of Care with at least three safety measures combined with the reweighting for all hospitals would result in 235 hospitals, out of 3,076 hospitals, receiving a lower Star Rating and the reduction by 1 star for two hospitals in the lowest quartile of Safety of Care that would otherwise still receive a 5-star rating if only the reweighting solution was applied. This option provides a more targeted solution to the issue of hospitals performing poorly in Safety of Care receiving a 5-star rating and applies equally to all hospitals, reserving the 5-star rating for hospitals achieving a minimum threshold in Safety of Care.

We also explored alternative options for emphasizing patient safety, such as applying only the 4-star rating maximum or combining reweighting of the Safety of Care measure group with a policy-based 1-star reduction, however, these options did not effectively reach our goal of emphasizing patient safety. In our analysis, applying a 4-star rating maximum to hospitals in the lowest quartile of Safety of Care with at least three safety measures would have less impact, resulting in only 19 out of 3,076 hospitals receiving a lower Star Rating from five stars to four stars. Conversely, applying a combination of reweighting the Safety of Care measure group with a 1-star reduction may be considered an ‘over-correction’, resulting in 635 out of 3,076 hospitals receiving a lower Star Rating with the greatest impact on hospitals already receiving two, three, or four stars in the current methodology.

Feedback solicited during fall 2023 from interested parties, including patients, patient advocates, technical experts, and clinicians, supported the increasing emphasis on Safety of Care in the Overall Hospital Quality Star Rating methodology.⁵³⁴ However, there was varying feedback from interested parties on the methods to do so, with concerns including a decreased emphasis on the other measure groups, particularly Mortality, and the adequacy of the Safety of Care group measures as currently established to truly represent the experience of patient safety at a hospital.

F. Solicitation of Public Comment

We are currently seeking comments on potential modifications to the Safety of Care measure group in the Overall Hospital Quality Star Rating methodology. We are requesting input from interested parties on the following options: (1) reweighting the Safety of Care measure group; (2) applying a policy-based adjustment that reduces the Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measures in the group) by one star; (3) reweighting the Safety of Care measure group combined with a policy-based 4-star rating maximum on Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measures in the group). Specifically, we are requesting comment on the following questions:

- Do you support re-weighting the Overall Hospital Quality Star Rating measure groups to give greater weight to Safety of Care as described in option 1? Do you agree with the potential new weights for each measure group (as shown in Table 103)?
- Do you support reducing the Star Rating for hospitals with a low Safety of Care score as described in option 2? Do you agree with the potential policy to apply a 1-star reduction to all hospitals in the lowest quartile of Safety of Care?

⁵³⁴ <https://mmshub.cms.gov/sites/default/files/Star-Ratings-TEP-Summary-Report-Oct23.pdf>

- Do you support a combination of reweighting the Safety of Care measure group with a 4-star maximum on Star Rating as described in option 3?
- Do you have feedback or preference towards an approach of both up-scoring high performers and down-scoring poor performers as in options 1 and 3, or an approach of just down-scoring poor performers as in option 2?
- What are other methodological approaches that could be used to emphasize the Safety of Care measure group?
- With respect to the potential changes to the Overall Hospital Quality Star Rating methodology, are there any special considerations for small, rural or safety net hospitals (including Critical Access hospitals)?

Any modification to the Overall Hospital Quality Star Rating methodology would be addressed through future notice-and-comment rulemaking.

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 2025 and subsequent years, we proposed 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 2025 and subsequent years we propose to keep the same format for the addenda A, B, and C, and we are not proposing any additional changes for CY 2025.

To view the Addenda to this proposed rule pertaining to CY 2025 payments under the OPPS, we refer readers to the CMS website at:

<https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>; select “CMS-1809-P” from the list of regulations. All OPPS

Addenda to this proposed rule are contained in the zipped folder titled “2025 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 2025 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-1809-P” from the list of regulations. The ASC Addenda to this proposed rule are contained in a zipped folder titled “2025 NPRM Addendum AA, BB, DD1, DD2, EE, and FF” in the related links section at the bottom of the page.

XXIV. 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):

If you comment on these information collection, 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 on/by September 9, 2024.

A. ICRs for the Hospital Outpatient Quality Reporting (OQR) Program

a. Background

In section XV of this proposed rule, we discuss the 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 2024 OP/ASC final rule with comment period (88 FR 82131 through 82140) for detailed discussions of the previously finalized Hospital OQR Program ICRs which are currently approved under OMB control number 0938-1109 (expiration date February 28, 2025).

In this proposed rule, we propose to adopt four web-based measures that would impact previously approved burden estimates: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (4) 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 2026 reporting period and mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

We also propose changes to the Hospital OQR Program that would not impact the previously approved burden estimates. We propose to remove two claims-based measures beginning with the CY 2025 reporting period/CY 2027 payment determination: (1) Magnetic

Resonance Imaging (MRI) Lumbar Spine for Low Back Pain measure; and (2) Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure. We further propose to modify the public reporting of data for the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) – Psychiatric/Mental Health Patients stratification so that it may be published on Care Compare in addition to the data.cms.gov downloadable files beginning in CY 2025. Lastly, we propose to require electronic health record (EHR) technology to be certified to all eCQMs available to report beginning with the CY 2025 reporting period/CY 2027 payment determination.

In the CY 2024 OPPI/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 (88 FR 82132). Specifically, we used the “general medical and surgical hospitals” industry to estimate the mean wage, as this categorization aligns the closest with the Hospital OQR Program care setting compared to other industries, such as “office of physicians” or “nursing care facilities.” The most recent data from BLS’ May 2023 National Occupational Employment and Wage Estimates reflects a mean hourly wage of \$27.69 per hour for medical records specialists working in “general medical and surgical hospitals” (SOC 29-2072).⁵³⁵ We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean 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 ($\$27.69 \times 2 = \55.38) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost

⁵³⁵ U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed April 29, 2024. Available at: <https://www.bls.gov/oes/current/oes292072.htm>.

burden to hospitals using a wage plus benefits estimate of \$55.38 per hour throughout the discussion in this section of this rule for the Hospital OQR Program.

In the CY 2024 OP/ASC final rule with comment period, our burden estimates were based on an assumption that approximately 3,350 hospital outpatient departments (HOPDs) would report data to the Hospital OQR Program (88 FR 82132). For this proposed rule, based on the most recent available data from the CY 2024 Hospital OQR Program payment determination, we estimate that 3,200 HOPDs will report data to the Hospital OQR Program for the CY 2025 reporting period/2027 payment determination.

b. Information Collection Burden Estimate for the Proposed Adoption of the Hospital Commitment to Health Equity Measure Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In section XIV.B.1 of this proposed rule, we propose to adopt the web-based HCHE measure beginning with the CY 2025 reporting period/CY 2027 payment determination. For this measure, HOPDs would be required to report on attestations of “yes” or “no” to a set of five domains related to organizational efforts towards health equity once annually using a CMS-designated information system, as described in section XIV.B.1.b of this proposed rule. We estimate the reporting burden associated with this measure to be, on average across all 3,200 HOPDs, no more than 10 minutes per HOPD per year, as we believe the burden for HOPDs to report this measure would be very similar to the burden for hospital inpatient departments to report the same measure once annually under the Hospital IQR Program. We refer readers to the currently approved burden estimate for the HCHE measure in the Hospital IQR Program under OMB control number 0938-1022 (expiration date January 31, 2026) and as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385).

Using an estimate of 10 minutes (or 0.167 hours) per HOPD per year, we estimate that this measure adoption would result in a total annual burden increase of 533 hours (0.167 hours × 3,200 HOPDs) at a cost of \$29,518 (533 hours × \$55.38/hr) across program-eligible HOPDs.

c. Information Collection Burden Estimate for the Proposed Adoption of the Screening for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.2 of this proposed rule, we propose to adopt the web-based Screening for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. For this measure, HOPDs would be required to report whether they screened patients for five Health Related Social Needs (HRSN) domains, as described in section XIV.B.2.a of this proposed rule.

HOPDs would be able to collect data for the measure using a self-selected screening tool. We expect that most HOPDs would likely collect data through a screening tool incorporated into their EHR or other patient intake process, such as those we describe as examples in section XIV.B.2.e of this proposed rule. We estimate the information collection burden related to conducting patient screening associated with this measure to be 2 minutes (0.033 hours) per patient. This is based on the currently approved burden estimate for the Hospital IQR Program under OMB control number 0938-1022 for the same measure with patient screening for the same HRSN domains and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385 through 49386).

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 American Hospital Association which estimates 2,399 outpatient visits per 1,000 population in CY 2022⁵³⁶ and multiplied this by the estimated total U.S. population in CY 2022⁵³⁷ to estimate the total

number of outpatient visits across all U.S. community hospitals. Then, in order to derive an estimate for only the 3,200 program-eligible HOPDs in the Hospital OQR Program, we multiplied the total number of outpatient visits by a ratio of program-eligible HOPDs to all U.S. community hospitals. Therefore, we estimate that each year 498,843,518 patients $(2,399 \text{ outpatient visits per } 1,000 \text{ population in CY } 2022) \times 333,287,557 \text{ total U.S population in } 2022 \times (3,200 \text{ HOPDs} \div 5,129 \text{ U.S community hospitals}^{538})$ would be screened when reporting on the measure becomes mandatory. As submission rates among facilities may vary, we conservatively estimate that for voluntary reporting for the CY 2025 reporting period, 50 percent of HOPDs would survey 50 percent of patients, and beginning with the first mandatory reporting period, 100 percent of HOPDs would survey 100 percent of patients.

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 \$24.49/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.⁵³⁹ To derive the costs for patients (or their representatives), a measurement of the usual weekly earnings of wage and salary workers of \$1,139 is divided by 40 hours to calculate an hourly pre-tax wage rate of \$28.48/hr.⁵⁴⁰ 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,⁵⁴¹ resulting in the post-tax hourly wage rate of \$24.49/hr. Unlike our state and private sector wage adjustments, we are not adjusting patient wages for fringe benefits and other indirect costs since the individuals’ activities, if any, would occur outside the scope of their employment.

Measure data aggregated to the hospital level as a numerator and a denominator would be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109 (expiration date January 31, 2026), we estimate a burden of 10 minutes per HOPD to report the measure data. Therefore, we estimate that each HOPD would spend 10 minutes (0.167 hours) annually to report the Screening for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total burden increase for patients of 4,115,459 hours (498,843,518 patients \times 50 percent response rate \times 50 percent of HOPDs \times 0.033 hours per patient) at a cost of \$100,787,591 (4,115,459 hours \times \$24.49/hr). Beginning with the CY 2026 mandatory reporting period, we estimate an annual total burden increase for patients of 16,461,836 hours (498,843,518 patients \times 0.033 hours per patient) at a cost of \$403,150,364 (16,461,836 hours \times \$24.49/hr).

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for program-eligible HOPDs of 267 hours (3,200 HOPDs \times 50 percent of HOPDs \times 0.167 hours per HOPDs) at a cost of \$14,786 (267 hours \times \$55.38/hr). Beginning with the CY 2026 mandatory reporting period, we estimate a total collection and reporting burden increase for program-eligible HOPDs of 533 hours (3,200 HOPDs \times 0.167 hours per HOPD) at a cost of \$29,518 (533 hours \times \$55.38/hr).

d. Information Collection Burden Estimate for the Proposed Adoption of the Screen Positive Rate for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.3 of this proposed rule, we propose to adopt the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028

payment determination. We refer readers to the currently approved burden estimate for the Screen Positive Rate for SDOH measure in the Hospital IQR Program under OMB control number 0938-1022 for the same measure and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386). As discussed in section XIV.B.3.g of this proposed rule, if a hospital participates in both the Hospital OQR and Hospital IQR Programs, the hospital would need to submit data on this measure separately under each program. As such, we are estimating the burden separately under each program.

For this measure, HOPDs would be required to report on the number of patients who screened positive for one or more of the five domains (reported as five separate rates to reflect each of the five HRSN domains) divided by the total number of patients screened. We previously included the collection burden associated with screening patients in our discussion of the Screening for SDOH measure. Thus, for the Screen Positive Rate for SDOH measure, we estimate only the additional burden for HOPD reporting via the HQR system since patients would not need to provide, and HOPDs would not need to collect, any additional information for this measure. We continue to estimate that, for voluntary reporting for the CY 2025 reporting period, 50 percent of HOPDs would submit data, and beginning with the first mandatory reporting period, 100 percent of HOPDs would submit data.

Measure data aggregated to the hospital level as a numerator and a denominator would be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938-1109, we estimate a burden of 10 minutes per HOPD to report the measure data. Therefore, we estimate that each HOPD would spend 10 minutes (0.167 hours) annually to report the Screen Positive Rate for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase of 267 hours ($0.167 \text{ hours} \times 3,200 \text{ HOPDs} \times 50 \text{ percent of HOPDs}$) at a cost of \$14,786 ($267 \text{ hours} \times \55.38), and beginning with the CY 2026 reporting period, we estimate a

total annual collection and reporting burden increase for hospitals of 533 hours (0.167 hours × 3,200 HOPDs) at a cost of \$29,518 (533 hours × \$55.38/hr) across all program-eligible HOPDs.

e. Information Collection Burden Estimate for the Proposed Adoption of 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 2026 Reporting Period and

Mandatory Reporting beginning with the CY 2027 Reporting Period/CY 2029 Payment

Determination

In section XV.C.1.b of this proposed rule, we propose to adopt the Information Transfer PRO-PM beginning with voluntary reporting for the CY 2026 reporting period and mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

The Information Transfer PRO-PM would use PRO data regarding recovery instructions, collected by HOPDs 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.

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 American Hospital Association related to hospital outpatient visits to estimate that each year 498,843,518 patients (2,399 outpatient visits per person in CY 2022⁵⁴² × 333,287,557 total U.S population in 2022⁵⁴³ × (3,200 HOPDs ÷ 5,129 U.S community hospitals⁵⁴⁴)) would be screened if the measure became mandatory. As submission rates among facilities may vary, we conservatively estimate that for voluntary reporting for the CY 2025 reporting period, 50 percent of HOPDs would survey 50 percent of patients, and beginning with the first mandatory reporting period,

100 percent of HOPDs would survey 100 percent of patients. While we have also proposed to allow HOPDs to report a sample of at least 300 completed patient surveys, we propose to require all patients to be surveyed for this measure once mandatory reporting begins.

We estimate each patient would require an average of 6 minutes⁵⁴⁵ (0.1 hours) to complete the survey. As described in section XXIV.B.c of this proposed rule, for purposes of calculating patient burden, we determine the cost for patients (or their representatives) undertaking administrative and other tasks, such as filling out a survey or intake form, using a post-tax wage of \$24.49/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.⁵⁴⁶ Unlike our state and private sector wage adjustments, we are not adjusting patient wages for fringe benefits and other indirect costs since the individuals’ activities, if any, would occur outside the scope of their employment.

Measure data would be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109, we estimate a burden of 10 minutes per HOPD to report the measure data. Therefore, we estimate that each HOPD would spend 10 minutes (0.167 hours) annually to report the Information Transfer PRO-PM data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total burden for patients of 12,471,088 hours (498,843,518 patients × 50 percent response rate × 50 percent of HOPDs × 0.1 hours per patient surveyed) at a cost of \$305,416,945 (12,471,088 hours × \$24.49/hr). Beginning with the CY 2026 mandatory reporting period, we estimate an annual total burden for

patients of 49,884,352 hours (498,843,518 patients × 0.1 hours per patient) at a cost of \$1,221,667,780 (49,884,352 hours × \$24.49/hr).

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden for program-eligible HOPDs of 267 hours (3,200 HOPDs × 50 percent of HOPDs × 0.167 hours per HOPDs) at a cost of \$14,786 (267 hours × \$55.38/hr). Beginning with the CY 2026 mandatory reporting period, we estimate a total collection and reporting burden for program-eligible HOPDs of 533 hours (3,200 HOPDs × 0.167 hours per HOPD) at a cost of \$29,518 (533 hours × \$55.38/hr).

f. Information Collection Burden for the Proposed Removal of Two Claims-Based Measures

In sections XV.C.2.a and XV.C.2.b of this proposed rule, we propose to remove two claims-based measures beginning with the CY 2025 reporting period/CY 2027 payment determination: (1) MRI Lumbar Spine for Low Back Pain measure; and (2) Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure. Because these measures are calculated using Medicare fee-for-service (FFS) claims that are already reported to the Medicare program for payment purposes, removing these measures would not result in a change in burden associated with OMB control number 0938–1109.

g. Information Collection Burden for the Proposal to Publicly Report Data for the Median Time for Discharged ED Patients – Psychiatric/Mental Health Patients Stratification on Care Compare Beginning in CY 2025

In section XV.F.2 of this proposed rule, we propose to publicly report data for the Median Time for Discharged ED Patients – Psychiatric/Mental Health Patients stratification on Care Compare beginning in CY 2025. Because we are not proposing to require HOPDs to collect or submit any additional data for purposes of this public reporting, this proposal would not result in a change in burden associated with OMB control number 0938–1109.

h. Information Collection Burden for the Proposal to Require EHR Technology to be Certified to All eCQMs Available to Report Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In section XV.E.2.b of this proposed rule, we propose to require EHR technology to be certified to all eCQMs (electronic clinical quality measures) available to report beginning with the CY 2025 reporting period/CY 2027 payment determination. We do not expect HOPDs would experience an increase in information collection burden associated with this proposal because the use of EHR technology that is certified to all available eCQMs is already required for the Promoting Interoperability Program (83 FR 41672) and the Hospital IQR Program (84 FR 42604).

g. Summary of Proposed Information Collection Burden Estimates for the Hospital OQR Program

In summary, we estimate that the proposals in this proposed rule would result in a total HOPD burden increase of 66,348,321 hours at a cost of \$1,624,936,216 annually for all 3,200 program-eligible HOPDs from the CY 2025 reporting period/CY 2027 payment determination through the CY 2027 reporting period/CY 2029 payment determination. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938-1109 (expiration date February 28, 2025). (See Tables 104, 105 and 106.)

TABLE 104: 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 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
Addition of the HCHE Measure	10	1	3,200	1	0.167	533	0	+533
Addition of the Screening for SDOH	0.033	1	1,600	77,944	2,572	4,115,459	0	+4,115,459

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2025 Reporting Period								
Measure (Voluntary Survey)								
Addition of the Screening for SDOH Measure (Voluntary Reporting)	10	1	1,600	1	0.167	267	0	+267
Addition of the Screen Positive Rate for SDOH (Voluntary Reporting)	10	1	1,600	1	0.167	267	0	+267
Total Change in Information Collection Burden Hours: +4,116,526								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+4,116,526) = \$100,846,681								

**TABLE 105: 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 reporting quarters per year	Number of HOPDs reporting	Average number records per HOPD 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
Addition of the HCHE Measure	10	1	3,200	1	0.167	533	0	+533
Addition of the Screening for SDOH Measure (Mandatory Survey)	0.033	1	3,200	155,889	5,144	16,461,836	0	+16,461,836
Addition of the Screening for SDOH Measure (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Addition of the Screen Positive Rate for SDOH (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Addition of the Information Transfer PRO-PM (Voluntary Survey)	0.1	1	1,600	77,944	7,794	12,471,088	0	+12,471,088

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2026 Reporting Period								
Addition of the Information Transfer PRO-PM (Voluntary Reporting)	10	1	1,600	1	0.167	267	0	+267
Total Change in Information Collection Burden Hours: +28,934,791								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+28,934,791) = \$708,670,649								

**TABLE 106: SUMMARY OF PROPOSED HOSPITAL OQR PROGRAM
INFORMATION COLLECTION BURDEN CHANGE BEGINNING WITH 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 reporting quarters per year	Number of HOPDs reporting	Average number records per HOPD 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
Addition of the HCHE Measure	10	1	3,200	1	0.167	533	0	+533
Addition of the Screening for SDOH Measure (Mandatory Survey)	0.033	1	3,200	155,889	5,144	16,461,836	0	+16,461,836
Addition of the Screening for SDOH Measure (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Addition of the Screen Positive Rate for SDOH (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Addition of the Information Transfer PRO-PM (Mandatory Survey)	0.1	1	3,200	155,889	15,589	49,884,352	0	+49,884,352
Addition of the Information Transfer PRO-PM	10	1	3,200	1	0.167	533	0	+533

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Reporting Period								
(Mandatory Reporting)								
Total Change in Information Collection Burden Hours: +66,348,321								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+66,348,321) = \$1,624,936,216								

We request comment on how we can reduce burden on HOPDs for both these new information collections as well as recommendations for the removal of other existing information collections to offset these new burdens.

B. ICRs for the Rural Emergency Hospitals Quality Reporting (REHQR) Program

a. Background

In section XVI of this proposed rule, we discuss the 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 2024 OPPI/ASC final rule with comment period (88 FR 82148 through 82149) for detailed discussions of the previously finalized REHQR Program ICRs, which are currently approved under OMB control number 0938-1454 (expiration date April 30, 2027).

In this proposed rule, we propose to adopt three web-based measures that would impact previously approved burden estimates: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 program determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination.

We also propose to extend the reporting period for the previously adopted Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure

beginning with the CY 2027 program determination. We believe this proposal would not impact the previously approved burden estimates if finalized.

In the CY 2024 OPPTS/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 (88 FR 82148). Specifically, we used the “general medical and surgical hospitals” industry to estimate the mean wage, as this categorization aligns the closest with the REHQR Program care setting compared to other medical record specialist related industries, such as “office of physicians” or “nursing care facilities.” The most recent data from BLS’ May 2023 National Occupational Employment and Wage Estimates reflects a mean hourly wage of \$27.69 per hour for medical records specialists working in “general medical and surgical hospitals” (SOC 29-2072).⁵⁴⁷ We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($\$27.69 \times 2 = \55.38) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to REHs.

In the CY 2024 OPPTS/ASC final rule with comment period, our burden estimates were based on an assumption that approximately 746 hospitals could transition to REH status assuming that all eligible hospitals in states which have passed or amended necessary legislation enabling transition to occur as of March 2023 choose to do so and we stated that we would update our estimates once more information was made available (88 FR 82148). For this proposed rule, based on the actual number of acute care and critical access hospital conversions to REH status as of April 22, 2024, we estimate that 25 REHs would report data to the REHQR

Program during the CY 2025 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.A of this proposed rule, REHs are required by statute to submit quality data. Therefore, for purposes of estimating burden, we assume that all 25 REHs would submit data under the REHQR Program beginning with the CY 2025 reporting period.

b. Information Collection Burden for the Proposed Adoption of the Hospital Commitment to Health Equity (HCHE) Measure Beginning With the CY 2025 Reporting Period/CY 2027 Program Determination

In section XIV.B.1 of this proposed rule, we propose to adopt the web-based HCHE measure beginning with the CY 2025 reporting period/CY 2027 program determination. For this measure, REHs would be required to report on attestations of “yes” or “no” to a set of five domains related to organizational efforts towards health equity, as described in section XIV.B.1.b of this proposed rule.

We estimate the reporting burden associated with this measure to be, on average across all 25 REHs, no more than 10 minutes per REH per year, as we believe the burden that is annually reported by hospital inpatient departments under the Hospital IQR Program would be very similar to annual reporting by REHs on the same measure. We refer readers to the currently approved burden for the HCHE measure in the Hospital IQR Program under OMB control number 0938-1022 (expiration date January 31, 2026) and as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385).

Using an estimate of 10 minutes (or 0.167 hours) per REH per year, we estimate that this measure adoption would result in a total annual burden increase of 4 hours ($0.167 \text{ hours} \times 25 \text{ REHs}$) at a cost of \$222 ($4 \text{ hours} \times \$55.38/\text{hr}$) across all REHs.

c. Information Collection Burden for the Proposed Adoption of the Screening for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting

Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Program Determination

In section XIV.B.2 of this proposed rule, we propose to adopt the Screening for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination. We refer readers to the currently approved burden for the Screening for SDOH measure for the Hospital IQR Program under OMB control number 0938-1022 (expiration date January 31, 2026). For this measure, REHs would be required to report whether they screened patients for five Health Related Social Needs (HRSNs) domains as described in section XIV.B.2.a of this proposed rule.

REHs would be able to collect data for the measure using a self-selected screening tool. We expect that most REHs would likely collect data through a screening tool incorporated into their EHR or other patient intake process, such as those we describe as examples in section XIV.B.2.e of this proposed rule. We estimate the information collection burden related to conducting patient screening associated with this measure to be 2 minutes (0.033 hours) per patient. This is based on the currently approved burden estimate for the Hospital IQR Program for the same measure with patient screening for the same HRSN domains and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385 through 49386).

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 a Definitive Healthcare survey which calculated that Medicare FFS patients account for 35.6 percent of hospital payer mix and a MedPAC report that determined hospitals which have converted to REH status average 4,200 outpatient visits for Medicare FFS beneficiaries to estimate that each year 11,798 ($4,200 \div 35.6$ percent) patients would be screened per REH when reporting on the

measure becomes mandatory.^{548,549} We therefore estimate a total of approximately 295,000 patients (11,798 patients × 25 REHs) would be screened across all 25 REHs. As submission rates among facilities may vary, we conservatively estimate that for voluntary reporting for the CY 2025 reporting period, 50 percent of REHs would survey 50 percent of patients, and beginning with the first mandatory reporting period, REHs would survey 100 percent of patients.

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 \$24.49/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.⁵⁵⁰ To derive the costs for patients (or their representatives), a measurement of the usual weekly earnings of wage and salary workers of \$1,139 is divided by 40 hours to calculate an hourly pre-tax wage rate of \$28.48/hr.⁵⁵¹ 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,⁵⁵² resulting in the post-tax hourly wage rate of \$24.49/hr. Unlike our state and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals’ activities, if any, would occur outside the scope of their employment.

Measure data aggregated to the hospital level as a numerator and a denominator would be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109 (expiration date February 28, 2025), which REHs would have been

eligible to report under prior to conversion to REH status, we estimate a burden of 10 minutes per REH to report the measure data. Therefore, we estimate that each REH would spend 10 minutes (0.167 hours) annually to report the Screening for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for patients of 2,434 hours (295,000 patients \times 50 percent response rate \times 50 percent of REHs \times 0.033 hours per patient) at a cost of \$59,609 (9,735 hours \times \$24.49/hr). Beginning with the CY 2026 reporting period, we estimate a total collection and reporting burden increase for patients of 9,735 hours (295,000 patients \times 0.033 hours per patient) at a cost of \$238,410 (9,735 hours \times \$24.49/hr).

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for REHs of 2 hours (25 REHs \times 50 percent of REHs \times 0.167 hours) at a cost of \$111 (2 hours \times \$55.38/hr). Beginning with the CY 2026 reporting period, we estimate a total collection and reporting burden increase for REHs of 4 hours (25 REHs \times 0.167 hours) at a cost of \$222 (4 hours \times \$55.38/hr).

d. Information Collection Burden for the Proposed Adoption of the Screen Positive Rate for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Program Determination

In section XIV.B.3 of this proposed rule, we propose to adopt the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination. We refer readers to the currently approved burden estimate for the Screen Positive Rate for SDOH measure in the Hospital IQR Program under OMB control number 0938-1022 for the same measure and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386).

For this measure, REHs would be required to report on an annual basis the number of patients who screened positive for one or more of the five domains (reported as five separate rates to reflect each of the five HRSN domains) divided by the total number of patients screened.

We previously included the burden associated with screening patients in our discussion of the Screening for SDOH measure. Thus, for the Screen Positive Rate for SDOH measure, we estimate only the additional burden for a REH reporting via the HQR system since patients would not need to provide, and REHs would not need to collect, any additional information for this measure. We continue to estimate that, for voluntary reporting for the CY 2025 reporting period, 50 percent of REHs would survey 50 percent of patients, and beginning with the first mandatory period, REHs would survey 100 percent of patients.

Measure data aggregated to the hospital level as a numerator and a denominator would be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109 (expiration date February 28, 2025), which REHs would have been eligible to report under prior to conversion to REH status, we estimate a burden of 10 minutes per REH to report the measure data. Therefore, we estimate that each REH would spend 10 minutes (0.167 hours) annually to report the Screen Positive Rate for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase of two hours ($0.167 \text{ hours} \times 25 \text{ REHs} \times 50 \text{ percent of REHs}$) at a cost of \$111 ($2 \text{ hours} \times \$55.38/\text{hr}$), and beginning with the CY 2026 reporting period, we estimate a total annual collection and reporting burden increase for REHs of 4 hours ($0.167 \text{ hours} \times 25 \text{ REHs}$) at a cost of \$222 ($4 \text{ hours} \times \$55.38/\text{hr}$) across all REHs.

e. Information Collection Requirements for the Proposal to Extend the Reporting Period from for the Risk-Standardized Hospital Visits within 7 Days after Hospital Outpatient Surgery Measure Beginning With the CY 2027 Program Determination

In section XVI.C.2 of this proposed rule, we propose to extend the reporting period from 1 year to 2 years for the Risk-Standardized Hospital Visits within 7 Days after Hospital Outpatient Surgery measure, beginning with the CY 2027 program determination. We refer readers to a similar proposal which was finalized for the claims-based Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure under the Hospital OQR Program in the CY 2019 OPPTS/ASC final rule (83 FR 59106).

Because this claims-based measure is calculated using data that are already reported to the Medicare program for payment purposes, there is no burden associated with the collection and submission of data for this measure. Accordingly, our proposal to extend the reporting period from 1 to 2 years would not result in additional burden for REHs.

f. Summary of Proposed Information Collection Burden Estimates for the REHQR Program

In summary, we estimate that the proposals in this proposed rule, if finalized as proposed, would result in an increase of 9,747 hours at a cost of \$239,076 for 25 REHs annually from the CY 2025 reporting period through the CY 2026 reporting period. We will submit these information collection estimates to OMB for approval under OMB control number 0938-1454 (expiration date April 30, 2027). (See Tables 107 and 108.)

TABLE 107: 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 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
Addition of the HCHE Measure	10	1	25	1	0.167	4	0	+4
Addition of the Screening for SDOH Measure (Voluntary Survey)	0.033	1	13	11,800	187.2	2,434	0	+2,434

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1454 for the CY 2025 Reporting Period								
Add Screening for SDOH Measure (Voluntary Reporting)	10	1	13	1	0.167	2	0	+2
Addition of the Screen Positive Rate for SDOH (Voluntary Reporting)	10	1	13	1	0.167	2	0	+2
Total Change in Information Collection Burden Hours: +2,442								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+2,442) = \$60,053								

TABLE 108: SUMMARY OF PROPOSED REHQ PROGRAM INFORMATION COLLECTION BURDEN CHANGE BEGINNING WITH 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 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
Addition of the Hospital Commitment to Health Equity (HCHE) Measure	10	1	25	1	0.167	4	0	+4
Addition of the Screening for Social Drivers of Health (SDOH) Measure (Mandatory Survey)	0.033	1	25	11,800	295,000	9,735	0	+9,735
Addition of the Screening for SDOH Measure (Mandatory Reporting)	10	1	25	1	0.167	4	0	+4
Addition of the Screen Positive Rate for SDOH (Mandatory Reporting)	10	1	25	1	0.167	4	0	+4
Total Change in Information Collection Burden Hours: +9,747								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+9,747) = \$239,076								

We request comment on how we can reduce burden on REHs for both these new information collection as well as recommendations for the removal of other existing information collections to offset these new burdens.

C. ICRs for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

a. Background

In section XVII of this proposed rule, we discuss the requirements for the ASCQR Program. We refer readers to the CY 2024 OPPS/ASC final rule (88 FR 82140 through 82148) for detail regarding the previously finalized ASCQR Program ICRs which are currently approved under OMB control number 0938-1270 (expiration date August 31, 2025).

In section XIV.B of this proposed rule, we propose to adopt three measures that would impact previously approved burden estimates: (1) the Facility Commitment to Health Equity (FCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. In section XVII.E.2.a of this proposed rule, we propose that ASCs would submit data annually for these measures using the CMS-designated information system (currently, the Hospital Quality Reporting [HQR] system).

In the CY 2024 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 (88 FR 82140). Specifically, we used the “general medical and surgical hospitals” industry to estimate the mean wage, as this categorization aligns the closest with the ASCQR Program care setting compared to other medical record specialist related

industries, such as “office of physicians” or “nursing care facilities.” The most recent data from BLS’ May 2023 National Occupational Employment and Wage Estimates reflects a mean hourly wage of \$27.69 per hour for medical records specialists working in “general medical and surgical hospitals” (SOC 29-2072).⁵⁵³ We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($\$27.69 \times 2 = \55.38) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we would calculate cost burden to ASCs using a wage plus benefits estimate of \$55.38 per hour throughout the discussion in this section of this rule for the ASCQR Program.

Based on the most recent analysis of the CY 2024 payment determination data, we found that, of the 5,536 ASCs that were actively billing Medicare, 4,196 were required to participate in the ASCQR Program. Of the 1,340 ASCs not required to participate in the program, 279 ASCs did so and met full requirements. On this basis, we estimate that 4,475 ASCs ($4,196 + 279$) would submit data for the ASCQR Program for the CY 2025 reporting period/CY 2027 payment determination.

b. Information Collection Burden for the Proposed Adoption of the Facility Commitment to Health Equity (FCHE) Measure Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In section XIV.B.1 of this proposed rule, we propose to adopt the FCHE measure for the ASCQR Program beginning with the CY 2025 reporting period/CY 2027 payment determination. For this measure, ASCs would be required to report an attestation of “yes” or

“no” to a set of five domains related to organizational efforts towards health equity, as described in section XIV.B.1.b of this proposed rule.

We estimate the reporting burden associated with this measure to be, on average across all 4,475 ASCQR Program eligible facilities, no more than 10 minutes per ASC per year, based on the currently approved burden for the same measure under the Hospital IQR Program under OMB control number 0938-1022 (expiration date January 31, 2026). This also aligns with our estimated burden per providers for HOPDs and REHs, discussed above.

Using an estimate of 10 minutes (0.167 hours) per ASC per year, we estimate that this measure adoption would result in a total annual collection and reporting burden increase of 746 hours ($0.167 \text{ hours} \times 4,475 \text{ ASCs}$) at a cost of \$41,313 ($746 \text{ hours} \times \$55.38/\text{hr}$) across program-eligible ASCs.

c. Information Collection Burden for the Proposed Adoption of the Screening for Social Drivers of Health (SDOH) Measure, Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.2 of this proposed rule, we propose to adopt the Screening for SDOH measure for the ASCQR Program beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. For this measure, ASCs would be required to report whether they screened patients for five Health Related Social Needs (HSRN) domains as described in section XIV.B.2.a of this proposed rule.

As described in section XIV.B.2.e of this proposed rule, ASCs would be able to collect data for this measure using a self-selected screening tool. We expect that most ASCs would collect data through a screening tool incorporated into their EHR or other patient intake process, such as those we describe as examples in section XIV.B.2.e of this proposed rule. We estimate the information collection burden related to conducting patient screening associated with this

measure would be 2 minutes (0.033 hours) per patient. This estimate is based on the currently approved burden for the Hospital IQR Program for the same measure, requiring the reporting of patient screening for the same HRSN domains and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385 through 49386).

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. We estimate that each year approximately 2,330 patients (10,427,619 admissions⁵⁵⁴ ÷ 4,475 ASCs) would be screened per ASC annually once reporting on the measure becomes mandatory. As submission rates among facilities may vary, we conservatively estimate that, for voluntary reporting for the CY 2025 reporting period, 50 percent of ASCs would survey 50 percent of patients, and beginning with the first mandatory reporting period, ASCs would survey and report on 100 percent of patients.

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 \$24.49/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.⁵⁵⁵ To derive the costs for patients (or their representatives), a measurement of the usual weekly earnings of wage and salary workers of \$1,139 is divided by 40 hours to calculate an hourly pre-tax wage rate of \$28.48/hr.⁵⁵⁶ 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,⁵⁵⁷ resulting in the post-tax hourly wage rate of \$24.49/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.

Measure data aggregated to the ASC level as a numerator and a denominator would be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the ASCQR Program under OMB control number 0938–1270 (expiration date August 31, 2025), we estimate a burden of 10 minutes per ASC to report the measure data. Therefore, we estimate that each ASC would spend 10 minutes (0.167 hours) annually to report the Screening for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for patients of 86,028 hours ($10,427,619 \text{ patients} \times 50 \text{ percent response rate} \times 50 \text{ percent of ASCs} \times 0.033 \text{ hours per patient}$) at a cost of \$2,106,826 ($86,028 \text{ hours} \times \$24.49/\text{hr}$). Beginning with the CY 2026 reporting period, we estimate a total collection and reporting burden increase for patients of 344,111 hours ($10,427,619 \text{ patients} \times 0.033 \text{ hours per patient}$) at a cost of \$8,427,278 ($344,111 \text{ hours} \times \$24.49/\text{hr}$).

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for program-eligible ASCs of 373 hours ($4,475 \text{ ASCs} \times 50 \text{ percent of ASCs} \times 0.167 \text{ hours}$) at a cost of \$20,657 ($373 \text{ hours} \times \$55.38/\text{hr}$). Beginning with the CY 2026 reporting period, we estimate a total collection and reporting burden increase for program-eligible ASCs of 746 hours ($4,475 \text{ ASCs} \times 0.167 \text{ hours}$) at a cost of \$41,313 ($746 \text{ hours} \times \$55.38/\text{hr}$).

d. Information Collection Burden for the Proposed Adoption of the Screen Positive Rate for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.3 of this proposed rule, we propose to adopt the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We refer readers to the currently approved burden for the Screen Positive Rate for SDOH measure in the Hospital IQR Program under OMB control number 0938-1022 for the same measure and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386). For this measure, we propose that ASCs would be required to report annually the number of patients who screened positive for one or more of the five domains (reported as five separate rates to reflect each of the five HRSN domains) divided by the total number of patients screened.

We previously included the burden associated with screening patients in our discussion of the Screening for SDOH measure. Thus, for the Screen Positive Rate for SDOH measure, we estimate only the additional burden for an ASC reporting via the HQR system since patients would not need to provide, and ASCs would not need to collect, any additional information for this measure. We continue to estimate that, for voluntary reporting for the CY 2025 reporting period, 50 percent of ASCs would survey 50 percent of patients, and beginning with the first mandatory reporting period, 100 percent of ASCs would submit data.

Measure data aggregated to the hospital level as a numerator and a denominator would be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the ASCQR Program under OMB control number 0938-1270 (expiration date August 31, 2025), we estimate a burden of 10 minutes per ASC to report the measure data. Therefore, we estimate that each ASC would spend 10 minutes (0.167 hours) annually to report the Screen Positive Rate for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase of 373 hours ($0.167 \text{ hours} \times 4,475 \text{ ASCs} \times 50 \text{ percent of ASCs}$) at a cost of \$20,657 ($373 \text{ hours} \times \55.38). Beginning with the CY 2026 reporting period, we estimate a total

annual collection and reporting burden increase for ASCs of 746 hours (0.167 hours × 4,475 ASCs) at a cost of \$41,313 (746 hours × \$55.38/hr) across program-eligible ASCs.

e. Summary of Proposed Information Collection Burden Estimates for the ASCQR Program

In summary, we estimate that the proposals in this proposed rule would result in an increase of 346,349 hours at a cost of \$8,551,217 for 4,475 program-eligible ASCs from the CY 2025 reporting period/CY 2027 payment determination through the CY 2026 reporting period/CY 2028 payment determination. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1270 (expiration date August 31, 2025). (See Tables 109 and 110.)

TABLE 109: 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 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
Addition of the FCHE Measure	10	1	4,475	1	0.167	746	0	+746
Addition of the Screening for SDOH Measure (Voluntary Survey)	2	1	2,238	1,165	38.4	86,040	0	+86,028
Addition of the Screening for SDOH Measure (Voluntary Reporting)	10	1	2,238	1	0.167	373	0	+373
Addition of the Screen Positive Rate for SDOH (Voluntary Reporting)	10	1	2,238	1	0.167	373	0	+373
Total Change in Information Collection Burden Hours: +87,520								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+87,520) = \$2,189,453								

**TABLE 110: 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 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
Addition of the FCHE Measure	10	1	4,475	1	0.167	746	0	+746
Addition of the Screening for SDOH Measure (Mandatory Survey)	2	1	4,475	2,330	76.9	344,111	0	+344,111
Addition of the Screening for SDOH Measure (Mandatory Reporting)	10	1	4,475	1	0.167	746	0	+746
Addition of the Screen Positive Rate for SDOH (Mandatory Reporting)	10	1	4,475	1	0.167	746	0	+746
Total Change in Information Collection Burden Hours: +346,349								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+346,349) = \$8,551,217								

D. ICRs Related to Medicaid Clinic Services Four Walls Exceptions

As discussed in section XVII of this proposed rule, we propose three additional exceptions to the four walls requirement under the Medicaid clinic services benefit at 42 CFR 440.90. Specifically, we propose to add a mandatory four walls exception for IHS/Tribal clinics at § 440.90(c) and optional exceptions for behavioral health clinics and clinics located in rural areas at § 440.90(d) and (e). To attest to compliance with proposed § 440.90(c) and to effectuate the options at proposed § 440.90(d) and (e), States that cover the clinic services benefit would have to submit one or more Medicaid State plan amendments (SPAs).

The PRA burden associated with submitting the SPAs implementing the proposed Medicaid clinic services four walls exceptions will be addressed as part of an associated SPA preprint being developed by CMS and submitted to OMB for approval under OMB control number 0938-1188 (CMS-10398).

E. ICRs for Changes to the Review Timeframes for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services (84 FR 61142, 61446 through 61456).⁵⁵⁸ As part of the CY 2021 OPPS/ASC final rule with comment period, we added additional service categories to the prior authorization process (85 FR 85866, 86236 through 86248). Through the CY 2023 OPPS/ASC final rule with comment period, we added an eighth service category to the prior authorization process for certain hospital OPD services (87 FR 71748, 72224 through 72233). The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In alignment with the CMS Interoperability and Prior Authorization final rule (87 FR 76238), we propose to change the current review timeframes for provisionally affirmed or non-affirmed requests from 10 business days to 7 calendar days for standard reviews after receiving the prior authorization request for OPD services under Medicare FFS. The ICR associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by providers. The prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding,

⁵⁵⁸ See also Correction Notice issued January 3, 2020 (85 FR 224).

and payment rules, and the request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the changes in review timeframes for the OPD prior authorization process will be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules. The submitter will then forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation. We expect that this information will generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task will be 30 minutes, equivalent to normal prepayment or postpayment medical review. We anticipate that most prior authorization requests will be sent by means other than mail, such as electronically or by fax. However, we estimate a cost of \$5 per request for mailing medical records. Based on data from 2019-2022, we estimate that there will be 127,397 initial requests mailed per year. In addition, we estimate there will be 41,806 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be \$846,015 (169,203 mailed requests x \$5). We also estimate that an additional 3 hours per provider will be required for attending educational meetings and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data from the Bureau of Labor Statistics (BLS) and based on the 2022 median rate for Miscellaneous Healthcare Support Occupations⁵⁵⁹. Based on the BLS information, we estimate an average clerical hourly rate of \$18.53 with a loaded rate of \$37.06. The prior authorization program does not create any new documentation or administrative requirements. Instead, it will just require the same documents needed to support claim payments

⁵⁵⁹ https://www.bls.gov/oes/current/oes_nat.htm

to be submitted earlier in the claim process. We use the clerical rate since we do not believe that clinical staff will need to spend more time completing the documentation than they will need in the absence of the prior authorization policy. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. We estimate that the total annual number of submissions will be 564,010 (394,808 submissions through fax or electronic means + 169,203 mailed submissions). Therefore, we estimate that the annual burden hours allotted across all providers will be 316,412 hours (.5 hours x 564,010 submissions plus 3 hours x 11,469 providers for education). The annual burden cost is \$12,572,244 (316,412 hours x \$37.06 plus \$846,015 for mailing costs). CMS estimates the annual burden to be 316,412 hours and \$12,572,244 million. The ICR approved under OMB control number 0938-1368 will be revised and submitted to OMB for approval of this extension.

Table 111 below is a chart reflecting the total burden and associated costs for the provisions included in this proposed rule with the comment period. The previously approved Paperwork Reduction Act package (CMS-10711) is currently undergoing the renewal process. CMS did not make any changes to the information collection, such as the number of respondents, responses, or other information collection requirements. However, there is a one-hour change in the burden hours, from 316,413 to 316,412, likely due to rounding up in the previous year's calculations. The burden costs have increased from \$11,561,950 to \$12,572,244 due to an increase in the average clerical hourly rate from \$17.13 in 2019 to \$18.53 in 2022.

TABLE 111: TOTAL BURDEN FOR NEW SERVICE CATEGORY

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process	-1	+\$1.0 million

* Numbers rounded.

F. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

In section XXII.B.2 of this proposed rule, we propose that for the FY 2026 payment determination, the submission of CCDEs and linking variables associated with the Hybrid Hospital-Wide Readmission (HWR) measure and the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure would remain voluntary. We are not proposing any other modifications to either measure.

In the FY 2020 IPPS/LTCH PPS final rule and the FY 2022 IPPS/LTCH PPS final rule, we estimated the burden for voluntary reporting for the Hybrid HWR (84 FR 42603 and 42604) and Hybrid HWM measures (86 FR 45508), respectively. In both final rules, we stated that we encourage all hospitals to submit data for the Hybrid HWR and Hybrid HWM measures during the voluntary reporting period. Our previously finalized burden estimates assume that all hospitals will participate during the voluntary reporting period in order to not underestimate the burden on participating hospitals. Therefore, we do not anticipate any changes to the burden currently approved for the Hospital IQR Program under OMB control number 0938-1022 (expiration date January 31, 2026).

G. ICRs for Continuous Eligibility (42 CFR 435.926 and 457.342)

In section XX of this proposed rule, we propose to align the Medicaid and CHIP regulations with the continuous eligibility requirements under section 5112 of Title V, subtitle B (hereafter, “section 5112”) of the CAA, 2023. To comply with section 5112 of the CAA, 2023, States must submit a CHIP SPA and a Medicaid SPA to provide continuous eligibility for children if they do not already do so in their CHIP or Medicaid State plans, or if their current continuous eligibility SPAs do not comply with the CAA, 2023 requirements. CMS has already received approval for the burden estimates for the CHIP continuous eligibility SPA under OMB control number 0938-1148 (CMS-10398) and for the Medicaid continuous eligibility SPA under OMB control number 0938-1188 (CMS-10434). We do not anticipate any changes to the approved burden estimates.

H. ICRs Regarding Organization, Staffing and Delivery of Services for Hospitals (§ 482.59 a and b) and CAHs (§ 485.649 a through b)

We calculated the estimated hourly rates based upon the national mean salary for that particular position increased by 100 percent to account for overhead costs and fringe benefits (using the May 2023 National Occupational Employment and Wage Estimates, Bureau of Labor Statistics (BLS) at https://www.bls.gov/oes/current/oes_nat.htm. The wage and salary data from the BLS do not include health, retirement, and other fringe benefits, or the rent, utilities, information technology, administrative, and other types of overhead costs supporting each employee. The HHS-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for including these overhead and fringe benefit costs.

Table 112 presents the BLS occupation code and title, the facility provider position, the estimated average or mean hourly wage, and the adjusted hourly wage (with a 100 percent markup of the salary to include fringe benefits and overhead costs).

TABLE 112: ESTIMATED HOURLY WAGE BY OCCUPATIONAL GROUP

BLS (NAICS) Occupation Code	BLS Occupation Category	Mean Hourly Wage (a)	Loaded Hourly Wage (b = a × 2)	Loaded Average Hourly Wage for Group (c =b1+b2...+bn/n)
Leadership & Senior Staff:				\$194
11-1011	Chief Executive	\$124.47	\$248.94	
11-9111	Medical and Health Services Manager	\$64.64	\$129.28	
23-1011	Lawyer	\$84.84	\$169.68	
29-1210	Physician	\$126.85	\$253.70	
11-3031	Financial Manager	\$84.05	\$168.10	
Administrative Staff:				\$68
11-3010	Administrative Services & Facilities Manager	\$56.56	\$113.12	
19-3022	Survey Researchers	\$32.05	\$64.10	
19-3099	Social Scientists	\$49.14	\$98.28	

BLS (NAICS) Occupation Code	BLS Occupation Category	Mean Hourly Wage (a)	Loaded Hourly Wage (b = a × 2)	Loaded Average Hourly Wage for Group (c =b1+b2...+bn/n)
43-6013	Medical Secretary	\$20.85	\$41.70	
29-2072	Medical Records Specialist	\$25.81	\$51.62	
43-4000	Information and Record Clerk	\$20.49	\$40.98	
Care Staff:				\$104
29-1210	Physician	\$126.85	\$253.70	
29-1071	Physician Assistant	\$62.74	\$125.48	
29-1171	Nurse Practitioner	\$61.78	\$123.56	
29-1141	Registered Nurse	\$45.42	\$90.84	
21-1022	Healthcare Social Worker	\$32.42	\$64.84	
31-1131	Nursing Assistant	\$19.04	\$38.08	
31-1120	Home Health and Personal Care Aide	\$16.05	\$32.10	
19-3033	Clinical and Counseling Psychologist	\$51.25	\$102.50	
Technical Staff:				\$112
15-0000	All Computer and Mathematical Occupations	\$54.39	\$108.78	
15-2051	Data Scientists	\$57.23	\$114.46	
All Staff (Average)				\$109
All Staff with Triple Weight to Care Staff (Average)				\$130
Patients:				\$31
00-000	All Occupations Average	\$31.48	\$62.96	

We propose new requirements for hospitals and CAHs that provide obstetrical (OB) services. We propose that if a hospital or Critical Access Hospital (CAH) provides OB services, such services must be well-organized and in accordance with nationally recognized acceptable standards of practices for physical and behavioral health of pregnant, birthing, and postpartum patients. We also propose that any outpatient OB services would be consistent in quality with

inpatient OB services in accordance with the complexity of services offered. In addition, we propose that the organization of the OB service be appropriate to the scope of services offered by the facility and integrated with other departments of the facility. We further propose that the OB patient care units be supervised by an individual with the necessary education and training, and specify that person should be an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy. In addition, hospitals and CAHs must delineate and document obstetrical privileges for all practitioners providing obstetrical care in accordance with the competencies of each practitioner.

For delivery of services, we propose that OB services must be consistent with the needs and resources of the facility. Policies governing OB care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety. We additionally propose that labor & delivery room suites have certain basic resuscitation equipment readily available, including a call-in-system, cardiac monitor, and fetal doppler or monitor. Furthermore, the service must ensure that it has adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the facility's QAPI program.

To identify the number of hospitals and CAHs that would be subject to the proposed provisions, we utilized the Center for Medicare and Medicaid Services' Provider of Services File – Hospital and Non-Hospital Facilities. We excluded hospitals and CAHs that do not provide obstetric services, as well as Rural Emergency Hospitals that are not subject to these CoPs. Using this methodology, we obtained a total of 513 CAHs and 4,415 hospitals that provide obstetric services.⁵⁶⁰

⁵⁶⁰ Provider of Services File – Hospital & Non-Hospital Facilities. Available at <https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data>. Accessed April 10, 2024.

We believe that most hospitals and CAHs that provide OB services already have internal standards and protocols to ensure that OB services are well organized and to provide high-quality care that is appropriate to the level of services provided and integrated with other departments of the facility. We also expect that they have internal standards and protocols to ensure compliance with nationally accepted guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events. Many hospital accrediting organizations also have specific requirements governing care for pregnant and postpartum patients that would meet the proposed requirements. For example, The Joint Commission (TJC) has wide-ranging requirements for hospitals that provide perinatal care, covering everything from providing information to families in a way that is easy to understand to providing initial care for complications such as hemorrhage, hypertensive disorders, fetal heart rate abnormalities.⁵⁶¹ We expect, however, that some hospitals and CAHs may need to spend time ensuring that these standards and their sources are well-documented.

As outlined in 84 FR 51732, writing new policies related to patient care is estimated to take eight hours for each member of the staff involved in the care policy. We have estimated wages as indicated in Table 112 and included the involvement of a physician at \$2,029.60 (8 × \$253.70), a lawyer at \$1357.44 (8 × \$169.68), a registered nurse at \$726.72 (8 × \$90.84), a medical secretary at \$333.6 (8 × \$41.70), and a medical and health services manager at \$1,034.24 (8 × \$129.28) for a total estimated cost of \$5,481.60 per policy. This estimate leads to an average hourly cost of \$137.04 ($\$5481.60 \div 40$) per staff member involved in ensuring that these standards and their sources are well-documented. We assume that documentation would consist of one comprehensive policy per facility.

⁵⁶¹ The Joint Commission Edition. Program: Perinatal Care, “Chapter: Provision of Care, Treatment, and Services.” Available at <https://e-dition.jcrinc.com/MainContent.aspx>. Accessed April 10, 2024.

We do not expect that all facilities would need to spend 40 hours to meet these requirements. We expect that there will be no burden for TJC-accredited facilities since the organization has wide-ranging requirements for hospitals and CAHs, with the requirements increasing as the complexity of OB care offered increases. To account for this reduction in the overall burden, we used CMS' CASPER (Certification and Survey Provider Enhanced Reports)⁵⁶² to identify TJC-accredited hospitals and CAHs. According to CASPER, approximately 72.2 percent of Medicare and Medicaid approved hospitals are accredited by The Joint Commission (TJC), as well as 25 percent of Critical Access Hospitals (CAHs).

To calculate the hourly burden for this proposed requirement, in Table 113 we multiply the number of facilities by the number of responses per facility, applying the discount for hospitals and CAHs that are accredited by TJC, by the hourly burden estimate. To determine the associated cost, we multiply the revised hourly burden estimate by the average hourly labor cost. Using this formula, in Table 113 we estimate a total burden of 79,853 hours at a cost of \$10,943,006.

Table 114 provides the annual burden estimate over a 10-year period. We do not estimate a burden for updating these policies and procedures after their initial development in year 1 since regularly reviewing and updating policies is a standard business practice for healthcare facilities that must comply with applicable federal, state, and local laws, regulations and ordinances that periodically change. As such, the total estimate over 10 years is 79,853 hours at a cost of \$10,943,006.

For the requirement that facilities delineate and document obstetrical privileges for all practitioners providing obstetrical care, we expect that most hospitals and CAHs already have knowledge regarding their practitioners' competencies. We expect, however, that they would need to spend time to build a roster of practitioners specifying each practitioner's privileges and

⁵⁶² Quality, Certification & Oversight Reports (QCOR). CASPER (4/16/2024). qcor.cms.gov.

to update this roster annually. We estimate that building and ensuring that this roster is up to date would take 8 hours of work annually by a medical secretary at \$333.6 (8 × \$41.70). As shown in Tables 115 and 116, we estimate that this provision would cost \$2,180,736 annually and \$21,807,360 over 10 years.

For the requirements that the OB patient care units be supervised by an individual with the necessary education and training, as well as ensuring that labor and delivery room suites have certain basic resuscitation equipment readily available, and that the facility has adequate provisions for obstetrical emergencies, we provide the estimated cost in the regulatory impact analysis section below.

TABLE 113: BURDEN ESTIMATE FOR ORGANIZATION, STAFFING, AND DELIVERY OF SERVICES REQUIREMENT BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	TJC Overlap Discount (d = 1 - TJC overlap discount)	Hourly Wage Cost (e)	Total Hourly Burden (f = b × c × d × e)	Total Hourly Burden Cost (g = e × f)
Hospital	5,797	5,797	40	0.278	\$137.04	64,463	\$8,833,960
CAH	513	513	40	0.75	\$137.04	15,390	\$2,109,046
Total	6,310	6,310				79,853	\$10,943,006

TABLE 114: 10 YEAR BURDEN ESTIMATE FOR ORGANIZATION, STAFFING, AND DELIVERY OF SERVICES REQUIREMENT

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total 10 Year Burden
Hourly Burden	79,853	0	0	0	0	0	0	0	0	0	79,853
Hourly Burden Cost	\$10,943,006	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$10,943,006

TABLE 115: BURDEN ESTIMATE FOR DELINEATING PRACTITIONERS OBSTETRICAL SERVICES BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Annualized Hourly Burden (b)	Hourly Wage Cost (c)	Total Hourly Burden (d = a × b)	Total Hourly Burden Cost (e = c × d)
CAH	513	8	\$43.20	4,104	\$177,293
Hospital	5,797	8	\$43.20	46,376	\$2,003,443

TABLE 116: 10 YEAR BURDEN ESTIMATE FOR DELINEATING PRACTITIONERS OF OBSTETRICAL SERVICES

Year	Hourly Burden	Hourly Burden Cost
1	50,480	\$2,180,736
2	50,480	\$2,180,736
3	50,480	\$2,180,736
4	50,480	\$2,180,736
5	50,480	\$2,180,736
6	50,480	\$2,180,736
7	50,480	\$2,180,736
8	50,480	\$2,180,736
9	50,480	\$2,180,736
10	50,480	\$2,180,736
10 Year total Cost	504,800	\$21,807,360

I. ICRs Regarding OB Staff Training for Hospitals (§482.59(c) and CAHs (§485.649(c))

We propose that hospitals and CAHs that provide OB services must develop policies and procedures to ensure that staff are trained on select topics related to improving the delivery of maternal care. The training must reflect the scope and complexity of services offered and must include, but is not limited to, facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility. They would also need to be trained in any additional topics as identified by the facility's QAPI program. We also propose that the governing body must identify and document which staff must complete annual training on these topics. The facility must further document that training was successfully completed and must be able to demonstrate staff knowledge on these topics. Lastly, we propose that the efficacy of the training must be reviewed and assessed on an ongoing basis, based on the results of data, measures, and quality indicators from its QAPI program.

As outlined in 84 FR 51732, writing new policies related to patient care is estimated to take eight hours for each member of the staff involved in the care policy. We have estimated wages as indicated in Table 112 and included the involvement of a physician at \$2,029.60 (8 × \$253.70), a lawyer at \$1357.44 (8 × \$169.68), a registered nurse at \$726.72 (8 × \$90.84), a medical secretary at \$333.6 (8 × \$41.70), and a medical and health services manager at \$1,034.24 (8 × \$129.28) for a total estimated cost of \$5,481.60 per policy. This estimate leads to an average hourly cost of \$137.04 ($\$5481.60 \div 40$) per staff member involved in ensuring that

these standards and their sources are well-documented. We assume that documentation would consist of one comprehensive policy per facility. We do not estimate a burden for reviewing and assessing the efficacy of these efforts since we address this below in the section, “Revisions to QAPI (§ 482.21) Standards for OB Services”. We also do not estimate a burden for documentation that training was completed as updating employee records is also a customary business practice. As indicated in Table 117 and Table 118, we estimate that the development of the proposed OB staff training policies and procedures will take 252,400 hours to complete and cost \$34,588,896.

TABLE 117: YEAR 1 BURDEN ESTIMATE FOR OB STAFF TRAINING POLICIES AND PROCEDURES BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	5,797	5,797	40	\$137.04	231,880	\$31,776,835
CAH	513	513	40	\$137.04	20,520	\$2,812,061
Total	6,310	6,310			252,400	\$34,588,896

TABLE 118: 10 YEAR BURDEN ESTIMATE FOR OB STAFF TRAINING POLICIES AND PROCEDURES

Year	Hourly Burden	Hourly Burden Cost
1	252,400	\$34,588,896
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
10 Year total Cost	252,400	\$34,588,896

J. ICRs Regarding Revisions to QAPI (§482.21) Standards for OB Services

We propose that hospitals and CAHs with OB services must use their QAPI program to address health disparities among OB patients on an ongoing basis. They must also measure and monitor for health disparities among OB patients and develop and implement actions to address

these disparities and monitor subsequent results. Moreover, on an annual basis, they must conduct at least one performance improvement project focused on reducing maternal health disparities. In addition to the proposed QAPI requirements, we propose that OB leadership be engaged in the facility's QAPI requirement. We further propose that if a Maternal Mortality Review Committee (MMRC) is available at the state or local jurisdiction in which the facility is located, the facility must and have a process for incorporating MMRC data and recommendations into the facility's QAPI program.

The costs associated with data collection would include the cost for facilities to modify their information technology infrastructure to ensure that they capture all features relevant for the diverse subpopulations that the facility identifies. Given that many facilities already collect some of these patient characteristics, such as race and ethnicity, we estimate that planning, programming, and performing quality checks would take 8 hours in the first year and 4 hours in all subsequent years. We anticipate a mixture of staff from computer and mathematical occupations would oversee these changes at an average hourly cost of \$108.78. This leads to an average cost of \$870.24 ($8 \times \108.78) per provider in the first year and \$435.12 ($4 \times \108.78) per provider in subsequent years. As indicated in Table 119 we estimate that in the first year, updating infrastructure would cost a total of \$5,491,214. In Table 120, we provide the estimated total 10-year cost which we estimate at \$30,201,679.

Based on our experience working with healthcare data, we anticipate that stratification of data and quality indicators, together with monitoring the results after actions are taken to address these disparities would take 8 hours annually. We anticipate that data scientists would oversee these efforts at an average hourly cost of \$114.46. This leads to an average cost of \$915.68 ($8 \times \114.46) per provider annually. Table 121 provides the estimated cost in year 1 and Table 122 provides the estimated cost over 10 years. We estimate an annual cost of \$5,777,941 with a total cost of \$57,779,408 over 10 years.

The final collection of information costs related to this requirement come from the proposed provision of information to MMRCs. We estimate that for each maternal death, collection of information to be submitted to the MMRC would take 4 hours of work by a physician at \$1,014.80 ($4 \times \253.70) and 4 hours of work by a medical records specialist \$206.48 ($4 \times \51.62) for a total estimated cost of \$1,221.28 per maternal death. This estimate leads to an average hourly cost of \$152.66 ($8 \div \$1,221.28$) per staff member involved in providing information to the MMRC.

The number of maternal deaths has varied widely in recent years. In 2021, there was a spike in maternal deaths with the number of deaths increasing to 1,205, compared to 861 deaths in 2020 and 754 deaths in 2019. Preliminary data from 2022 suggests that the number of maternal deaths is declining and beginning to return to pre-2021 levels with 818 recorded deaths. Given uncertainty about how many deaths will occur in future years, we assume that an average of 850 deaths annually. A review of public sources suggests that most states have MMRCs and, as such, most hospitals and CAHs would be subject to this provision. While many hospitals and CAHs are already providing information to MMRCs, we are not able to estimate the exact number of deaths that are already being reviewed. As such, we continue to assume that 850 deaths would be subject to this proposed provision annually. We also assume that facilities would provide the information to only one MMRC even if they are located in a jurisdiction that has both a state and local MMRC. Since we are unable to divide deaths that occur in hospitals and CAHs, we provide a single cost estimate for both facility types. Table 119 provides the estimated annual cost for the proposed MMRC reporting provisions and Table 120 provides the estimated cost over 10 years.

TABLE 119: YEAR 1 BURDEN ESTIMATE FOR QAPI DATA SYSTEM MODIFICATIONS BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)
Hospital	5,797	5,797	8	\$108.78	46,376
CAH	513	513	8	\$108.78	4,104

Total	6,310	6,310		50,480
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TABLE 120: 10 YEAR BURDEN ESTIMATE FOR QAPI DATA SYSTEM MODIFICATIONS

Year	Hourly Burden	Hourly Burden Cost
1	50,480	\$5,491,214
2	25,240	\$2,745,607
3	25,240	\$2,745,607
4	25,240	\$2,745,607
5	25,240	\$2,745,607
6	25,240	\$2,745,607
7	25,240	\$2,745,607
8	25,240	\$2,745,607
9	25,240	\$2,745,607
10	25,240	\$2,745,607
10 Year total Cost	277,640	\$30,201,679

TABLE 121: YEAR 1 BURDEN ESTIMATE FOR QAPI DATA STRATIFICATION AND MONITORING BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	5,797	5,797	8	\$114.46	46,376	\$5,308,197
CAH	513	513	8	\$114.46	4,104	\$469,744
Total	6,310	6,310			50,480	\$5,777,941

TABLE 122: 10 YEAR BURDEN ESTIMATE FOR QAPI DATA STRATIFICATION AND MONITORING

Year	Hourly Burden	Hourly Burden Cost
1	50,480	\$5,777,941
2	50,480	\$5,777,941
3	50,480	\$5,777,941
4	50,480	\$5,777,941
5	50,480	\$5,777,941
6	50,480	\$5,777,941
7	50,480	\$5,777,941
8	50,480	\$5,777,941
9	50,480	\$5,777,941
10	50,480	\$5,777,941
10 Year total Cost	504,800	\$57,779,408

TABLE 123: YEAR 1 BURDEN ESTIMATE FOR MMRC REPORTING

Provider Type	Number of Providers	Annual Maternal Deaths (a)	Hourly Burden per Death (b)	Hourly Wage Cost (c)	Total Hourly Burden (d = a × b)	Total Hourly Burden Cost (e = c × d)
Hospitals and CAHs	6,310	850	8	\$152.66	6,800	\$1,038,088

TABLE 124: 10 YEAR BURDEN ESTIMATE FOR MMRC REPORTING

Year	Hourly Burden	Hourly Burden Cost
1	6,800	\$1,038,088
2	6,800	\$1,038,088
3	6,800	\$1,038,088
4	6,800	\$1,038,088
5	6,800	\$1,038,088
6	6,800	\$1,038,088
7	6,800	\$1,038,088
8	6,800	\$1,038,088
9	6,800	\$1,038,088
10	6,800	\$1,038,088
10 Year total Cost	68,000	\$10,380,880

K. ICRS Regarding Emergency Services Readiness in Emergency Services (\$482.55) for Hospitals

We propose a new standard for emergency services readiness and to improve staff readiness for providing emergency services to all hospital patients, including pregnant and postpartum patients. The first proposed standard would require hospitals with emergency services to have adequate provisions and protocols, consistent with nationally accepted guidelines, for the care of patients with emergency conditions (including but not limited to patients with OB emergencies, complications, immediate post-delivery care). Applicable staff would be required to be trained on these protocols and provisions. We also propose that equipment, supplies, and medication used in treating emergency cases are kept at the hospital and are readily available for treating emergency cases.

As outlined in 84 FR 51732, writing new policies related to patient care is estimated to take eight hours for each member of the staff involved in the care policy. Since the proposed standard for emergency services involves adding a new standard to an existing policy, we

estimate that it would take half the amount of time as writing a new policy, or 4 hours for each staff member involved. We have estimated wages as indicated in Table 112 and included the involvement of a physician at \$1,014.80 (4 × \$253.70), a lawyer at \$678.72 (4 × \$169.68), a registered nurse at \$363.36 (4 × \$90.84), a medical secretary at \$166.80 (4 × \$41.70), and a health services manager at \$517.12 (4 × \$129.28) for a total estimated cost of \$2,740.80 per policy. This estimate leads to an average hourly cost of \$137.04 (\$2,740.80 ÷ 20) per staff member involved in developing this standard. We do not estimate a burden for updating standards since reviewing and updating policies and procedures is a customary business practice. As indicated in Table 125 and Table 126, we estimate that creating this standard would cost hospitals \$15,888,418 with a total hourly burden of 115,940 hours.

TABLE 125: YEAR 1 BURDEN ESTIMATE FOR EMERGENCY SERVICES READINESS

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	5,797	5,797	20	\$137.04	115,940	\$15,888,418

TABLE 126: 10 YEAR BURDEN ESTIMATE FOR EMERGENCY SERVICES READINESS

Year	Hourly Burden	Hourly Burden Cost
1	115,940	\$15,888,418
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
10 Year total Cost	115,940	\$15,888,418

L. Transfer Protocols in Discharge Planning (§482.43) for Hospitals

We propose transfer protocol requirements for hospitals transferring patients under their care to the appropriate level of care, including to another hospital, as necessary to meet the needs

of the patient and stabilize any emergency conditions (including but not limited to patients with OB emergencies, complications, immediate post-delivery care). 87 FR 40350 estimated that for rural emergency hospitals (REHs), developing a transfer agreement with at least one hospital would require 2 hours of work from an administrator and a clerical person. We believe that hospitals would face a similar burden for this requirement. Using estimated wages as indicated in Table 112, we estimate that this requirement would include the involvement of a medical secretary at \$83.40 (2×41.70) and a medical and health services manager at \$258.56 (2×129.28) for a total estimate cost of \$341.96 per hospital. This estimate leads to an average hourly cost of \$85.49 ($\$341.96 \div 4$) per staff member involved in developing this standard. We do not estimate a burden for updating transfer protocols since reviewing and updating policies and procedures is a customary business practice. As indicated in Table 126 and Table 127, we estimate that creating these protocols would cost hospitals \$1,982,342 with a total hourly burden of 23,188 hours.

TABLE 127: YEAR 1 BURDEN ESTIMATE FOR TRANSFER PROTOCOLS

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	5,797	5,797	4	\$85.49	23,188	\$1,982,342

TABLE 128: 10 YEAR BURDEN ESTIMATE FOR TRANSFER PROTOCOLS

Year	Hourly Burden	Hourly Burden Cost
1	23,188	\$1,982,342
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
10 Year total Cost	23,188	\$1,982,342

M. Total Costs for all ICRs Related to Maternal Health

In Tables 129 and 130, we provide the total hourly burden estimate and cost for all proposed collection of information requirements related to maternal health as outlined in Tables 114, 116, 118, 120, 122, 124, 126, and 128. Overall, we estimate that the proposed requirements would have a total burden of 1,826,621 hours over 10 years at a cost of \$183,571,989.

We would note that our estimates rely on two key assumptions. First, our estimates are not able to take into account maternal deaths that hospitals and CAHs are already reporting to MMRCs. We seek comments on ways to identify the number of deaths already being reported to avoid overestimating the cost of this requirement. Second, we assume that facilities located in a jurisdiction with more than one MMRC would only report deaths to a single MMRC. Some facilities could, however, report this information to more than one MMRCs. We seek comments on both these assumptions.

TABLE 129: MATERNAL HEALTH COLLECTION OF INFORMATION REQUIREMENTS HOURLY BURDEN

Year	Organization, Staffing, and Delivery of Services	Delineating Practitioners of Obstetrical Services	OB Staff Training Policies and Procedures	QAPI Data System Modifications	QAPI Data Stratification and Monitoring	MMRC Reporting	Emergency Services Readiness	Transfer Protocols	Hourly Burden for All Requirements
1	79,853	50,480	252,400	50,480	50,480	6,800	115,940	23,188	629,621
2	0	50,480	0	25,240	50,480	6,800	0	0	133,000
3	0	50,480	0	25,240	50,480	6,800	0	0	133,000
4	0	50,480	0	25,240	50,480	6,800	0	0	133,000
5	0	50,480	0	25,240	50,480	6,800	0	0	133,000
6	0	50,480	0	25,240	50,480	6,800	0	0	133,000
7	0	50,480	0	25,240	50,480	6,800	0	0	133,000
8	0	50,480	0	25,240	50,480	6,800	0	0	133,000
9	0	50,480	0	25,240	50,480	6,800	0	0	133,000
10	0	50,480	0	25,240	50,480	6,800	0	0	133,000
10 Year Total Cost	79,853	504,800	252,400	277,640	504,800	68,000	115,940	23,188	1,826,621

TABLE 130: MATERNAL HEALTH COLLECTION OF INFORMATION REQUIREMENTS HOURLY BURDEN COST

Year	Organization, Staffing, and Delivery of Services	Delineating Practitioners of Obstetrical Services	OB Staff Training Policies and Procedures	QAPI Data System Modifications	QAPI Data Stratification and Monitoring	MMRC Reporting	Emergency Services Readiness	Transfer Protocols \$482.43	Hourly Burden Cost for All Requirements
1	\$10,943,006	\$2,180,736	\$34,588,896	\$5,491,214	\$5,777,941	\$1,038,088	\$15,888,418	\$1,982,342	\$77,890,641
2	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
3	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
4	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
5	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
6	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
7	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
8	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
9	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
10	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
10 Year Total Cost	\$10,943,006	\$21,807,360	\$34,588,896	\$30,201,677	\$57,779,410	\$10,380,880	\$15,888,418	\$1,982,342	\$183,571,989

XXV. 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.

XXVI. 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 2025. 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 are proposing to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2023, through and including December 31, 2023, and processed through June 30, 2024, and updated HCRIS cost report information.

This proposed rule is also necessary to make updates to the ASC payment rates for CY 2025, 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 2025. 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, 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).

This proposed rule is also necessary to create three additional exceptions to the four walls requirement under the Medicaid clinic services benefit at 42 CFR 440.90. Specifically, we

propose to add a mandatory four walls exception for IHS/Tribal clinics at 42 CFR 440.90(c) and optional exceptions for behavioral health clinics and clinics located in rural areas at 42 CFR 440.90(d) and (e). As discussed in section XVII.A of this proposed rule, our current regulation at 42 CFR 440.90(b) allows for an exception to the four walls requirement only for certain clinic services furnished to individuals who are unhoused.

This proposed rule is also necessary to improve the quality of obstetrical services in hospitals and Critical Access Hospitals (CAHs). The United States has the highest maternal mortality rate among OECD countries.⁵⁶³ This mortality rate has increased sharply in recent years rising from 17.4 deaths per 100 thousand live births in 2018, to 32.9 deaths per 100 thousand live births in 2021⁵⁶⁴, with most of the increased deaths in 2020 and 2021 being Covid-19 related deaths.⁵⁶⁵ The causes of pregnancy-related deaths has shifted in recent years with a decline in traditional causes, such as hemorrhage, hypertensive disorders of pregnancy, and thromboembolism, and an increase in cardiovascular problems and other medical conditions.^{566,567} Nearly a third of all pregnancy-related deaths occur between the day of delivery and the 6 days that follow, with another 20 percent of deaths occurring 7 to 42 days postpartum.⁵⁶⁸

Within the United States, there are widespread differences in maternal mortality rates based on age, race, and geographical location. According to the National Center for Health Statistics, the maternal mortality rates for women in the United States over 40 years of age in 2021 was nearly 8 times greater than for women under 25 years of age, with mortality rates for non-Hispanic black women over 40 years of age more than 21 times higher than the rate for

⁵⁶³ Tikkanen, R., et al., *Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries*. 2020, Commonwealth Fund.

⁵⁶⁴ Hoyert, D.L., *Maternal Mortality Rates in the United States, 2021*. 2023, NCHS Health E-Stats.

⁵⁶⁵ United States Government Accountability Office, *MATERNAL HEALTH: Outcomes Worsened and Disparities Persisted During the Pandemic*. 2022.

⁵⁶⁶ Creanga, A.A., et al., *Pregnancy-Related Mortality in the United States, 2011–2013*. *Obstetrics & Gynecology*, 2017. 130(2): 366-373.

⁵⁶⁷ Wang, S., et al., *Maternal Mortality in the United States: Trends and Opportunities for Prevention*. *Annual Review of Medicine*, 2023. 74(1): 199-216.

⁵⁶⁸ Peterson, E.E., et al., *Vital Signs: Pregnancy-Related Deaths, United States, 2011–2015, and Strategies for Prevention, 13 States, 2013–2017*. *Morbidity and Mortality Weekly Report*, 2019. 68(18): 423-429.

Hispanic women under 25 years of age.⁵⁶⁹ Similarly, pregnancy-related mortality rates are higher in rural areas vis-à-vis urban areas.⁵⁷⁰ Beyond deaths, maternal morbidity, defined as “any health condition attributed to and/or aggravated by pregnancy and childbirth that has a negative impact on the woman’s wellbeing”⁵⁷¹, remains a common occurrence, with rates also varying by age and race.^{572,573}

Pregnancy-related mortality and morbidity have large health and economic costs. One study estimates that between 2018 and 2020, pregnancy-related mortalities lead to the loss of nearly 114,000 years of potential life lost (YPLL) and cost more than \$27.4 billion based on the value of statistical life (VSL).⁵⁷⁴ Another study finds that severe maternal morbidity, as measured by 21 ICD-10 codes that the Centers for Disease Control and Prevention (CDC) identified, is associated with a 75 percent increase in costs for Medicaid patients and a more than doubling in costs for commercially insured patients during the prenatal to 30 days post-partum period.⁵⁷⁵ Focusing specifically on nine maternal morbidities among the 2019 US birth cohort from birth to 5-years postpartum, researchers estimated they had a cost of \$32.3 billion for birthing parents and their children, with \$18.7 billion due to medical costs and \$13.6 billion coming from non-medical costs.⁵⁷⁶

Although studies vary in their methodology, time period pre-post birth analyzed, medical conditions analyzed, and cost estimates, they overall suggest that maternal morbidity and

⁵⁶⁹ Hoyert, D.L., *Maternal Mortality Rates in the United States, 2021*. 2023, NCHS Health E-Stats.

⁵⁷⁰ Merkt, P.T., et al., *Urban-rural differences in pregnancy-related deaths, United States, 2011–2016*. *American Journal of Obstetrics and Gynecology*, 2021. 225(2): 183.e1-183.e16.

⁵⁷¹ Firoz, T., et al., *Measuring maternal health: focus on maternal morbidity*. *Bull World Health Organ*, 2013. 91(10): 794-796.

⁵⁷² Liese, K.L., et al., *Racial and Ethnic Disparities in Severe Maternal Morbidity in the United States*. *Journal of Racial and Ethnic Health Disparities*, 2019. 6(4): p. 790-798.

⁵⁷³ Leonard, S.A., et al., *Racial and ethnic disparities in severe maternal morbidity prevalence and trends*. *Annals of Epidemiology*, 2019. 33: 30-36.

⁵⁷⁴ White Robert, S., et al., *Economic burden of maternal mortality in the USA, 2018–2020*. *Journal of Comparative Effectiveness Research*, 2022. 11(13): 927-933.

⁵⁷⁵ Black, C.M., et al., *Costs of Severe Maternal Morbidity in U.S. Commercially Insured and Medicaid Populations: An Updated Analysis*. *Women's Health Reports*, 2021. 2(1): 443-451.

⁵⁷⁶ O’Neil, S.S., et al., *Societal cost of nine selected maternal morbidities in the United States*. *PLOS ONE*, 2022. 17(10): e0275656.

mortality impose a high health and safety, as well as economic costs on birth parents, children, and society.⁵⁷⁷ Given these costs, we are implementing conditions of participation (COPs) that are designed to help reduce maternal mortality and morbidity.

We propose requirements that hospital and CAH OB patient care units be supervised by an individual with the necessary education and training and have certain basic resuscitation equipment readily available. We also propose that staff involved with OB services be trained on key topics related to improving the delivery of maternal care. Hospitals and CAHs would also be required to utilize data from their QAPI program to implement one quality improvement project to address disparities in maternal care and to engage with MMRCs and integrate information from MMRCs into their QAPI program. We also propose that hospitals and CAHs have basic resuscitation equipment available and train their staff on emergency procedures for all patients. Finally, we propose that all hospital staff receive annual training on proper transfer protocols.

B. Overall Impact of Provisions of this Proposed Rule

We have examined the impacts of this rule, as required by Executive Order 12866, as amended, on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled “Modernizing Regulatory Review” (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866, as amended, and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public

⁵⁷⁷ Moran, P.S., et al., *Economic burden of maternal morbidity – A systematic review of cost-of-illness studies*. PLOS ONE, 2020. 15(1): e0227377.

health and safety effects, distributive impacts, and equity). Executive Order 14094 titled “Modernizing Regulatory Review” (hereinafter, the Modernizing E.O.) amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), 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, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President’s priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) (\$200 million or more in any 1 year). Based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by an effect on the economy of \$200 million or more in any 1 year. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined that this rulemaking is “significant”. 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 2025, compared to CY 2024, due to the changes to the OPPS in this proposed rule, would be approximately \$1.78 billion. Taking into account our estimated changes in enrollment,

utilization, and case-mix for CY 2025 we estimate that the OPSS expenditures, including beneficiary cost-sharing, for CY 2025 would be approximately \$88.2 billion, which is approximately \$5.2 billion higher than estimated OPSS expenditures in CY 2024. Table 131 of this proposed rule displays the distributional impact of the proposed CY 2025 changes in OPSS payment to various groups of hospitals and for CMHCs.

We note that under our proposed CY 2025 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 would increase total OPSS payments by 2.6 percent in CY 2025. 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 OPSS payments because these changes to the OPSS 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 2024 and CY 2025, considering all budget-neutral payment adjustments, changes in estimated total outlier payments, the application of the frontier State wage adjustment, 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 would increase total estimated OPSS payments by 2.3 percent.

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 2025 compared to CY 2024, to be approximately \$202 million. Tables 132 and 133 of this proposed rule display the redistributive impact of the CY 2025 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

We estimate that under our proposal to create three additional exceptions to the Medicaid clinic services benefit four walls requirement for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas that total Medicaid transfers would increase by \$1.18 billion for fiscal years 2025 through 2029. This includes a Federal impact of \$1.15 billion and State impact of \$30 million.

For the OB services provisions of this proposed rule, in Tables 160 and 161, we provide the total estimated cost and hourly burden of these proposed requirements both annually and over 10 years, excluding collection of information costs that we have already estimated above. Overall, we estimate that these proposed requirements would cost an average of approximately \$428 million and take 2.8 million hours to complete. Over 10 years, we estimate that the total cost would be approximately \$4.28 billion and take 28.3 million hours to complete. Below, we provide the cost estimates for each of the proposed requirements.

C. Detailed Economic Analyses

1. Estimated Effects of OPSS Changes in this Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2025 policy changes on various hospital groups. We post our hospital-specific estimated payments for CY 2025 on the CMS website with the other supporting documentation for this final rule with comment period. 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-1809-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 131 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 OPSS Changes on Hospitals

Table 131 shows the estimated impact of this 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 131, and we discuss them separately below, because CMHCs have historically been paid only for partial hospitalization services under the OPSS and are a different provider type from hospitals. In the CY 2024 OPSS/ASC final rule (88 FR 81833), we finalized paying CMHCs for partial hospitalization services and intensive outpatient services under APCs 5851 through 5854. For CY 2025, we propose to maintain the same APC structure and update each APC payment rate to reflect the most recent available cost data.

The estimated increase in the total payments made under the OPSS 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 2025 is 3.0 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.0 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.4 percentage point for CY 2025 (which is also the productivity adjustment for FY 2025 in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36205)) resulting in the proposed CY 2025 OPD fee schedule increase factor of 2.6 percent. We are using the OPD fee schedule increase factor of 2.6 percent in the calculation of the proposed CY 2025 OPDS 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 131 of this proposed rule.

To illustrate the impact of the CY 2025 changes, our analysis begins with a baseline simulation model that uses the CY 2024 relative payment weights, the FY 2024 final IPPS wage indexes that include reclassifications, and the final CY 2024 conversion factor. Table 131 shows the estimated redistribution of the increase or decrease in payments for CY 2025 over CY 2024 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2024 and CY 2025 (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 2.6 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated impact taking into account all payments for

CY 2025 relative to all payments for CY 2024, including the impact of changes in estimated outlier payments and changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we proposed to maintain the current adjustment percentage for CY 2025. 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 2025 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 2024 and CY 2025 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2025 would increase Medicare OPPS payments by an estimated 2.3 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 2.4 percent increase in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 131 shows the total number of facilities (3,511), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2023 hospital outpatient and CMHC claims data to model CY 2024 and CY 2025 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 2024 or CY 2025 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 (3,413), 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 32 CMHCs at the bottom of the impact table (Table 131 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 a decrease of 0.1 percent to an increase of 0.3, depending on the number of beds. Rural hospitals will experience an estimated decrease of 0.1 overall. Major teaching hospitals will 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 2025 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 2024 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 2025 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 2025, 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 different from the 0.88 PCR target adopted in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81589). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying 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.

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 2025 scaled weights and a CY 2024 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2024 and CY 2025.

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 2.6 percent. Overall, these changes would increase payments to urban hospitals by 2.8 percent and to rural hospitals by 3.5 percent. Rural

sole community hospitals would receive an estimated increase of 3.4 percent while other rural hospitals would receive an estimated increase of 3.6 percent.

Column 5: All Changes for CY 2025

Column 5 depicts the full impact of the proposed CY 2025 policies on each hospital group by including the effect of all changes for CY 2025 and comparing them to all estimated payments in CY 2024. Column 5 shows the combined budget neutral effects of Columns 2 and 3; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G of proposed rule; the change in 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 XIV of this proposed rule); and other proposed rule adjustments to the CY 2025 OPPS payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2024 update (and assumed, for modeling purposes, to be the same number for CY 2025), we included 106 hospitals in our model because they had both CY 2023 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2025 would increase payments to all facilities by 2.3 percent for CY 2024. We modeled the independent effect of all changes in Column 5 using the final relative payment weights for CY 2024 and the proposed relative payment weights for CY 2025. We used the final conversion factor for CY 2024 of \$87.382 and the proposed CY 2025 conversion factor of \$89.379 discussed in section II.B of this proposed rule.

Column 5 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572) of 4.1 percent (1.04142) to increase charges on the CY 2023 claims, and we used the overall CCR in the April 2024 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2024. Using the CY 2023 claims and a 4.1 percent charge inflation factor, we currently estimate that outlier payments for CY 2024, using a multiple threshold of 1.75 and a fixed-dollar

threshold of \$7,750, would be approximately 0.85 percent of total payments. The estimated current outlier payments of 0.85 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 8.5 percent (1.084555) and the CCRs in the April 2024 OPSF, with an adjustment of 1.03331 (89 FR 36573), to reflect relative changes in cost and charge inflation between CY 2023 and CY 2025, to model the proposed CY 2025 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed dollar threshold of \$8,000. The charge inflation and CCR inflation factors are discussed in detail in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572 through 36573).

Overall, we estimate that facilities will experience an increase of 2.3 percent under this proposed rule in CY 2025 relative to total spending in CY 2024. This projected increase (shown in Column 5) of Table 131 of this proposed rule reflects the proposed 2.6 percent OPD fee schedule increase factor, adding the 0.15 difference in estimated outlier payments between CY 2024 (0.85 percent) and CY 2025 (1.0 percent), minus 0.44 percent for the change in the pass-through payment estimate between CY 2024 and CY 2025. We estimate that the combined effect of all changes for CY 2025 would increase payments to urban hospitals by 2.4 percent. Overall, we estimate that rural hospitals would experience a 2.8 percent increase as a result of the combined effects of all the changes for CY 2025.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes would include an increase of 2.1 percent for major teaching hospitals and an increase of 2.5 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 2.6 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 2.3 percent, proprietary hospitals would experience an increase of 3.5 percent, and governmental hospitals will experience an increase of 2.4 percent.

c. Estimated Effects of OPSS Changes on CMHCs

The last line of Table 131 demonstrates the isolated impact on CMHCs, which historically have only furnished partial hospitalization services under the OPPS. As discussed in section VIII.C of this proposed rule, we propose for CY 2025 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 care as seen in the CY 2023 claims used for ratesetting in this proposed rule. We note that the CY 2023 claims used for this CY 2025 proposed rule do not include any provision of IOP services. We did not exclude days with one or two services from our modeling for CY 2025, because our proposed rule policy would pay the per diem rate for APC 5853 for such days beginning in CY 2025. As a result of the final PHP APC changes for CMHCs, we estimate that CMHCs would experience a 7.2 percent increase in CY 2025 payments relative to their CY 2024 payments (shown in Column 5). For a detailed discussion of our proposed PHP policies, please see section VIII of this proposed rule.

Column 3 shows the estimated impact of adopting the proposed FY 2025 wage index values, which result in an estimated change of 0.7 percent to CMHCs. Column 4 shows that combining the OPD fee schedule increase factor, along with the proposed changes in APC policy for CY 2025 and the proposed FY 2025 wage index updates, would result in an estimated increase of 7.7 percent.

TABLE 131: ESTIMATED IMPACT OF THE PROPOSED CY 2025 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	(1)	(2)	(3)	(4)	(5)
	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	All Changes
ALL PROVIDERS *	3,511	0.0	0.1	2.7	2.3
ALL HOSPITALS	3,413	0.1	0.2	2.9	2.4
(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS	2,722	0.1	0.1	2.8	2.4
LARGE URBAN (GT 1 MILL.)	1,291	0.2	-0.3	2.4	2.2
OTHER URBAN (LE 1 MILL.)	1,431	0.0	0.4	3.1	2.5

	(1)	(2)	(3)	(4)	(5)
	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	All Changes
RURAL HOSPITALS	691	-0.1	1.0	3.5	2.8
SOLE COMMUNITY	356	-0.1	0.9	3.4	2.7
OTHER RURAL	335	-0.1	1.0	3.6	3.1
BEDS (URBAN)					
0 - 99 BEDS	920	0.3	0.4	3.3	2.8
100-199 BEDS	763	0.2	0.2	3.0	2.5
200-299 BEDS	423	0.2	-0.1	2.7	2.3
300-499 BEDS	383	0.1	0.1	2.9	2.4
500 + BEDS	233	-0.1	0.0	2.5	2.2
BEDS (RURAL)					
0 - 49 BEDS	330	0.0	1.0	3.6	2.9
50- 100 BEDS	203	-0.1	0.6	3.2	2.5
101- 149 BEDS	83	-0.2	1.0	3.4	3.0
150- 199 BEDS	44	-0.2	1.4	3.8	3.0
200 + BEDS	31	-0.2	1.1	3.4	3.1
REGION (URBAN)					
NEW ENGLAND	121	0.0	-1.8	0.7	0.5
MIDDLE ATLANTIC	298	0.0	-0.6	2.0	1.8
SOUTH ATLANTIC	445	0.1	0.3	3.0	2.7
EAST NORTH CENT.	417	-0.1	0.4	3.0	2.7
EAST SOUTH CENT.	166	0.0	1.7	4.3	3.9
WEST NORTH CENT.	177	-0.1	1.6	4.1	2.8
WEST SOUTH CENT.	453	0.4	1.6	4.7	4.3
MOUNTAIN	210	0.1	0.0	2.7	1.8
PACIFIC	386	0.2	-1.2	1.6	1.4
PUERTO RICO	49	0.9	0.3	3.7	3.3
REGION (RURAL)					
NEW ENGLAND	21	-0.2	0.8	3.2	2.9
MIDDLE ATLANTIC	53	-0.2	0.6	3.1	2.6
SOUTH ATLANTIC	109	-0.1	0.1	2.5	2.1
EAST NORTH CENT.	110	-0.2	0.9	3.3	3.0
EAST SOUTH CENT.	132	-0.2	1.9	4.4	3.9
WEST NORTH CENT.	79	-0.1	1.8	4.3	3.0
WEST SOUTH CENT.	122	0.3	1.5	4.4	4.0
MOUNTAIN	41	-0.2	1.6	4.0	1.9
PACIFIC	24	-0.2	-1.0	1.4	1.1
TEACHING STATUS					
NON-TEACHING	2,093	0.2	0.2	3.0	2.5
MINOR	882	0.1	0.5	3.2	2.7
MAJOR	438	-0.1	-0.2	2.3	2.1

	(1)	(2)	(3)	(4)	(5)
	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	All Changes
DSH PATIENT PERCENT					
0	8	1.4	-0.1	3.9	5.4
GT 0 - 0.10	223	0.4	0.6	3.6	3.0
0.10 - 0.16	207	0.3	0.3	3.2	2.6
0.16 - 0.23	524	0.3	0.0	3.0	2.5
0.23 - 0.35	1,151	0.0	0.4	3.1	2.5
GE 0.35	905	-0.1	-0.1	2.4	2.1
DSH NOT AVAILABLE **	395	2.6	0.0	5.2	4.9
URBAN TEACHING/DSH					
TEACHING & DSH	1,163	0.0	0.1	2.7	2.3
NO TEACHING/DSH	1,156	0.2	0.1	2.9	2.4
NO TEACHING/NO DSH	8	1.4	-0.1	3.9	5.4
DSH NOT AVAILABLE2	395	2.6	0.0	5.2	4.9
TYPE OF OWNERSHIP					
VOLUNTARY	1,967	0.0	0.1	2.7	2.3
PROPRIETARY	1,017	0.8	0.6	4.0	3.5
GOVERNMENT	429	-0.1	0.1	2.7	2.4
CMHCs	32	4.3	0.7	7.7	7.2
Column (1) shows total hospitals and/or CMHCs.					
Column (2) includes all proposed CY 2025 OPPS policies and compares those to the CY 2024 OPPS.					
Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2025 hospital inpatient wage index. The final rural SCH adjustment would continue our current policy of 7.1 percent, so the budget neutrality factor is 1. The final budget neutrality adjustment for the cancer hospital adjustment is 1.0006 because the proposed CY 2025 target payment-to-cost ratio is less than the CY 2024 PCR target.					
Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.6 percent OPD fee schedule update factor (3.0 percent reduced by 0.4 percentage points for the productivity adjustment).					
Column (5) 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 the frontier adjustment to Column 3 in this table.					
These 3,511 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.					
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.					

d. 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 OPSS 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 17.8 percent for all services paid under the OPSS in CY 2025. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2025 comprehensive APC payment policy discussed in section II.A.2.b of this proposed rule. 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.

e. Estimated Effects of OPSS Changes on Other Providers

The relative payment weights and payment amounts established under the OPSS affect the payments made to ASCs, as discussed in section XIII of this final rule. Hospitals, CMHCs, and ASCs would be affected by the changes in this proposed rule. Additionally, as discussed in section VIII.A.2 of this proposed rule, we established payment for IOP furnished by RHCs, FQHCs, and Opioid Treatment Programs. These providers of IOP are not paid under the OPSS and are not included in the impact analysis shown in Table 131. However, the proposed payment amount for OPSS 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.

f. Estimated Effects of OPSS Changes on the Medicare and Medicaid Programs

The effect of the update on the Medicare program is expected to be an increase of \$1.78 billion in program payments for OPSS services furnished in CY 2025. 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 \$155 million in CY 2025. 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 \$155 million Medicaid increase, approximately \$90 million would be from the Federal government and \$65 million would be from State governments.

g. Alternative OPSS Policies Considered

Alternatives to the OPSS changes we proposed and the reasons for our selected alternatives are discussed throughout this proposed rule.

h. Proposed Add-On Payment for High-Cost Drugs to the Indian Health Service (IHS) All-Inclusive Rate (AIR)

For CY 2025, we propose to pay Indian Health Service (IHS) and tribal hospitals separately for high-cost drugs (Part B drugs with daily costs over \$1,334) furnished in hospital outpatient departments through an add-on payment, in addition to the All-Inclusive Rate (AIR), using the IHS authority⁵⁷⁸ under which the annual AIR is calculated. This policy is projected to increase Medicare program expenditures by approximately \$30 million in CY 2025. We refer

⁵⁷⁸ Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

readers to section X.C of this proposed rule for further discussion of this policy.

2. Estimated Effects of CY 2024 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 2025 ASC relative payment weights by scaling the proposed CY 2025 OPPS relative payment weights by the proposed CY 2025 ASC scalar of 0.873. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 132 and 133.

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. 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 2025 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which is the hospital market basket update for CY 2025. We calculated the proposed CY 2025 ASC conversion factor by adjusting the CY 2024 ASC conversion factor by 0.9958 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2024 and CY 2025, which includes our proposed limit on wage index declines of greater than 5 percent, and by applying the CY 2025 productivity-adjusted hospital market basket update factor of 2.6 percent (which is equal to the proposed inpatient hospital market basket percentage increase of 3.0 percent reduced by a

productivity adjustment of 0.4 percentage point). The proposed CY 2025 ASC conversion factor is \$54.675 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 2025 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2023 and CY 2025 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2025 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 eye, digestive system, or orthopedic procedures. The combined effect of the proposed update to the CY 2025 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 2025 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2023 claims data. Table 132 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2024 payments to estimated CY 2025 payments, and Table 133 shows a comparison of estimated CY 2024

payments to estimated CY 2025 payments for procedures that we estimate would receive the most Medicare payment in CY 2024.

In Table 132, 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 132.

- 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 2024 ASC Payments were calculated using CY 2023 ASC utilization data (the most recent full year of ASC utilization) and CY 2024 ASC payment rates. The surgical specialty groups are displayed in descending order based on estimated CY 2024 ASC payments.

- Column 3—Estimated CY 2025 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 2025 compared to CY 2024.

As shown in Table 132, 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 2025 would result in a 2 percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 2 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 2 percent increase in aggregate payment amounts for nervous system

procedures, a 3 percent increase in aggregate payment amounts for digestive system procedures, a 2 percent increase in aggregate payment amounts for cardiovascular system procedures, and a 2 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 2.6 percent payment rate update which is offset by roughly 0.4 percentage points as a result of the proposed CY 2025 ASC wage indexes and the proposed ASC wage index scalar of 0.9958, resulting in a net 2.2 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 2.2 percent increase, depending on if payment weights in the OPSS 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 3 percent increase in gastrointestinal procedure payments. The increase in payment rates for gastrointestinal procedures is a result of relative increase in the OPSS relative weights for the Upper GI Procedures and Lower GI Procedures clinical families. These changes are further increased by the 2.2 percent ASC overall rate increase for these procedures. For estimated changes for selected procedures, we refer readers to Table 132 provided later in this section.

TABLE 132: ESTIMATED IMPACT OF THE CY 2025 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2024 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2024 ASC Payments (in Millions) (2)	Estimated CY 2025 Percent Change (3)
Total	\$6,810	2
Eye	\$2,003	2
Musculoskeletal	\$1,320	2
Nervous System	\$1,227	2
Gastrointestinal	\$1,005	3
Cardiovascular	\$332	2
Genitourinary	\$257	2

Table 133 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2025. The table displays 30 of the procedures receiving the greatest estimated CY 2024 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2024 program payment.

- Column 1–CPT/HCPCS code.
- Column 2–Short Descriptor of the HCPCS code.
- Column 3–Estimated CY 2024 ASC Payments were calculated using CY 2023 ASC utilization (the most recent full year of ASC utilization) and the CY 2024 ASC payment rates.

The estimated CY 2024 payments are expressed in millions of dollars.

- Column 4–Estimated CY 2025 Percent Change reflects the percent differences between the estimated ASC payment for CY 2024 and the estimated payment for CY 2025 based on the proposed update.

TABLE 133: ESTIMATED IMPACT OF THE PROPOSED CY 2025 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2024 ASC Payment (in millions) (3)	Estimated CY 2025 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	\$1,329	2
27447	Total knee arthroplasty	\$336	2
45380	Colonoscopy and biopsy	\$256	3
45385	Colonoscopy w/lesion removal	\$241	3
63685	Ins/rplc spi npg/rcvr pocket	\$214	4
63650	Implant neuroelectrodes	\$181	3
43239	Egd biopsy single/multiple	\$177	6
27130	Total hip arthroplasty	\$168	2
66991	Xcapsl ctrc rmvl insj 1+	\$127	0
64483	Njx aa&/strd tfrm epi l/s 1	\$107	2
64590	Ins/rpl prph sac/gstr npg/r	\$103	2
66982	Xcapsl ctrc rmvl cplx wo ecp	\$97	2
64635	Destroy lumb/sac facet jnt	\$87	3
29827	Sho arthrs srg rt8tr cuf rpr	\$85	3
36902	Intro cath dialysis circuit	\$76	4
64493	Inj paravert f jnt l/s 1 lev	\$72	2
64561	Implant neuroelectrodes	\$68	4
66821	After cataract laser surgery	\$66	2
G0105	Colorectal scrn; hi risk ind	\$65	3

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2024 ASC Payment (in millions) (3)	Estimated CY 2025 Percent Change (4)
0784T	Ins/rplmt eltrd ra spi nstim	\$52	-4
65820	Relieve inner eye pressure	\$48	2
0275T	Perq lamot/lam lumbar	\$47	4
G0121	Colon ca scrn not hi rsk ind	\$44	3
C9740	Cysto impl 4 or more	\$43	6
62323	Njx interlaminar lmr/sac	\$42	5
15823	Revision of upper eyelid	\$40	3
64721	Carpal tunnel surgery	\$39	3
64628	Trml dstrj ios bvn 1st 2 l/s	\$35	1
27279	Arthr si jt perq/min nvas	\$34	3
27446	Revision of knee joint	\$32	2

c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2025 update to the ASC payment system would be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the new procedures to be designated as office-based for CY 2025. First, other than certain preventive services where coinsurance and the Part B deductible is 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 OPSS, 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 OPSS. Therefore, the beneficiary coinsurance amount under the ASC payment system will usually be less than the OPSS 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 OPSS 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 OPSS 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 2025, 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://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf>), we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this proposed rule. The first accounting statement, Table 134, illustrates the classification of expenditures for the CY 2025 estimated hospital OPPS incurred benefit impacts associated with the final CY 2024 OPD fee schedule increase. The second accounting statement, Table 135, illustrates the classification of expenditures associated with the 3.1 percent CY 2025 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers. The third accounting statement, Table 136 contains the classification of the costs associated with the proposed health and safety standards for obstetrical services in hospitals and critical access hospitals. This includes the total cost, benefits and transfers as outlined in the collection of information section in Table 130, and the regulatory impact analysis as provided in Table 161. Since there are no transfers and we are not able to quantify the benefits of these provisions, we do not include them in the table. This statement provides our best estimate for the proposed

health and safety standards for obstetrical services in hospitals and critical access hospitals provisions.

TABLE 134: ACCOUNTING STATEMENT: CY 2025 ESTIMATED HOSPITAL OPPTS TRANSFERS FROM CY 2024 TO CY 2025 ASSOCIATED WITH THE CY 2025 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	\$1,780 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPTS

TABLE 135: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2024 TO CY 2025 AS A RESULT OF THE CY 2025 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	\$150 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	\$150 million

TABLE 136: ACCOUNTING STATEMENT: HEALTH AND SAFETY STANDARDS FOR OBSTETRICAL SERVICES IN HOSPITALS AND CRITICAL ACCESS HOSPITALS

Category	Estimate	Units		
		Year Dollar	Discount Rate	Period Covered
Annualized Monetized Costs (\$million/year)	454	2023	2%	2024-2033

TABLE 137: FOUR WALLS: ACCOUNTING STATEMENT: MEDICAID CLINIC SERVICES FOUR WALLS EXCEPTIONS

Annual monetized transfers	Primary estimate (in millions of dollars)	Low estimate (in millions of dollars)	High estimate (in millions of dollars)	Units		
				Year dollars	Discount rate (percent)	Period covered
From Federal Government to States....	213.6	102.3	339.1	2025	2	2025-2029
From States to Health Care Providers...	219.6	103.8	357.8	2025	2	2025-2029

3. Effects of Changes in Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

a. Background

We refer readers to the CY 2024 OPPTS/ASC final rule with comment period (88 FR 81961 through 82012) for the previously estimated effects of changes to the Hospital OQR Program for the CY 2026 payment determination and subsequent years. Of the 3,062 hospital outpatient departments (HOPDs) that met eligibility requirements for the CY 2024 payment determination for the Hospital OQR Program, we determined that 117 HOPDs did not meet the requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor while an additional 58 HOPDs elected not to participate.

b. Impact of CY 2025 OPPTS/ASC Proposed Rule Proposals

In this proposed rule, we propose to adopt four measures: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (4) 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 2026 reporting period and mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

In addition, we propose to remove two claims-based measures beginning with the CY 2025 reporting period/CY 2027 payment determination: (1) the MRI Lumbar Spine for Low Back Pain measure; and (2) the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure. We further propose to require electronic health record (EHR) technology to be certified to all electronic clinical quality measures (eCQMs) available to

report for the CY 2025 reporting period/CY 2027 payment determination and subsequent years.

Lastly, we propose to modify the public reporting of data for the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) – Psychiatric/Mental Health Patients stratification so that it may be published on Care Compare in addition to the data.cms.gov downloadable files beginning in CY 2025.

We refer readers to section XXIV.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 Hospital OQR Program for the estimated 3,200 program-eligible HOPDs. A summary table (see Table 106) shows an estimated total information collection and reporting burden increase of 66,348,321 hours at a cost of \$1,624,936,216 annually associated with our proposals for the CY 2027 reporting period/CY 2029 payment determination and subsequent years compared to our currently approved information collection burden estimates.

In section XIV.B.1 of this proposed rule, we propose to adopt the HCHE measure. For HOPDs to receive a point for each of the domains in the measure, affirmative attestations are required for each of the elements within a domain. To attest affirmatively to all of the domains in the measure, HOPDs may incur costs associated with activities such as updating facility policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, and training staff. The extent of these costs would vary depending on what activities the HOPD is already performing, HOPD size, and the choices each HOPD makes in order to meet the criteria necessary to attest affirmatively.

In section XIV.B.2 of this proposed rule, we propose to adopt the Screening for SDOH measure. HOPDs that are not currently administering some screening mechanism and elect to begin doing so as a result of this measure adoption proposal would likely incur some non-recurring costs associated with changes in workflow and information systems to collect the data.

The extent of these costs is difficult to quantify as different HOPDs may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.). In addition, depending on the method of data collection utilized, the time required to complete the screening may add a negligible amount of time to patient visits.

In section XIV.B.3 of this proposed rule, we propose to adopt the Screen Positive Rate for SDOH measure, which would not result in any additional economic impacts beyond those discussed for the associated Screening for SDOH measure or in section XXIV.B (Collection of Information) of this proposed rule.

In section XV.C.1.b of this proposed rule, 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). For HOPDs 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 HOPDs 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 hospitals will report data for this measure directly to CMS, we assume some hospitals 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, 2024), an estimate of approximately \$4,000 per hospital is used to account for these costs.

In section XV.E.2.b of this proposed rule, we propose to require EHR technology to be certified to all eCQMs available to report. We do not expect HOPDs would experience an increase in information collection burden for the Hospital OQR Program as discussed in section XXIV.B (Collection of Information) of this proposed rule, because this proposal does not require

HOPDs to submit new data to CMS and the use of EHR technology that is certified to all available eCQMs has been required for the Medicare Promoting Interoperability Program (83 FR 41672) and the Hospital IQR Program (84 FR 42604). In addition, due to the differences in the build of respective CEHRT deployed in HOPDs, the mapping required to capture required data for measure calculation, and the range of HOPD participation in the development, implementation, and testing of new CEHRT functionality, an estimated cost impact of the policy is not quantifiable as it will vary by CEHRT and HOPD. For certifying a new eCQM in the eCQM measure set specifically, we expect some costs for HOPDs so that HOPDs have the option to report it.

In section XV.F.2 of this proposed rule, we propose to publicly report data for the Median Time for Discharged ED Patients – Psychiatric/Mental Health Patients stratification on Care Compare, which would not result in any additional economic impacts beyond those discussed in section XXIV.B (Collection of Information) of this proposed rule.

4. Effects of Changes in Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

a. Background

We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82149) for the previously estimated effects of changes to the REHQR Program for the CY 2024 reporting period and subsequent years. For the CY 2025 reporting period, we have estimated there would be 25 REHs mandated to report under the REHQR Program based on hospital conversions as of April 22, 2024. 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 2025 OPPS/ASC Proposed Rule Proposals

In this proposed rule, we propose to adopt three measures: (1) the Hospital Commitment to Health Equity (HCHE) measure beginning with the CY 2025 reporting period; (2) the Screening for Social Drivers of Health (SDOH) measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period; and (3) the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period. We also propose to extend the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure beginning with the CY 2025 reporting period.

We refer readers to section XXIV.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 REHQR Program for the estimated 25 REHs. A summary table (see Table 108)) demonstrates an estimated total information collection and reporting burden for 25 REHs of 9,747 hours at a cost of \$239,076 annually associated with our proposals for the CY 2026 reporting period/CY 2028 program determination and subsequent years.

In section XIV.B.1 of this proposed rule, we propose to adopt the HCHE measure. For REHs to receive a point for each of the domains in the measure, affirmative attestations are required for each of the statements within a domain. To attest affirmatively to all of the domains in the measure, REHs may incur costs associated with activities such as updating facility policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, and training staff. The extent of these costs would vary depending on what activities the REH is already performing, and the individual choices each REH makes in order to meet the criteria necessary to attest affirmatively.

In section XIV.B.2 of this proposed rule, we propose to adopt the Screening for SDOH measure. REHs that are not currently administering some screening mechanism and elect to

begin doing so as a result of this measure adoption proposal would likely incur some costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different REHs may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.). In addition, depending on the method of data collection utilized, the time required to complete the screening may add a negligible amount of time to patient visits.

In section XIV.B.3 of this proposed rule, we propose to adopt the Screen Positive Rate for SDOH measure, which would not result in any additional economic impacts beyond those discussed for the associated Screening for SDOH measure or in section XXIV.C (Collection of Information) of this proposed rule.

In section XVI.C.2 of this proposed rule, we propose to extend the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure from 1 to 2 years and to establish when an REH would be required to submit data under the REHQR Program after converting to an REH, which, if finalized as proposed, would not result in any additional economic impacts beyond those discussed in section XXIV.C (Collection of Information) of this proposed rule.

5. Effects of Changes in Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

a. Background

We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82143) for the previously estimated effects of changes to the ASCQR Program for the CY 2027 payment determination. In section XVII of this proposed rule, we discuss our proposals affecting the ASCQR Program. Based on the most recent analysis of the CY 2024 payment determination data, we found that, of the 5,536 ambulatory surgical centers (ASCs) that were actively billing Medicare, 4,196 were required to participate in the ASCQR Program. Of the 1,340 ASCs not required to participate in the program, 279 ASCs did so and met full

requirements. On this basis, we estimate that 4,475 ASCs (4,196 + 279) would submit data for the ASCQR Program for the CY 2025 reporting period unless otherwise noted. We note that this estimate is a decrease of 334 ASCs from our estimate of 4,809 provided in the CY 2024 OPPS/ASC final rule with comment period (88 FR 82143) due to results from more recent data analysis regarding numbers of eligible ASCs.

b. Impact of CY 2025 OPPS/ASC Proposed Rule Proposals

In section XIV.B of this proposed rule, we propose to adopt three measures: (1) the Facility Commitment to Health Equity (FCHE) measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

We refer readers to section XXIV.D (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 4,475 program-eligible ASCs. A summary table (see Table 110)) demonstrates an estimated total information collection and reporting burden increase for 4,475 ASCs of 346,349 hours at a cost of \$8,551,217 annually associated with our proposals for the CY 2026 reporting period/CY 2028 payment determination and subsequent years, compared to our currently approved information collection burden estimates.

In section XIV.B.1 of this proposed rule, we propose to adopt the FCHE measure. For ASCs to receive a point for each of the domains in the measure, affirmative attestations are required for each of the statements within a domain. To attest affirmatively to all of the domains in the measure, ASCs may incur costs associated with activities such as updating facility

policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, and training staff. The extent of these costs would vary depending on what activities the ASC is already performing, ASC size, and the individual choices each ASC makes in order to meet the criteria necessary to attest affirmatively.

In section XIV.B.2 of this proposed rule, we propose to adopt the Screening for SDOH measure. ASCs that are not currently administering some screening mechanism and elect to begin doing so as a result of this measure adoption proposal would likely incur some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different ASCs may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.). In addition, depending on the method of data collection utilized, the time required to complete the screening may add a negligible amount of time to patient visits.

In section XIV.B.3 of this proposed rule, we propose to adopt the Screen Positive Rate for SDOH measure, which would not result in any additional economic impacts beyond those discussed for the associated Screening for SDOH measure or in section XXIV.D (Collection of Information) of this proposed rule.

6. Effects of Changes in Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section XXII of this proposed rule, we propose that for the FY 2026 payment determination, the submission of core clinical data elements and linking variables associated with the Hybrid Hospital-Wide Readmission (HWR) measure and the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure would remain voluntary. This proposal would have no impact on participating hospitals because we are not modifying either measure.

7. Effects of Proposed Changes for Individuals Currently or Formerly in the Custody of Penal Authorities

a. Medicare FFS No Legal Obligation to Pay Payment Exclusion and Incarceration (revisions to 42 CFR 411.4)

The individuals currently or formerly in the custody of penal authorities provisions are discussed in section XXIII of this proposed rule. Section XXIII of this proposed rule describes our proposals to revise the regulations to clarify the “no legal obligation to pay” payment exclusion codified in regulation at § 411.4. Specifically, we propose to narrow the description of custody in § 411.4(b) because we no longer believe that certain classes of individuals should be presumed to be in custody for purposes of the no legal obligation to pay payment exclusion, reorganize and renumber the regulation at § 411.4(b), make certain non-substantive edits to § 411.4(a) to align the regulatory text with the statutory no legal obligation to pay payment exclusion, and define “penal authority.”

We expect that our proposal to narrow the description of “custody” will reduce burden for individuals on bail, parole, probation, or home detention and those providers and suppliers that treat them, because it will no longer be necessary to rebut the presumption that such individuals do not have a legal obligation to pay for their own healthcare in order for Medicare to pay for their health care items or services. We anticipate that our proposed revisions will ensure that Medicare properly pays for services for individuals who are on bail, parole, probation, or home detention. We also anticipate that this proposal will have a negligible impact on Medicare costs, as it does not add new covered services or benefits; rather, the proposed revisions merely remove a real or perceived barrier so that individuals on bail, parole, probation, or home detention can more easily access the Medicare benefits for which they are legally entitled.

b. Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals

We propose to revise, the eligibility criteria for the Medicare special enrollment period (SEP) for formerly incarcerated individuals at §§ 406.27(d)(1) and 407.23(d)(1). Specifically, for releases on and after January 1, 2025, we propose to base the determination of when an individual is no longer incarcerated on SSA’s data collected in its systems for determining

OASDI benefit suspensions in section 202(x)(1)(A) of the Act and any additional documentation provided by individuals to demonstrate that they have been released from incarceration. Our proposal would limit the current eligibility criteria for this SEP, which reference to the Medicare payment exclusion at § 411.4(b), to releases between January 1, 2023, and December 31, 2024.

The SEP for formerly incarcerated individuals at §§ 406.27(d)(1) (for Premium Part A) and 407.23(d)(1) (for Part B) starting in 2023 provides eligible individuals an opportunity to enroll in Medicare upon release from incarceration without waiting for the General Enrollment Period (GEP) and facing penalties for delayed enrollment. We anticipate that the proposed revisions to the SEP for formerly incarcerated individuals will provide clarity and make accessing this SEP easier upon release from incarceration, especially for a population facing many challenges reintegrating into society. However, we do not anticipate a significant impact on utilization of the SEP since there is no evidence that the current requirements have created barriers to those who want to use the SEP. As a result of this assumption, we expect a negligible impact on Medicare costs.

8. Estimated Effects of Medicaid Clinic Services Four Walls Exceptions

a. Background

As discussed in more detail in section XVIII, we propose to add exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas. The exception for IHS/Tribal clinics would be mandatory for States that cover the clinic services benefit while the exceptions for behavioral health clinics and clinics located in rural areas would be at State option. We believe that this proposal will help States strengthen and improve access to Medicaid clinic services for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas, and that it is responsive to the concerns we have heard from Tribes, the TTAG, the STAC, States, and other interested parties. In addition, we believe this proposal will advance health

equity and improve health care access for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas.

b. Overall Estimated Effects of Medicaid Clinic Services Four Walls Exceptions

The aggregate economic impact of this proposed regulation is estimated to be \$1.18 billion in transfers for fiscal years 2025-2029. This includes a Federal impact of \$1.15 billion and impacts to States of \$30 million. For the purposes of this analysis, we estimated the impacts separately for Medicaid clinic services furnished outside of the four walls for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas. Uncertainties in the estimate result in an estimated range of \$554 million to \$1.82 billion in the Federal impact and a range of \$7 million to \$95 million in the State impact.

Current Medicaid clinic services expenditures were estimated using financial reporting for 2022. Estimated expenditures for IHS/Tribal Medicaid clinic services represent those expenditures not attributable to the following Medicaid services: inpatient hospital, outpatient hospital, prescription drugs, FQHC, and RHCs; in 2022, these expenditures included expenditures for IHS/Tribal Medicaid clinic services provided outside of the four walls (due to the grace period discussed below). We assumed that 15 percent of expenditures for Medicaid clinic services were related to behavioral health based on general behavioral health utilization and spending patterns. We assumed that 17 percent of remaining Medicaid clinic services expenditures were attributable to clinics in rural areas based on 17 percent of the Medicaid population residing in rural areas. Estimated baseline Federal Medicaid expenditures for Medicaid clinic services in 2025 are \$934 million at IHS/Tribal clinics, \$530 million for behavioral health services provided at Medicaid clinics, and \$495 million for Medicaid clinic services provided in rural areas. The estimates for behavioral health services provided at Medicaid clinics and Medicaid clinic services provided in rural areas do not include Medicaid clinic services expenditures from IHS/Tribal clinics.

It is important to note that IHS/Tribal clinic services provided outside of the clinic's four walls are currently being paid for by Medicaid programs, under a CMS "grace period" that currently extends through February 11, 2025. For a more detailed discussion on this grace period please see section XVIII.A of this proposed rule. Unless the proposed exception for IHS/Tribal clinics is finalized, States will not be permitted to pay for Medicaid clinic services provided outside of the four walls of an IHS/Tribal clinic after February 11, 2025, when the grace period ends.

Table 138 demonstrates our estimates for the economic impact of an exception to the Medicaid clinic services four walls requirement for IHS/Tribal clinics. For the proposed IHS/Tribal clinic exception at 42 CFR 440.90(c), we assumed that 19 percent of current total IHS/Tribal clinic services expenditures were for services provided outside of clinics, based on information provided by the Tribes. Allowing current claiming practices to continue, trended for changes in expected cost, utilization, and enrollment each year, we estimate that Federal expenditures for services provided outside of clinics will be \$1.09 billion for fiscal years 2025 through 2029. State expenditures on Medicaid clinic services provided to AI/AN Medicaid beneficiaries by IHS/Tribal clinics are Federally matched at 100 percent. State expenditures on Medicaid clinic services provided to Medicaid beneficiaries who are not AI/AN are matched at the otherwise applicable Federal matching percentage, which is generally less than 100 percent. The estimate assumes 100 percent Federal share for all IHS/Tribal clinic services expenditures, but we acknowledge that a very small portion of these IHS/Tribal clinic services expenditures may be attributed to Medicaid beneficiaries who are not AI/AN, resulting in State expenditures. Data from which to estimate these State expenditures were unavailable for this analysis. Note that this impact estimate does reflect or account for the grace period only through February 11, 2025, the baseline for the impact estimate does not reflect or account for the grace period for dates after the expiration of the grace period. From February 12, 2025 forward, the estimate compares projections under current law, which does not allow States to pay for Medicaid clinic

services provided outside of clinics against projections under the proposed regulation, which would permit States to pay for IHS/Tribal clinic services provided outside of clinics. When the grace period is factored into the analysis for dates after the expiration of the grace period and spending under the proposed regulation is compared to expenditures under current practice, which allows payment for clinic services provided outside of IHS/Tribal clinics due to the grace period, we estimate little to no impact.

TABLE 138: IHS/TRIBAL CLINIC EXCEPTION FEDERAL SHARE IMPACT FOR 5 YEARS

	2025 (in millions)	2026 (in millions)	2027 (in millions)	2028 (in millions)	2029 (in millions)	5-year total (in millions)
High Estimate	\$329	\$328	\$326	\$325	\$323	\$1,631
Best Estimate	\$219	\$218	\$217	\$216	\$216	\$1,086
Low Estimate	\$110	\$109	\$109	\$108	\$108	\$544

Tables 139 and 140 demonstrate our estimates for the economic impact of exceptions to the four walls requirement under the Medicaid clinic services benefit for behavioral health clinics and clinics located in rural areas that are not IHS/Tribal clinics. We acknowledge that we have not included a definition of “rural” in proposed rule text, but are considering defining that term in the final rule and are considering various approaches to doing so, on which we seek comment. For purposes of our estimates of the economic impact of our proposed exception to the four walls requirement for clinics located in rural areas, our analysis defines rural areas using the RUCA classifications. We also acknowledge that for our proposed exception to the four walls requirement for behavioral health clinics would include any clinic services furnished outside of the four walls by a behavioral health clinic, including non-behavioral clinic services such as physical health services. However, for purposes of our economic impact we are unable to quantify the cost of non-behavioral clinic services. For our proposed behavioral health clinic exception at 42 CFR 440.90(d) and clinics located in rural areas exception at 42 CFR 440.90(e), we assumed a 5 percent increase in current spending in each category due to increased payment

for clinic services performed outside of the four walls. Growth in utilization and expenditures for clinic services provided both by behavioral health clinics and clinics in rural areas is expected to be limited by provider shortages in these areas of practice. Because the proposed exceptions at 42 CFR 440.90(d) and (e) are at State option, we assume that States representing 25 percent of States providing coverage of the Medicaid clinic services benefit will implement one or both of the optional exceptions. Estimated expenditures are trended each year for changes in expected cost, utilization, and enrollment. We estimate that Federal expenditures will be \$35 million for fiscal years 2025 through 2029 for clinic services furnished by behavioral health clinics, and \$30 million for fiscal years 2025 through 2029 for clinic services furnished by clinics in rural areas.

TABLE 139: BEHAVIORAL HEALTH CLINIC EXCEPTION IMPACT FOR 5 YEARS

	2025 (in millions)	2026 (in millions)	2027 (in millions)	2028 (in millions)	2029 (in millions)	5-year total (in millions)
Federal Share Impacts						
High Estimate	\$18	\$18	\$18	\$18	\$18	\$90
Best Estimate	\$7	\$7	\$7	\$7	\$7	\$35
Low Estimate	\$1	\$1	\$1	\$1	\$1	\$5
State Share Impacts						
High Estimate	\$9	\$9	\$9	\$9	\$9	\$45
Best Estimate	\$3	\$3	\$3	\$3	\$3	\$15
Low Estimate	\$1	\$1	\$1	\$1	\$1	\$5

TABLE 140: CLINIC LOCATED IN RURAL AREAS EXCEPTION IMPACT FOR 5 YEARS

Clinic located in rural areas exception (dollars in millions)	2025 (in million)	2026 (in millions)	2027 (in millions)	2028 (in millions)	2029 (in millions)	5-year total
Federal Share Impacts						
High Estimate	\$20	\$20	\$20	\$20	\$20	\$100
Best Estimate	\$6	\$6	\$6	\$6	\$6	\$30
Low Estimate	\$1	\$1	\$1	\$1	\$1	\$5
State Share Impacts						
High Estimate	\$10	\$10	\$10	\$10	\$10	\$50
Best Estimate	\$3	\$3	\$3	\$3	\$3	\$15
Low Estimate	\$1	\$1	\$0	\$0	\$0	\$2

Projected Medicaid clinic services expenditures may differ from our current estimates, including the amounts broken out for IHS/Tribal clinics, clinic services provided by behavioral health clinics, and clinic services provided by clinics in rural areas. There is uncertainty in how much current and projected IHS/Tribal Medicaid clinic services spending is attributable to Medicaid clinic services provided outside of the four walls. The IHS/Tribal clinic impact may range from \$544 million to \$1.63 billion over 5 years due to uncertainty in the level of spending for Medicaid clinic services provided outside of IHS/Tribal clinics. Uncertainty in provider availability and beneficiary demand result in uncertainty in the potential for changes in utilization and costs. The Federal impact for Medicaid clinic services furnished by behavioral health clinics may range from \$5 million to \$90 million and the Federal impact for clinic services furnished by clinics in rural areas may range from \$5 million to \$100 million over five years. State impacts over five years may range from \$5 million to \$45 million for clinic services furnished by behavioral health clinics and \$2 million to \$50 million for clinic services furnished by clinics in rural areas.

Table 141 demonstrates the total economic impact for our proposed regulation to include exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas. The total estimated impact of this proposed regulation over five years is \$1.18 billion, including Federal impact of \$1.15 billion and State impact of \$30 million. The impact may range from a low of \$561 million to a high of \$1.92 billion, including a range in the Federal estimate of \$554 million to \$1.82 billion and a range in the State impact of \$7 million to \$95 million.

TABLE 141: TOTAL IMPACT ESTIMATES FOR FIVE YEARS

	Federal Share Impact (in millions)	State Share Impact (in millions)	Total Impact (in millions)
IHS/Tribal clinic exception	\$1,086	\$0	\$1,086
Behavioral health clinic exception	\$35	\$15	\$50

Clinics located in rural areas exception	\$30	\$15	\$45
All clinic services exceptions	\$1,151	\$30	\$1,181

c. Benefits of Medicaid Clinic Services Four Walls Exceptions

The proposed changes to the Medicaid clinic services benefit are expected to benefit Medicaid beneficiaries, Tribes, and States by improving access to care for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics in rural areas. The proposed exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas would help improve access to care for these clinics' patient populations by allowing services to be furnished where the beneficiary is located. We refer readers to section XVIII.B of this proposed rule for more robust discussions on how the populations served by these clinics might benefit from exceptions to the Medicaid clinic services benefit four walls requirement and how these exceptions would improve access to care. These potential benefits cannot be monetarily quantified at this time.

d. Alternative Medicaid Clinic Services Four Walls Exceptions Considered

We considered a few different alternatives in determining the best way to address the concerns we heard from Tribes, the TTAG, the STAC, States, and other interested parties about the four walls requirement under the Medicaid clinic services benefit. We considered including an exception to the four walls requirement only for the population served by IHS/Tribal clinics, but we viewed that alternative as too limited. As we discuss in detail in section XVIII.B of this proposed rule, we concluded that the patient populations served by behavioral health clinics and clinics in rural areas might also benefit from exceptions to the four walls requirement for those clinics. We also considered proposing an exception, in addition to the three exceptions we propose in this rule, for any other populations that are identified by States as likely to meet the four criteria described in this proposed rule as warranting an exception to the four walls

requirement and that have no alternative access to services through Medicaid benefits that are not subject to a four walls requirement under Federal Medicaid law. Ultimately, it is our understanding that other populations are better able to access services through Medicaid benefits to which a four walls requirement does not apply under Federal Medicaid law (for example, FQHC services, RHC services, outpatient hospital services, etc.) than the populations targeted by the proposed exceptions. As we indicate in section XVIII.B of this proposed rule, we invite comment on our assumptions about other populations that may benefit from an exception to the four walls requirement under the Medicaid clinic services benefit. We also considered making the exceptions to the four walls requirement mandatory for behavioral health clinics and clinics located in rural areas, but, as we discuss in more detail in section XVIII.B of this proposed rule, it is our understanding that there is greater State variability in the degree to which the populations targeted by the behavioral health and rural exceptions meet the four criteria we identified than the population served by IHS/Tribal clinics. We note for readers that we also invited public comment on these assumptions in section XVIII.B of this proposed rule. Finally, as we discuss in section XVIII.B of this proposed rule, we have not proposed a specific definition of rural for our exception for clinics located in rural areas and invite public comment on the alternatives we are considering and describe in that section of the proposed rule.

9. Effects of Continuous Eligibility in Medicaid and CHIP

As discussed in section XX of this proposed rule, we propose to codify the requirement of the CAA, 2023 for States to provide 12 months of continuous eligibility for children under age 19 enrolled in Medicaid and CHIP, with limited exceptions. In addition, we propose to remove the option to disenroll children from CHIP during a continuous eligibility period due to failure to pay premiums. These regulation changes implement the statutory requirement in section 5112 of Title V, subtitle B of the Consolidated Appropriations Act, 2023.

The proposed regulation to require 12-month continuous eligibility in Medicaid and CHIP is estimated to increase annual average enrollment in Medicaid and CHIP by

approximately 124,000 by 2028 (75,000 in Medicaid and 49,000 in CHIP). The total estimated impact of this proposed regulation over 5 years is \$2,466 million, including Federal impact of \$1,592 million and state impact of \$874 million. Enrollment may range from an increase of around 92,000 to an increase of around 159,000 by 2028. The total impact may range from a low of \$1,837 million to a high of \$3,154 million, including a range in the Federal estimate of \$1,185 million to \$2,039 million and a range in the state impact of \$652 million to \$1,115 million. (See Table 142.)

TABLE 142: IMPACT OF 12-MONTH CONTINUOUS ELIGIBILITY IN MEDICAID AND CHIP

(dollars in millions)	2024	2025	2026	2027	2028	5-year total
Federal Share Impacts						
Best Estimate	\$250	\$326	\$332	\$339	\$345	\$1,592
Low Estimate	\$186	\$243	\$248	\$252	\$256	\$1,185
High Estimate	\$319	\$419	\$426	\$434	\$441	\$2,039
State Share Impacts						
Best Estimate	\$148	\$177	\$180	\$183	\$186	\$874
Low Estimate	\$111	\$132	\$134	\$137	\$138	\$652
High Estimate	\$189	\$225	\$230	\$234	\$237	\$1,115

TABLE 143: ACCOUNTING STATEMENT FOR 12-MONTH CONTINUOUS ELIGIBILITY IN MEDICAID AND CHIP

Annual monetized transfers	Transfers			Units		
	Primary estimate (in millions of dollars)	Low estimate (in millions of dollars)	High estimate (in millions of dollars)	Year dollars	Discount rate (percent)	Period covered
From Federal Government to States....	317.8	236.4	407	2025	2	2024-2028
From States to Health Care Providers...	174.8	130.3	222.7	2025	2	2024-2028

10. Effects of Proposed Requirements for Obstetrical Services in Hospitals and Critical Access Hospitals (CAHs)

a. Organization, Staffing and Delivery of Services for Hospitals (§ 482.59 a through b) and CAHs (§ 482.649 a through b)

In section XXIV, we have estimated the cost for hospitals and CAHs to develop internal standards and protocols to ensure that services are well organized and to provide high-quality care that is appropriate to the level of services provided and integrated with other departments of the facility, as well as to ensure compliance with nationally recognized and evidence-based guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events. We have also estimated the cost for hospitals and CAHs to delineate and document obstetrical privileges for all practitioners providing obstetrical services in accordance with the competencies of each practitioner. Below, we estimate the cost for ensuring that OB patient care units (i.e., labor rooms, delivery rooms, including rooms for operative delivery, and post-partum/recovery rooms whether combined or separate) be supervised by an individual with the necessary education and training, and specify that person should be an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy. We also estimate the cost for the proposal that are also proposing that labor and delivery room suites have certain basic resuscitation equipment readily available, including a call-in-system, cardiac monitor, and a fetal doppler or monitor.

While hospitals and CAHs already likely to already have an individual supervising OB patient care unit, there is variation across facilities regarding whether they have the necessary education and training related to OB patient care. Many facilities, especially larger hospitals that have large birth volumes, are likely to already have an experienced individual with the necessary education and training. Smaller facilities with lower birth volumes, in contrast, may be less likely to have an individual and need to recruit a new individual to meet the proposed requirement.

Given uncertainty about the number of facilities that already have an experienced individual who would meet the requirement, we assume that each facility would need to hire one individual, who we assume would be a registered nurse, to meet the requirement. To estimate the cost of hiring this individual, we reviewed research related to the cost of registered nurse turnover. A review of academic literature found that each RN turnover cost employers between \$21,514 and \$88,000.⁵⁷⁹ We take the midpoint of these two estimates, or \$54,757 per individual hired. As shown, in Tables 144 and 145, we estimate that this requirement will cost facilities \$345,516,670 in both year 1 and over 10 years. We seek comments on data sources to estimate the number of facilities that are likely to already have an individual who meets the proposed requirements. We also seek comments on other sources of data to estimate the cost for hiring an individual with the necessary education and training to meet this requirement.

TABLE 144: QUALIFIED OB SUPERVISOR COST

Provider Type	Number of Providers (a)	Staff Members Needed per Provider (b)	Total Staff Members Needed (c = a × b)	Average Cost per Staff Member (d)	Total Annual Cost (e = c × d)	Average Cost per Facility (f = e / b)
CAH	513	1	513	\$54,757	\$28,090,341	\$54,757
Hospital	5,797	1	5,797	\$54,757	\$317,426,329	\$54,757

TABLE 145: QUALIFIED OB SUPERVISOR 10 YEAR COST

Year	Total Cost
1	\$345,516,670
2	\$0
3	\$0
4	\$0
5	\$0
6	\$0
7	\$0
8	\$0
9	\$0
10	\$0
10 Year Total Cost	\$345,516,670

⁵⁷⁹ Bae, S.H., *Noneconomic and economic impacts of nurse turnover in hospitals: A systematic review*. Int Nurs Rev, 2022. 69(3): 392-404.

To estimate the cost for having certain basic resuscitation equipment readily available, we reviewed public data sources to estimate the cost of purchasing a call-in system, cardiac monitor, and a fetal doppler or monitor. While we were not able to identify public estimates for the price of call-in systems, based on our experience we estimate that they would cost \$2500 to \$3500 per system. Reviewing the webpages of various online suppliers, we found that fetal dopplers and fetal monitors cost between \$502 and \$8,995^{580,581} and cardiac monitors cost between \$1,071 and \$10,246.⁵⁸² For each of these systems, we use the mid-point of the price estimate and assume that each call-in system would cost \$3,000, each fetal monitor or fetal doppler would cost \$4,749, and each cardiac monitor would cost \$5,659.

According to the Centers for Disease Control and Prevention there were a total of 3,667,758 births in 2022.⁵⁸³ With a total of 6,310 hospitals and CAHs with obstetrical units, this leads to an average of 581 ($3,667,758 \div 6,310$) births per hospital and CAH or an average of 1.59 births per facility per day. We estimate that each birth will take 1 day on average. To account for variation in birth volumes throughout the year, we assume that each facility would need to prepare for double the number of average births per day, or 3.18 patients. Since equipment cannot be divided, we assume that facilities will need to have equipment available for 4 patients daily. We assume that each facility already has one fetal monitor and cardiac monitor but do not assume that they will have a call-in system.

⁵⁸⁰ Medical, U. *FETAL DOPPLERS*. 2024 May 8, 2024 [cited 2024 May 8]; Available from: <https://www.usamedicalsurgical.com/fetal-dopplers/>.

⁵⁸¹ CardiacDirect. *Fetal Monitors*. 2024 [cited 2024 May 8]; Available from: https://www.cardiacdirect.com/product-category/fetal-monitors/?utm_source=google&utm_medium=cpc&utm_term=fetal%20heart%20monitor&utm_content=!acq!v3!1163626993_kwd-295102856827__607346518010_g_c__&utm_campaign=FetalMonitor&gad_source=1&gclid=EA1aIQobChMIsLqp o8f-hQMVLyetBh3deAZuEAAYASAAEgIcx_D_BwE.

⁵⁸² CardiacDirect. *Patient Monitors*. 2024 May 8, 2024 [cited 2024 May 8]; Available from: https://www.cardiacdirect.com/product-category/patient-monitors/?min_price=0&max_price=10250&page=1.

⁵⁸³ Osterman, M.J.K.H., Brady E., Martin, Joyce A.; Driscoll, Anne K.; Valenzuela, Claudia P., *Births: Final Data for 2022*, in *National Vital Statistics Reports*, U.S.D.o.H.a.H. Services, Editor. 2024, Centers for Disease Control and Prevention.

Based on our experience working in obstetrical units, we estimate a fetal doppler or monitor would be needed for each room/suite, a call-in system would be needed for each room/suite, and cardiac monitors would be needed for half the rooms/suites. As such, we estimate that each facility would need to purchase 3 fetal monitors or fetal dopplers at \$14,247 ($\$4,749 \times 3$), 1 cardiac monitor at \$5,659 ($\$5,659 \times 1$), and 4 call-in systems at \$12,000 ($\$3,000 \times 4$) for an average per facility cost of \$31,906. As indicate in tables 146 and 147, we estimate that this requirement would cost a total of \$201,326,860 over 10 years.

TABLE 146: OBSTETRICAL EQUIPMENT COST

Provider Type	Number of Providers (a)	Average Per Facility Cost (b)	Total Annual Cost (c = a × b)	Average Cost per Facility (d = c / b)
CAH	513	\$31,906	\$16,367,778	\$31,906
Hospital	5,797	\$31,906	\$184,959,082	\$31,906

TABLE 147: OBSTETRICAL EQUIPMENT 10 YEAR COST

Year	Total Cost
1	\$201,326,860
2	\$0
3	\$0
4	\$0
5	\$0
6	\$0
7	\$0
8	\$0
9	\$0
10	\$0
10 Year Total Cost	\$201,326,860

b. OB Staff Training for Hospitals (\$482.59(c)) and CAHs (\$485.649(c))

We propose that hospitals and CAHs with OB services must develop policies and procedures to ensure that staff are trained on key topics related to improving the delivery of maternal care. The training must reflect the scope and complexity of services offered, including, but not limited to, evidence-based best practices and protocols to improve the delivery of maternal care within the facility. We also propose that they use findings from their QAPI to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis. We also propose that the governing body must identify and document which staff

must complete annual training on these topics. The facility must further document that training was successfully completed and must be able to demonstrate staff knowledge on these topics.

In the collection of information section, we have already estimated the costs for developing policies and procedures to ensure that staff are trained on key topics related to improving the delivery of maternal care, as well as documentation that training was completed and staff knowledge on these topics. We estimate that staff training on evidence-based best practices and protocols would take 2 hours per employee and that each facility would spend 1 hour training staff on additional topics identified by the facility's QAPI program. This leads to a total hourly burden of 3 hours per employee trained.

While hospitals and CAHs have flexibility regarding which OB staff will receive training, we expect that they would likely to focus their training on medical staff who are working directly with OB patients. This includes surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, registered nurses (RNs), and Licensed Practical Nurses/Licensed Vocational Nurses (LPNs/LVNs).

To estimate the number of employees in CAHs and hospitals that would likely receive training, we first obtained data from the Bureau of Labor Statistics (BLS) on the number of surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, RNs, and LPNs/LVNs working in hospitals (NAICS 622000). Since the BLS does not provide separate employment statistics for CAHs and hospitals, we assume that the number of employees needing training and, henceforth, the costs would be in proportion to the size of facilities, specifically the number of certified beds. We obtained information on the number of certified beds in hospitals and CAHs from CMS' Q1 2024 Provider of Services File – Hospital &

Non-Hospital Facilities.⁵⁸⁴ Using this database, we estimate that 98.88 percent of certified beds for hospitals with OB services are in hospitals with the remaining 1.12 percent in CAHs.

In hospitals, which have a larger number of beds, there is likely to be a greater division of staff among units, with medical staff specifically designated to work in OB units and with pregnant patients, while other medical staff members will not work with pregnant patients. In contrast, critical access hospitals (CAHs), which are smaller in size, are likely to have medical staff that work across units given their small size. Based on our experience, we estimate that between 10 and 30 percent of medical staff in hospitals and 60 to 100 percent of medical staff in CAHs would receive the training. Given the variation for hospitals, we take the midpoint of the two estimates and assume that 20 percent of hospital medical staff and 80 percent of medical staff in CAHs would receive training. We also assume that each facility would require staff to be trained on these topics annually. As indicated in Table 148 and Table 149, we estimate that the proposed requirements would have an annual cost of approximately \$150 million with an average per facility cost of \$24,719 for hospitals and \$12,601 for CAHs. Over 10 years, the proposed requirements are estimated to take 14.2 million hours to complete and cost approximately \$1.50 billion.

We seek comments on whether hospitals and CAHs would require more or fewer groups of medical staff or other facility staff to receive this training. We are also seeking comments regarding data sources with other ways to measure share of staff who are likely to receive training in each facility type.

TABLE 148: OBSTETRICAL SERVICES STAFF TRAINING ANNUAL COST

⁵⁸⁴ Centers for Medicare and Medicaid Services. Provider of Services File - Hospital & Non-Hospital Facilities, Q1 2024. <https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data> (Accessed April 30, 2024).

Provider Type	Number of Providers (a)	Number of Certified Beds (b)	Share of all Hospital and CAH Certified Beds (c)	Total Yearly Cost if All Hospital and CAH Medical Staff were Trained (d)	Total Hospital and CAH Medical Staff (e)	Share of Medical Staff Receiving Training (f)	Total Number of Staff Members (g = c × e)	Total Annual Cost (h = c × d × f)	Total Hourly Burden (i = f × g × 3)	Average Cost per Staff Member (j = h / (f × g))	Average Cost per Facility (k = h / a)
CAH	513	12,582	0.011	\$724,555,386	2,284,580	0.8	25,478	\$6,464,223	61,147	\$317	\$12,601
Hospital	5,797	1,115,641	0.989	\$724,555,386	2,284,580	0.2	2,259,102	\$143,295,022	1,355,461	\$317	\$24,719

TABLE 149: OBSTETRICAL SERVICES STAFF TRAINING 10 YEAR COST

Year	Total Hourly Burden	Total Hourly Burden Cost
1	1,416,608	\$149,759,244
2	1,416,608	\$149,759,244
3	1,416,608	\$149,759,244
4	1,416,608	\$149,759,244
5	1,416,608	\$149,759,244
6	1,416,608	\$149,759,244
7	1,416,608	\$149,759,244
8	1,416,608	\$149,759,244
9	1,416,608	\$149,759,244
10	1,416,608	\$149,759,244
10 Year Total Cost	14,166,080	\$1,497,592,442

c. Quality Assessment and Performance Improvement Program (QAPI) for Hospitals

(§482.21(b)(4)) and CAHs (§485.641(e)(1))

At §482.21(b)(4) and §485.641(e) we are proposing modification to the QAPI program for hospitals and CAHs with OB services, respectively. Specifically, for obstetrical patients, facilities would have four new requirements: (1) analyzing data and quality indicators collected for the QAPI program by diverse subpopulations, as identified by the facility among obstetrical patients ; (2) measuring, analyzing and tracking data, measures, and quality indicators on patient outcomes and disparities in processes of care, and services and operations, among obstetrical patients; (3) analyzing and prioritizing patient health outcomes and disparities, developing and implementing actions to improve patient health outcomes and disparities, measuring results, and tracking performance to ensure improvements are sustained when disparities exist among

obstetrical patients; and (4) conducting at least one performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of obstetrical patients annually.

In the ICR, we have already discussed the expected burden for collecting data and quality indicators for obstetric patients and their outcomes and disparities in processes of care and services and operations. We believe that these data would serve as the foundation to allow facilities to develop and implement actions to improve outcomes and reduce disparities when they exist. We would expect that these data would likely be the focus of the required performance improvement project focused on improving health outcomes and reducing disparities among obstetrical patients.

To estimate the cost of tracking and implementing at least one quality improvement project, we utilized estimates from existing regulations governing QAPI program. Specifically, 81 FR 68688 estimates that collecting and analyzing data for all a long-term care facilities' improvement projects will take 20 hours, with another 20 years annually spent on implementing and documenting improvement projects. Given that the requirement we are proposing involves only a single improvement project and we have already accounted for the costs of collecting the data in the ICR, we anticipate that the ongoing annual burden for each facility to analyze the data and implement and document their improvement project(s) will be 30 hours. Using loaded hourly wage rates from Table 112, we anticipate that this will include the participation of a hospital executive at \$1,861.28 ($\232.66×8 hours), an RN at \$931.00 ($\93.10×10 hours), a physician at \$1,729.64 ($\216.08×8 hours), and a data scientist at \$368.96 ($\92.24×4 hours) for a total per facility cost of \$4,889.88 annually and an average hourly cost of \$163. As indicated in tables 150 and 151, we estimate that this requirement will cost \$30,855,143 annually and \$308,551,428 over 10 years.

TABLE 150: ANNUAL COST FOR ADDRESSING HEALTH EQUITY THROUGH QAPI PROGRAM

Provider Type	Number of Providers (a)	Annualized Hourly Burden (b)	Hourly Wage Cost (c)	Total Hourly Burden (d = a × b)	Total Hourly Burden Cost (e = c × d)
CAH	513	30	\$163.00	15,390	\$2,508,508
Hospital	5,797	30	\$163.00	173,910	\$28,346,634

TABLE 151: 10 YEAR COST FOR ADDRESSING HEALTH EQUITY THROUGH QAPI PROGRAM

Year	Total Hourly Burden	Total Hourly Burden Cost
1	189,300	\$30,855,143
2	189,300	\$30,855,143
3	189,300	\$30,855,143
4	189,300	\$30,855,143
5	189,300	\$30,855,143
6	189,300	\$30,855,143
7	189,300	\$30,855,143
8	189,300	\$30,855,143
9	189,300	\$30,855,143
10	189,300	\$30,855,143
10 Year Total Cost	1,893,000	\$308,551,430

d. Maternal Health QAPI Activities for Hospitals (\$482.21(e)) and CAHs (\$485.641(d)(4))

Using loaded hourly wage rates from Table 112, we expect that when the MMRC provides information to hospitals and CAHs, incorporating this information into the facility’s QAPI program would include the participation of a physician at \$864.32 ($\216.08×4 hours) and an RN at \$372.40 ($\93.10×4 hours) for a total cost of \$1,236.72 per facility. Altogether, we estimate that annually it would take 8 hours to complete at an average hourly cost of \$154.59 ($\$1236.72 \div 8$ hours) per facility. As indicated in tables 152 and 153, we estimate that total annual cost will be \$7,803,703 and the 10-year total cost will be \$7,803,703.

TABLE 152: MMRC INFORMATION AND QAPI INCORPORATION ANNUAL COST

Provider Type	Number of Providers (a)	Annualized Hourly Burden (b)	Hourly Wage Cost (c)	Total Hourly Burden (d = a × b)	Total Hourly Burden Cost (e = c × d)
CAH	513	8	\$154.59	4,104	\$634,437
Hospital	5,797	8	\$154.59	46,376	\$7,169,266

TABLE 153: MMRC INFORMATION AND QAPI INCORPORATION 10 YEAR COST

Year	Total Hourly Burden	Total Hourly Burden Cost
1	50,480	\$7,803,703
2	50,480	\$7,803,703

Year	Total Hourly Burden	Total Hourly Burden Cost
3	50,480	\$7,803,703
4	50,480	\$7,803,703
5	50,480	\$7,803,703
6	50,480	\$7,803,703
7	50,480	\$7,803,703
8	50,480	\$7,803,703
9	50,480	\$7,803,703
10	50,480	\$7,803,703
10 Year Total Cost	504,800	\$78,037,030

e. Emergency Services Readiness for Hospitals (§482.55(c)) and CAHs (§ 485.618(e))

The proposed standard for emergency services readiness aims to improve staff readiness for providing emergency services to all hospital and CAH patients, including pregnant and postpartum patients. It would require hospitals and CAHs with emergency services to have adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines, for the care of patients with emergency conditions. Hospitals and CAHs would be required to train applicable emergency services personnel, as determined by the facility, on these protocols and provisions on an annual basis and document that applicable staff have successfully completed the training and demonstrate their knowledge on these topics. For hospitals only, provisions must include equipment, supplies, and medication used in treating emergency cases. Provisions must include: (1) Drugs, blood and blood products, and biologicals commonly used in emergency procedures; (2) Equipment and supplies commonly used in emergency procedures; and (3) a call-in-system for each patient in each emergency services treatment area.

In section XXIV, we have already discussed the cost for hospitals to ensure that they have adequate protocols in place for emergency services, as well as to document that applicable staff have successfully completed the training and demonstrate their knowledge on these topics. The proposed training requirement for hospitals and CAHs provides flexibility regarding which staff will receive training. We expect, however, that they would likely focus their training on medical staff within emergency departments. This staff includes surgeons, physicians, physician

assistants, nurse practitioners, nurse midwives, nurse anesthetists, registered nurses, and LPNs/LVNs.

To estimate the number of employees in CAHs and REHs that would likely receive training, we first obtained data from the Bureau of Labor Statistics (BLS) on the number of surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, registered nurses, and LPNs/LVNs working in hospitals (NAICS 622000). Since the BLS does not provide separate employment statistics for CAHs and hospitals, we assume that the number of employees needing training and, henceforth, the costs would be in proportion to the size of facilities, specifically the number of certified beds. We obtained information on the number of certified beds in hospitals and CAHs from CMS' Q1 2024 Provider of Services File – Hospital & Non-Hospital Facilities.⁵⁸⁵ Using this database, we estimate that 98.88 percent of certified beds for hospitals are in hospitals with the remaining 1.12 percent in CAHs.

Based on our experience, we expect that initial staff training would take approximately 3 hours per employee. Using data from Table 112 on loaded wage rates for each employee type, we estimated the cost for training all medical staff in hospitals and CAHs in year 1 using the following formula: loaded wage rate for medical staff (surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, registered nurses, and LPNs/LVNs) × total number of each medical staff type working in hospitals and CAHs × 3 hours per employee. Using this formula, we estimate that training all medical staff would cost \$724,555,386.

In hospitals, which have a larger number of beds, there is likely to be a greater division of staff among units, with medical staff specifically designated to work in emergency departments. In contrast, CAHs, which are smaller in size, are likely to have medical staff that work across units given their small size. We assume, therefore, that 20 percent of medical staff in hospitals

⁵⁸⁵ Centers for Medicare and Medicaid Services. Provider of Services File - Hospital & Non-Hospital Facilities, Q1 2024. <https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data> (Accessed April 30, 2024).

and all medical staff in CAHs would receive the training. To calculate the year 1 cost for hospitals and CAHs, therefore, we use the following formula: Total cost for training all hospital/CAH medical staff \times % hospital(CAH) medical staff receiving training \times Share of all Hospital and CAH Certified Beds. As indicated in Table 154, we expect that the proposed requirement would cost approximately \$8 million for CAHs and \$143 million for hospitals in year 1.

For subsequent years, we expect that refresher training for medical staff, who received the full training in previous years, would take 1 hour to complete. In addition, new staff would need to receive the full 3-hour training. With an annual hospital turnover rate of approximately 21 percent⁵⁸⁶, we would expect 21 percent of employees each year to be new employees who would need 3 hours of training and 79 percent of employees would need 1 hour of training. To calculate the burden for years 2 to 10, therefore, we use the following formula: (Total cost for training all hospital/CAH medical staff \times % hospital(CAH) medical staff needing initial training \times Share of all Hospital and CAH Certified Beds) + (Total cost for training all hospital/CAH medical staff \times % hospital(CAH) medical staff receiving needing initial training \times Share of all Hospital and CAH Certified Beds). As indicated in Table 155 using this formula, we estimate that the rule would cost approximately \$72 million in years 2 to 10. Table 156 provides the total cost over 10 years which we estimate at \$796,234,077.

TABLE 154: YEAR 1 EMERGENCY SERVICES PROTOCOL TRAINING COST

Provider Type	Number of Providers (a)	Number of Certified Beds (b)	Share of all Hospital and CAH Certified Beds (c)	Total Yearly Cost if All Hospital and CAH Medical Staff were Trained (d)	Total Hospital and CAH Medical Staff (e)	Share of Medical Staff Receiving Training (f)	Total Number of Staff Members (g = c \times e)	Total Hourly Annual Cost (h = c \times d \times f)	Total Hourly Burden (i = f \times g \times 3)	Average Cost per Staff Member (j = h / (f \times g))	Average Cost per Facility (k = h / a)
CAH	513	12,582	0.011	\$724,555,386	2,284,580	1	25,478	\$8,080,278	76,433	\$317	\$15,751

⁵⁸⁶ Nursing Solutions Incorporated, 2024 NSI National Health Care Retention & RN Staffing Report. 2024.

Hospital	5,797	1,115,641	0.989	\$724,555,386	2,284,580	0.2	2,259,102	\$143,295,022	1,355,461	\$317	\$24,719
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TABLE 155: YEAR 2 EMERGENCY SERVICES PROTOCOL TRAINING COST

Provider Type	Number of Providers (a)	Number of Certified Beds (b)	Share of all Hospital and CAH Certified Beds (c)	Total Yearly Cost if All Hospital and CAH Medical Staff were Trained (d)	Total Hospital and CAH Medical Staff (e)	Share of Medical Staff Receiving Training (f)	Total Number of Staff Members (g = c × e)	Total Hourly Annual Cost (h = c × d × f)	Total Hourly Burden (i = (f × g × .79 × 1) + (f × g × .21 × 3))	Average Cost per Staff Member (j = h / (f × g))	Average Cost per Facility (k = h / a)
CAH	513	12,582	0.011	\$342,956,216	2,284,580	1	25,478	\$3,824,665	36,178	\$150	\$7,455
Hospital	5,797	1,115,641	0.989	\$342,956,216	2,284,580	0.2	2,259,102	\$67,826,310	641,585	\$150	\$11,700

TABLE 156: 10 YEAR EMERGENCY SERVICES PROTOCOL TRAINING COST

Year	Total Hourly Burden	Total Hourly Burden Cost
1	1,431,895	\$151,375,300
2	677,763	\$71,650,975
3	677,763	\$71,650,975
4	677,763	\$71,650,975
5	677,763	\$71,650,975
6	677,763	\$71,650,975
7	677,763	\$71,650,975
8	677,763	\$71,650,975
9	677,763	\$71,650,975
10	677,763	\$71,650,975
10 Year Total Cost	7,531,766	\$796,234,077

To estimate the cost for having certain basic resuscitation equipment readily available, we consulted with medical experts on the requirements. Based on their experience, we expect that the most hospitals with emergency services will already have drugs, blood and blood products, and biologicals commonly used in emergency procedures, as well as equipment and supplies commonly used in emergency procedures. As such, we do not estimate a burden for these requirements. There is likely, however, to be wide variation in hospitals for the call-in systems. Based on our experience, we estimate that 50 percent of hospitals will already have call-in systems while 50 percent will need to install them in their emergency departments.

As we noted above in estimating the cost for call-in system for obstetrical rooms/suites, while we were not able to identify public estimates for the price of call-in systems, based on our experience we estimate that they would cost \$2500 to \$3500 per system, and we utilize the mid-point of the price estimate and assume each call-in system will cost \$3000. We assume that 20 percent of hospital beds are allocated for emergency services and assume that there will need to be a call-in system for each bed. As indicated in Tables 157 and 158, we estimate that this requirement would cost a total of \$334,629,300 in year 1 and over 10 years. We seek comments on data sources that we can use to estimate the number of hospitals that already have call-in systems as well as the share of hospital beds that are devoted to emergency care.

TABLE 157: Year 1 Emergency Services’ Call-In System Requirement Cost

Provider Type	Hospital Beds (b)	Number of Providers (a)	Share of Hospitals Needing Call-in Systems (c)	Share of Beds Needing Call-In System (d)	Call-In Systems Needed (e = b × c × d)	Price per Call-In System (f)	Total Annual Cost (g = e × f)	Average Cost per Facility (h = g / (a × c))
Hospital	1,115,641	5,797	0.5	0.2	111,564	\$3,000	\$334,692,300	\$115,471

TABLE 158: 10 Emergency Services’ Call-In System Requirement Cost

Year	Total Cost
1	\$334,692,300
2	\$0
3	\$0
4	\$0
5	\$0
6	\$0
7	\$0
8	\$0
9	\$0
10	\$0
10 Year Total Cost	\$334,692,300

f. Transfer Protocols in Discharge Planning for Hospitals (§482.43(c))

We propose that hospitals have written policies and procedures for transferring patients under their care to the appropriate level of care, promptly and without undue delay to meet patients’ needs. Since hospital inpatients are included in those who may need to be transferred,

we believe that medical staff across hospitals, and not just those in emergency departments, would need to receive training on transfer protocols. Specifically, we expect that all surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists in hospitals would receive this training. We do not expect, however, that LPNs would receive this training and similarly expect that most RNs would not receive this training. Rather, we expect that among RNs, only experienced RNs who serve as transfer coordinators would receive it and estimate that this is only 5 percent of RNs nationwide. We estimate that each employee would require 1 hour of training annually and assume that that this training would occur on an annual basis. As indicated in tables 159 and 160, we expect that this requirement to cost \$71,246,104 annually and \$710,461,040 over 10 years.

TABLE 159: Transfer Protocol Training Annual Cost

Provider Type	Number of Providers (a)	Number of Certified Beds (b)	Share of all Hospital and CAH Certified Beds (c)	Total Hospital and CAH Medical Staff Receiving Training (d)	Total Number of Staff Members Receiving Training (e = c × d)	Total Hourly Annual Cost (f = e × j)	Total Hourly Burden (g = f × g)	Average Cost per Staff Member (h = f / g)	Average Cost per Facility (k = h / a)
Hospital	5797	1,115,641	0.989	422,240	417,531	\$71,246,104	417,531	\$171	\$12,290

TABLE 160: Transfer Protocol Training Annual Cost 10 Year Cost

Year	Total Hourly Burden	Total Hourly Burden Cost
1	417,531	\$71,246,104
2	417,531	\$71,246,104
3	417,531	\$71,246,104
4	417,531	\$71,246,104
5	417,531	\$71,246,104
6	417,531	\$71,246,104
7	417,531	\$71,246,104
8	417,531	\$71,246,104
9	417,531	\$71,246,104
10	417,531	\$71,246,104
10 Year Total Cost	4,175,310	\$710,461,040

g. Summary of Regulatory Impact Analysis for Obstetrical and Emergency Services

In Tables 160 and 161 we provide an estimate of the total annual and 10-year financial and hourly burden for the proposed requirements related to obstetrical and emergency services

that include: (1) organization, staffing, and delivery of services for hospitals and CAHs as outlined in Table 145 and Table 147; (2) obstetrical services staff training for hospitals and CAHs as outlined in Table 149; (3) quality assessment and performance improvement program requirements for hospitals and CAHs as outlined in Table 151; (4) maternal health QAPI activity requirements for hospitals and CAHs as outlined in Table 153; (5) emergency services readiness requirements for hospitals and CAHs in Table 156 and Table 158; and (6) transfer protocols training for hospitals as outlined in Table 160. These estimates exclude the cost for collection of information requirements that we have estimated above in Table 129 and 130 to cost \$174,597,139 million over 10 years and take 1,768,881 hours to complete. Overall, we estimate the total financial cost of the requirements would be approximately \$4.27 billion and take 28.3 million hours to complete over 10 years.

We are seeking comments on several issues related to the regulatory impact analysis, including the following:

- Are there additional data sources that estimate the number of medical staff, who work with obstetrical patients?
- Are there additional data sources to estimate the number of hospital and CAH obstetrical rooms/suites?
- Are there any additional data sources to estimate the cost for the provisions of cardiac monitors, call-in systems, and fetal doppler or monitors?
- Are there additional data sources to estimate the number of medical staff who work with emergency care units?
- Are there data sources to estimate the number of hospital room/suites that are allocated for emergency services?
- Are there any additional staff members who are likely to receive training for emergency services and obstetrical services?

Obstetrical Services Staff Training	Addressing Health Equity Through QAPI Program	MMRC Information and QAPI Incorporation	Patient Transfer Training	Emergency Preparedness Training	Total Hourly Cost for All Requirements
14,166,080	1,893,000	504,800	4,175,310	7,531,766	28,270,956

h. Benefits

There are a wide variety of benefits associated with the proposed requirements for obstetrical services in hospitals and CAHs.

First, there are the financial benefits. As we noted above in the statement of need, research suggests that maternal mortality and morbidity have widespread negative effects on pregnant and postpartum patients and their families and high financial costs for payors. One study found that pregnancy-related mortality cost in the United States more than \$27.4 billion and resulted in the loss of 114,000 years of potential life between 2018 and 2020.⁵⁸⁷ Another study showed that from birth to 5 years postpartum, nine maternal morbidities among the 2019 US birth cohort cost birthing parents and their children \$32.3 billion, with \$18.7 billion due to medical costs and \$13.6 billion related to non-medical costs.^{588,589} A third study found that severe maternal morbidity during the prenatal to 30 day postpartum period was associated with a 75 percent increase in medical costs for patients utilizing Medicaid and a more than doubling in medical costs for commercially insured patients.⁵⁹⁰ While these studies vary in their methodology, the pre-post birth time period analyzed, medical conditions analyzed, and cost

⁵⁸⁷ White Robert, S., et al., *Economic burden of maternal mortality in the USA, 2018–2020*. Journal of Comparative Effectiveness Research, 2022. 11(13): 927-933.

⁵⁸⁸ O’Neil, S.S., et al., *Societal cost of nine selected maternal morbidities in the United States*. PLOS ONE, 2022. 17(10): e0275656.

⁵⁸⁹ These nine conditions included the following: amniotic fluid embolism, cardiac arrest, gestational diabetes mellitus, hemorrhage, hypertensive disorders, mental health conditions, renal disease, sepsis, and venous thromboembolism.

⁵⁹⁰ Black, C.M., et al., *Costs of Severe Maternal Morbidity in U.S. Commercially Insured and Medicaid Populations: An Updated Analysis*. Women's Health Reports, 2021. 2(1): 443-451.

estimates, they suggest that maternal morbidity and mortality impose high health and safety, as well as economic costs on birth parents, children, payors, and society.⁵⁹¹

We believe that the policies we are proposing will help reduce maternal morbidity and mortality and their associated costs for pregnant and postpartum patients and their families, as well as payors. Specifically, the proposed requirements that OB services are well-organized and in accordance with acceptable standards of practices, have adequate provisions and protocols for OB emergencies, complications, immediate post-delivery care and other patient health and safety events as identified as part of the facility's QAPI program, and that OB patient care units are supervised by an individual with the necessary education and training will provide the foundation for ensuring uniform high-quality OB services. Similarly, requiring hospitals and CAHs to delineate and document obstetrical privileges for all practitioners will benefit patients by helping ensure that practitioners have the necessary education, training, and experience to provide safe, effective care and safely perform specific procedures. Finally, the requirement that labor and delivery room suites have certain basic resuscitation equipment readily available will help ensure efficient and effective care that can help reduce patient morbidity and mortality. Similarly, OB staff training and appropriate transfer protocols can also help avert avoidable maternal complications and deaths.⁵⁹² Finally, engagement with recommendations from MMRCs and QAPI stratification of data can help facilities better identify unfavorable patient health and safety outcomes, which can allow them to better tailor policies to address these issues.

Beyond reductions in maternal morbidity and mortality and their associated financial benefits, the proposed policies are likely also to reduce inequality among pregnant and postpartum women from different groups. For example, research shows that among women with any form of disability, there is a heightened risk for labor and delivery complications, as well as

⁵⁹¹ Moran, P.S., et al., *Economic burden of maternal morbidity – A systematic review of cost-of-illness studies*. PLOS ONE, 2020. 15(1): e0227377.

⁵⁹² <https://saferbirth.org/aim-obstetric-emergency-readiness-resource-kit/>

severe maternal morbidity and mortality. If hospitals and CAHs include training that helps health care practitioners better understand these risks and be more comfortable providing care to women with a disability, they may be able to better provide safe, high quality obstetric care, reducing obstetrical complications. Research also suggests that due to insufficient patient education by staff, women with limited English proficiency (LEP) experience disparities in obstetric care and are at risk for mental health conditions, including post-partum depression and substandard newborn care following neonatal ICU discharge.⁵⁹³ If facilities engage in increasing language-concordant care and awareness among providers regarding the use of medical interpreters and materials in diverse languages, they may be able to improve patient satisfaction, decrease medical errors, and improve patient safety.^{594,595} Similarly, stratification of patient data can produce insights into health disparities that allow facilities to develop interventions to reduce them, with research showing that data collection and analysis by patient subgroup within health care facilities has an important impact on improving patient care consistently across patient populations.^{596,597,598, 599, 600}

Beyond the benefits for obstetrical patients, our proposed requirements are likely to have positive effects on the health and safety for patients generally. Our proposed requirements for hospitals to have written policies and procedures for transferring patients under their care and train medical staff regarding transfer protocols can support hospitals in expediting transfers when

⁵⁹³ Togioka, Brandon & Seligman, Katherine & Delgado Upegui, Carlos. (2022). Limited English proficiency in the labor and delivery unit. *Current Opinion in Anesthesiology*. 35. 285-291.

⁵⁹⁴ Sentell, Tetine & Chang, Ann & Ahn, Hyeong Jun & Miyamura, Jill. (2015). Maternal Language and Adverse Birth Outcomes in a Statewide Analysis. *Women & health*. 56. 10.1080/03630242.2015.1088114.

⁵⁹⁵ <https://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf>

⁵⁹⁶ Weinick, R.M. and R. Hasnain-Wynia, Quality Improvement Efforts Under Health Reform: How To Ensure That They Help Reduce Disparities—Not Increase Them. *Health Affairs*, 2011. 30(10): p. 1837-1843.

⁵⁹⁷ Bardach, N.S. and M.D. Cabana, The unintended consequences of quality improvement. *Curr Opin Pediatr*, 2009. 21(6): p. 777-82.

⁵⁹⁸ Perzynski, A.T., et al., Patient portals and broadband internet inequality. *J Am Med Inform Assoc*, 2017. 24(5): p. 927-932.

⁵⁹⁹ Antonio, M.G., O. Petrovskaya, and F. Lau, Is research on patient portals attuned to health equity? A scoping review. *J Am Med Inform Assoc*, 2019. 26(8-9): p. 871-883.

⁶⁰⁰ Sequist, T.D., et al., Effect of quality improvement on racial disparities in diabetes care. *Arch Intern Med*, 2006. 166(6): p. 675-81.

necessary. Efficient transfers to hospitals that can treat complex conditions and provide higher levels of care for all patients as needed. Similarly, our proposed requirement that hospitals with emergency services must have adequate provisions and protocols for the care of patients with emergency conditions and train applicable staff on these protocols and provisions, is also likely to improve patient health and safety. Additional obstetric training for emergency department staff improves staff competencies (i.e., skills, knowledge, comfort, confidence, and effectiveness) in managing obstetric emergencies, supporting improved maternal health and safety^{601,602,603,604,605,606}, while training in pediatric readiness^{607,608}, and geriatric readiness^{609,610,611,612,613} improves staff capabilities in caring for these populations.

We seek comments on additional benefits from our proposed requirements, as well as ways to quantify the health, safety, and financial benefits we have identified above.

i. Alternatives Considered

⁶⁰¹ Burke SM, Schmitt T, Kennedy P, et al. Emergency Medicine Obstetrics and Gynecology: A Case-Based Curriculum for Residents. *MedEdPORTAL*. 2023;19:11330.

⁶⁰² Espey E, Baty G, Rask J, Chungtuycyco M, Pereda B, Leeman L. Emergency in the clinic: a simulation curriculum to improve outpatient safety. *Am J Obstet Gynecol*. Dec 2017;217(6):699.e1-699.e13.

⁶⁰³ Cooper MI, Papanagnou D, Meguerdichian M, Bajaj K. Emergency Obstetrics for the Emergency Medicine Provider. *MedEdPORTAL*. Oct 13 2016;12:10481.

⁶⁰⁴ Jacobs PJ. Using High-Fidelity Simulation and Video-Assisted Debriefing to Enhance Obstetrical Hemorrhage Mock Code Training. *J Nurses Prof Dev*. Sep/Oct 2017;33(5):234-239.

⁶⁰⁵ Hopmann P, Varre JS, Duncan G, Devoe WB, Gable BD. Multidisciplinary Simulation of Trauma in Pregnancy with Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Utilization. *Cureus*. Dec 2022;14(12):e32820.

⁶⁰⁶ Harrington J, Duncan G, D. Angelo K G. Multidisciplinary Simulation Improves Resident Confidence for Pregnant Patients Requiring Surgical Intervention. *Cureus*. Mar 2022;14(3):e23454.

⁶⁰⁷ Ames, S.G., et al., Emergency Department Pediatric Readiness and Mortality in Critically Ill Children. *Pediatrics*, 2019. 144(3).

⁶⁰⁸ Newgard, C.D., et al., Emergency Department Pediatric Readiness and Short-term and Long-term Mortality Among Children Receiving Emergency Care. *JAMA Network Open*, 2023. 6(1): p. e2250941-e2250941.

⁶⁰⁹ Keyes, D.C., et al., Impact of a New Senior Emergency Department on Emergency Department Recidivism, Rate of Hospital Admission, and Hospital Length of Stay. *Annals of Emergency Medicine*, 2014. 63(5): p. 517-524.

⁶¹⁰ Dresden, S.M., et al., Geriatric Emergency Department Innovations: The Impact of Transitional Care Nurses on 30-day Readmissions for Older Adults. *Acad Emerg Med*, 2020. 27(1): p. 43-53.

⁶¹¹ Foo, C.L., et al., Geriatric assessment and intervention in an emergency department observation unit reduced re-attendance and hospitalisation rates. *Australas J Ageing*, 2012. 31(1): p. 40-6.

⁶¹² Chong, E., et al., Emergency Department Interventions for Frailty (EDIFY): Front-Door Geriatric Care Can Reduce Acute Admissions. *Journal of the American Medical Directors Association*, 2021. 22(4): p. 923-928.e5.

⁶¹³ Gettel, C.J., et al., An Outcome Comparison Between Geriatric and Nongeriatric Emergency Departments. *Ann Emerg Med*, 2023. 82(6): p. 681-689.

We considered a variety of approaches when developing the proposed obstetrical services requirements for hospitals and CAHs. One approach was to leave the development of policies to improve obstetrical services to accrediting agencies or individual States. We decided against this approach, however, since there is likely to be wide variation across States and accrediting agencies in their requirements, leading to variation in obstetrical services for patients depending on the facility or State where they are located.

We also considered requiring specific topics for the proposed OB services training requirement as well as for the requirement to train staff on the protocols for the care of patients with emergency conditions. We ultimately decided, however, to provide facilities with flexibility in how they approach these trainings so that they could provide it in a way that leads to the best improvements in and highest quality of care for pregnant and postpartum women. Similarly, we considered defining specific subpopulations that facilities must analyze when using their QAPI program to identify inequalities in health outcomes. Ultimately, however, we decided to provide facilities with flexibility regarding which subpopulations they analyze since features of patient populations are likely to vary greatly across different facilities.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing 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 thought 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 that 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 BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$115.22 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 or final rule. For each entity that reviews the rule, the estimated cost is \$921.76 (8 hours x \$115.22). Therefore, we estimate that the total cost of reviewing this regulation is \$3,481,487.52 (\$921.76 x 3,777).

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing 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 thought 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 that 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 BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$129.28 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 or final rule. For each entity that reviews the rule, the estimated cost is \$1,034.24 (8 hours x \$129.28). Therefore, we estimate that the total cost of reviewing this regulation is \$3,903,221.76 (\$1,034.24 x 3,777).

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 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. For details, we refer readers to the Small Business Administration's "Table of Size Standards" at <http://www.sba.gov/content/table-small-business-sizestandards>.

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 be reached by the requirements proposed in this proposed rule. As a result, the Secretary has determined that this proposed rule may have a significant 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 3 percent; therefore, it should have a negligible impact on approximately 533 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 Analysis

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 2024, that threshold is approximately \$183 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector. This proposed rule would not impose a mandate that would result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than \$183 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 131 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.4 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 proposed 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 XXIII of this proposed rule, this rule should not have a significant effect on small rural hospitals.

H. Conclusion

The changes we are finalizing in this proposed rule would affect all classes of hospitals paid under the OPSS as well as both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPSS would experience a modest increase or a minimal decrease in payment for services furnished under the OPSS in CY 2025. Table U168 demonstrates the estimated distributional impact of the OPSS budget neutrality requirements that would result in a 2.3 percent increase in payments for all services paid under the OPSS in CY 2025, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, and estimated payment for outliers, changes to the pass-through payment estimate, and changes to outlier payments. However, some classes of providers that are paid under the OPSS would experience more significant gains or losses in OPSS payments in CY 2025.

The updates we are making to the ASC payment system for CY 2025 would affect each of the approximately 6,100 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to

which the ASC provides a different set of procedures in the coming year than in previous years.

Table U169 demonstrates the estimated distributional impact among ASC surgical specialties of the productivity-adjusted hospital market basket update factor of 2.6 percent for CY 2025.

Finally, our proposal to include additional exceptions to the four walls requirement under the Medicaid clinic services for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas is estimated to have an \$1.18 billion impact in transfers for fiscal years 2025-2029. Table 110 demonstrates the Federal and State share impacts on IHS/Tribal clinics, behavioral health clinics, clinics located in rural areas, and in aggregate. As explained earlier in this section of the proposed rule, there is uncertainty in the potential for changes in utilization and costs of clinic services because of uncertainty in provider availability and beneficiary demand.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 21, 2024.

List of Subjects

42 CFR Part 406

Diseases, Health facilities, Medicare.

42 CFR Part 407

Medicare.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, 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.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs-health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Wages.

42 CFR Part 440

Grant programs – health, Medicaid.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Incorporation by Reference, Medicaid,
Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

1. The authority citation for part 406 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–2, 1395i–2a, 1395p, 1395q and 1395hh.

2. Section 406.27 is amended by revising paragraph (d) to read as follows:

§ 406.27 Special enrollment periods for exceptional conditions.

* * * * *

(d) *SEP for formerly incarcerated individuals.* An SEP exists for Medicare eligible individuals who are no longer incarcerated on or after January 1, 2023.

(1) *SEP parameters and duration before January 1, 2025—(i) Eligibility.* An individual is eligible for this SEP if they are released from the custody of penal authorities between January 1, 2023, and December 31, 2024, as described in § 411.4(b) of this subchapter. The individual must demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Medicare premium Part A due to being in custody of penal authorities and there is a record of release either through discharge documents or data available to SSA.

(ii) *SEP duration.* The SEP starts the day of the individual’s release from the custody of penal authorities and ends the last day of the 12th month after the month in which the individual is released from the custody of penal authorities.

(2) *SEP parameters and duration beginning January 1, 2025—(i) Eligibility.* An individual is eligible for this SEP if they are released from confinement in a jail, prison, or other penal institution or correctional facility on or after January 1, 2025, and demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Medicare premium Part A due to being so confined, and there is a record of release, either through discharge documents or data available to SSA.

(ii) *SEP duration.* The SEP starts the day an individual is released from confinement as determined by SSA and ends the last day of the 12th month after the month in which the individual is released from confinement in a jail, prison, or other penal institution or correctional facility.

(3) *Entitlement*—(i) *General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(ii) *Special rule.* An individual has the option of requesting entitlement for a retroactive period of up to 6 months provided the date does not precede the month of their release from incarceration, the date is on or after January 1, 2023, and the individual pays the monthly premiums for the period of coverage (as required under § 406.32(f)). If retroactive enrollment is requested and the application is filed within the first 6 months of the SEP, the effective date is retroactive to the beginning of the month of their release from incarceration. If retroactive enrollment is requested and the application is filed in the last 6 months of the SEP, the coverage effective date is retroactive to the 6th month before the month of enrollment.

* * * * *

PART 407—SUPPLEMENTARY MEDICAL INSURANCE (SMI) ENROLLMENT AND ENTITLEMENT

3. The authority citation for part 407 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395p, 1395q, and 1395hh.

4. Section 407.23 is amended by revising paragraph (d) to read as follows:

§ 407.23 Special enrollment periods for exceptional conditions.

* * * * *

(d) *SEP for formerly incarcerated individuals.* An SEP exists for Medicare eligible individuals who are no longer incarcerated on or after January 1, 2023.

(1) *SEP parameters and duration before January 1, 2025—(i) Eligibility.* An individual is eligible for this SEP if they are released from the custody of penal authorities between January 1, 2023, and December 31, 2024, as described in § 411.4(b) of this subchapter. The individual must demonstrate that they are eligible for Medicare and failed to enroll or reenroll in SMI due to being in the custody of penal authorities and there is a record of release either through discharge documents or data available to SSA.

(ii) *SEP duration.* The SEP starts the day of the individual's release from the custody of penal authorities and ends the last day of the 12th month after the month in which the individual is released from the custody of penal authorities.

(2) *SEP parameters and duration beginning January 1, 2025—(i) Eligibility.* An individual is eligible for this SEP if they are released from confinement in a jail, prison, or other penal institution or correctional facility on or after January 1, 2025, and demonstrate that they are eligible for Medicare and failed to enroll or reenroll in SMI due to being so confined, and there is a record of release, either through discharge documents or data available to SSA.

(ii) *SEP duration.* The SEP starts the day an individual is released from confinement as determined by SSA and ends the last day of the 12th month after the month in which the individual is released from confinement in a jail, prison, or other penal institution or correctional facility.

(3) *Entitlement—(i) General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on after January 1, 2023.

(ii) *Special rule.* An individual has the option of requesting entitlement for a retroactive period of up to 6 months provided the date does not precede the month of their release from incarceration, the date is on or after January 1, 2023, and the individual pays the monthly

premiums for the period of coverage (as required under § 408.4). If retroactive enrollment is requested and the application is filed within the first 6 months of the SEP, the effective date is retroactive to the beginning of the month of their release from incarceration. If retroactive enrollment is requested and the application is filed in the last 6 months of the SEP, the coverage effective date is retroactive to the 6th month before the month of enrollment.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

5. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

6. Section 410.27 is amended by revising paragraph (a)(1)(iv)(B)(I) 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) * * *

(I) 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. Through December 31, 2025, 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

* * * * *

7. 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) Through December 31, 2025, 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).

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

8. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn.

9. Section 411.4 is revised to read as follows:

§ 411.4 Items and services for which neither the beneficiary nor any other person is legally obligated to pay.

(a) *General rule.* Except in the case of Federally qualified health center services and as provided in § 411.8(b) (for services paid by a governmental entity), Medicare may not pay for an item or service under part A or part B if—

(1) The individual has no legal obligation to pay for the item or service; and

(2) No other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for the item or service.

(b) *Special conditions for payment for items or services furnished to an individual in the custody of a penal authority.* (1) An individual in the custody of a penal authority is considered

to have a legal obligation to pay for items or services furnished to the individual only if the following conditions are met:

(i) State or local law requires the individual to pay the cost of items and services that the individual receives ;

(ii) The penal authority enforces the requirement to pay for items or services by billing all individuals who receive such items or services , whether or not covered by Medicare or any other health insurance; and

(iii) The penal authority pursues collection of amounts owed for items or services received in the same way and with the same vigor that it pursues the collection of other debts.

(2) For purposes of this paragraph, a penal authority means a police department or other law enforcement agency, a government agency operating under a penal statute, or a State, local or Federal jail, prison, penitentiary, or similar institution.

(3) For purposes of this paragraph, an individual is considered to be in the custody of a penal authority if the individual is:

(i) Under arrest;

(ii) Incarcerated in a jail, prison, penitentiary, or similar institution;

(iii) Temporarily outside of a jail, prison, penitentiary, or similar institution on medical furlough or similar arrangement;

(iv) Escaped from confinement by a penal authority;

(v) Required to reside in a mental health facility under a penal statute or rule; or

(vi) Required to reside in a halfway house under any of the following conditions:

(A) Residents are precluded from working outside the facility in employment that is available to individuals who are not under penal authority supervision;

(B) Residents may not use community resources (for example, libraries, grocery stores, recreation, or educational institutions) at will; or

(C) Residents may not seek health care items and services in the broader community to the same or similar extent as individuals who are not under penal authority supervision.

PART 416—AMBULATORY SURGICAL SERVICES

10. The authority citation for part 416 continues to read as follows:

Authority:42 U.S.C. 1302 and 1395hh.11. Section 416.164 is amended by revising paragraphs (a)(4) and (b)(6) to read as follows:

§ 416.164 Scope of ASC Services.

(a) * * *

(4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS);

* * * * *

(b) * * *

(6) Non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174;

* * * * *

12. Section 416.171 is amended by revising paragraph (b)(1) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(1) Covered ancillary services specified in § 416.164(b), with the exception of radiology services and certain diagnostic tests as provided in § 416.164(b)(5) and non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174.

* * * * *

13. Revise § 416.174 to read as follows:

§ 416.174 Payment for non-opioid pain management drugs, biologicals, and medical devices.

(a) Eligibility for separate payment for non-opioid pain management drugs and biologicals. From January 1, 2025 through December 31, 2027, a non-opioid drug or biological is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(1) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j), or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product also has 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.

(2) The drug or biological does not have transitional pass-through payment status under § 419.64 of this subchapter. In the case where a drug or biological otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in this paragraph (a) during such calendar year on the first day of the next quarter following the expiration of its pass-through status.

(3) The drug or biological has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this part.

(b) Eligibility for separate payment for non-opioid medical devices. From January 1, 2025, through December 31, 2027, a medical device is eligible for separate payment for an applicable calendar year if CMS determines it meets all of the following requirements through that year's rulemaking:

(1) The medical device is used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, and has an application under section 515 of the Federal Food, Drug, and Cosmetic Act that has been approved with respect to the device, has 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.

(2) The medical device 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.

(3) The medical device does not have transitional pass-through payment status under § 419.66 of this subchapter. In the case where a medical device otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the medical device will qualify for separate payment as specified in this paragraph (b) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(4) The medical device has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this part.

(c) *Payment Amount.* From January 1, 2025 through December 31, 2027, the amount of payment for a qualifying non-opioid treatment for pain relief is as follows:

(1) For a qualifying drug or biological as defined in paragraph (a) of this section, the amount of payment is the amount determined under section 1847A of the Act for the drug or biological that exceeds the portion of the otherwise applicable Medicare OPD fee schedule amount, which is determined to be zero dollars for calendar year 2025, subject to paragraph (c)(3) of this section.

(2) 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, which is determined to be zero dollars for calendar year 2025, subject to paragraph (c)(3) of this section.

(3) *Payment limitation.* The payment amounts in paragraphs (c)(1) and (2) of this section shall not exceed the estimated average of 18 percent of the OPD fee schedule amount of the

volume weighted average of the five OPD services with which the non-opioid treatment for pain relief is furnished most frequently.

14. Section 416.320 is amended by revising paragraph (b) to read as follows:

§ 416.320 Retention and removal of quality measures under the ASCQR Program.

* * * * *

(b) *Immediate measure suspension.* If CMS determines that the collection and reporting activities related to a measure potentially raise patient safety concerns, CMS will immediately suspend the measure from the ASCQR Program and will promptly notify ASCs and the public of the suspension of the measure. CMS will address the suspension and propose to retain, modify, or remove the measure in the next feasible rulemaking cycle.

* * * * *

**PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT
DEPARTMENT SERVICES**

15. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

16. Section 419.2 is amended by revising paragraph (b)(15) to read as follows:

§ 419.2 Basis of payment.

* * * * *

(b) * * *

(15) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year, contrast agents, and pharmacologic stress agents);

* * * * *

17. Section 419.41 is amended by adding paragraphs (h) and (i) to read as follows:

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

* * * * *

(h) *Payment for non-passthrough therapeutic radiopharmaceuticals.* For a therapeutic radiopharmaceutical for which payment is not packaged into a payment for a covered outpatient department (OPD) service (or group of services) and that does not have a transitional pass-through payment status as described in § 419.64, to calculate the program payment and copayment amounts CMS does the following:

(1) Determines the Average Sales Price (ASP) for the therapeutic radiopharmaceutical for the quarter established under the methodology described by section 1847A of the Act. If that amount is not available, then CMS calculates the mean unit cost (MUC) using the most recently available claims data for that therapeutic radiopharmaceutical.

(2) Subtracts from the amount determined under paragraph (h)(1) of this section the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the amount determined under paragraph (h)(1) of this section (less any applicable deductible under paragraph (h)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (h)(3) of this section from the amount determined under paragraph (h)(1) of this section (less any applicable deductible determined under paragraph (h)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (h)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

(i) *Payment for non-passthrough diagnostic radiopharmaceuticals.* For a diagnostic

radiopharmaceutical for which payment is not packaged into a payment for a covered outpatient department (OPD) service (or group of services) and that does not have transitional pass-through payment status as described in § 419.64, to calculate the program payment and copayment amounts CMS does the following:

(1) Calculates the mean unit cost (MUC) using the most recently available claims data for that diagnostic radiopharmaceutical.

(2) Subtracts from the amount determined under paragraph (i)(1) of this section the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the amount determined under paragraph (i)(1) of this section (less any applicable deductible under paragraph (h)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (i)(3) of this section from the amount determined under paragraph (i)(1) of this section (less any applicable deductible determined under paragraph (i)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (i)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

18. Section 419.43 is amended by adding paragraph (k) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(k) *Payment for non-opioid pain management drugs and biologicals.* (1) *Eligibility for separate payment for non-opioid pain management drugs and biologicals.* From January 1, 2025, through December 31, 2027, a drug or biological is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(i) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j), or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product has 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.

(ii) The drug or biological does not have transitional pass-through payment status under § 419.64 of this subchapter. In the case where a drug or biological otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in this paragraph (k) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(iii) The drug or biological has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this section.

(2) *Eligibility for separate payment for non-opioid medical devices.* From January 1, 2025, through December 31, 2027, a medical device is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(i) The medical device, is used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, and has 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 510(k) of such Act pursuant to subsection (l) or (m) or section 510 of such Act or section 520(g) of such Act.

(ii) The medical device 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.

(iii) The medical device does not have transitional pass-through payment status under § 419.66. In the case where a medical device otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the medical device will qualify for separate payment as specified in paragraph (k)(2) of this section during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(iv) The medical device has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this section.

(3) *Payment Amount.* From January 1, 2025, through December 31, 2027, the amount of payment for a qualifying non-opioid treatment for pain relief is as follows:

(i) For a qualifying drug or biological as defined in paragraph (k)(1) of this section, the amount of payment is the amount determined under section 1847A for the drug or biological 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 paragraph (k)(3)(iii) of this section.

(ii) For a qualifying medical device as defined in paragraph (k)(2) 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 that the Secretary determines is associated with the device, subject to paragraph (k)(3)(iii) of this section.

(iii) *Payment limitation.* The payment amounts in paragraph (k)(3)(i) and (ii) of this section shall not exceed the estimated average of 18 percent of the OPD fee schedule amount of the volume weighted average of the five OPD services with which the non-opioid treatment for pain relief is furnished most frequently.

19. Section 419.46 is amended by revising paragraph (i)(2) and adding paragraph (j) to read as follows:

§ 419.46 Requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(i) * * *

(2) *Immediate measure suspension.* If CMS determines that the collection and reporting activities related to a measure potentially raise patient safety concerns, CMS will immediately suspend the measure from the Hospital OQR Program and will promptly notify hospitals and the public of the suspension of the measure. CMS will address the suspension and propose to retain, modify, or remove the measure in the next feasible rulemaking cycle.

* * * * *

(j) *Requirements for submission of electronic clinical quality measures (eCQMs) under the Hospital OQR Program*

(1) Hospitals must utilize certified technology updated to be consistent with the Office of the National Coordinator for Health IT's (ONC) health IT certification criteria, as adopted and updated in 45 CFR 170.315.

(2) Hospitals must use electronic health record (EHR) technology certified to all eCQMs that are available to report under the Hospital OQR Program.

(3) Hospitals must 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.

20. Section 419.47 is amended by –

- a. Revising the section heading;
- b. Revising paragraph (a); and
- c. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 419.47 Coding and Payment for Category B Investigational Device Exemption (IDE) Studies and Devices/Drugs Studied in a Clinical Trial with a Medicare Coverage with Evidence Development (CED) Designation.

(a) *Creation of a new HCPCS code for Category B IDE Studies that have a treatment arm and a placebo control arm.* CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which will include both the treatment and placebo control arms, related device(s) of the study, as well as routine care items and services, as specified under § 405.201 of this chapter, when CMS determines that:

* * * * *

(c) *Creation of a new HCPCS code for devices/drugs and controls studied in clinical trials with the Medicare CED designation that have a study device/drug and a control arm.* CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a device/drug and a control arm studied in a clinical trial with the Medicare CED designation, which will include the study device/drug and control arm, when CMS determines that:

(1) The Medicare National Coverage Determination process determines that a coverage with evidence development is required to study a device/drug in a clinical trial; and

(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.

(d) *Payment for devices/drugs studied in clinical trials with the Medicare CED designation.* Where CMS creates a new HCPCS code or revises an existing HCPCS code under paragraph (c) of this section, CMS will:

(1) Make a single packaged payment for the HCPCS code that includes payment for the study device/drug and any control; and

(2) Calculate the single packaged payment rate for the HCPCS code based on an adjusted payment level representing the study device/drug and any control based on available pricing data and frequency of utilization of the study device/drug and any control in the study population.

21. Section 419.82 is amended by revising paragraph (d)(1)(iii) to read as follows:

§ 419.82 Prior authorization for certain covered hospital outpatient department services.

* * * * *

(d) * * *

(1) * * *

(iii) The provisional affirmation or non-affirmation will be issued within 7 calendar days of receipt of the prior authorization request.

* * * * *

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

22. The authority citation for part 435 continues to read as follows:

Authority: 42 U.S.C. 1302.

23. Section 435.926 is amended by revising paragraphs (b) introductory text, (b)(1), (c)(1); and (d)(1) to read as follows:

§ 435.926 Continuous eligibility for children.

* * * * *

(b) *Eligibility.* The agency must provide continuous eligibility for the period specified in paragraph (c) of this section for an individual who is:

(1) Under age 19; and

* * * * *

(c) * * *

(1) The length of the continuous eligibility period is 12 months.

* * * * *

(d) * * *

(1) The child attains age 19;

* * * * *

PART 440—SERVICES: GENERAL PROVISIONS

24. The authority citation for part 440 continues to read as follows:

Authority: 42 U.S.C. 1302.

25. Section 440.90 is revised to read as follows:

§ 440.90 Clinic services.

Clinic services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients (services in paragraphs (a), (b), and (c) of this section are a mandatory part of clinic services, while services in paragraphs (d) and (e) of this section are optional):

(a) Services furnished at the clinic by or under the direction of a physician or dentist.

(b) Services furnished outside the clinic, by clinic personnel under the direction of a physician, to an individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

(c) Services furnished outside a clinic that is a facility of the Indian Health Service, whether operated by the Indian Health Service or by a Tribe or Tribal organization (as authorized by the Indian Self-Determination and Education Assistance Act (ISDEAA), Pub. L. 93-638), by clinic personnel under the direction of a physician.

(d) Services furnished outside of a clinic that is primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health and substance use disorders, by clinic personnel under the direction of a physician.

(e) Services furnished outside of a clinic that is located in a rural area and is not a rural health clinic (as referenced in section 1905(a)(2)(B) of the Social Security Act and 440.20(b) of this subpart) by clinic personnel under the direction of a physician.

PART 457— ALLOTMENTS AND GRANTS TO STATES

26. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

27. Revise § 457.342 to read as follows:

§ 457.342 Continuous eligibility for children.

(a) A State must provide continuous eligibility for children under a separate CHIP in accordance with the terms of § 435.926 of this chapter, and subject to a child remaining ineligible for Medicaid, as required by section 2110(b)(1) of the Act and § 457.310 (related to the definition and standards for being a targeted low-income child) and the requirements of section 2102(b)(3) of the Act and § 457.350 (related to eligibility screening and enrollment).

(b) [Reserved]

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

28. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

29. Section 482.21 is amended by –

- a. Adding paragraph (b)(4);
- b. Redesignating paragraph (e) and (f) as (f) and (g), respectively; and
- c. Adding new paragraph (e).

The additions read as follows:

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(b) * * *

(4) For hospitals that offer obstetrical services, the hospital must utilize its QAPI program to assess and improve health outcomes and disparities among obstetrical patients on an ongoing basis. At a minimum, the hospital must:

(i) Analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the hospital among obstetrical patients.

(ii) Measure, analyze, and track data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations among obstetrical patients.

(iii) Analyze and prioritize patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained among obstetrical patients.

(iv) Conduct at least one measurable performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of obstetrical patients annually.

* * * * *

(e) *Standard: Maternal Health QAPI activities.* For hospitals that offer obstetrical services, the following additional QAPI requirements apply:

(1) Obstetrical services leadership must engage in QAPI as specified in § 482.21 for obstetrical services, including but not limited to participating in data collection and monitoring as specified in § 482.21(b).

(2) If a maternal mortality review committee (MMRC) is available at the state or local jurisdiction in which the hospital is located, the facility leadership, obstetrical services leadership, or their designate(s) must further have a process for incorporating MMRC(s) data and recommendations into the hospital QAPI program as specified in § 482.21(b).

* * * * *

30. Section 482.43 is amended by revising paragraphs (c) and adding paragraph (d) to read as follows:

§ 482.43 Condition of participation: Discharge planning.

* * * * *

(c) *Standard: Transfer protocols.* The hospital must have written policies and procedures for transferring patients under its care (inclusive of inpatient services) to the appropriate level of care (including to another hospital) as needed to meet the needs of the patient. The hospital must also provide training to relevant staff regarding the hospital policies and procedures for transferring patients under its care.

(d) *Standard: Requirements related to post-acute care services.* For those patients discharged home and referred for HHA services, or for those patients transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, the following requirements apply, in addition to those set out at paragraphs (a) and (b) of this section:

(1) The hospital must include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care post-hospital extended care services, SNF, IRF, or LTCH services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must make the patient aware of the need to verify with their managed care organization which practitioners, providers or certified suppliers are in the managed care organization's network. If the hospital has information on which practitioners, providers or certified supplies are in the network of the patient's managed care organization, it must share this with the patient or the patient's representative.

(iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the patient's representative.

(2) The hospital, as part of the discharge planning process, must inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services and must, when possible, respect the patient's or the patient's representative's goals of care and treatment preferences, as well as other preferences they express. The hospital must not specify or otherwise limit the qualified providers or suppliers that are available to the patient.

(3) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of part 420, subpart C, of this chapter.

31. Section 482.55 is amended by adding paragraph (c) to read as follows:

§ 482.55 Condition of participation: Emergency services.

* * * * *

(c) *Standard: Emergency services readiness.* In accordance with the complexity and scope of services offered, there must be adequate provisions and protocols to meet the emergency needs of patients.

(1) *Protocols.* Protocols must be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions, including but not limited to patients with obstetrical emergencies, complications, and immediate post-delivery care.

(2) *Provisions.* Provisions include equipment, supplies, and medication used in treating emergency cases. Such provisions must be kept at the hospital and be readily available for treating emergency cases to meet the needs of patients. The available provisions must include the following:

(i) Drugs, blood and blood products, and biologicals commonly used in life-saving procedures;

(ii) Equipment and supplies commonly used in life-saving procedures; and

(iii) Each emergency services treatment area must have a call-in-system for each patient.

(3) *Staff training.* Applicable staff, as identified by the hospital, must be trained annually on the protocols and provisions implemented pursuant to this section.

(i) The governing body must identify and document which staff must complete such training.

(ii) The hospital must document in the staff personnel records that the training was successfully completed.

(iii) The hospital must be able to demonstrate staff knowledge on the topics implemented pursuant to this section.

(iv) The hospital must use findings from its quality assessment and performance improvement (QAPI) program, as required at § 482.21, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

32. Section 482.59 is added to subpart D to read as follows:

§ 482.59 Condition of participation: Obstetrical services.

If the hospital offers obstetrical services, the services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for the health care (including physical and behavioral health) of pregnant, birthing, and postpartum patients. If outpatient obstetrical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* The organization of the obstetrical services must be appropriate to the scope of the services offered. As applicable, the services must be integrated with other departments of the hospital.

(1) Labor and Delivery rooms/suites (including labor rooms, delivery rooms (including rooms for operative delivery), and post-partum/recovery rooms whether combined or separate) must be supervised by an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy.

(2) Obstetrical privileges must be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner. The obstetrical service must maintain a roster of practitioners specifying the privileges of each practitioner.

(b) *Standard: Delivery of service.* Obstetrical services must be consistent with needs and resources of the facility. Policies governing obstetrical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety.

(1) The following equipment must be available to the labor and delivery room suites: call-in-system, cardiac monitor, and fetal doppler or monitor.

(2) There must be adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines, for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the QAPI program (§482.21). Provisions include equipment (in addition to the equipment required under (b)(1)), supplies, and medication used in treating emergency cases. Such provisions must be kept on the hospital and be readily available for treating emergency cases.

(c) *Standard: Staff training.* The hospital must develop policies and procedures to ensure to ensure that relevant staff are trained on select topics for improving the delivery of maternal care.

(1) Training concepts must reflect the scope and complexity of services offered within the facility, including but not limited to:

(i) Facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility; and

(ii) The hospital must use findings from its quality assessment and performance improvement (QAPI) program, as required at § 482.21, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

(2) The governing body must identify and document which staff must complete annual training on the topics identified at § 482.59(c)(1).

(3) The hospital must document in the staff personnel records that the training was successfully completed.

(4) The hospital must be able to demonstrate staff knowledge on the topics identified at § 482.59(c)(1).

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

33. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh).

34. Section 485.618 is amended by –

a. Revising paragraph (e); and

b. Adding paragraph (f).

The revision and addition reads as follows:

§ 485.618 Condition of participation: Emergency Services

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(e) *Standard: Emergency services readiness.* In accordance with the complexity and scope of services offered, there must be adequate provisions (as required under paragraphs (b) and (c) of this section) and protocols to meet the emergency needs of patients.

(1) *Protocols-* Protocols must be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions, including but not limited to patients with obstetrical emergencies, complications, and immediate post-delivery care.

(2) Staff training- Applicable staff, as identified by the CAH, must be trained annually on the protocols and provisions implemented pursuant to this section.

(i) The governing body must identify and document which staff must complete such training.

(ii) The CAH must document in the staff personnel records that the training was successfully completed.

(iii) The CAH must be able to demonstrate staff knowledge on such training.

(iv) The CAH must use findings from its quality assessment and performance improvement (QAPI) program, as required at §485.641, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

(f) *Standard: Coordination with emergency response systems.* The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

35. Section 485.641 is amended by –

- a. Adding paragraph (d)(4); and
- b. Revising paragraph (e).

The addition and revision reads as follows:

§ 485.641 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(d) * * *

(4) For CAHs that offer obstetrical services, the following additional QAPI requirements apply:

(i) Obstetrical services leadership must engage in QAPI as specified in this section for obstetrical services, including but not limited to participating in data collection and monitoring as specified in paragraphs (d) and (e) of this section.

(ii) If a maternal mortality review committee (MMRC) is available at the state or local jurisdiction in which the CAH is located, the facility leadership, obstetrical services leadership, or their designate(s) must further have a process for incorporating MMRC(s) data and recommendations into the CAH QAPI program as specified in this section.

(e) *Standard: Program data collection and analysis.* The program must incorporate quality indicator data including patient care data, in order to achieve the goals of the QAPI program. For CAHs that offer obstetrical services, the CAH must utilize its QAPI program to assess and improve health outcomes and disparities among obstetrical patients on an ongoing basis. At a minimum, the CAH must:

(1) Analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the CAH among obstetrical patients.

(2) Measure, analyze, and track health equity data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations, and outcomes among obstetrical patients.

(3) Analyze and prioritize identified patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained when disparities exist among obstetrical patients.

(4) Conduct at least one measurable performance improvement project focused on improving health outcomes and disparities among the CAH's population(s) of obstetrical patients annually.

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36. Section 485.649 is added to subpart S to read as follows:

§ 485.649 Condition of participation: Obstetrical Services.

If the CAH offers obstetrical services, the services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for the health care (including physical and behavioral health) of pregnant, birthing, postpartum patients. If outpatient obstetrical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* The organization of the obstetrical services must be appropriate to the scope of the services offered. As applicable, the services must be integrated with other departments of the CAH.

(1) Labor and Delivery rooms/suites (including labor rooms, delivery rooms (including rooms for operative delivery), and post-partum/recovery rooms whether combined or separate) must be supervised by an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a Doctor of Medicine or a Doctor of Osteopathy (MD/DO).

(2) Obstetrical privileges must be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner. The obstetrical service must maintain a roster of practitioners specifying the privileges of each practitioner.

(b) *Standard: Delivery of service.* Obstetrical services must be consistent with needs and resources of the CAH. Policies governing obstetrical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety.

(1) The following equipment must be available to the labor and delivery room suites: call-in-system, cardiac monitor, and fetal doppler or monitor.

(2) There must be adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines, for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the QAPI program (§ 485.641). Provisions include equipment (in addition to the equipment

required under (b)(1) of this section), supplies, and medication used in treating emergency cases. Such provisions must be kept on the CAH and be readily available for treating emergency cases.

(c) *Standard: Staff training.* The CAH must develop policies and procedures to ensure to ensure that relevant staff are trained on select topics for improving the delivery of maternal care.

(1) Training concepts must reflect the scope and complexity of services offered within the facility, including but not limited to:

(i) Facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility; and

(ii) The CAH must use findings from its quality assessment and performance improvement (QAPI) program, as required at § 485.641, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

(2) The governing body must identify and document which staff must complete annual training on the topics identified at paragraph (c)(1) of this section.

(3) The CAH must document in the staff personnel records that the training was successfully completed.

(4) The CAH must be able to demonstrate staff knowledge on the topics identified at paragraph (c)(1) of this section.

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