



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 416, 419, 424, 485, 488, 489

Office of the Secretary

45 CFR Part 180

[CMS-1786-P]

RIN 0938-AV09

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction

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 2024 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. This proposed rule also would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Rural Emergency Hospital Quality Reporting (REHQR) Program. This proposed rule would also

establish payment for certain intensive outpatient services under Medicare, beginning January 1, 2024. In addition, this proposed rule would update and refine requirements for hospitals to make public their standard charge information and enforcement of hospital price transparency. We also propose to codify provisions of the Consolidated Appropriations Act, 2023, in Community Mental Health Centers Conditions of Participation (CoPs). We propose to revise the personnel qualifications of Mental Health Counselors and add personnel qualifications for Marriage and Family Therapists in the CMHC CoPs. We also seek comment on separate payment under the Inpatient Prospective Payment System (IPPS) for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. Finally, we propose to address any future revisions to the IPPS Medicare Code Editor (MCE), including any additions or deletions of claims edits, as well as the addition or deletion of ICD-10 diagnosis and procedure codes to the applicable MCE edit code lists, outside of the annual IPPS rulemakings. Additionally, we propose a technical correction to the Rural Emergency Hospital Conditions of Participation.

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

ADDRESSES: In commenting, please refer to file code CMS-1786-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-1786-P,

P.O. Box 8010,

Baltimore, MD 21244-1810.

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-1786-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:

Elise Barringer, Elise.Barringer@cms.hhs.gov or 410-786-9222.

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

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov or Mitali Dayal via email at Mitali.Dayal2@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.

Biosimilars Packaging Exception, contact Gil Ngan via email at gil.ngan@cms.hhs.gov.

Blood and Blood Products, contact Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov.

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

Cardiac Rehabilitation, Intensive Cardiac Rehabilitation and Pulmonary Rehabilitation Services, contact Nate Vercauteren via email at Nathan.Vercauteren@cms.hhs.gov.

CMS Web Posting of the OPSS and ASC Payment Files, contact Chuck Braver via email at Chuck.Braver@cms.hhs.gov.

Community Mental Health Centers (CMHC) Conditions of Participation, contact Mary Rossi-Coajou via email at Mary.RossiCoajou@cms.hhs.gov or Cara Meyer via email at Cara.Meyer@cms.hhs.gov.

Composite APCs (Multiple Imaging and Mental Health), via email at Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov.

Comprehensive APCs (C-APCs), contact Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov.

COVID-19 Final Rules, contact Elise Barringer via email at Elise.Barringer@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 Elise Barringer via email at Elise.Barringer@cms.hhs.gov.

Hospital Price Transparency (HPT), contact Terri Postma via email at PriceTransparencyHospitalCharges@cms.hhs.gov.

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

Inpatient Prospective Payment System (IPPS) Medicare Code Editor, contact Mady Hue via e-mail at Marilu.Hue@cms.hhs.gov.

Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes, contact Emily Yoder via email at Emily.Yoder@cms.hhs.gov

Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs), contact Elise Barringer via email at Elise.Barringer@cms.hhs.gov.

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

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

Opioid Treatment Program (OTP) Intensive Outpatient Services (IOP) contact Lindsey Baldwin via email at Lindsey.Baldwin@cms.hhs.gov and Ariana Pitcher at Ariana.Pitcher@cms.hhs.gov.

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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, or Gil Ngan via email at Gil.Ngan@cms.hhs.gov, or 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.

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.

Request for Public Comments on Potential Payment under the IPPS for Establishing and Maintaining Access to Essential Medicines, contact DAC@cms.hhs.gov

Rural Emergency Hospital Conditions of Participation, contact Kianna Banks via email Kianna.Banks@cms.hhs.gov.

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

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

Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Intensive Outpatient Services (IOP), contact Michele Franklin via email at Michele.Franklin@cms.hhs.gov.

Separate Payment for High-Cost Drugs Provided by Indian Health Service and Tribally-Owned Facilities, contact Elise Barringer via email at Elise.Barringer@cms.hhs.gov.

Skin Substitutes, contact Josh McFeeters via email at Joshua.McFeeters@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 Web site 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.

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 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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>.

The Addenda relating to the ASC payment system are available at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices>.

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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, 2024. 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 ASC Quality Reporting (ASCQR) Program, and Rural Emergency Hospital Quality Reporting (REHQR) Program. In addition, this proposed rule would establish payment for intensive outpatient services under Medicare, beginning January 1, 2024. This proposed rule would also update and refine the requirements for hospitals to make public their standard charges and CMS enforcement of hospital price transparency regulations. In addition, this proposed rulemaking would also update the Community Mental Health Center (CMHC) Conditions of Participation (CoPs). We propose to revise the personnel qualifications of Mental Health Counselor's (MHCs) and add personnel qualifications for Marriage and Family Therapists (MFTs) in the CMHC CoP. Finally, we propose to remove discussion of the IPPS Medicare Code Editor (MCE) from the annual IPPS rulemakings, beginning with the FY 2025 rulemaking. Additionally, we propose a technical correction to the Rural Emergency Hospital (REH) CoPs under the standard for the designation and certification of REHs.

2. Summary of the Major Provisions

- *OPPS Update:* For 2024, we propose to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.8 percent. This proposed 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 0.2 percentage point. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case mix) for calendar year (CY) 2024

would be approximately \$88.6 billion, an increase of approximately \$6.0 billion compared to estimated CY 2023 OPPS payments.

We propose to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services.

- *Data used in Proposed CY 2024 OPPS/ASC Ratesetting:* To set proposed 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 2024 OPPS ratesetting. Therefore, we propose to resume our typical data process of using the most updated cost reports and claims data available for CY 2024 OPPS ratesetting.

- *Partial Hospitalization Update:* For CY 2024, we propose changes to our methodology used to calculate the Community Mental Health Center (CMHC) and hospital-based PHP (HB PHP) geometric mean per diem costs, as well as proposing changes to expand PHP payment from two APCs to four APCs.

- *Proposed Medicare Payment for Intensive Outpatient Programs:* Beginning in CY 2024, we propose to establish payment for intensive outpatient programs (IOPs) under Medicare. We propose the scope of benefits, physician certification requirements, coding and billing, and payment rates under the IOP benefit. IOP services may be furnished in hospital outpatient departments, community mental health centers (CMHCs), federally qualified health centers (FQHC), and rural health clinics (RHC). We also propose to establish payment for intensive outpatient services provided by opioid treatment programs (OTPs) under the existing OTP benefit.

- *Changes to the Inpatient Only (IPO) List:* For 2024, we are not proposing to remove any services from the IPO list.

- *340B-Acquired Drugs:* For CY 2024, we propose to continue to apply the default rate, generally average sales price (ASP) plus 6 percent, to 340B acquired drugs and biologicals. Therefore, drugs and biologicals acquired under the 340B program would be paid at the same payment rate as those drugs and biologicals not acquired under the 340B program.

- *Biosimilar Packaging Exception:* For CY 2024, we propose to except biosimilars from the OPSS threshold packaging policy when their reference biologicals are separately paid. In addition, if a reference product's per-day cost falls below the threshold packaging policy, we propose that all the biosimilars related to the reference product would be similarly packaged.

- *Proposal to Pay IHS and Tribal Hospitals that Convert to a Rural Emergency Hospital (REH) Under the IHS All-Inclusive Rate (AIR):* For CY 2024, we propose that IHS and tribal hospitals that convert to an REH be paid for hospital outpatient services under the same all-inclusive rate that would otherwise apply if these services were performed by an IHS or tribal hospital that is not an REH. We also propose that IHS and tribal hospitals that convert to an REH would receive the REH monthly facility payment consistent with how this payment is applied to REHs that are not tribally or IHS operated.

- *Device Pass-Through Payment Applications:* For CY 2024, we received 6 applications for device pass-through payments. We solicit public comment on these applications and will make final determinations on these applications in the CY 2024 OPSS/ASC final rule with comment period.

- *Cancer Hospital Payment Adjustment:* For CY 2024, we propose to continue providing 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 PHE impact on claims and cost data used to calculate the target PCR, we have maintained the CY 2021 target PCR of 0.89 through CYs 2022 and 2023. In this proposed rule, we propose 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 propose to use a target PCR of 0.88 to determine the CY 2024 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.88 for each cancer hospital.

- *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 propose to extend our policy to update the ASC payment system using the hospital market basket update an additional two years – through CYs 2024 and 2025. Using the hospital market basket methodology, for CY 2024, we propose to increase payment rates under the ASC payment system by 2.8 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a hospital market basket percentage increase of 3.0 percent reduced by a productivity adjustment of 0.2 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 2024 will be approximately \$6.0 billion, an increase of approximately \$170 million compared to estimated CY 2023 Medicare payments.

- *Changes to the List of ASC Covered Surgical Procedures:* For CY 2024, we propose to add 26 dental surgical procedures to the ASC covered procedures list (CPL) based upon existing criteria at § 416.166.

- *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program measure set, we propose to: (1) remove the Left Without Being Seen measure beginning with the CY 2024 reporting period/2026 payment determination; (2) modify the

COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure beginning with the CY 2024 reporting period/CY 2026 payment determination; (3) modify the Cataracts: Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery measure beginning with the voluntary CY 2024 reporting period; (4) modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2024 reporting period/CY 2026 payment determination; (5) re-adopt with modification the Hospital Outpatient Volume Data on Selected Outpatient Procedures measure beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (6) adopt the 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) beginning with the voluntary CYs 2025 and 2026 reporting periods, and mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination; (7) adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient) measure, beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (8) amend multiple codified regulations to replace references to “QualityNet” with “CMS-designated information system” or “CMS website,” and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants. We are also requesting public comment on: (1) patient and workforce safety (including sepsis); (2) behavioral health (including suicide prevention); and (3) telehealth as potential future measurement topic areas in the Hospital OQR Program.

- *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program measure set, we propose to: (1) modify the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure beginning with the CY 2024 Reporting Period/CY 2026

payment determination; (2) modify the Cataracts: Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery measure beginning with the voluntary CY 2024 reporting period; (3) modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2024 reporting period/CY 2026 payment determination; (4) re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical Procedures measure beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (5) adopt the 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) beginning with the voluntary CYs 2025 and 2026 reporting periods, and mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination; and (6) amend multiple codified regulations to replace references to “QualityNet” with “CMS-designated information system” or “CMS website,” and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

- *Rural Emergency Hospital Quality Reporting (REHQR) Program*: For the REHQR Program, we propose to: (1) codify the statutory authority for the REHQR Program; (2) adopt and codify policies related to measure retention, measure removal, and measure modification; (3) adopt one chart-abstracted measure and three claims-based measures for the REHQR Program measure set and establish related reporting requirements beginning with the CY 2024 reporting period; (4) adopt and codify policies related to public reporting of data; (5) codify foundational requirements related to REHQR Program participation; (6) adopt and codify policies related to the form, manner, and timing of data submission under the REHQR Program; (7) adopt and codify a review and corrections period for submitted data; and (8) adopt and codify an Extraordinary Circumstances Exception (ECE) process for data submission requirements. We

are also requesting comment on the following potential measures and approaches for implementing quality reporting under the REHQR Program: (1) electronic clinical quality measures (eCQMs); (2) care coordination measures; and (3) a tiered quality measure approach.

- *Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes:* For CY 2024, we propose technical refinements to the existing coding for remote mental health services to allow for multiple units to be billed daily. We also propose to create a new, untimed code to describe group psychotherapy. Finally, we propose to delay any in-person visit requirements until the end of CY 2024.

- *Proposed OPPS Payment for Dental Services:* For CY 2024, we propose to assign 229 HCPCS codes describing dental services to various clinical APCs to align with Medicare payment provisions regarding dental services in the CY 2023 PFS final rule.

- *Comment Solicitation on Payment for High-Cost Drugs Provided by Indian Health Service and Tribally-Owned Facilities:* We are seeking comment on whether Medicare should pay separately for high-cost drugs provided by IHS and tribally-owned facilities.

- *Supervision by Nurse Practitioners, Physician Assistants and Clinical Nurse Specialists of Cardiac, Intensive Cardiac and Pulmonary Rehabilitation Services Furnished to Outpatients:* For CY 2024, to comply with section 51008 of the Bipartisan Budget Act of 2018 and to ensure consistency with proposed revisions to § 410.47 and § 410.49 in the CY 2024 PFS proposed rule, we propose to revise § 410.27(a)(1)(iv)(B)(1) to expand the practitioners who may supervise cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR), and pulmonary rehabilitation (PR) services to include nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs). We also propose to allow for the direct supervision requirement for CR, ICR, and PR to include virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024 and extend this policy to the nonphysician practitioners, that is NPs, PAs, and CNSs, who are eligible to supervise these services in CY 2024. *Payment for Intensive Cardiac Rehabilitation*

Services (ICR) Provided by an Off-Campus, Non-Excepted Provider Based Department (PBD) of a Hospital: For CY 2024, to address an unintended reimbursement disparity created by application of the off-campus, non-excepted payment rate to intensive cardiac rehabilitation services (ICR), we propose to pay for ICR services furnished by an off-campus, non-excepted PBD of a hospital at 100 percent of the OPPS rate, which is the amount paid for these services under the PFS.

- *Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges:* We propose to amend several of our hospital price transparency (HPT) requirements in order to improve our monitoring and enforcement capabilities by way of improving access to, and the usability of, hospital standard charge information; reduce the compliance burden on hospitals by providing CMS templates and technical guidance for display of hospital standard charge information; align, where feasible, certain hospital price transparency requirements and processes with requirements and processes we have implemented in the Transparency in Coverage (TIC) initiative; and make other modifications to our monitoring and enforcement capabilities that will, among other things, increase its transparency to the public. Specifically, we propose to: (1) add definitions for “CMS template”, “consumer-friendly expected allowed charges”, “encode”, and “machine-readable file” (MRF); (2) require hospitals to affirm the accuracy and completeness of data in their MRF; (3) revise and expand the data elements hospitals must include in the MRF; (4) require hospitals to conform to a CMS template layout and other technical specifications for encoding standard charge information in the MRF; (5) require hospitals to establish and maintain a txt file and footer as specified by CMS; and (6) revise our enforcement process by updating our methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, working with health system officials to address noncompliance issues in one or more hospitals that are part of a health system, and publicizing more information about CMS enforcement activities related to individual hospital compliance. Additionally, we are seeking comment on

additional considerations for improving compliance and aligning consumer-friendly policies and requirements with other federal price transparency initiatives.

- *Community Mental Health Center (CMHC) Conditions of Participation (CoPs)*: We propose to update the CMHC CoPs to implement the provisions of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-238) by establishing coverage of intensive outpatient services (IOP) in CMHCs. The CAA, 2023 also established a new Medicare benefit category for services furnished and directly billed by Mental Health Counselors (MHCs) and Marriage and Family Therapists (MFTs). We propose to revise the personnel qualifications of MHCs and add personnel qualifications for MFTs in the CMHC CoPs.

- *Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor*: Consistent with the process that is used for updates to the Integrated Outpatient Code Editor (I/OCE) and other Medicare claims editing systems, we propose to remove discussion of the IPPS Medicare Code Editor (MCE) from the annual IPPS rulemakings, beginning with the FY 2025 rulemaking, and to generally address future changes or updates to the MCE through instruction to the MACs.

- *Request for Public Comments on Potential Payment under the IPPS and OPSS for Establishing and Maintaining Access to Essential Medicines*: We are seeking comment on, and may consider finalizing based on the review of comments received, as early as for cost reporting periods beginning on or after January 1, 2024, separate payment under IPPS, for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. An adjustment under OPSS could be considered for future years.

- *Rural Emergency Hospital (REH) Conditions of Participation (CoPs)*: We propose a technical correction to the REH CoPs under the standard for the “Designation and certification of 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 changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of all OPSS Changes

Table 100 in section XXVI.C of this proposed rule displays the distributional impact of all the OPSS changes on various groups of hospitals and CMHCs for CY 2024 compared to all estimated OPSS payments in CY 2023. We estimate that the proposed policies in this proposed rule would result in a 2.9 percent overall increase in OPSS payments to providers. We estimate that total OPSS payments for CY 2024, including beneficiary cost-sharing, to the approximately 3,600 facilities paid under the OPSS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately \$1.9 billion compared to CY 2023 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPSS policies on CMHCs because CMHCs have historically only been paid for partial hospitalization services under the OPSS. Beginning in CY 2024, they will also be 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 5.8 percent increase in CY 2024 payments to CMHCs relative to their CY 2023 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the fiscal year (FY) 2024 IPPS proposed rule wage indexes would result in no change for urban hospitals under the OPSS and a 1.4 percent increase for rural hospitals. These wage indexes include the continued implementation of the Office of Management and Budget (OMB) labor market area delineations

based on 2010 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

We are implementing the reduction to the cancer hospital payment adjustment for CY 2024 required by section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act, and the proposed target payment-to-cost ratio (PCR) for CY 2024 cancer hospital adjustment of 0.89. However, as Section 16002 requires that we reduce the target PCR by 0.01, that brings the proposed target PCR to 0.88 instead. This is 0.01 less than the target PCR of 0.89 from CY 2021 through CY 2023, which was previously held at the pre-PHE target.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2024 OPPS/ASC, we propose an OPD fee schedule increase factor of 2.8 percent and applying that proposed increase factor to the conversion factor for CY 2024. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals would experience an increase in payments of approximately 2.8 percent and that rural hospitals would experience an increase in payments of 4.4 percent. Classifying hospitals by teaching status, we estimate non-teaching hospitals would experience an increase in payments of 3.5 percent, minor teaching hospitals would experience an increase in payments of 3.0 percent, and major teaching hospitals would experience an increase in payments of 2.4 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would experience an increase of 3.0 percent in payments, while hospitals with government ownership would experience an increase of 2.8 percent in payments. We estimate that hospitals with proprietary ownership would experience an increase of 3.4 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 2024 payment rates, compared to estimated CY 2023 payment rates, generally ranges between a decrease of 6 percent and an increase of 7 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 would increase payments by \$170 million under the ASC payment system in CY 2024.

f. Impacts of Hospital Price Transparency

We propose to enhance automated access to hospital MRFs and aggregation and use of MRF data are estimated to increase burden on hospitals, including a one-time mean of \$2,787 per hospital, and a total national cost of \$19,784,539 ($\$2,787 \times 7,098$ hospitals). The cost estimate reflects estimated costs ranging from \$1,274 and \$4,181 per hospital, and a total national cost ranging from \$9,040,620 to \$29,676,809. As discussed in detail in section XXVI of this proposed rule, we believe that the benefits to the public (and to hospitals themselves) outweigh the burden imposed on hospitals.

B. Legislative and Regulatory Authority for the Hospital OPPS

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

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: the Medicare, Medicaid, and SCHIP Benefits Improvement and

Protection Act of 2000 (BIPA) (Pub. L. 106-554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA) (Pub. L. 109-432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110-173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (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 proposed rule. 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;
- and
- Indian Health Service (IHS) hospitals.

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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>.

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 22, 2022. 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 2018, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (83 FR 3715). 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 OPPS.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 22, 2022, meeting that the subcommittees continue. We accepted this recommendation.

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

F. Public Comments Received on the CY 2023 OPPS/ASC Final Rule With Comment Period

We received approximately 12 timely pieces of correspondence on the CY 2023 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 4, 2022 (87 FR 71748). In-scope comments related to the interim APC assignments and/or status

indicators of new or replacement Level II HCPCS codes (identified with comment indicator “NI” in OPPS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule).

II. Proposed Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

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

For the CY 2024 OPPS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2024, and before January 1, 2025 (CY 2024), using the same basic methodology that we described in the CY 2023 OPPS/ASC final rule with comment period (86 FR 63466), using CY 2022 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 2024, we began with approximately 180 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, 2022, and before January 1, 2023, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 93 million final action claims to develop the proposed CY 2024 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

Addendum N to this proposed rule (which is available via the Internet on the CMS website at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>) includes the proposed list of bypass codes for CY 2024. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2022 and, therefore, includes codes that were in effect in CY 2022 and used for billing. We propose to retain deleted bypass codes on the proposed CY 2024 bypass list because these codes existed in CY 2022 and were covered OPD services in that period, and CY 2022 claims data were used to calculate proposed CY 2024 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 the proposed rule. HCPCS codes that we propose to add for CY 2024 are identified by asterisks (*) in the fourth column of Addendum N.

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

For CY 2024, 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 2024 APC payment rates are based, we calculated hospital-specific departmental CCRs for each hospital for which we had CY 2022 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2021. For the proposed CY 2024 OPPS payment rates, we used the set of claims processed during CY 2022. 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 2022 (the year of claims data we used to calculate the proposed CY 2024 OPPS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2022 Data specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

In the CY 2023 OPPS/ASC final rule with comment period, a few commenters recommended that we revise our revenue code-to-cost center crosswalk to provide consistency with the NUBC definitions and to improve the accuracy of cost data for OPPS ratesetting with respect to chimeric antigen receptor therapy (CAR-T) administration services (87 FR 71758). In that final rule with comment period, we stated that we intend to explore the implications of this recommendation further and may consider such changes in future rulemaking. For this CY 2024 OPPS/ASC proposed rule, we explored the impacts of the commenters' recommendation from the CY 2023 OPPS/ASC final rule with comment period that we assign primary cost centers to certain CAR-T-related revenue codes that were not previously assigned cost centers. Specifically, for this CY 2024 OPPS/ASC proposed rule, we explored the commenter's

recommendations regarding changes to the revenue code-to-cost center crosswalk, which included:

- Revising revenue codes 0870 (Cell/Gene Therapy General Classification) and 0871 (Cell Collection) to be mapped to a primary cost center of 9000 (Clinic);
- Revising revenue codes 0872 (Specialized Biologic Processing and Storage - Prior to Transport) and 0873 (Storage and Processing After Receipt of Cells from Manufacturer) to be mapped to a primary cost center of 3350 (Hematology);
- Revising revenue codes 0874 (Infusion of Modified Cells) and 0875 (Injection of Modified Cells) to be mapped to a primary cost center of 6400 (Intravenous Therapy), and;
- Revising revenue codes 0891 (Special Processed Drugs - FDA Approved Cell Therapy) and 0892 (Special Processed Drugs - FDA Approved Gene Therapy) to be mapped to a primary cost center of 7300 (Drugs Charged to Patients).

After reviewing the impact of these crosswalk revisions on our proposed CY 2024 OPPS APC geometric mean costs, we only observed an increase in the geometric mean cost of CPT code 0540T (Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous) – from \$148.31 to \$294.17 for this proposed rule – as a result of the revenue code for CPT code 0540T being assigned to a new cost center and the new corresponding cost-to-charge ratio. We did not observe any significant impact on APC geometric mean costs or payment as a result of these revisions. We believe these revisions would provide greater consistency with the NUBC definitions (which already adopted these revenue code revisions) and more accurately account for the costs of CAR-T administration services under the OPPS. Therefore, for CY 2024 and subsequent years, we propose to adopt the aforementioned revisions

to revenue codes 0870, 0871 0872, 0873, 0874, 0875, 0891, and 0892 in our revenue code-to-cost center crosswalk.

We solicit comment on our proposed changes to the revenue code-to-cost center crosswalk for CY 2024.

In accordance with our longstanding policy, similar to our finalized policy for CY 2023 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 2024, 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 2024. The Hospital OPSS page on the CMS website on which this proposed rule is posted (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>) 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/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/index.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html), includes information about obtaining the “OPPS Limited Data Set,” which now includes the additional variables previously available only in the OPSS Identifiable Data Set, including ICD-10-CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2022 claims that are used to calculate the proposed payment rates for this proposed rule.

Previously, the OPSS established the scaled relative weights on which payments are based using APC median costs, a process described in the CY 2012 OPSS/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 OPSS/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 OPSS 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 OPSS payment rates for CY 2024 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/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html)). 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 OPSS, 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 2024 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 2024 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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

a. Proposed 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, 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.

Because this proposed hospital-specific, simulated, blood-specific CCR methodology takes into account the unique charging and cost accounting structure of each hospital, 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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>) for the proposed CY 2024 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 through 50525) for a more comprehensive discussion of the blood-specific CCR methodology;

- the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810) for a detailed history of the OPPS payment for blood and blood products; and
- the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795 through 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.

We propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy – cancer treatment through solid source radioactive implants – consisting of a seed or seeds (or radioactive source) (“brachytherapy sources”) separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals’ charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals’ charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. 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 2024, except where otherwise indicated, we propose to use the costs derived from CY 2022 claims data to set the proposed CY 2024 payment rates for brachytherapy sources because CY 2022 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 2024 OPPTS. We proposed this methodology for CY 2024 and subsequent years. 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 OPPTS, as discussed in section II.A.2 of this proposed rule. We also propose for CY 2024 and subsequent years, to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60537). For CY 2024 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 OPPTS/ASC final rule with comment period (72 FR 66785). For CY 2024 and subsequent years, we also propose to continue the policy we first implemented in the CY 2010 OPPTS/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 OPPTS/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 2024 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 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, and CY 2023 OPPS/ASC final rules with comment period (85 FR 85879 through 85880 and 86 FR 63469 and 87 FR 71760 through 71761), 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 CY 2021, for CY 2022, and for CY 2023.

After reviewing CY 2022 claims data available for this proposed rule, we observed three claims that reported HCPCS code C2645. Each claim reported one unit of HCPCS code C2645 and the geometric mean unit cost from these three claims yielded \$168.67. We are unable to use these claims for ratesetting purposes given the reporting of only one unit per claim and the high geometric mean cost. Therefore, we propose to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2023 payment rate of \$4.69 per mm² for HCPCS code C2645, which is assigned to APC 2648 (Brachytx planar, p-103), for CY 2024.

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

For CY 2024, we propose to designate five brachytherapy APCs as Low Volume APCs as these APCs meet our criteria to be designated as a Low Volume APC. 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 2024

(1) Background

In the CY 2014 OPSS/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 OPSS 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 OPSS payment and implemented 25 C-APCs beginning in CY 2015 (79 FR 66809 through 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 70 (80 FR 70332; 81 FR 79584 through 79585; 83 FR 58844 through 58846; 84 FR 61158 through 61166; 85 FR 85885; 86 FR 63474; and 87 FR 71769).

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 OPSS 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 through 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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>). If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C-APC service when it appears on an outpatient claim with a primary C-APC service.

The C-APC policy payment methodology set forth in the CY 2014 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 OPPS/ASC final rule with comment period, we define the C-APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator “J1”¹, excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator “J1” are assigned to C-APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

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

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator “T”;
- 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

¹ Status indicator “J1” denotes Hospital Part B Services Paid Through a Comprehensive APC. Further information can be found in CY 2024 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 2024 Addendum D1.

visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and

- Does not contain services described by a HCPCS code to which we have assigned status indicator “J1”.

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

Services included under the C-APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes

that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

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

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 of 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

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

multiple “J1” services on a claim map to the same C-APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator “J1” to the most appropriate C-APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

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

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

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status

indicator “J1” (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C-APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

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

We package payment for all add-on codes into the payment for the C-APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPSS/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 2024, 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 2024, 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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>).

Addendum J to this proposed rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and be reassigned to the next higher cost C-APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first four digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C-APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that will be reassigned to C-APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this proposed rule allows interested parties the opportunity to better assess the impact associated with the assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

(2) 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 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 has 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 has been 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 have 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. Please see Addendum J for the CY 2024 comprehensive 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 OPSS when it appears on the same claim as a primary C-APC service.

(4) Additional C-APCs for CY 2024

For CY 2024 and subsequent years, we propose to continue to apply the C-APC payment policy methodology. We refer readers to the CY 2017 OPSS/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 OPSS. As a result of our annual review of the services and the APC assignments under the OPSS, we are not proposing to convert any standard APCs to C-APCs in CY 2024, but we are creating two new APCs that will both be C-APCs. Thus, we propose that the number of C-APCs for CY 2024 would be 72 C-APCs.

For this proposed rule, we propose to split the Level 2 Intraocular APC (APC 5492) into two and assign the higher cost procedures previously within this APC to a new Level 3 Intraocular APC (APC 5493). The previous Level 3, Level 4, and Level 5 Intraocular APCs (APCs 5493, 5494, and 5495) will be renamed the Level 4, Level 5, and Level 6 Intraocular APC (APCs 5494, 5495, and 5496), respectively. We refer readers to section III.E of this proposed rule for more information regarding this proposal.

We also propose to add a new Level 2 Abdominal/Peritoneal/Biliary and Related Procedures APC (APC 5342) to improve clinical and resource homogeneity in the Level 1 Abdominal/Peritoneal/Biliary and Related Procedures APC (APC 5341).

Table 1 lists the proposed C-APCs for CY 2024. All C-APCs are 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 for CY 2024.

TABLE 1: PROPOSED CY 2024 C-APCs

C-APC	CY 2024 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	
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	

C-APC	CY 2024 APC Group Title	Clinical Family	New C-APC
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	*
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 OPSS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPSS 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 OPSS 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 OPSS, we currently have composite policies for mental health services and multiple imaging services. We refer readers to the CY 2008 OPSS/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 OPSS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPSS/ASC final rule with comment period (82 FR 59241 through 59242 and 59246 through 52950) for more recent background.

(1) Mental Health Services Composite APC

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. We refer readers to the April 7, 2000 OPSS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPSS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2018 OPSS/ASC proposed rule and final rule with comment period (82 FR 33580 through 33581 and 59246 through 59247, respectively), 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 that will be paid for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital will continue to be paid the payment rate for composite APC 8010. Under this policy, the Integrated OCE (I/OCE) will 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 5863 for all of the specified mental health services furnished by the hospital on that single date of service. 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.

We propose 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 3 partial hospitalization services provided in a day by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2024. In addition, we propose to set the payment rate for composite APC 8010 at the same payment rate that we propose for APC 5863, which is a partial hospitalization per diem payment rate for 3 partial hospitalization services furnished in a day by a hospital, and that the hospital continue to be paid the proposed payment rate for composite APC 8010. While APC 5863 is no longer the maximum partial hospitalization per diem payment rate for a hospital, due to proposed APC 5864, which is 4 or more hospital-based PHP services per day, discussed in section VIII.B of this proposed rule, we believe it is still appropriate to apply the APC 5863 per diem payment amount as the upper limit on payment per day for individual OPPS mental health services. This is because the daily mental health cap would not be expected to reach a level of intensity beyond 3 services per day, as described by APC 5863. The PHP is meant to be the most intensive mental health services program, requiring inpatient care if PHP is not received. We would not anticipate more than three services per patient on a given day, as patients needing additional services in one day would potentially require an inpatient admission., as described by APC 5863. Thus, setting the mental health cap at APC 5863, rather than the 4 service per day APC 5864, is more consistent with our longstanding policy, which has been for the 3 service per day APC. We note that the proposed CY 2024 payment amount for APC 5863 would be comparable to the CY 2023 payment amount for APC 5863, which is the PHP APC used to set the daily mental health cap for CY 2023.

However, 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, we are also soliciting comment on whether the next higher level APC, proposed APC 5864, which is for

four hospital-based PHP services per day, would be appropriate to use as the daily mental health cap.

(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 2 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 2024, 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 2024, except where otherwise indicated, we propose to use the costs derived from CY 2022 claims data to set the proposed CY 2024 payment rates. Therefore, for CY 2024, the payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) are based on proposed geometric mean costs calculated from CY 2022 claims available for this 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 have used the same methodology that we use 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.b of this proposed rule.

For CY 2024, we were able to identify approximately 0.95 million “single session” claims out of an estimated 2.0 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 47.5 percent of all eligible claims, to calculate the proposed CY 2024 geometric mean costs for the multiple imaging composite APCs. Table 2 of this proposed rule 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 2024.

TABLE 2: OPPTS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2024 APC 8004 (Ultrasound Composite)	CY 2024 Approximate APC Geometric Mean Cost = \$313.97
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 2024 APC 8005 (CT and CTA without Contrast Composite)*	CY 2024 Approximate APC Geometric Mean Cost = \$229.30
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 2024 APC 8006 (CT and CTA with Contrast Composite)	CY 2024 Approximate APC Geometric Mean Cost = \$434.54
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
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 2024 APC 8007 (MRI and MRA without Contrast Composite)*	CY 2024 Approximate APC Geometric Mean Cost = \$533.84
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 2024 APC 8008 (MRI and MRA with Contrast Composite)	CY 2024 Approximate APC Geometric Mean Cost = \$847.83
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 OPSS

Like other prospective payment systems, the OPSS 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 OPSS 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 OPSS 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 and Comment Solicitation on Packaged Items and Services

For CY 2024, 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 2024, we do not propose any changes to the overall packaging policy previously 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.

While we do not propose any changes to the overall packaging policy above, we solicit comments on potential modifications to our packaging policy as described in the following sections.

c. Comment Solicitation 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 sections 1833(t)(16) and 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) 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. Because the additional payments are required to begin on January 1, 2025, we will include our proposals to implement the CAA, 2023 section 4135 amendments in the CY 2025 OPPS/ASC proposed rule. We discuss section 4135 of CAA, 2023 at length in section XIII.F of this proposed rule, where we solicit comment on numerous aspects of this future policy. While we expect this policy to operate similarly in the ASC and HOPD settings, we welcome comment on whether there are any HOPD specific payment issues we should take into consideration as we plan to implement section 1833(t)(16)(G) of the Act for CY 2025.

d. Comment Solicitation on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

(i) Background on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

Under the OPPTS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. As the products are packaged according to the policies in § 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals 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.

Diagnostic radiopharmaceuticals, which include contrast agents, stress agents, and other products, 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 through 71963), commenters recommended that CMS always pay separately for diagnostic radiopharmaceuticals paid under the OPPTS, 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.

CMS has previously 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 more accurately reflect the costs of diagnostic radiopharmaceuticals. 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 through 71963).

Importantly, commenters historically have also been concerned that packaging payment for precision diagnostic radiopharmaceuticals in the outpatient 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 through 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 OPSS packaging policies. Commenters also suggested that CMS pay separately under the OPSS 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 in order to establish appropriate payment rates in the future. Many of these comments and our responses have been discussed in rulemaking since the policy to package diagnostic radiopharmaceuticals was adopted. We refer readers to the CY 2023 OPSS/ASC final rule with comment period (87 FR 71962 through 71963) for the most recent discussion of this subject.

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, the payment for the radiopharmaceuticals should be reflected within the payment for the primary procedure. We note

that ratesetting uses the geometric mean of reported procedure costs 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, 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 radiopharmaceutical packaged with the associated procedure reflect the combined cost of the procedure and the radiopharmaceutical used in the procedure.

As CMS has reiterated over the years, we believe these packaging policies are inherent principles of the OPSS and are essential to a prospective payment system. We are also committed to ensuring beneficiary access to diagnostic radiopharmaceuticals while also ensuring the availability of new and innovative diagnostic tools for Medicare beneficiaries. Therefore, we are seeking public comments on potential modifications to our packaging policy for diagnostic radiopharmaceuticals in order to ensure equitable payment and continued beneficiary access.

Depending on the comments we receive in response to this comment solicitation, we may adopt as final alternative payment mechanisms for radiopharmaceuticals for CY 2024 in the CY 2024 OPSS/ASC final rule with comment period.

(ii) Comment Solicitation on Potential Issues Caused by Current Payment of Diagnostic Radiopharmaceuticals Under the OPSS

We are soliciting comment on how the OPSS 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. We seek information on specific cost-prohibitive diagnostic radiopharmaceuticals that commenters believe are superior to alternative diagnostic modalities. We are interested to learn the specific clinical scenarios that exist for which it is only clinically appropriate to use the more expensive

diagnostic radiopharmaceutical, rather than a lower cost alternative, as well as what clinical scenarios exist in which the only diagnostic modality is a high-cost radiopharmaceutical. We are seeking information or evidence that these high-cost diagnostic radiopharmaceuticals have unique clinical value, and access has been negatively impacted by our packaging policy. We are also seeking information about whether commenters believe these high-cost and low-utilization diagnostic radiopharmaceuticals are being appropriately utilized according to their clinical treatment algorithm, meaning the stepwise procedures generally accepted by the medical community for diagnosis, or clinical practice guidelines.

We are also interested in learning more about whether there is a difference in outcomes for patients, or patient quality of care, based on the radiopharmaceutical used as well as whether there is a difference for hospitals, such as in terms of financial outcomes, based on the radiopharmaceutical that used.

(iii) Comment Solicitation on New Approaches to Payment of Diagnostic Radiopharmaceuticals Under the OPPS

In addition, we are soliciting comment on the following potential approaches that would enhance beneficiary access, while also maintaining the principles of the outpatient prospective payment system. These approaches include: (1) paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of \$140; (2) establishing a specific per-day cost threshold that may be greater or less than the OPPS 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.

To expand upon the first listed option on which we solicit comments, we are specifically seeking comments about whether we should use our statutory authority for separately payable

drugs, biologicals, and radiopharmaceuticals under 1833(t)(14)(A)(iii)(II) of the Act in order to pay separately for diagnostic radiopharmaceuticals and subject those diagnostic radiopharmaceuticals to the longstanding OPPS drug packaging threshold policy, proposed to be \$140 for CY 2023. Or said another way, payment for diagnostic radiopharmaceuticals with per-day costs greater than \$140 would not be packaged and would be paid separately based on available average sales price (ASP), wholesale acquisition cost (WAC), or average wholesale price (AWP) data with the applicable add-on. This would be similar to payment for therapeutic radiopharmaceuticals and other drugs and biologicals as discussed in section V.B. of this proposed rule. We believe this could be a reasonable first step as this threshold is well understood and known to commenters as therapeutic drugs, biologicals, and radiopharmaceuticals are currently paid separately if they have a calculated per-day cost above this threshold and are not policy-packaged. However, it is also our longstanding belief that diagnostic radiopharmaceuticals should have their payment packaged as they function as supplies during a diagnostic test or procedure and enable the provision of an independent service and are not themselves the primary therapeutic modality. We seek additional information from interested parties on this approach.

Regarding the second listed option, we seek comment on whether to pay separately for a diagnostic radiopharmaceutical with a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold. Specifically, we are interested to learn why interested parties believe a threshold-based policy is important as well as interested parties' rationale for creating a threshold that would be different from the OPPS drug packaging threshold.

Regarding the third listed option, we have heard from some interested parties that they believe APC restructuring, including adding additional nuclear medicine APCs for services utilizing high-cost diagnostic radiopharmaceuticals, would be appropriate. We seek comment as to how these interested parties specifically envision operationalizing this approach and what advantage this approach would have for beneficiaries, hospitals, and CMS over other options.

For the fourth listed option, we recently became aware that some interested parties believe that CMS packaging policies could influence participation of beneficiaries and testing sites in clinical trials, particularly those studying Alzheimer's disease, and are interested to learn more about these concerns. While we believe there could be a multitude of reasons for difficulty in recruiting study sites and beneficiaries for clinical trials, including the COVID-19 PHE, we are requesting comment as to whether CMS should consider creating payment policies for diagnostic radiopharmaceuticals used in clinical trials. Specifically, we are interested to learn what commenters believe an appropriate payment mechanism would be for these diagnostic radiopharmaceuticals, whether there are certain disease states or categories of trials for which we should target our payment policies, ways in which this policy could help promote equitable recruitment and diverse participation, and the method by which CMS should determine which clinical trial diagnostic radiopharmaceuticals should be subject to this policy.

Finally, for approach five, we are seeking comment on new codes that CMS could adopt that may incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals. CMS could create indication-specific coding to reflect the imaging procedure and the target of the imaging procedure. For example, CMS could create a code to represent a PET scan that detects a specific protein. If multiple diagnostic radiopharmaceuticals are available to use during this PET scan to detect this specific protein, then their payment would be packaged into the payment for this newly created code and reflected in the payment for this code. Therefore, if there is a specific clinical indication for which only very costly diagnostic radiopharmaceuticals are available, our data would appropriately reflect their utilization. Alternatively, if there is a specific clinical indication in which a wide variety of diagnostic radiopharmaceuticals can be used, all with varying costs, then our data would reflect this and our payment rates would not incentivize a higher-cost diagnostic radiopharmaceutical when there is a lower-cost, but clinically similar, diagnostic radiopharmaceutical alternative. This coding approach could be coupled with the restructuring of the nuclear medicine APC

family. We believe this approach of more granular coding could allow for more specific data to be reported and thus more targeted and appropriate payment rates to be developed. This approach would also help to maintain the principles of a prospective payment system by maintaining current packaging policies as payment for the diagnostic radiopharmaceutical would continue to be packaged into the payment for the procedure in which the diagnostic radiopharmaceutical is used.

We also seek additional explanation from interested parties as to why they believe their suggested approach is the best policy approach to ensure beneficiary access to diagnostic radiopharmaceuticals and equitable payment for innovative and effective technologies. We welcome comment regarding ideas discussed in this section, discussed in prior rulemaking, or new ideas for payment for diagnostic radiopharmaceuticals in OPSS.

Finally, we are interested in hearing from stakeholders how the discussed policy modifications might impact our overarching goal of utilizing packaging policies to better align OPSS policies with that of a prospective payment system rather than a fee schedule. We would also like to know if making any of the policy changes discussed previously 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 note that depending on the comments received, we may adopt as final one or more alternative payment mechanisms for radiopharmaceuticals for CY 2024.

4. Calculation of OPSS Scaled Payment Weights

We established a policy in the CY 2013 OPSS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPSS. In the CY 2023 OPSS/ASC final rule with comment period (87 FR 71778 through 71780), we applied this policy and calculated the relative payment weights for each APC for CY 2023 that were shown in Addenda A and B of the CY 2023 OPSS/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 2023 OPPTS/ASC final rule with comment period (87 FR 71757 through 71777). For CY 2024, as we did for CY 2023, we propose to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2024 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 OPPTS/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 any and all clinic visits under the OPPTS. 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 OPPTS 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 OPPTS (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 2024, as we did for CY 2023, 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 OPPTS services. For CY 2024, as we did for CY 2023, 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 2024 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we propose to compare the estimated aggregate weight using the CY 2023 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2024 unscaled relative payment weights.

For CY 2023, we multiplied the CY 2023 scaled APC relative payment weight applicable to a service paid under the OPSS by the volume of that service from CY 2022 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 2024, we propose to apply the same process using the estimated CY 2024 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2023 estimated aggregate weight by the unscaled CY 2024 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/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/index.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html). Click on the link labeled “CY 2024 OPSS/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 “2024 NPRM OPSS Claims Accounting (PDF)”.

We propose to compare the estimated unscaled relative payment weights in CY 2024 to the estimated total relative payment weights in CY 2023 using CY 2022 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 2024 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2024 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4529 to ensure that the proposed CY 2024 relative payment weights are scaled to be budget neutral. The proposed CY 2024 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 2024 OPSS.

B. Proposed Conversion Factor Update

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 rate 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 rate 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 2024 IPPS/Long Term Care Hospital (LTCH) PPS proposed rule (88 FR 27004 through 27005), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2022 forecast, the proposed FY 2024 IPPS market basket percentage increase was 3.0 percent. We note that under our regular process for the CY 2024 OPSS/ASC final rule, we would use the market basket update for the FY 2024 IPPS/LTCH PPS final rule,

which would be based on IHS Global, Inc.'s second quarter 2023 forecast of the FY 2024 IPPS market basket percentage increase. If that forecast is different than the IPPS market basket percentage increase used for this proposed rule, the CY 2024 OPSS/ASC final rule OPD rate increase factor would reflect that updated forecast of the market basket percentage increase.

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, and then revised this methodology, as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of private nonfarm business productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity. However, as mentioned, the data and methods are unchanged. Please see www.bls.gov for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at <https://www.cms.gov/Research-Statistics-Dataand-Systems/Statistics-Trends-andReports/MedicareProgramRatesStats/MarketBasketResearch>. 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 2024 IPPS/LTCH PPS proposed rule (88 FR 27005), the proposed productivity adjustment for FY 2024 was 0.2 percentage point.

Therefore, we propose that the productivity adjustment for the CY 2024 OPSS would be 0.2 percentage point. We also propose that if more recent data subsequently become available after the publication of this 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 2024 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 OPSS payment rates being less than rates for the preceding year. As described in further detail below, we propose for CY 2024 an OPD fee schedule increase factor of 2.8 percent for the CY 2024 OPSS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.0 percent, less the proposed 0.2 percentage point productivity adjustment).

We propose that hospitals that fail to meet the Hospital OQR Program reporting requirements would be subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPSS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIV of this proposed rule.

To set the OPPS conversion factor for 2024, we propose to increase the CY 2023 conversion factor of \$85.585 by 2.8 percent reflecting the proposed IPPS hospital market basket update. In accordance with section 1833(t)(9)(B) of the Act, we propose further to adjust the conversion factor for CY 2024 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 0.9974 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2024 IPPS wage indexes to those payments using the FY 2023 IPPS wage indexes, as adopted on a calendar year basis for the OPPS. We further propose to calculate an additional budget neutrality factor of 0.9975 to account for our proposed policy to cap wage index reductions for hospitals at 5 percent on an annual basis.

For the CY 2024 OPPS, 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 2024 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 1.0005 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), requires that we reduce the target PCR by 0.01, which brings the proposed target PCR to 0.88. This is 0.01 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 2024 would equal approximately \$234.1 million, which represents 0.26 percent of total projected CY 2024 OPSS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.16 percent estimate of pass-through spending for CY 2023 and the 0.26 percent estimate of proposed pass-through spending for CY 2024, resulting in a proposed decrease to the conversion factor for CY 2024 of 0.1 percent.

Proposed estimated payments for outliers would remain at 1.0 percent of total OPSS payments for CY 2024. We estimated for this proposed rule that outlier payments would be approximately 0.78 percent of total OPSS payments in CY 2023; the 1.00 percent for proposed outlier payments in CY 2024 would constitute a 0.22 percent increase in payment in CY 2024 relative to CY 2023.

For CY 2024, 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 0.8 percent (that is, the proposed OPD fee schedule increase factor of 2.8 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2024 of \$85.782 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.706 in the conversion factor relative to hospitals that met the requirements).

In summary, for 2024, we propose to use a reduced conversion factor of \$85.782 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.706 in the conversion factor relative to hospitals that met the requirements).

For 2024, we propose to use a conversion factor of \$87.488 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 2.8 percent for CY 2024, the required proposed wage index budget neutrality adjustment of approximately 0.9974, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9975, the proposed cancer hospital payment adjustment of 1.0005, and the proposed adjustment of an decrease of 0.1 percentage point of projected OPPS spending for the difference in pass-through spending, which results in a proposed conversion factor for CY 2024 of \$87.488. The calculations we performed to determine the CY 2024 proposed conversion factor are shown in Table 3.

Table 3. CALCULATION OF CY 2024 PROPOSED OPPS CONVERSION FACTOR

<p><u>Start:</u> CY 2023 Final OPPS Conversion Factor = \$85.585</p>
<p><u>Step 1a:</u> Adjust the conversion factor to temporarily account for additional drug and device pass-through spending and outlier spending in CY 2023. This action causes an increase in the conversion factor. So, the amount of both drug and device pass-through spending (0.0016) 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 2023.</p> <p>➤ $1.0000 - (0.0016 + 0.01) = 0.9884$</p> <p><u>Step 1b:</u> Divide \$85.585 by 0.9884</p> <p>➤ $\\$85.585 / 0.9884 = \mathbf{\\$86.589}$</p>
<p><u>Step 2:</u> Adjust the conversion factor by the required wage index budget neutrality adjustment of approximately 0.9974. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with \$86.589.</p> <p>➤ $\\$86.589 * 0.9974 = \mathbf{\\$86.364}$</p>
<p><u>Step 3:</u> Adjust the conversion factor by the proposed 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9975. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with \$86.364.</p> <p>➤ $\\$86.364 * 0.9975 = \mathbf{\\$86.148}$</p>

Step 4: Adjust the conversion factor by the proposed cancer hospital payment adjustment of 1.0005. Because the PCR for cancer hospitals is declining between CY 2023 and CY 2024, it increases the amount of OPPS outpatient hospital spending for providers that are not cancer hospitals and is multiplied with \$86.148.

➤ $\$86.148 * 1.0005 = \mathbf{\$86.191}$

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

➤ $\$86.191 * 1.0000 = \mathbf{\$86.191}$

Step 6a: Adjust the conversion factor by the proposed OPD fee schedule increase factor of 0.028 for CY 2024. The proposed OPD fee schedule increase factor increases outpatient hospital spending in CY 2024 over CY 2023 and is added to 1.0000 which represents total outpatient hospital OPPS spending in CY 2023.

➤ $1.0000 + 0.028 = 1.0280$

Step 6b: Multiply \$86.191 by 1.0280.

➤ $\$86.191 * 1.0280 = \mathbf{\$88.605}$

Step 7a: Adjust the conversion factor to remove additional drug and device pass-through spending and outlier spending for CY 2024. This action causes a decrease in the conversion factor. So, the amount of both drug and device pass-through spending (0.0026) 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.

➤ $1.0000 - (0.0026 + 0.01) = 0.9874$

Step 7b: Multiply \$88.605 by 0.9874 to get the CY 2024 proposed OPPS conversion factor.

➤ $\$88.605 / 0.9874 = \mathbf{\$87.488}$

Finish: **CY 2024 Proposed OPPS Conversion Factor = \$87.488**

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.B of this proposed rule.

The OPSS labor-related share is 60 percent of the national OPSS 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 OPSS 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 OPSS final rule with comment period (70 FR 68553). We propose to continue this policy for the CY 2024 OPSS. We refer readers to section II.H 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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>)), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2024 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 OPSS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPSS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPSS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPSS 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 OPSS. As initially explained in the September 8, 1998 OPSS proposed rule (63 FR 47576), we believe that using the IPPS 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. 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 OPPI/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 2024, 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 2023 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 through 53370; for FY 2014, 78 FR 50590 through 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; and for FY 2023, 87 FR 49006.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2024 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 proposed to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to exclude "dual reclass" hospitals (hospitals with simultaneous § 412.103 and 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 26973 through 26974). 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 2024 IPPS/LTCH PPS proposed rule (88 FR 26963 through 26986) for a detailed discussion of all proposed changes to the FY 2024 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 2024 would not be less than 95 percent of its final wage index for FY 2023, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We stated that we believe this policy would increase the predictability of IPPS payments for hospitals and mitigate instability and significant negative impacts to hospitals resulting from changes to the wage index. It would also eliminate the need for temporary and potentially uncertain transition adjustments to the wage index in the future due to specific policy changes or circumstances

outside hospitals' control. Except for newly opened hospitals, we will 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, 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 above).

Core Based Statistical Areas (CBSAs) are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and 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 received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at:

<https://www.census.gov/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 crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the 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 2024, under the OPSS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

We propose to use the FY 2024 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 2024. Therefore, any policies and adjustments for the FY 2024 IPPS post-reclassified wage index would be reflected in the final CY 2024 OPSS wage index beginning on January 1, 2024. We refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26963 through 26986) and the proposed FY 2024 hospital wage index files posted on the CMS website at <https://www.cms.gov/medicare/acute-inpatient-pps/fy-2024-ippss-proposed-rule-home-page>. With regard to budget neutrality for the CY 2024 OPSS wage index, we refer readers to section II.B 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 2024. We refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26963 through 26986) for a detailed discussion of the proposed changes to the FY 2024 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)). 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 2024, 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). Furthermore, we propose that the wage index that would apply for CY 2024 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, 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 2024, 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 2024 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 2024 IPPS/LTCH PPS proposed rule (available via the internet on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index>) identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2024 IPPS/ LTCH PPS proposed rule (available for download via the website above) identifies IPPS hospitals that would receive the out-migration adjustment for FY 2024. We are including the outmigration adjustment information from Table 2 associated with the FY 2024 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/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/index](#). At this link, readers will find a link to the proposed FY 2024 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 NO: 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. 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 CY 2024 OPSS proposed rule Claims Accounting Narrative that is posted on our website. We propose to calculate the default ratios for CY 2024 using the most recent cost report data. We will update these ratios in the final rule with comment period if more recent cost report data are available.

We no longer publish a table in the **Federal Register** containing the statewide average CCRs in the annual OPSS proposed rule and final rule with comment period. These CCRs with

the upper limit will be available for download with each OPSS 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 “Hospital Outpatient Regulations and Notices” and then select the relevant regulation 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 2024

In the CY 2006 OPSS 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 OPSS, excluding drugs, biologicals, brachytherapy sources, 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 OPSS 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 OPSS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPSS, 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 OPSS/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 2023.

For CY 2024, 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 2024

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 OPPS and a “pre-BBA amount.” That is, cancer hospitals are permanently held harmless to their “pre-BBA amount,” and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The “pre-BBA amount” is the product of the hospital’s reasonable costs for covered outpatient department services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The “pre-BBA amount” and the determination of the base PCR are defined at § 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10 (OMB NO: 0938-0050), respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

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

by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 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 4 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2023.

TABLE 4: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT PAYMENT-TO-COST RATIOS (PCRs), CY 2012 THROUGH CY 2023

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

2. Proposed Policy for CY 2024

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 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 2024.

To calculate the proposed CY 2024 target PCR, we would use the same extract of cost report data from HCRIS used to estimate costs for the CY 2024 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 2022 claims data that we used to model the impact of the proposed CY 2024 APC relative payment weights (3,406 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2024 OPSS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2017 to 2022; however, the cost reporting periods were predominantly from fiscal years ending in 2021 and 2022. We then removed the cost report data of the 47 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 14 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 3,345 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimate that, on average, the OPSS payments to other hospitals furnishing services under the OPSS were approximately 86 percent of reasonable cost (weighted average PCR of .86). 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 0.85 for each cancer hospital.

However, we note that a proposed cancer hospital target PCR of 0.85 for CY 2024 is dramatically lower than the target PCR from previous years. Historically, as shown in Table 4, the target PCR for cancer hospitals has been between 0.88 and 0.92. In light of our concerns about the impact of the COVID-19 PHE on CY 2020 claims and cost data, we finalized a policy to continue the target PCR of 0.89 from CY 2021 for CY 2022 and for CY 2023 as an appropriate cancer hospital adjustment under our authority described in section 1833(t)(2)(E) of the Act. We believe the impact of the COVID-19 PHE claims and cost data used to calculate the target PCR of 0.85 may continue to have some limited influence on our target PCR calculations. However, 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 do not know if the changes in the data that have yielded a significantly lower PCR for non-cancer hospitals using the most recently available data 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. We are concerned that using the 0.85 target PCR calculated from the most recent data could lead to instability in cancer hospital adjustment payments and volatility in the PCR as we transition to utilizing post-PHE data. Therefore, in this CY 2024 OPPTS/ASC proposed rule, we propose to transition 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 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 this CY 2024

OPPS/ASC proposed rule, we propose to reduce the CY 2023 target PCR of 0.89 by 1 percentage point and propose a cancer hospital target PCR of 0.88 for CY 2024.

Table 5 shows the estimated percentage increase in OPSS payments to each cancer hospital for CY 2024, due to the cancer hospital payment adjustment policy. The actual, final amount of the CY 2024 cancer hospital payment adjustment for each cancer hospital would be determined at cost report settlement and would depend on each hospital's CY 2024 payments and costs from the settled CY 2024 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 5: ESTIMATED CY 2024 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPSS Payments for CY 2024 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	43.9%
050660	USC Norris Cancer Hospital	30.2%
100079	Sylvester Comprehensive Cancer Center	41.9%
100271	H. Lee Moffitt Cancer Center & Research Institute	25.0%
220162	Dana-Farber Cancer Institute	41.1%
330154	Memorial Sloan-Kettering Cancer Center	56.9%
330354	Roswell Park Cancer Institute	19.1%
360242	James Cancer Hospital & Solove Research Institute	11.6%
390196	Fox Chase Cancer Center	22.1%
450076	M.D. Anderson Cancer Center	47.7%
500138	Seattle Cancer Care Alliance	39.4%

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 2023, 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 \$8,625 (the fixed-dollar amount threshold) (87 FR 71788 through 71790). 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 2022 OPSS payments, using CY 2022 claims available for this CY 2024 OPSS proposed rule, is approximately 0.88 percent. Therefore, for CY 2022, we estimate that we did not meet the outlier target by 0.12 percent of total aggregated OPSS payments.

For this proposed rule, using CY 2022 claims data and CY 2023 payment rates, we estimate that the aggregate outlier payments for CY 2023 would be approximately 0.78 percent of the total CY 2023 OPPS payments. We provide estimated CY 2024 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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

2. Outlier Calculation for CY 2024

For CY 2024, we propose to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We propose that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. In this CY 2024 OPPS/ASC proposed rule, we propose to modify our outlier policy and which APCs are eligible for an outlier payment if a CMHC's cost for 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 2024 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we propose that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus \$8,350.

We calculated the proposed fixed-dollar threshold of \$8,350 using the standard methodology most recently used for CY 2023 (87 FR 71788 through 71790). For purposes of estimating outlier payments for CY 2024, we use the hospital-specific overall ancillary CCRs available in the April 2023 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 2024 hospital outlier payments, we inflate the charges on the CY 2022 claims using the same proposed charge inflation factor of 1.118412 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27220). We used an inflation factor of 1.05755 to estimate CY 2023 charges from the CY 2022 charges reported on CY 2022 claims before applying CY 2023 CCRs to estimate the percent of outliers paid in CY 2023. The proposed methodology for determining these charge inflation factors is discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27219 through 27220). 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 2024 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2024 OPSS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2024, we propose to apply an adjustment factor of 0.977799 to the CCRs that were in the April 2023 OPSF to trend them forward from CY 2023 to

CY 2024. The methodology for calculating the proposed CCR adjustment factor, as well as the solicitation of comments on an alternative approach, is discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27221).

To model hospital outlier payments for the CY 2024 proposed rule, we apply the overall CCRs from the April 2023 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.977799 to approximate CY 2024 CCRs) to charges on CY 2022 claims that were adjusted (using the proposed charge inflation factor of 1.118412 to approximate CY 2024 charges). We simulated aggregated CY 2022 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 2024 OPSS payments. We estimated that a proposed fixed-dollar threshold of \$8,350, 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 XIV 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 CY 2024 OPSS/ASC 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 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 2024 scaled weight for the APC by the CY 2024 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 2024 OPSS 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 OPSS, 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 OPSS/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 OPSS 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 2024 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 propose to continue to apply for the CY 2024 OPSS wage index any adjustments for the FY 2024 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 propose to apply for the CY 2024 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 2024 IPPS wage index, which are listed in Table 3 associated with the FY 2024 IPPS proposed rule and available via the Internet on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>. (Click on the link on the left side of the screen titled “FY 2024 IPPS Proposed Rule Home Page” and select “FY 2024 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.

$Y = .40 * (\text{national unadjusted payment rate}).$

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.

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

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

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

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

Adjusted Medicare Payment = $X_a + Y$

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that would apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The proposed CY 2024 full national unadjusted payment rate for APC 5071 is \$675.15. The proposed reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is \$661.98. 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 \$405.09 (.60 * \$675.15). The labor-related portion of the proposed reduced national adjusted payment is approximately \$397.19 (.60 * \$675.15).

Step 2 & 3. The FY 2024 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of the proposed IPPS 2024 wage index policies, is 1.3631.

Step 4. The wage adjusted labor-related portion of the proposed full national unadjusted payment is approximately \$522.18 (\$405.09 * 1.3631). The wage adjusted labor-related portion of the proposed reduced national adjusted payment is approximately \$541.41 (\$397.19 * 1.3631).

Step 5. The nonlabor-related portion of the proposed full national unadjusted payment is approximately \$270.06 (.40 * \$675.15). The nonlabor-related portion of the proposed reduced national adjusted payment is approximately \$264.79 (.40 * \$661.98).

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 \$822.24 (\$552.18 + \$270.06). The sum of the portions of the proposed reduced national adjusted payment is approximately \$806.20 (\$541.41 + \$264.79).

Proposed Full national unadjusted payment rate	Proposed Reduced national adjusted payment rate
\$882.24	\$806.20

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services.

Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished

in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

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

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116-260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section X.B, “Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests,” of the CY 2022 OPPS/ASC final rule with comment

period for the full discussion of this policy (86 FR 63740 through 63743). Under the regulation at 42 CFR 410.152(l)(5)(i)(B), the Medicare Part B payment percentage for colorectal cancer screening tests described in the regulation at § 410.37(j) that are furnished in CY 2023 through 2026 (and the corresponding reduction in coinsurance) 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 are currently being implemented through program instruction, as permitted under section 1847A(c)(5)(C) of the Act. As such, we issued final 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.^{4,5} 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>. We also refer readers to the CY 2024 Medicare Physician Fee Schedule (PFS) proposed rule for a detailed discussion of proposals related to inflation-adjusted beneficiary coinsurance and Medicare payment for Medicare Part B rebatable drugs.

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

⁴ <https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf>

⁵ 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/mcpartbdrugavgsalesprice>

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 calendar quarters in which the amount specified 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 amount specified in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a selected drug.

Paragraph (9) of section 1833(i) of the Act and subparagraph (F) of section 1833(t)(8) of the Act, as added by section 11101(b) of the IRA, also provide that in lieu of the amounts of payment otherwise applicable under the ASC payment system and 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 inflation-adjusted payment

amount of a Part B rebatable drug exceeds the payment amount described in 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), the Part B payment will, subject to the deductible and sequestration, equal the difference between such payment amount and the inflation-adjusted coinsurance amount.

In this proposed rule, we propose to codify 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 proposed in the CY 2024 PFS proposed rule (§§ 410.152(m) and 489.30(b)(6)). We also propose to amend 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 propose to codify 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), as proposed in the CY 2024 PFS proposed rule to codify the cost sharing amounts for Part B rebatable drugs with prices increasing at a rate faster than inflation. We are not proposing any changes to the ASC regulations at 42 CFR part 416 to reflect the Medicare payment amount for Part B rebatable drugs with prices increasing at a rate faster than inflation, because 42 CFR 416.171(b) already incorporates, for the ASC payment system, the payment amounts that apply for the OPSS under 42 CFR part 419. Part 419 would include our proposed new § 419.41(e), which addresses Medicare payment for Part B rebatable drugs under the OPSS.

2. Proposed OPSS Copayment Policy

For CY 2024, 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 OPSS 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, 2024 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 2024, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

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

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

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

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

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

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

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

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

We noted in the CY 2004 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 OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

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

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

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its proposed payment rate. For example, using APC 5071, \$135.03 is approximately 20 percent of the full national unadjusted payment rate of \$675.15. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule with comment period (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 proposed rule. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H of this proposed rule.

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

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

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

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

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

The unadjusted copayments for services payable under the OPPS that would be effective January 1, 2024 are shown in Addenda A and B to this proposed rule (which are available via the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed CY 2024 OPD 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 PLAA 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 OPSS payment system. Specifically, we recognize the following codes on OPSS 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 2024 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 2023 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2023 update, 67 new HCPCS codes were established and made effective on April 1, 2023. Through the April 2023 OPSS quarterly update CR (Transmittal 11937, Change Request 13136, dated March 31, 2023), 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 6 (New HCPCS Codes Effective April 1, 2023). 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, 2023, 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 (OPPS Comment Indicators) are available via the Internet on the CMS website.

TABLE 6: NEW HCPCS CODES EFFECTIVE APRIL 1, 2023

CY 2023 HCPCS Code	CY 2023 Long Descriptor
A2019	Kerecis omega3 marigen shield, per square centimeter
A2020	Ac5 advanced wound system (ac5)
A2021	Neomatrix, per square centimeter
A4341	Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each
A4342	Accessories for patient inserted indwelling intraurethral drainage device with valve, replacement only, each
A4560	Neuromuscular electrical stimulator (nmes), disposable, replacement only
A6590	External urinary catheters; disposable, with wicking material, for use with suction pump, per month
A6591	External urinary catheter; non-disposable, for use with suction pump, per month
A7049	Expiratory positive airway pressure intranasal resistance valve
C9145	Injection, aprepitant, (aponvie), 1 mg
C9146	Injection, mirvetuximab soravtansine-gynx, 1 mg
C9147	Injection, tremelimumab-actl, 1 mg
C9148	Injection, teclistamab-cqyv, 0.5 mg
C9149	Injection, teplizumab-mzwv, 5 mcg
E0677	Non-pneumatic sequential compression garment, trunk
E0711	Upper extremity medical tubing/lines enclosure or covering device, restricts elbow range of motion
E1905	Virtual reality cognitive behavioral therapy device (cbt), including pre-programmed therapy software
J0208	Injection, sodium thiosulfate, 100 mg
J0218	Injection, olipudase alfa-rpcp, 1 mg
J0612	Injection, calcium gluconate (fresenius kabi), per 10 mg
J0613	Injection, calcium gluconate (wg critical care), per 10 mg
J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose
J1449	Injection, eflapegrastim-xnst, 0.1 mg
J1747	Injection, spesolimab-sbzo, 1 mg
J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg
J9196	Injection, gemcitabine hydrochloride (accord), not therapeutically equivalent to j9201, 200 mg
J9294	Injection, pemetrexed (hospira) not therapeutically equivalent to j9305, 10 mg
J9296	Injection, pemetrexed (accord) not therapeutically equivalent to j9305, 10 mg
J9297	Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg
K1006	Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system

CY 2023 HCPCS Code	CY 2023 Long Descriptor
K1035	Molecular diagnostic test reader, nonprescription self-administered and self-collected use, fda approved, authorized or cleared
L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
M0010	Enhancing oncology model (eom) monthly enhanced oncology services (meos) payment for eom enhanced services
Q4265	Neostim tl, per square centimeter
Q4266	Neostim membrane, per square centimeter
Q4267	Neostim dl, per square centimeter
Q4268	Surgraft ft, per square centimeter
Q4269	Surgraft xt, per square centimeter
Q4270	Complete sl, per square centimeter
Q4271	Complete ft, per square centimeter
Q5127	Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg
Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg
Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg
Q5130	Injection, pegfilgrastim-pbbk (flyntra), biosimilar, 0.5 mg
0364U	Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate
0365U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of bladder cancer
0366U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer
0367U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection
0368U	Oncology (colorectal cancer), evaluation for mutations of APC, BRAF, CTNNB1, KRAS, NRAS, PIK3CA, SMAD4, and TP53, and methylation markers (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132 and TWIST1), multiplex quantitative polymerase chain reaction (qPCR), circulating cell-free DNA (cfDNA), plasma, report of risk score for advanced adenoma or colorectal cancer
0369U	Infectious agent detection by nucleic acid (DNA and RNA), gastrointestinal pathogens, 31 bacterial, viral, and parasitic organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique
0370U	Infectious agent detection by nucleic acid (DNA and RNA), surgical wound pathogens, 34 microorganisms and identification of 21 associated antibioticresistance genes, multiplex amplified probe technique, wound swab

CY 2023 HCPCS Code	CY 2023 Long Descriptor
0371U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine
0372U	Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score
0373U	Infectious agent detection by nucleic acid (DNA and RNA), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen
0374U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine
0375U	Oncology (ovarian), biochemical assays of 7 proteins (follicle stimulating hormone, human epididymis protein 4, apolipoprotein A-1, transferrin, beta-2 macroglobulin, prealbumin [ie, transthyretin], and cancer antigen 125), algorithm reported as ovarian cancer risk score
0376U	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancerspecific mortality, includes predictive algorithm to androgen deprivationtherapy response, if appropriate
0377U	Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables)
0378U	RFC1 (replication factor C subunit 1), repeat expansion variant analysis by traditional and repeat-primed PCR, blood, saliva, or buccal swab
0379U	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by nextgeneration sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden
0380U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and CYP2D6 deletion or duplication analysis with reported genotype and phenotype
0381U	Maple syrup urine disease monitoring by patient-collected blood card sample, quantitative measurement of alloisoleucine, leucine, isoleucine, and valine, liquid chromatography with tandem mass spectrometry (LCMS/MS)
0382U	Hyperphenylalaninemia monitoring by patient-collected blood card sample, quantitative measurement of phenylalanine and tyrosine, liquid chromatography with tandem mass spectrometry (LC-MS/MS)
0383U	Tyrosinemia type I monitoring by patient-collected blood card sample, quantitative measurement of tyrosine, phenylalanine, methionine, succinylacetone, nitisinone, liquid chromatography with tandem mass spectrometry (LC-MS/MS)

CY 2023 HCPCS Code	CY 2023 Long Descriptor
0384U	Nephrology (chronic kidney disease), carboxymethyllysine, methylglyoxal hydroimidazolone, and carboxyethyl lysine by liquid chromatography with tandem mass spectrometry (LCMS/MS) and HbA1c and estimated glomerular filtration rate (GFR), with risk score reported for predictive progression to high-stage kidney disease
0385U	Nephrology (chronic kidney disease), apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and insulin-like growth factor binding protein 3 (IGFBP3) by enzyme-linked immunoassay (ELISA), plasma, algorithm combining results with HDL, estimated glomerular filtration rate (GFR) and clinical data reported as a risk score for developing diabetic kidney disease
0386U	Gastroenterology (Barrett’s esophagus), P16, RUNX3, HPP1, and FBN1 methylation analysis, prognostic and predictive algorithm reported as a risk score for progression to high-grade dysplasia or esophageal cancer

2. July 2023 HCPCS Codes Proposed Rule Comment Solicitation

For the July 2023 update, 97 new codes were established and made effective July 1, 2023. Through the July 2023 OPPS quarterly update CR (Transmittal 12077, Change Request 13210, dated June 13, 2023), we recognized several new codes for payment and assigned them to appropriate interim OPPS status indicators and APCs. In this proposed rule, we solicit public comments on the proposed APC and status indicator assignments for the codes listed in Table 7 (New HCPCS Codes Effective July 1, 2023). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of proposed status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. In addition, the new codes are assigned to comment indicator “NP” in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and comments will be accepted on their interim APC assignments. The complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the Internet on the CMS website.

TABLE 7: NEW HCPCS CODES EFFECTIVE JULY 1, 2023

CY 2023 HCPCS Code	CY 2023 Long Descriptor
C9150	Xenon Xe-129 hyperpolarized gas, diagnostic, per study dose
C9151	Injection, pegcetacoplan, 1 mg
C9784	Gastric restrictive procedure, endoscopic sleeve gastropasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components.
C9786	Echocardiography image post processing for computer aided detection of heart failure with preserved ejection fraction, including interpretation and report
C9787	Gastric electrophysiology mapping with simultaneous patient symptom profiling
J0137	Injection, acetaminophen (hikma) not therapeutically equivalent to J0131, 10 mg
J0206	Injection, allopurinol sodium, 1 mg
J0216	Injection, alfentanil hydrochloride, 500 micrograms
J0457	Injection, aztreonam, 100 mg
J0665	Injection, bupivacaine, not otherwise specified, 0.5 mg
J0736	Injection, clindamycin phosphate, 300 mg
J0737	Injection, clindamycin phosphate (baxter), not therapeutically equivalent to J0736, 300 mg
J1440	Fecal microbiota, live - jslm, 1 ml
J1576	Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1805	Injection, esmolol hydrochloride, 10 mg
J1806	Injection, esmolol hydrochloride (wg critical care) not therapeutically equivalent to J1805, 10 mg
J1811	Insulin (fiasp) for administration through dme (i.e., insulin pump) per 50 units
J1812	Insulin (fiasp), per 5 units
J1813	Insulin (lyumjev) for administration through dme (i.e., insulin pump) per 50 units
J1814	Insulin (lyumjev), per 5 units
J1836	Injection, metronidazole, 10 mg
J1920	Injection, labetalol hydrochloride, 5 mg
J1921	Injection, labetalol hydrochloride (hikma) not therapeutically equivalent to J1820, 5 mg
J1941	Injection, furosemide (furoscix), 20 mg
J1961	Injection, lenacapavir, 1 mg
J2249	Injection, remimazolam, 1 mg
J2305	Injection, nitroglycerin, 5 mg
J2329	Injection, ublituximab-xiyy, 1mg
J2371	Injection, phenylephrine hydrochloride, 20 micrograms
J2372	Injection, phenylephrine hydrochloride (biorphen), 20 micrograms
J2427	Injection, paliperidone palmitate extended release (invega hafyera, or invega trinza), 1 mg
J2561	Injection, phenobarbital sodium (sezaby), 1 mg
J2598	Injection, vasopressin, 1 unit
J2599	Injection, vasopressin (american reagent) not therapeutically equivalent to J2598, 1 unit

CY 2023 HCPCS Code	CY 2023 Long Descriptor
J2806	Injection, sincalide (maia) not therapeutically equivalent to j2805, 5 micrograms
J7213	Injection, coagulation factor ix (recombinant), ixinity, 1 i.u.
J9029	Injection, nadofaragene firadenovec-vncg, per therapeutic dose
J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg
J9058	Injection, bendamustine hydrochloride (apotex), 1 mg
J9059	Injection, bendamustine hydrochloride (baxter), 1 mg
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg
J9259	Injection, paclitaxel protein-bound particles (american regent) not therapeutically equivalent to j9264, 1 mg
J9322	Injection, pemetrexed (bluepoint) not therapeutically equivalent to J9305, 10 mg
J9323	Injection, pemetrexed ditromethamine, 10 mg
J9347	Injection, tremelimumab-actl, 1 mg
J9350	Injection, mosunetuzumab-axgb, 1 mg
J9380	Injection, teclistamab-cqyv, 0.5 mg
J9381	Injection, teplizumab-mzwv, 5 mcg
Q4272	ESA no a, per square centimeter
Q4273	Eason air, per square centimeter
Q4274	ESA no ac, per square centimeter
Q4275	Eason aca, per square centimeter
Q4276	Orion, per square centimeter
Q4277	Woundplus membrane or e-graft, per square centimeter
Q4278	Epieffect, per square centimeter
Q4280	Xcell amnio matrix, per square centimeter
Q4281	Barrera sl or barrera dl, per square centimeter
Q4282	Cygnus dual, per square centimeter
Q4283	Biovance tri-layer or biovance 3l, per square centimeter
Q4284	Dermabind sl, per square centimeter
Q5131	Injection, adalimumab-aacf (idacio), biosimilar, 20 mg
0791T	Motor-cognitive, semi-immersive virtual reality–facilitated gait training, each 15 minutes (List separately in addition to code for primary procedure)
0792T	Application of silver diamine fluoride 38%, by a physician or other qualified health care professional
0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance
0794T	Patient-specific, assistive, rules-based algorithm for ranking pharmaco-oncologic treatment options based on the patient's tumor-specific cancer marker information obtained from prior molecular pathology, immunohistochemical, or other pathology results which have been previously interpreted and reported separately

CY 2023 HCPCS Code	CY 2023 Long Descriptor
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)
0796T	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; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)
0797T	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; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0798T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (ie, right atrial and right ventricular pacemaker components)
0799T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component
0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
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)
0802T	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; right atrial pacemaker component
0803T	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; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)

CY 2023 HCPCS Code	CY 2023 Long Descriptor
0804T	Programming device evaluation (in person) with iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care professional, leadless pacemaker system in dual cardiac chambers
0805T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); percutaneous femoral vein approach
0806T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); open femoral vein approach
0807T	Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with previously acquired computed tomography (CT) images, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report
0808T	Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with computed tomography (CT) images taken for the purpose of pulmonary tissue ventilation analysis, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report
0809T	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intra-articular implant(s), including allograft or synthetic device(s)
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies
0387U	Oncology (melanoma), autophagy and beclin 1 regulator 1 (AMBRA1) and loricrin (AMLo) by immunohistochemistry, formalin-fixed paraffin-embedded (FFPE) tissue, report for risk of progression
0388U	Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection
0389U	Pediatric febrile illness (Kawasaki disease [KD]), interferon alpha-inducible protein 27 (IFI27) and mast cell-expressed membrane protein 1 (MCEMP1), RNA, using reverse transcription polymerase chain reaction (RT-qPCR), blood, reported as a risk score for KD
0390U	Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score
0391U	Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splice site variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score
0392U	Drug metabolism (depression, anxiety, attention deficit hyperactivity disorder [ADHD]), gene-drug interactions, variant analysis of 16 genes, including deletion/duplication analysis of CYP2D6, reported as impact of gene-drug interaction for each drug

CY 2023 HCPCS Code	CY 2023 Long Descriptor
0393U	Neurology (eg, Parkinson disease, dementia with Lewy bodies), cerebrospinal fluid (CSF), detection of misfolded α -synuclein protein by seed amplification assay, qualitative
0394U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 16 PFAS compounds by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative
0395U	Oncology (lung), multi-omics (microbial DNA by shotgun nextgeneration sequencing and carcinoembryonic antigen and osteopontin by immunoassay), plasma, algorithm reported as malignancy risk for lung nodules in early-stage disease
0396U	Obstetrics (pre-implantation genetic testing), evaluation of 300000 DNA single-nucleotide polymorphisms (SNPs) by microarray, embryonic tissue, algorithm reported as a probability for single-gene germline conditions
0397U	Oncology (non-small cell lung cancer), cell-free DNA from plasma, targeted sequence analysis of at least 109 genes, including sequence variants, substitutions, insertions, deletions, select rearrangements, and copy number variations
0398U	Gastroenterology (Barrett esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score for progression to high-grade dysplasia or cancer
0399U	Neurology (cerebral folate deficiency), serum, detection of anti-human folate receptor IgGbinding antibody and blocking autoantibodies by enzyme-linked immunoassay (ELISA), qualitative, and blocking autoantibodies, using a functional blocking assay for IgG or IgM, quantitative, reported as positive or not detected
0400U	Obstetrics (expanded carrier screening), 145 genes by nextgeneration sequencing, fragment analysis and multiplex ligationdependent probe amplification, DNA, reported as carrier positive or negative
0401U	Cardiology (coronary heart disease [CAD]), 9 genes (12 variants), targeted variant genotyping, blood, saliva, or buccal swab, algorithm reported as a genetic risk score for a coronary event

3. October 2023 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, 2023, in the CY 2024 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 2023 OPSS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2024, 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 those new HCPCS codes that will be effective October 1, 2023, 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 2024 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2025 OPPS/ASC final rule with comment period.

4. January 2024 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, 2024, in the CY 2024 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2025 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the proposed new C-codes and G-codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2024, we propose to include the new Level II HCPCS codes effective January 1, 2024, in Addendum B to the CY 2024 OPPS/ASC final rule with comment period, which would be incorporated in the January 2024 OPPS quarterly update CR. Specifically, for CY 2024, 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, 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 2024 OPPS/ASC final rule with comment period on the status indicator and

APC assignments, which would then be finalized in the CY 2025 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 2024 OPSS update, we received the CPT codes that will be effective January 1, 2024, 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 2024 CPT codes in Addendum O, specifically under the column labeled “CY 2024 OPSS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code.” The final HCPCS code numbers will be included in the CY 2024 OPSS/ASC final rule with comment period.

In summary, we solicit public comments on the proposed CY 2024 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2024. Because the CPT codes listed in Addendum B appear with short descriptors only, 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 2024 OPSS/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 OPSS can be found in Addendum D2 to this proposed rule. We note that OPSS 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 8 (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 8: 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 2023	HCPCS (CPT and Level II codes)	April 1, 2023	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
July 2023	HCPCS (CPT and Level II codes)	July 1, 2023	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
October 2023	HCPCS (CPT and Level II codes)	October 1, 2023	CY 2024 OPPS/ASC final rule with comment period	CY 2025 OPPS/ASC final rule with comment period
January 2024	CPT Codes	January 1, 2024	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2024	CY 2024 OPPS/ASC final rule with comment period	CY 2025 OPPS/ASC final rule with comment period

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 OPSS, 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 2024, 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 take into account 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 2024 OPPS update will be discussed in the relevant specific sections throughout the CY 2024 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to 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 2024, 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 2024 OPSS 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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity in the APCs for which we are not proposing a 2 times rule exception, we propose to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2024 included in this proposed rule are related to changes in costs of services that were observed in the CY 2022 claims data available for CY 2024 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, 2023, OPSS Addendum B Update, which is available via the Internet on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates>.

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we propose to make for CY 2024, 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 2022 claims data available for this proposed rule, we found 21 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 2024 and found that all of the 21 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2022 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 9 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 9 of this proposed rule lists the 21 APCs for which we propose to make an exception under the 2 times rule for CY 2024 based on the criteria cited above and claims data submitted between January 1, 2022 and December 31, 2022, and processed on or before December 31, 2022, 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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>.

TABLE 9: PROPOSED CY 2024 APC EXCEPTIONS TO THE 2 TIMES RULE

APC	APC Group Title
5012	Clinic Visits and Related Services
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5301	Level 1 Upper GI Procedures
5303	Level 3 Upper GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5572	Level 2 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5674	Level 4 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5811	Manipulation Therapy
5821	Level 1 Health and Behavior Services
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. Proposed New Technology APCs

1. Background

In the CY 2002 OPSS 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 OPSS 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 a pass-through payment); and (3) the service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act (66 FR 59898 through 59903). For additional information about our New Technology APC policy, we refer readers to

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/passthrough_payment](#) on the CMS website and then follow the instructions to access the MEARIS™ system for OPSS New Technology APC applications.

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 2023, 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.

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 OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

Some services assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims (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 OPPS/ASC final rule with comment period, to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). Specifically, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we would calculate and present the result of each statistical methodology (arithmetic mean, geometric mean, and median) based on up to 4 years of claims data and solicit public comment on which methodology should be used to establish the payment rate for the low-volume new technology service. In the CY 2022 OPPS/ASC final rule (86 FR 63529), we replaced the New Technology APC low volume policy with the universal low volume APC policy. Unlike the New Technology APC low volume policy, the universal low volume APC policy applies to clinical APCs and brachytherapy APCs, in addition to procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data

to set the payment rate for the APC. We refer readers to the CY 2022 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 2024, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this proposed rule (which is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>).

2. Procedures Assigned to New Technology APC Groups for CY 2024

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 2024, 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.⁶ This therapy is administered

⁶ Luxturna. FDA Package Insert. Available: <https://www.fda.gov/media/109906/download>.

through a subretinal injection, which interested parties describe as an extremely delicate and sensitive surgical procedure. The FDA package insert describes one of the steps for administering Luxturna as, “after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana.”

Interested parties, including the manufacturer of Luxturna[®], recommended CPT code 67036 (Vitreotomy, mechanical, pars plana approach) for the administration of the gene therapy.⁷ 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 OPPI/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

⁷ LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS.
https://mysparkgeneration.com/pdf/Reimbursement_Guide_for_Treatment_Centers_Interactive_010418_FINAL.pdf

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.

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

Based on the claims data available for the CY 2023 OPPS/ASC final rule, 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.

CPT code 0810T (*Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies*) will be effective July 1, 2023. We recognize the similarity between HCPCS code C9770 and CPT code 0810T; therefore, we propose to delete HCPCS code C9770 effective December 31, 2023, and to recognize CPT code 0810T starting January 1, 2024. We propose to determine the payment rate for the procedure using the claims data for HCPCS code C9770. Similar to CY 2023, for CY 2024, given that there are only 10 single frequency claims available for ratesetting, we propose to designate CPT code 0810T as a low volume procedure under our universal low volume APC policy and 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, we determined the geometric mean cost to be \$3,944, the arithmetic mean cost to be \$4,192, and the median cost to be \$4,148. 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 \$4,192 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 2024. Additionally, we propose to perform a similar analysis using updated claims data in the CY 2024 OPSS/ASC final rule with comment period and update the APC placement as needed.

Please refer to Table 10 below for the proposed OPSS New Technology APC and status indicator assignments for HCPCS code C9770 and CPT code 0810T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 10: CY 2023 AND PROPOSED CY 2024 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9770 AND CPT CODE 0810T

HCPCS Code	Long Descriptor	CY 2023 OPSS SI	CY 2023 OPSS APC	Proposed CY 2024 OPSS SI	Proposed CY 2024 OPSS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1562	D	N/A
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	E1	N/A	T	1563

b. 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 (for example, 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 OPPI, we estimated the likely cost of the procedure would be between \$8,001 and \$8,500.

In claims data available for CY 2019 for the CY 2021 OPPI/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 were no claims reported in CY 2020, CY 2021, or CY 2022 for HCPCS code C9751. Therefore, for CY 2024, the only available claims for HCPCS code C9751 continue to be from CY 2019; and the reported claims are the same claims used to calculate the payment rate for the service in the CY 2021, CY 2022, and CY 2023 OP/ASC final rules with comment period. Given the low number of claims for this procedure, we propose to continue to designate this procedure as a low volume procedure under our universal low volume policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the procedure to the appropriate New Technology APC. Because our proposal uses the same claims as we used for CY 2021, CY 2022, and CY 2023, the same values for the geometric mean cost, arithmetic mean cost, and the median cost are used to propose a payment rate for CY 2024. Once again, the median (\$3,708) was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology continues to fall within the cost band for New Technology APC 1562 (New Technology—Level 25 (\$3501–\$4000)). Therefore, we propose to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 (\$3501–\$4000)), with a proposed payment rate of \$3,750.50 for CY 2024.

Please refer to Table 11 below for the proposed OPPTS New Technology APC and status indicator assignment for HCPCS code C9751 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 11: PROPOSED CY 2024 OPPTS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9751

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPTS SI	Proposed CY 2024 OPPTS 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

c. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1518, 1521, and 1522)

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 (\$2001–\$2500)) with a payment rate of \$2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 (\$2501–\$3000)) with a payment rate of \$2,750.50. We did not receive any claims data for these services for either of the CY 2021 or CY 2022 OPPTS proposed or final rules. Therefore, we continued to assign CPT code 78431 to APC 1522 (New Technology—Level 22 (\$2001–\$2500)) with a payment rate of \$2,250.50 in CY 2021 and CY 2022. Likewise, we continued to assign CPT codes 78432 and 78433 to APC 1523 (New Technology—Level 23 (\$2501–\$3000)) with a payment rate of \$2,750.50.

For CY 2023, we used CY 2021 claims data to determine the payment rates for CPT codes 78431, 78432, and 78433. Based on our analysis of the available claims data, for CY 2023, we assigned CPT code 78431 to APC 1523 (New Technology—Level 23 (\$2501–\$3000)) with a

payment rate of \$2,750.50; CPT code 78432 to APC 1520 (New Technology - Level 20 (\$1801-\$1900)) with a payment rate of \$1,850.50 based on the application of the universal low-volume policy; and CPT code 78433 to APC 1521 (New Technology - Level 21 (\$1901-\$2000)) with a payment rate of \$1,950.50.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. CPT code 78431 had over 22,000 single frequency claims in CY 2022. The geometric mean for CPT code 78431 was approximately \$2,300, which is an amount that is below the cost band for APC 1523 (New Technology—Level 23 (\$2501–\$3000)), where the procedure is currently assigned. We propose, for CY 2024, that CPT code 78431 be reassigned to APC 1522 (New Technology—Level 22 (\$2001–\$2500)) with a payment rate of \$2,250.50. Please refer to Table 12 below for the proposed New Technology APC and status indicator assignments for CPT code 78431.

There were only six single frequency claims in CY 2022 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 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 and CY 2022, our analysis found the geometric mean cost of the service is approximately \$1,658, the arithmetic mean cost of the service is approximately \$1,445, and the median cost of the service is approximately \$1,562. The geometric mean was the statistical methodology that estimated the highest cost for the service. The geometric mean cost of \$1,658, is an amount that is below the cost band for APC 1520 (New Technology—Level 20 (\$1801–\$1900)), where the procedure is currently assigned. Therefore, we propose, for CY 2024, to assign CPT code 78432 to APC 1518 (New Technology - Level 18 (\$1601-\$1700)) with a payment rate of \$1,650.50. Please refer to Table 12 for the proposed New Technology APC and status indicator assignments for CPT code 78432.

There were over 1200 single frequency claims for CPT code 78433 in CY 2022. The geometric mean for CPT code 78433 was approximately \$1,960, which is an amount that is within the cost band for APC 1521 (New Technology - Level 21 (\$1901-\$2000)), to which it is currently assigned. Therefore, for CY 2024, we propose to continue to assign CPT code 78433 to APC 1521 with a payment rate of \$1,950.50.

Please refer to Table 12 below for the proposed OPSS New Technology APC and status indicator assignment for CPT codes 78431, 78432, and 78433 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 12: FINAL CY 2023 AND PROPOSED CY 2024 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Final CY 2023 OPSS SI	Final CY 2023 OPSS APC	Proposed CY 2024 OPSS SI	Proposed OPSS CY 2024 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	1523	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	1518
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	1521

d. V-Wave Medical Interatrial Shunt Procedure (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 OPSS/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 receiving 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 OPSS 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, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of \$17,500.50 for CY 2023.

For CY 2024, the OPSS payment rates are proposed to be based on available CY 2022 claims data. Although HCPCS code C9758 was effective January 1, 2020, we have no claims data at this time. Because we have no claims data, for CY 2024, we propose to continue to assign HCPCS code C9758 to New Technology APC 1590 with a proposed payment rate of \$17,500.50.

Please refer to Table 13 below for the proposed OPSS New Technology APC and status indicator assignment for HCPCS code C9758 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 13: PROPOSED CY 2024 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2024 OPSS SI	Proposed CY 2024 OPSS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, transesophageal C9758 echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound,	T	1590

	fluoroscopy), performed in an approved investigational device exemption (IDE) study		
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e. Corvia Medical Interatrial Shunt Procedure (APC 1592)

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

As we stated in the CY 2021 OPSS 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. But 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 used the same claims data as was used in the CY 2021 OPSS final rule to determine the payment rate for HCPCS code C9760 because there were no claims for this service in CY 2019, the year used for ratesetting for CY 2022. Accordingly, we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2022. For CY 2023, we used claims data from CY 2021 through CY 2022 to determine the payment rate for HCPCS code C9760. Because there were no claims for this service, we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2023.

For CY 2024, the OPSS payment rates are proposed to be based on available CY 2022 claims data. There was only one claim for HCPCS code C9760 within this time period. As this is below the threshold of 100 claims for a service within a year, we would designate C9760 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 C9760 to the appropriate New Technology APC. Using the only one claim available for HCPCS code C9760, the geometric mean, arithmetic mean, and median costs are estimated to be approximately \$7945 for this service. However, because there is only a single claim for HCPCS code C9760, its payment rate appears to be an outlier based on the cost information we received from the manufacturer. Therefore, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service. Therefore, we propose to continue assigning HCPCS code C9760 to New Technology APC 1592.

Please refer to Table 14 below for the proposed OPSS New Technology APC and status indicator assignment for HCPCS code C9760 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 14: PROPOSED CY 2024 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NON-RANDOMIZED, NON-BLINDED INTERATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2024 OPSS SI	Proposed CY 2024 OPSS APC
C9760	Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy)	T	1592

f. 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)). 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 FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. Patients must be monitored by a health care provider for at least 2 hours after receiving their esketamine nasal spray dose, the prescriber and patient must both sign a Patient Enrollment Form, and the product must only be administered in a certified medical office where the health care provider can monitor the patient.

A treatment session of esketamine consists of instructed nasal self-administration by the patient followed by a period of post-administration observation of the patient under direct supervision of a health care professional. 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. This is the first FDA approval of esketamine for any use. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients require either two devices (for a 56 mg dose) or three devices (for an 84 mg dose) per treatment.

Please 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. Please see the CY 2021 OPPTS/ASC final rule with comment period (85 FR 85948), CY 2022 OPPTS/ASC final rule with comment period (86 FR 63538), and the CY 2023 OPPTS/ASC final rule with comment period (87 FR 71816-71817) for the updates to the APC assignments for G2082 and G2083 we have made in past rules.

For CY 2024, the OPPTS payment rates are proposed to be based on available CY 2022 claims data as the available single frequency claims exceed the 100 claims threshold generally used for our universal low volume policy. Therefore, for CY 2024, 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 1513 (New Technology - Level 13 (\$1101 - \$1200)) with a payment rate of \$1,150.50 based on its geometric mean cost of \$1,138, which was calculated using the available 294 single frequency claims from CY 2022 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 \$1,693, which was calculated using the available 1581 single frequency claims from CY 2022 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 15. The proposed CY 2024 payment rates for these HCPCS codes can be found in Addendum B to this proposed rule.

TABLE 15: FINAL CY 2023 AND PROPOSED CY 2024 OPPTS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Final CY 2023 OPPTS SI	Final CY 2023 OPPTS APC	Proposed CY 2024 OPPTS SI	Proposed CY 2024 OPPTS APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1512	S	1513
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1516	S	1518

g. 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, the OPPS payment rates are proposed to be based on available CY 2022 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 2024, we propose to continue to assign CPT code 0693T to APC 1505 with a proposed payment rate of \$350.50.

Please refer to Table 16 below for the proposed OPPS New Technology APC and status indicator assignment for CPT code 0693T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 16: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505

h. Liver Histotripsy Service (APC 1575)

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.⁸ 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 each time it is reported on a claim. For CY 2023, we assigned CPT code 0686T to New Technology APC 1575 (New Technology – Level 38 (\$10,000 - \$15,000) with a payment rate of \$12,500. However, 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, the proposed payment for CPT code 0686T in CY 2024 would reflect payment for both the service that is performed and the device used each time it is reported on a claim.

For CY 2024, the OPSS payment rates are proposed to be based on available CY 2022 claims data. There are only two claims for CPT code 0686T within this time period. We note that 0686T was still designated as a Category A IDE study for these claims and therefore, the payment for these claims only included payment for the cost of the service. As the available claims data is below the threshold of 100 claims for a service within a year, we could 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. Based on the two available claims in CY 2022, when CPT code 0686T was still designated as a Category A IDE study, the geometric mean is estimated to be: \$4,466; the median is estimated to be: \$4,480; and the arithmetic mean is estimated to be: \$4,480. Because \$4,480 is the greatest of these methodologies, we would use this value to set the payment rate for CPT code 0686T. However, we have concerns that the available claims data and universal low volume APC policy calculations would not accurately capture the cost of the service following its approval as a Category B IDE study in March of

⁸ 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>.

2023. If 0686T were still designated as a Category A IDE study, then the two claims available would be appropriate to set its payment rate, as the claims reflect the cost of the service and exclude the cost of the device. However, because CPT code 0686T was approved as a Category B IDE study, meaning Medicare coverage and payment of the device is no longer statutorily prohibited, the two CY 2022 claims available would not accurately capture the cost of 0686T for CY 2024.

Therefore, based on the service costs reflected in the available claims and our estimates of the cost of the Category B device, for CY 2024, we propose to maintain CPT code 0686T’s current APC assignment. Specifically, we propose to assign CPT code 0686T to APC 1575 (New Technology – Level 38 (\$10,001 - \$15,000)) with a payment rate of \$12,500.50.

Please refer to Table 17 below for the proposed OPSS New Technology APC and status indicator assignment for CPT code 0686T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 17: PROPOSED CY 2024 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Proposed CY 2024 OPSS SI	Proposed CY 2024 OPSS APC
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1575

i. Liver Multiscan Service (APC 1505)

Effective July 1, 2021, CPT codes 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) and 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); single organ (list separately in addition to code for primary procedure)) are associated with the Liver MultiScan 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. For CY 2023, 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 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. We identified only 39 claims each for CPT code 0648T and CPT code 0649T during this time period. As this is below the threshold of 100 claims for a service within a year, we propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT 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 data for CPT code 0648T found the geometric mean cost of the service is approximately \$269, the arithmetic mean cost of the service is approximately \$320, and the median cost of the service is approximately \$313. Our analysis of the data for CPT code 0649T found the geometric mean cost of the service is approximately \$102, the arithmetic mean cost of the service is approximately \$136, and the median cost of the service is approximately \$83. The arithmetic

mean was the statistical methodology that estimated the highest cost for CPT codes 0648T and 0649T. In accordance to our SaaS Add-on Codes policy (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the identical APCs and the same status indicator assignments as their standalone codes. Consistent with our SaaS Add-on Codes policy, CPT code 0649T, the add-on code for LiverMultiScan would be assigned to the identical APC and status indicator to CPT code 0648T, the standalone code for the same service. Therefore, we propose, for CY 2024, to assign CPT codes 0648T and 0649T to APC 1505 (New Technology - Level 5 (\$301 - \$400)) with a payment rate of \$350.50.

Please refer to Table 18 below for the proposed OPPS New Technology APC and status indicator assignments for CPT codes 0648T and 0649T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 18: FINAL CY 2023 AND PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER MULTISCAN SERVICE

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ	S	1511	S	1505
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	S	1511	S	1505

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
	anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)				

j. Minimally Invasive Glaucoma Surgery (MIGS) (APC 5493)

Prior to CY 2022, extracapsular cataract removal with insertion of intraocular lens was reported using CPT codes describing cataract removal alongside a CPT code for device insertion. Specifically, the procedure was described using CPT codes 66982 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (for example, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation) or 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation) and 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion).

For CY 2022, the AMA’s CPT Editorial Panel created two new Category I CPT codes describing extracapsular cataract removal with insertion of intraocular lens prosthesis, specifically, CPT codes 66989 (Extracapsular cataract removal w/IOL insertion, complex; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more) and 66991 (Extracapsular cataract removal w/IOL insertion; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device,

without extraocular reservoir, internal approach, one or more); deleted a Category III CPT code, specifically, CPT code 0191T, describing insertion of anterior segment aqueous drainage device; and created a new Category III CPT code, specifically, CPT code 0671T, describing anterior segment aqueous drainage device without concomitant cataract removal.

For CY 2022, we finalized the assignment of CPT codes 66989 and 66991 to New Technology APC 1563 (New Technology—Level 26 (\$4001– \$4500)). We stated that we believed that the change in coding for MIGS is significant in that it changes longstanding billing for the service from reporting two separate CPT codes to reporting a single bundled code. Without claims data, and given the magnitude of the coding change, we explained that we did not believe we had the necessary information on the costs associated with CPT codes 66989 and 66991 to assign them to a clinical APC at that time. We maintained these APC assignments for CY 2023.

For CY 2023, the payment rates were based on claims data submitted between January 1, 2021, and December 31, 2021, and processed on or before June 30, 2022, and CCRs, if available. Because CPT codes 66989 and 66991 were effective January 1, 2022, and we had no claims data for CY 2022, we finalized continued assignment of CPT codes 66989 and 66991 to New Technology APC 1563.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. For CY 2024, based on our analysis of claims data, we found a total of 898 single frequency claims and an estimated geometric mean cost of \$5,241.55 for CPT code 66989 and a total of 5,576 single frequency claims and an estimated geometric mean cost of \$4,957.01 for CPT code 66991. Given the claims volume, we believe it is appropriate to reassign the service to a clinical APC using our regular process of using the most recent year of claims data for a procedure. Upon review, we determined that the most appropriate clinical APC family for CPT codes 66989 and 66991 would be the Intraocular Procedures APC family (APC 5491 through 5495). However, there was a large payment rate difference between the level 2 Intraocular

Procedures APC (APC 5492), which has a payment rate of \$3,970.62, and the level 3 Intraocular Procedures APC (APC 5493), which has a payment rate of \$14,067.62. Assigning CPT codes 66989 and 66991 to either APC 5492 or 5493 would result in a payment rate that would not reflect the cost for these procedures.

Therefore, given the significant difference in payment between APC 5492 and APC 5493, we believe it is appropriate to restructure the Intraocular Procedures APC family. Specifically, we propose to create a sixth level in the Intraocular Procedures APC family by dividing APC 5492 into two APCs—an APC for services with a geometric mean cost of less than \$5,000 and an APC for services with a geometric mean cost of greater than, or equal to, \$5000. We believe that the creation of an additional level in the Intraocular APC family will create a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. See section III.E. (OPPS APC-Specific Policies: Intraocular Procedures) of this proposed rule for a detailed discussion of our proposal to restructure the Intraocular Procedures APC family. Reorganizing the Intraocular Procedures APCs would create a proposed Level 3 APC to be referred to as “Proposed APC 5493” with a payment rate of approximately \$5,110.58 which is closer to the geometric mean of CPT codes 66989 and 66991. We note that, although these services have different estimated geometric mean costs, interested parties have indicated that it is preferable that they be placed within the same APC due to clinical similarity; therefore, we propose to reassign CPT codes 66989 and 66991 to Proposed APC 5493 for CY 2024.

The proposed clinical APC and status indicator assignments for CPT codes 66989 and 66991 are found in Table 19. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule.

TABLE 19: CY 2023 FINAL AND CY 2024 PROPOSED OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 66989 AND 66991

HCPCS Code	Long Descriptor	Final CY 2023 OPPS	Final CY 2023 OPPS	Proposed CY 2024 OPPS	Proposed CY 2024 OPPS
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		SI	APC	SI	APC
66989	Extracapsular cataract removal w/IOL insertion, complex; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	S	1563	S	5493
66991	Extracapsular cataract removal w/IOL insertion; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	S	1563	S	5493

k. 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 OPPS; however, interested parties have indicated that there are substantial resource costs of around \$1,900 to \$2,400 associated with calibration and fitting of 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 (\$1801–\$1900)) 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, the OPSS payment rates are proposed to be based on available CY 2022 claims data. The Scalp Cooling service became effective in the OPSS in CY 2022, and we have identified 11 single frequency paid claims for CPT code 0662T for CY 2022. 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 \$831.16; the median is \$797.63; and the arithmetic mean is \$1284.59. Therefore, for CY 2024, we propose to designate this service as a low volume service under our universal low volume APC policy and reassign CPT code 0662T to APC 1514 (New Technology - Level 14 (\$1201- \$1300)) with a payment rate of \$1250.50 for CY 2024 based on the arithmetic mean of \$1284.59.

Please refer to Table 20 below for the proposed OPSS New Technology APC and status indicator assignment for CPT code 0662T. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 20: FINAL CY 2023 AND PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE SCALP COOLING PROCEDURE

CPT Code	Long Descriptor	Final CY 2023 OPSS SI	Final CY 2023 OPSS APC	Proposed CY 2024 OPSS SI	Proposed CY 2024 OPSS APC
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1520	S	1514

1. 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 (e.g., CT surveillance versus invasive procedure). For CY 2023, we assigned CPT codes 0721T and 0722T to APC New Technology 1508 (New Technology - Level 8 (\$601-\$700)).

For CY 2024, the OPSS payment rates are proposed to be based on available CY 2022 claims data. There are no claims available for CPT codes 0721T and 0722T. Therefore, for CY 2024, we propose to continue assigning CPT codes 0721T and 0722T to New Technology APC 1508.

Please refer to Table 21 below for the proposed OPSS New Technology APC and status indicator assignment for HCPCS codes 0721T and 0722T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 21: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2024 OPSS SI	Proposed CY 2024 OPSS 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

CPT Code	Long Descriptor	Proposed CY 2024 OPSS SI	Proposed CY 2024 OPSS APC
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

m. 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 (e.g., organ, gland, tissue, target structure) during the same session) and 0724T (Quantitative magnetic resonance cholangiopancreatography (qmrpc), 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)) 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. For CY 2023, we assigned CPT codes 0723T and 0724T to New Technology APC 1511 (New Technology - Level 11(\$900-\$1,000)).

For CY 2024, the OPSS payment rates are proposed to be based on available CY 2022 claims data. For CPT code 0723T, there were no claims during this time period. Because there are no claims available, we propose to continue to assign CPT code 0723T to New Technology APC 1511 with a payment rate of \$950.50.

For CPT code 0724T, there was only one claim for CY 2022. As this is below the threshold of 100 claims for a service within a year, we could propose to designate CPT code 0724T 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 based on up to 4 years of claims data to assign the service to an appropriate New Technology APC. Because there is only one claim available, the geometric mean, arithmetic mean, and median costs are estimated to be \$26 for this service. However, because there is only a single claim for CPT code 0724T, the single claim available appears to be an outlier based on the cost information we received from the manufacturer. Therefore, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service. Therefore, for CY 2024, we propose to continue assigning CPT code 0724T to New Technology APC 1511 with a payment rate of \$950.50.

Please refer to Table 22 below for the proposed OPSS New Technology APC and status indicator assignment for HCPCS code 0724T for CY 2024. The proposed CY 2024 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 QMRCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2024 OPSS SI	Proposed CY 2024 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

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
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

n. CardiAMP (APC 1590)

The CardiAMP cell therapy IDE studies are two randomized, double-blinded, controlled IDE studies: the CardiAMP Cell Therapy Chronic Myocardial Ischemia Trial⁹ and the CardiAMP Cell Therapy Heart Failure Trial.¹⁰ The two trials are designed to investigate the safety and efficacy of autologous bone marrow mononuclear cells 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

⁹ 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>.

¹⁰ 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>.

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 transendocardial 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 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There are no available claims for ratesetting for CY 2024. Therefore, for CY 2024, we propose to continue assigning HCPCS code C9782 to New Technology APC 1590 with a payment rate of \$17,050.50.

Please refer to Table 23 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9782 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 23: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE CARDIAMP CELL THERAPY IDE STUDIES

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590

o. Surfacor® 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 Surfacar® 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 2024, the OPSS payment rates are proposed to be based on available CY 2022 claims data. Although HCPCS code C9780 was effective October 1, 2021, we have no claims data at this time. Because we have no claims data available, for CY 2024, we propose to continue to assign HCPCS code C9780 to APC 1534 with a proposed payment rate of \$8,250.50.

Please refer to Table 24 below for the proposed OPSS New Technology APC and status indicator assignment for HCPCS code C9780 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 24: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR SURFACER® INSIDE-OUT® ACCESS CATHETER SYSTEM PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2024 OPSS SI	Proposed CY 2024 OPSS 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

p. Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (APC 1580)

HCPCS code 0424T (Insertion or replacement of a neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)) is associated with the use of the Remede® System, which is used to treat adult patients with moderate to severe Central Sleep Apnea. HCPCS code 0424T was first effective in January 1, 2016, and subsequently assigned to Comprehensive APC 5464 (Neurostimulator and Related Procedures APC – Level 4). For CY 2021, we created a 5-

level structure for the Neurostimulator and Related Procedure APC series, and consequently, assigned HCPCS code 0424T to the highest level in the series: Comprehensive APC 5465 (Neurostimulator & Related Procedures APC – Level 5). For CY 2023, we proposed to continue the 5-level structure for the Neurostimulator and Related Procedure APC series, while also soliciting comment on the creation of an additional Level 6 APC in the series. In the CY 2023 final rule with comment period, we finalized our proposal to continue the 5-level APC structure based on a determination that the existing structure remained appropriate based on clinical and cost characteristics. However, we also recognized that CPT code 0424T was not appropriately assigned to the Comprehensive APC 5465 based on a significant difference between its geometric mean cost and that of the APC. Therefore, for CY 2023, we finalized the assignment of HCPCS code 0424T to New Technology APC 1581 (New Technology – Level 44 (\$50,001-\$60,000)).

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There are only 30 claims for HCPCS code 0424T available during this time period. As this is below the threshold of 100 claims for a service within a year, we propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign HCPCS code 0424T to the appropriate New Technology APC. Considering the available claims data for HCPCS code 0424T, the arithmetic mean is \$49,468; the median is \$48,285; and the geometric mean cost is \$44,287. Of these, the arithmetic mean 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 1580 (New Technology - Level 43 (\$40,001-\$50,000)) with a payment rate of \$45,000.50. Therefore, for CY 2024, we propose to assign HCPCS code 0424T to New Technology APC 1580. We note that for the CY 2024 update, the CPT Editorial Panel is deleting HCPCS code 0424T and replacing it with placeholder code 3X008 effective January 1, 2024. Consequently, we propose to assign HCPCS code 0424T to status indicator "D" to indicate

the code will be deleted and assigning its replacement code, specifically, placeholder code 3X008, to APC 1580 for CY 2024. For placeholder code 3X008, the final 5-digit CPT code number will be listed in the CY 2024 OPSS/ASC final rule with comment period.

Please refer to Table 25 below for the proposed OPSS New Technology APC and status indicator assignment for placeholder code 3X008 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

TABLE 25: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR HCPCS 0424T/3X008

HCPCS Code	Long Descriptor	Final CY 2023 OPSS SI	Final CY 2023 OPSS APC	Proposed CY 2024 OPSS SI	Proposed CY 2024 OPSS APC
0424T	Insertion or replacement of a neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator	S	1581	D	N/A
3X008	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	N/A	N/A	S	1580

q. Cleerly Labs (APC 1511)

Cleerly Labs is a Software as a Service (SaaS) that assesses the extent of coronary artery disease severity using Atherosclerosis Imaging-Quantitative Computer Tomography (AI-QCT). 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.

In the CY 2021 OPSS/ASC final rule with comment period, we assigned the CPT codes 0623T, 06234T, 0625T, 0626T codes to status indicator “E1” to indicate that the codes are not payable by Medicare when submitted on outpatient claims because the service had not received FDA clearance at the time of the assignment.

For the October 2022 update, based on our review of the New Technology application submitted to CMS for OPSS payment consideration, we evaluated the current status indicator assignments for CPT codes 0623T-0626T. 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, we assigned CPT code 0625T to a separately payable status. Specifically, in the October 2022 OPSS Update CR (Change Request 12885, Transmittal 11594, dated September 9, 2022), we reassigned CPT code 0625T to status indicator “S” (Significant Procedures, Not Discounted when Multiple. Paid under OPSS; separate APC payment) and APC 1511 (New Technology -

Level 11 (\$900 - \$1000)) with a payment rate of \$950.50, effective October 1, 2022, following our review of the manufacturer's New Technology APC application.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There are 90 claims for CPT code 0625T during this time period. As this is below the threshold of 100 claims for a service within a year, we could propose to designate CPT code 0625T 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 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 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 acknowledge that, because CPT code 0625T was only made separately payable as part of the OPPS in October 2022, and, therefore, the claims available only reflect two months of data, we have concerns 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 propose to maintain CPT code 0625T's current assignment. Specifically, for CY 2024, we propose to continue to assign CPT code 0625T to New Technology APC 1511 with a payment rate of \$950.50.

Please refer to Table 26 below for the proposed OPPS New Technology APC and status indicator assignment for CPT code 0625T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the Internet on the CMS website.

**TABLE 26: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS
INDICATOR ASSIGNMENTS FOR CLEARLY LABS
HCPCS CODE 0625T**

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	S	1511

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

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a policy to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year. For this proposed rule, CY 2022 claims are generally the claims used for ratesetting; and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2022 that can be used for ratesetting would be low volume APCs subject to our universal low volume APC policy. As we stated in the CY 2022 OPPS/ASC final rule with comment period, we adopted this policy to reduce the volatility in the payment rate for those APCs with fewer than 100 single claims. Where a clinical or brachytherapy APC has fewer than 100 single claims that can be used for ratesetting, under our low volume APC payment adjustment policy, we determine the APC cost as the greatest of the geometric mean cost, arithmetic mean cost, or median cost based on up to four years of claims data. We excluded APC 5853 (Partial Hospitalization for CMHCs) and APC 5863 (Partial Hospitalization for Hospital-based PHPs) from our universal low volume APC policy given the different nature of policies that affect the partial hospitalization program. We also excluded APC 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) as our current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

Based on claims data available for this proposed rule, we propose to designate five brachytherapy APCs and five clinical APCs as low volume APCs under the OPPS. The five brachytherapy APCs and five clinical APCs meet our criteria of having fewer than 100 single claims in the claims year used for ratesetting (CY 2022 for this proposed rule). Eight of the ten APCs were designated as low volume APCs in CY 2023. Based on data for this CY 2024 OPPS/ASC proposed rule, APC 2642 (Brachytx, stranded, C-131) now meets our criteria to be designated a Low Volume APC; and we propose to designate it as such for CY 2024. Further, with the proposed addition of Level 6 Intraocular APC (APC 5496), as discussed in section III.E of this proposed rule, and the reassignment of certain intraocular procedures from Level 2 to Level 3, the Level 4 Intraocular APC (which was the Level 3 Intraocular APC in CY 2023), now meets our criteria to be designated a Low Volume APC; and we propose to designate it as such for CY 2024.

Table 27 includes the APC geometric mean cost without the low volume APC designation, that is, if we calculated the geometric mean cost based on CY 2022 claims data available for ratesetting; the median, arithmetic mean, and geometric mean cost using up to four years of claims data based on the APC's designation as a low volume APC; and the statistical methodology we propose to use to determine the APC's cost for ratesetting purposes for CY 2024. As discussed in our CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), given our concerns with CY 2020 claims data as a result of the PHE, the four years of claims data we proposed to use to calculate the costs for these APCs are CYs 2018, 2019, 2021, and 2022.

TABLE 27: COST STATISTICS FOR PROPOSED LOW VOLUME APCS USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2024

APC	APC Description	CY 2022 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	Proposed CY 2024 APC Cost
2632	Iodine I-125 sodium iodide	0	---*	\$31.74	\$61.83	\$41.06	\$61.83
2635	Brachytx, non-str, HA, P-103	21	\$98.73	\$58.38	\$60.86	\$54.77	\$60.86
2636	Brachy linear, non-str, P-103	1	\$89.34	\$22.17	\$57.15	\$33.66	\$57.15
2642	Brachytx, stranded, C-131	76	\$99.92	\$79.90	\$100.65	\$79.90	\$100.65
2647	Brachytx, NS, Non-HDRIr-192	2	\$452.28	\$201.69	\$403.29	\$167.08	\$403.29
5244	Level 4 Blood Product Exchanges and Related Services	55	\$52,105.34	\$45,729.50	\$53,360.21	\$44,947.25	\$53,360.21
5494	Level 4 Intraocular Procedures	50	\$13,410.30	\$13,305.40	\$14,227.94	\$13,410.31	\$14,227.94
5495	Level 5 Intraocular Procedures	88	\$7,399.50	\$16,660.19	\$16,269.57	\$12,817.68	\$16,660.19
5496	Level 6 Intraocular Procedures	26	\$11,183.21	\$17,309.37	\$15,981.28	\$14,084.23	\$17,309.37
5881	Ancillary Outpatient Services When Patient Dies	91	\$7,701.96	\$7,018.18	\$13,576.10	\$7,777.84	\$13,576.10

* For this proposed rule, there are no CY 2022 claims that contain the HCPCS code assigned to APC 2632 that are available for CY 2024 OPPTS/ASC ratesetting.

E. Proposed APC-Specific Policies: Intraocular Procedures

In reviewing the claims data available for the CY 2024 OPPTS proposed rule, we believed that it was appropriate to create an additional Intraocular Procedures level, between the current Level 2 and 3 APCs. We last adjusted the number of APCs in the Intraocular Procedures family

in CY 2020, when we reestablished APC 5495 (Level 5 Intraocular Procedures) to accommodate the procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) based on its estimated cost (84 FR 61249 through 61250). Creating a new APC in the Intraocular Procedures family will allow for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Therefore, for the CY 2024 OPSS, we propose to establish a six-level APC structure for the Intraocular Procedures series. We noted that in addition to creating the new level, we also proposed to assign CPT codes 66989 (Extracapsular cataract removal w/IOL insertion, complex; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more) and 66991 (Extracapsular cataract removal w/IOL insertion; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more) to the new Level 3 APC, as discussed in further detail in section III.C.2.j. (Minimally Invasive Glaucoma Surgery (MIGS) (APC 5493)) of this proposed rule.

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 OPPS/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 OPPS 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 OPPS 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.¹¹

¹¹ To apply for OPPS transitional device pass-through status, applicants complete an application that is subject to the Paperwork Reduction Act (PRA). This collection (CMS-10052) has an OMB control number of 0938-0857 and an expiration date of November 30, 2025.

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 15 device categories eligible for pass-through payment. These devices are listed in Table 28 of this proposed rule where we detail the expiration dates of pass-through payment status for each of the 15 devices currently receiving device pass-through payment.

In the CY 2022 OPPS/ASC final rule with comment period we used CY 2019 claims data, rather than CY 2020 claims data, to inform CY 2022 ratesetting (86 FR 63755). As a result, we utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose pass-through payment status expired between December 31, 2021 and September 30, 2022 to mimic continued pass-through payment, promote adequate access to innovative therapies for Medicare beneficiaries, and gather sufficient data for purposes of assigning these devices to clinical APCs (86 FR 63755). A full discussion of this finalized policy is included in section X.F of the CY 2022 OPPS/ASC final rule with comment (86 FR 63755).

Section 4141(a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117-328) amended section 1833(t)(6) by adding a new subparagraph (K), which extended the device pass-through status under paragraph (6) for a 1-year period beginning January 1, 2023, for device categories whose period of pass-through status would have ended on December 31, 2022.

There are five device categories for which pass-through status would have ended on December 31, 2022, but which will now end on December 31, 2023. Pass-through status began for these device categories on January 1, 2020.

TABLE 28: DEVICES WITH PASS-THROUGH STATUS EXPIRING IN THE FOURTH QUARTER OF 2023, IN 2024, OR IN 2025

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1824*	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2023
C1982*	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2023
C1839*	Iris prosthesis	1/1/2020	12/31/2023
C1734*	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2023
C2596*	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s)	1/1/2021	12/31/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024
C1831	Personalized, anterior and lateral interbody cage (implantable)	10/1/2021	9/30/2024
C1832	Autograft suspension, including cell processing and application, and all system components	1/1/2022	12/31/2024
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	1/1/2022	12/31/2024
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system	1/1/2023	12/31/2025
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	1/1/2023	12/31/2025
C1747	Endoscope, single-use (i.e. disposable), urinary tract, imaging/illumination device (insertable)	1/1/2023	12/31/2025

*Device for which pass-through status was extended for a 1-year period by section (a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117-328), titled Extension of Pass-Through Status Under the Medicare Program for Certain Devices Impacted by COVID-19.

2. New Device Pass-Through Applications for CY 2024

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at § 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA approval or clearance and FDA marketing authorization (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and

- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not “insignificant” relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) the estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and

temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and

- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

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 OPSS 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 OPSS 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 2024

We received six complete applications by the March 1, 2023 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in this proposed rule. We received three of the applications in the second quarter of 2022, one of the applications in the third quarter of 2022, no applications in the fourth quarter of 2022, and two of the applications in the first quarter of 2023. One of the applications was approved for device

pass-through status during the quarterly review process: MY01 Continuous Compartmental Pressure Monitor, which was submitted on May 31, 2022 and conditionally approved as HCPCS code C1834 on October 1, 2022. However, after further review, we determined that the conditional approval was in error, and consequently, we deleted code C1834 on March 31, 2023.

Applications received for the later deadlines for the remaining 2023 quarters (the quarters beginning June 1, September 1, and December 1 of 2023), if any, will be discussed in the CY 2025 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed because of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>.

Discussions of the applications we received by the March 1, 2023 deadline are included below.

(1) Alternative Pathway Device Pass-Through Applications

We received two device pass-through applications by the March 2023 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 are eligible to apply under the alternative pathway.

(a) CavaClear Inferior Vena Cava (IVC) Filter Removal Laser Sheath

Phillips North America, LLC submitted an application for a new device category for transitional pass-through payment status for CavaClear Inferior Vena Cava (IVC) Filter Removal Laser Sheath (CavaClear) for CY 2024. Per the applicant, CavaClear is a breakthrough device intended for tissue ablation in the removal of embedded IVC filters that have failed a previous retrieval method. IVC filters are used to capture blood clots and prevent them from moving to the lungs in patients with venous thromboembolism. Per the applicant, research has shown that IVC filters may have long-term complications, including device migration, filter fracture, and

IVC occlusion; as a result, FDA issued a safety notice that recommends that physicians remove retrievable IVC filters as soon as they are no longer needed. The applicant stated that CavaClear facilitates the detachment of firmly adherent IVC filters using ultraviolet laser energy. The applicant explained that CavaClear uses circumferential tissue ablation that can aid in capturing the filter within seconds of laser activation, which can help increase physician efficiency, and may help lower costs by reducing the number of retrieval attempts to remove an embedded IVC filter.

According to the applicant, CavaClear is a 14F or 16F laser catheter used for the intra-operative removal of IVC filters. The applicant further explained that CavaClear consists of optical fibers arranged in a circle, sandwiched between inner and outer polymer tubing. The fibers terminate at the distal end within a polished tip and at the proximal end within a coupler that mates with the excimer laser. According to the applicant, inner and outer stainless-steel bands, which form a radiopaque marker, protect the optical fibers at the distal tip. The applicant also stated that CavaClear was designed to slide through an introducer sheath and with an inner lumen to allow an appropriate traction platform to pass through it. Per the applicant, the device facilitates detachment of IVC filters from the IVC wall using ultraviolet laser energy and subsequent collapse of the filter, partially within the laser sheath and entirely within the introducer sheath. The laser sheath was designed for use with the CVX-300[®] Excimer Laser or Philips Laser System (PLS), which allows the multifiber laser sheaths to transmit ultraviolet energy to the tissue at the distal tip of the device. The applicant further explained that, when activated, the laser ablates the tissue and frees the IVC filter from overgrowth in a controllable fashion. The applicant stated that by using cool ultraviolet laser energy around the embedded IVC filter, CavaClear can assist in fast filter capture with low force.

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), CavaClear received FDA Breakthrough Device designation effective

April 23, 2021, for the ablation of tissue in the removal of IVC filters that have failed a previous retrieval method. FDA granted the applicant De Novo classification for CavaClear (laser-powered IVC filter retrieval catheter) on December 21, 2021, for the same indication as the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for CavaClear on May 30, 2022, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comment on whether CavaClear meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, CavaClear is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted into the patient through the insertion of a laser catheter temporarily for the interoperative removal of IVC filters as required at § 419.66(b)(3).

We are inviting public comment on whether CavaClear meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant also claimed that CavaClear meets the criterion because it is not equipment, 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 comment on whether CavaClear 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 CavaClear as an IVC

filter removal device that uses a laser to ablate tissue and is intended to facilitate detaching and removing indwelling IVC filters. Per the applicant, CavaClear is the first and only FDA-cleared solution for advanced IVC filter removal, and the applicant claimed that no previous device categories for pass-through payment appropriately describe CavaClear. Per the applicant, the possible existing pass-through code -- HCPCS code C2629 (Introducer/sheath, other than guiding, other than intracardiac electrophysiological, laser) – does not appropriately describe CavaClear because CavaClear uses a unique laser mechanism of action, unlike the snag, snare, and forcep method to remove IVC filters; CavaClear is not intended to remove pacemaker and defibrillator leads like the products described by C2629; and CavaClear impacts different anatomy than the products described by C2629. Specifically, the applicant asserted that C2629 includes devices that are indicated to remove implanted pacemaker and defibrillator leads and devices via a catheter inserted into the vascular system. In addition, the applicant noted that FDA granted CavaClear De Novo classification, reflecting that there is no legally marketed predicate device for CavaClear.

We note, based on the description the applicant provided, that CavaClear is a laser sheath intended for use in the IVC, which is not intracardiac, and thus could be encompassed by the descriptor of C2629. We also note that another existing pass-through payment category may appropriately describe CavaClear. Specifically, we believe that C1773 (Retrieval device, insertable (used to retrieve fractured medical devices)) may appropriately describe CavaClear. Pass-through payment category C1773 is a broad category descriptor for a device that retrieves another device within a patient's vascular system. Based on the description the applicant provided, CavaClear is a device (a laser-powered sheath that uses a laser to ablate tissue in the IVC) used to retrieve another medical device (an IVC filter device), which is consistent with the descriptor for C1773. In this context, we believe CavaClear may be similar to the devices currently described by C2629 and C1773, and therefore, CavaClear may also be appropriately described by C2629 and C1773.

We are inviting public comment on whether CavaClear 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 is included in the category that has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body party 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. CavaClear has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation, and therefore, appears to meet the criterion at § 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine if 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 cost significance requirements. The applicant stated that CavaClear would be reported with HCPCS code listed in Table 29.

TABLE 29: HCPCS CODE REPORTED WITH CAVACLEAR

HCPCS Code	Long Descriptor	SI	APC
37193	Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	J1	5183

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 with comment period (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. For our calculations, we used APC 5183, which had a CY 2022 payment rate of \$2,923.63 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 37193 had a device offset amount of \$762.48 at the time the application was received.¹²

According to the applicant, the cost of CavaClear is \$3,165.00.

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 estimated average reasonable cost of \$3,165.00 for CavaClear is 108.26 percent of the applicable APC payment amount for the service related to the category of devices of \$2,923.63 ($(\$3,165.00/\$2,923.63) \times 100 = 108.26$ percent). Therefore, we believe CavaClear meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$3,165 for CavaClear is 415.09 percent of the cost of the device-related portion of the APC payment

¹² We note that the applicant selected a value of \$537.36 for the device offset amount. However, the value selected is inconsistent with the device offset amount related to HCPCS 37193 in APC 5183 found in Addendum P to the CY 2022 OPPI/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPPI Addendum (87 FR 2060). We selected the value of \$762.48, which we believe is the accurate value. Based on our initial assessment for this proposed rule, using the device offset amount of \$762.48 would result in CavaClear meeting the cost significance requirement.

amount for the related service of \$762.48 ($((\$3,165.00/\$762.48) \times 100 = 415.09$ percent).

Therefore, we believe CavaClear meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$3,165.00 for CavaClear and the portion of the APC payment amount for the device of \$762.48 is 82.18 percent of the APC payment amount for the related service of \$2,923.63 ($((\$3,165.00 - 762.48)/\$2,923.63) \times 100 = 82.18$ percent). Therefore, we believe that CavaClear meets the third cost significance requirement.

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

(b) CERAMENT[®] G

BONESUPPORT AB submitted an application for a new device category for transitional pass-through payment status for CERAMENT[®] G for CY 2024. Per the applicant, CERAMENT[®] G is a single-use implantable bone void filler combination device/drug that remodels into bone and elutes gentamicin. The applicant further explained that CERAMENT[®] G is an adjunct to systematic antibiotic therapy as part of the surgical treatment of osteomyelitis (i.e., bone infection) in the extremities and is used where there is a need for supplemental bone void filler material. The applicant asserted that CERAMENT[®] G can reduce the recurrence of chronic osteomyelitis from gentamicin-sensitive microorganisms to protect bone healing and augment provisional hardware to help support bone fragments during the surgical procedure. The applicant stated that CERAMENT[®] G is the first on-label solution for a one-stage surgical approach to treating bone infections with its unique dual mode of action: (1) promote bone healing (bone remodeling), and (2) protect bone healing (elution of a local broad-spectrum

antibiotic). According to the applicant, once implanted, CERAMENT® G resorbs overtime and remodels into bone in 6 to 12 months.

Per the applicant, CERAMENT® G is comprised of three key compounds: (1) hydroxyapatite (HA), (2) calcium sulfate (CaS), and (3) gentamicin sulfate. According to the applicant, by combining calcium sulfate and hydroxyapatite, a balance is achieved between implant resorption rate and bone remodeling rate. The applicant further explained that the CaS acts as a resorbable carrier for HA. The applicant described that HA has a slow resorption rate and high osteoconductivity promoting bone remodeling and thus gives long-term structural support to the newly-formed bone. The gentamicin sulfate is a broad-spectrum aminoglycoside antibiotic that is sensitive to a spectrum of aerobic bacteria, particularly gram-negative bacilli, as well as aerobic gram-positive cocci, in particular *Staphylococcus aureus*, some coagulase negative staphylococci (CoNS) (e.g., *Staphylococcus epidermidis*), and some strains of streptococci. According to the applicant, the gentamicin sulfate is present in the bone void filler to prevent colonization from gentamicin-sensitive microorganisms to protect bone healing.

Per the applicant, CERAMENT® G is comprised of eight components (these components contain the three key compounds as well as other parts for the successful application of CERAMENT® G): (1) CERAMENT® CMI, a closed mixing injection system pre-packed with ceramic bone substitute (CBS), is a mixture of the CaS (60 wt percent) and HA (40 wt percent). The applicant further explained that the mixing device is comprised of a 60 mL syringe, which in its proximal part is equipped with a movable combined plunger and mixing paddle, and in its distal part with a luer-lock connection. The movable mixing paddle allows effective mixing of the material inside the syringe. Calcium Sulfate and Hydroxyapatite (CSH) are the setting component of the bone void filler, and per the applicant, this component will react to calcium sulfate dihydrate (CSD) and will be resorbed over time, giving place for natural bone to grow into the bone graft. The applicant described that CSD is added as a seeding agent to accelerate the setting reaction of CSH to CSD, and that HA is an osteoconductive mineral similar to natural

bone (this part of the bone graft substitute will not be resorbed and does not need to be surgically removed). The applicant stated that CSH and CSD conform to specifications based on the monograph Calcium Sulfate Dihydrate 0982, European Pharmacopoeia (EP) and the Official Monograph for Calcium Sulfate U.S. Pharmacopoeia /National Formulary (USP) as well as internal requirements; (2) CERAMENT® ID, an injection device used to inject the paste into the bone void or gap; (3) Valve, a needleless valve needed for the transfer of the ceramic paste from the CERAMENT® CMI to the CERAMENT® ID; (4) Tip Extenders, which are sterile, plastic needles with an inner diameter of 2.55 mm and two lengths (50 and 100 mm), that are connected to the CERAMENT® ID to facilitate placement of the paste at the debridement site; (5) CERAMENT® GENTAMICIN, the gentamicin sulfate in a glass vial equipped with a stopper and a cap. The gentamicin sulfate subcomponent has a potency equivalent to $\geq 590\mu\text{g}$ gentamicin/mg (anhydrous substance) and is dissolved in the 0.9 percent sterile sodium chloride solution and mixed with the CBS powder. Per the applicant, the prepared paste sets to a calcium sulfate dihydrate matrix with embedded hydroxyapatite particles, and gentamicin sulfate. The applicant further explained that it delivers 17.5 mg gentamicin per mL paste. Per the applicant, the gentamicin sulfate subcomponent complies with the EP monograph for gentamicin sulfate; (6) CERAMENT® MIXING LIQUID, a sterile sodium chloride, (NaCl) solution, 9 mg per mL in a glass vial. Per the applicant, it is the liquid component of CERAMENT® G. This component contains water which is needed for the calcium sulfate reaction to occur. The liquid meets requirements of the compendial excipient of USP/EP grade and is also registered in the inactive ingredient database; (7) BONESUPPORT DP, which includes two ventilated dispensing pins to facilitate easy handling when preparing the gentamicin solution; and (8) BONESUPPORT SYRINGE, a single packed, sterile 10 mL syringe with a male/female rotator assembly, and is used when preparing the gentamicin solution.

According to the applicant, after the surgical site has been prepared and any dead bone is debrided (i.e., removed), the CERAMENT® G paste is prepared by the surgeon or surgical

technician by: (1) mixing the gentamicin powder with the provided saline to make a gentamicin liquid; (2) adding the gentamicin liquid to the powder in the CERAMENT® CMI syringe and mixing the gentamicin liquid and powder; and (3) transferring the resulting paste to a smaller delivery syringe. Four minutes after the start of mixing, the paste is ready to be used as a bone void filler. Per the applicant, it can be injected using the tip extenders provided in the kit or by attaching a needle to the delivery syringe, or it can be placed into a bead mold to form beads. Fifteen minutes after the start of mixing, CERAMENT® G can be drilled into, if required. At 20 minutes, it is fully set, at which time the wound can be closed.

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), CERAMENT® G received FDA Breakthrough Device designation effective March 12, 2020, as a resorbable, gentamicin-eluting ceramic bone graft substitute intended for use as a bone void filler as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis. By eluting gentamicin, CERAMENT® G can inhibit the colonization of gentamicin-sensitive microorganisms to protect bone healing. CERAMENT® G can augment provisional hardware to help support bone fragments during the surgical procedure and is resorbed and replaced by bone during the healing process. FDA granted the applicant De Novo classification for CERAMENT® G under the generic name, resorbable calcium salt bone void filler containing a single approved aminoglycoside antibacterial substance on May 17, 2022, for the same indication as the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for CERAMENT® G on May 31, 2022, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comment on whether CERAMENT® G meets the newness criterion at § 419.66(b)(1).

With respect to the integral part of the service criterion at § 419.66(b)(3), the applicant did not indicate whether CERAMENT® G is integral to the service provided. However, per the applicant, CERAMENT® G is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted into the patient as required at § 419.66(b)(3).

We are inviting public comment on whether CERAMENT® G meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant did not address whether CERAMENT® G is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if CERAMENT® G is a supply or material furnished incident to a service.

We are inviting public comment on whether CERAMENT® G 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 CERAMENT® G as a single-use implantable bone void filler combination device/drug that remodels into bone and elutes gentamicin. The applicant asserted that there are no existing bone void filler devices cleared or approved for use in the U.S. for single stage surgical reconstruction of bone defects that provide stability, promote bone formation, and effectively support the surgical treatment of infection by antibiotic elution. However, for comparison purposes, the applicant listed HCPCS code C1734 (Orthopedic/device/drug matrix for opposing bone-to-bone or soft-tissue-to-bone

(implantable)), as a device category that it considers similar to CERAMENT® G's device category.¹³

The applicant stated that CERAMENT® G differs from the bone substitutes AUGMENT® and AUGMENT® Injectable (devices described by HCPCS code C1734). We note that CMS approved an application for AUGMENT® Bone Graft as a new device category for transitional pass-through payment status and established HCPCS code C1734 as a new device category beginning in CY 2020. We refer readers to the CY 2019 OPSS/ASC final rule with comment period (84 FR 61292 through 61294) for a full discussion of the AUGMENT® Bone Graft application and decision.¹⁴ The applicant asserted that CERAMENT® G and AUGMENT® differ in terms of the product composition and mechanism of action, or intended use. In addition, the applicant asserted that the products are intended for different groups of patients. With respect to composition, per the applicant, CERAMENT® G consists of HA, CaS, and gentamicin sulfate. In contrast, the applicant stated that AUGMENT® consists of beta-tricalcium phosphate (β -TCP) and recombinant human platelet-derived growth factor (rhPDGF-BB), and AUGMENT® Injectable consists of β -TCP, rhPDGF-BB, and a collagen matrix. With respect to the mechanism of action, the applicant stated that CaS in CERAMENT® G acts as a resorbable carrier for HA, which has a slow resorption rate and high osteoconductivity, providing a scaffold for new bone generation. The applicant further explained that by combining CaS and HA, a balance is achieved between implant resorption rate and bone remodeling rate, and by eluting gentamicin, CERAMENT® G can reduce the recurrence of chronic osteomyelitis from gentamicin-sensitive microorganisms to protect bone healing. In contrast, according to the applicant, the rhPDGF-BB in AUGMENT® acts as a chemo-attractant and mitogen for cells involved in wound healing and

¹³ HCPCS code C1734 is a device category for which pass-through status was extended for a 1-year period beginning January 1, 2023, by section (a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117-328), titled Extension of Pass-Through Status Under the Medicare Program for Certain Devices Impacted by COVID-19.

<https://www.cms.gov/files/document/r11801cp.pdf>

¹⁴ <https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf>

through its promotion of angiogenesis at the site of healing, and the β - TCP acts as a bone void filler to prevent soft tissue from collapsing into the void.

Per the applicant, CERAMENT[®] G is indicated for use as a bone void filler in skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis in defects in the extremities. In contrast, per the applicant, AUGMENT[®] and AUGMENT[®] Injectable¹⁵ are indicated for use as an alternative to autograft in arthrodesis in patients who require a bone fusion, such as patients who have arthritis, avascular necrosis, joint instability or deformity, or joint arthroplasty of the ankle and/or hindfoot. Further, the applicant asserted that AUGMENT[®] cannot be used in the patients for whom CERAMENT[®] G is indicated because AUGMENT[®] is specifically contraindicated in patients with an active infection at the operative site.

We note that, based on the description of the device provided by the applicant, CERAMENT[®] G and AUGMENT[®] differ in terms of composition and intended use, but also note that device categories are not intended to be device specific. Rather, device categories are intended to encompass any device that can be appropriately described by the category. As such, when we evaluate a potential pass-through device to determine whether it meets the device category criterion at § 419.66(c)(1), we compare the subject device to the device category descriptor rather than to the specific device for which the device category was created. Specifically, C1734 describes any device that meets the following descriptor: Orthopedic/device/drug matrix for opposing bone-to-bone or soft-tissue-to-bone (implantable), and per the applicant, CERAMENT[®] G is described as an implantable device/drug matrix that, with its intended use, will oppose soft-tissue-to-bone. In this context, we believe CERAMENT[®]

¹⁵ The applicant differentiates itself from AUGMENT[®] and AUGMENT[®] Injectable, but does not use the term “AUGMENT[®] Bone Graft” in the application. However, the link provided in the application goes to the AUGMENT[®] webpage that describes AUGMENT[®] Regenerative Solutions, AUGMENT[®] Bone Graft and AUGMENT[®] Injectable. We use the term “AUGMENT[®]” to collectively refer to the AUGMENT[®] products described herein and those listed on the AUGMENT[®] website. The applicant provided webpage (in footnote): AUGMENT BONE GRAFT website: <http://www.augmentbonegraft.com/healthcare-professionals/>

G may be similar to the devices currently described by C1734, and therefore CERAMENT® G may also be appropriately described by C1734.

We are inviting public comment on whether CERAMENT® G 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. CERAMENT® G 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 appears to meet the criterion at § 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement.

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 CERAMENT® G would be reported with HCPCS codes listed in Table 30.

TABLE 30: HCPCS CODES REPORTED WITH CERAMENT® G

HCPCS Code	Long Descriptor	SI	APC
21510	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess), thorax	**	**
23035	Incision, bone cortex (e.g., osteomyelitis or bone abscess), shoulder area	J1	5112

HCPCS Code	Long Descriptor	SI	APC
23170	Sequestrectomy (e.g., for osteomyelitis or bone abscess), clavicle	J1	5113
23172	Sequestrectomy (e.g., for osteomyelitis or bone abscess), scapula	**	**
23174	Sequestrectomy (e.g., for osteomyelitis or bone abscess), humeral head to surgical neck	**	**
23180	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), clavicle	J1	5114
23182	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), scapula	J1	5114
23184	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), proximal humerus	J1	5114
23935	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess), humerus or elbow	J1	5113
24134	Sequestrectomy (e.g., for osteomyelitis or bone abscess), shaft or distal humerus	J1	5114
24136	Sequestrectomy (e.g., for osteomyelitis or bone abscess), radial head or neck	**	**
24138	Sequestrectomy (e.g., for osteomyelitis or bone abscess), olecranon process	J1	5114
24140	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), humerus	J1	5113
24145	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), radial head or neck	J1	5114
24147	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), olecranon process	J1	5113
25035	Incision, deep, bone cortex, forearm and/or wrist (e.g., osteomyelitis or bone abscess)	J1	5114
25150	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis); ulna	J1	5113
25151	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis); radius	J1	5113
26230	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis); metacarpal	J1	5113
26992	Incision, bone cortex, pelvis and/or hip joint (e.g., osteomyelitis or bone abscess)	**	**
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (e.g., osteomyelitis or bone abscess); superficial	**	**
27071	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (e.g., osteomyelitis or bone abscess); deep (subfascial or intramuscular) abscess); deep (subfascial or intramuscular)	**	**
27303	Incision, deep, with opening of bone cortex, femur or knee (e.g., osteomyelitis or bone abscess)	**	**
27360	Partial excision (craterization, saucerization, or diaphysectomy) bone, femur, proximal tibia and/or fibula (e.g., osteomyelitis or bone abscess)	J1	5113
27607	Incision (e.g., osteomyelitis or bone abscess), leg or ankle	J1	5113

HCPCS Code	Long Descriptor	SI	APC
27640	Partial excision (craterization, saucerization, or diaphysectomy), bone (e.g., osteomyelitis); tibia	J1	5113
27641	Partial excision (craterization, saucerization, or diaphysectomy), bone (e.g., osteomyelitis); fibula	J1	5113
28005	Incision, bone cortex (e.g., osteomyelitis or bone abscess), foot	J1	5113
28120	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); talus or calcaneus	J1	5113
28122	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus	J1	5113

** Denotes a HCPCS code that was not evaluated for the cost criterion because the HCPCS code was not included in Addendum P to the CY 2022 OPSS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPSS Addendum (87 FR 2060).

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 with comment period (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. For our calculations, we used APC 5112, which had a CY 2022 payment rate of \$1,422.51 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 23035 had a device offset amount of \$217.36 at the time the application was received. We note that the applicant submitted cost information for two different device sizes (5 ml and 10 ml) for CERAMENT® G. Per the applicant, the average patient will require approximately 10 ml per procedure, with a weighted cost of \$7,567.00 per patient.

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 estimated average reasonable cost of \$7,567.00 for CERAMENT® G is 531.95 percent of the applicable APC payment amount for the service related to the category of devices of \$1,422.51

$((\$7,567.00/\$1,422.51) \times 100 = 531.95 \text{ percent})$. Therefore, we believe CERAMENT® G 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 \$7,567.00 for CERAMENT® G is 3,481.32 percent of the cost of the device-related portion of the APC payment amount for the related service of \$217.36 ($((\$7,567.00/\$217.36) \times 100 = 3,481.32 \text{ percent})$). Therefore, we believe that CERAMENT® G 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 \$7,567.00 for CERAMENT® G and the portion of the APC payment amount for the device of \$217.36 is 516.67 percent of the APC payment amount for the related service of \$1,422.51 ($((\$7,567.00 - \$217.36)/\$1,422.51) \times 100 = 516.67 \text{ percent})$). Therefore, we believe that CERAMENT® G meets the third cost significance requirement.

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

(2) Traditional Device Pass-Through Applications

(a) Ambu® aScope™ 5 Broncho HD

Ambu Inc. submitted an application for a new device category for transitional pass-through payment status for the Ambu® aScope™ 5 Broncho HD for CY 2024. Per the applicant,

the Ambu® aScope™ 5 Broncho HD is one component of the Ambu® aScope™ 5 Broncho HD System which consists of: (1) the Ambu® aScope™ 5 Broncho HD (5.0/2.2 or 5.6/2.8), a sterile, single-use, disposable flexible/rigid bronchoscope; and (2) Ambu® aBox™ 2, a compatible, reusable display unit. The applicant is only seeking a new device category for transitional pass-through payment status for the Ambu® aScope™ 5 Broncho HD component.

Per the applicant, the Ambu® aScope™ 5 Broncho HD, consists of: (1) a handle, to hold the scope (designed for left and right hand); (2) a control lever, to move the distal tip up or down in a single plane; (3) a working channel and working channel port, for instillation of fluids and insertion of endotherapy instruments; (4) a biopsy valve, to be attached to the working channel port, for insertion of endotherapy instruments or attachment of a syringe; (5) a suction connector, for connection of suction tubing; (6) a suction button, to activate suction when pressed; (7) endoscope buttons 1 and 2 (depending on settings in display unit the two remote switches allow for direct activation on handle of four different functionalities such as image and video capturing, initiate advanced red contrast (ARC), and zoom); (8) a rotation control ring, for rotation of the insertion cord during procedure; (9) a tube connection, for fixation of tubes with standard connector during procedure; (10) an insertion cord and insertion portion, flexible airway insertion cord; (11) bending section, maneuverable part; (12) distal tip, which contains the camera, light source (two light-emitting diodes (LEDs)), and the working channel exit; (13) display unit connector, to connect to the port on the Ambu® aBox™ 2 display unit; (14) a cable, to transmit the image signal to the Ambu® aBox™ 2 display unit; (15) a protective handle cover, to protect the control lever during transport and storage; (16) a protective pipe, to protect the insertion cord during transport and storage ; and (17) an introducer, to facilitate introduction of luer lock syringes.

The applicant stated that the Ambu® aScope™ 5 Broncho HD is an imaging/illumination bronchoscope device that uses an integrated camera module and built-in dual LED illumination to provide access to, and imaging of, the lungs for diagnostic and therapeutic purposes for

pulmonology patients. The device is intended for endoscopy and endoscopic surgery within the lungs, also known as bronchoscopy. According to the applicant, the Ambu® aScope™ 5 Broncho HD was designed to perform a wide array of diagnostic and interventional pulmonology procedures. The applicant noted that the Ambu® aScope™ 5 Broncho HD is a single-use bronchoscope designed to be used with the Ambu® aBox™ 2 display unit, endotherapy instruments, and other ancillary equipment for bronchoscopic procedures and examination within the airways and the tracheobronchial tree. It is intended to provide visualization via the compatible display unit, the Ambu® aBox™ 2, and to allow passage of endotherapy instruments via its working channel.

Per the applicant, the Ambu® aScope™ 5 Broncho HD bronchoscope is inserted into the patient airway through either the mouth, nose, or via a tracheostomy, if present. The applicant explained that when the Ambu® aScope™ 5 Broncho HD bronchoscope has reached the correct position, endotherapy instruments can be inserted into the working channel system of the bronchoscope. Per the applicant, an introducer supplied with the bronchoscope can be attached to the working channel port via a luer lock adaptor, while the bronchoscope is in use. The applicant noted that the suction system may be used to remove blood, saliva, and mucus from the airway. The applicant indicated that a bronchoscope operator monitors the field of view via the integrated camera of the Ambu® aScope™ 5 Broncho HD bronchoscope and the procedure is finished when the device is pulled out completely.

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 July 25, 2022, the applicant received 510(k) clearance from FDA for the Ambu® aScope™ 5 Broncho HD as a device to be used for endoscopic procedures and examination within the airways and tracheobronchial tree. We received the application for a new device category for transitional pass-through payment status for the Ambu® aScope™ 5

Broncho HD on February 28, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Ambu® aScope™ 5 Broncho HD is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted as required by § 418.66(b)(3).

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant did not address whether the Ambu® aScope™ 5 Broncho HD is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if the Ambu® aScope™ 5 Broncho HD is a supply or material furnished incident to a service.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD 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 the Ambu® aScope™ 5 Broncho HD as a single-use, disposable, digital flexible/rigid bronchoscope that is used in pulmonary procedures (bronchoscopy) to diagnose and treat conditions of the lungs, including tumors or bronchial cancer, airway blockage (obstruction), narrowed areas in airways (strictures), inflammation, and infections such as tuberculosis (TB), pneumonia, fungal or parasitic lung infections, interstitial pulmonary disease, causes of persistent cough, causes of coughing up blood, spots seen on chest X-rays, and vocal cord paralysis. The applicant claimed

that the Ambu® aScope™ 5 Broncho HD is different from other endoscopes because it is a single-use endoscope indicated for use in the respiratory system, the device records snapshots or video of images, and the device is temporarily inserted into the patient airway to diagnose and treat lung problems. According to the applicant, there are two possible existing pass-through device categories, represented by the following codes: C1748 (Endoscope, single-use (i.e., disposable), upper gastrointestinal tract (GI), imaging/illumination device (insertable)); and C1747 (Endoscope, single-use (i.e., disposable), urinary tract, imaging/illumination device (insertable)). The applicant noted that while these two codes are for single-use endoscopic devices, they are only appropriate for GI and urinary tract imaging, respectively. Therefore, the applicant asserted that these two codes would not apply to a single-use, disposable, bronchoscopy for use in pulmonary procedures. We note that while C1748 and C1747 are intended to be used in different anatomical areas of the patient, the codes for both device categories describe devices that are single use and have imaging capabilities.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD 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 the Ambu® aScope™ 5 Broncho HD represents a substantial clinical improvement over existing technologies by: (1) elimination of complex cleaning/reprocessing procedures, (2) reduction of microbial transmission and

infection since it is single-use, (3) elimination of the need for continuous training of reprocessing staff, (4) minimization of the risk of patient cross-contamination, (5) assurance that a sterilized scope will be used each time, and (6) assurance that there will be no biofilm from endoscope channels. The applicant provided four articles, an FDA guidance letter, and an FDA safety notice specifically for the purpose of addressing the substantial clinical improvement criterion.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD eliminates complex cleaning/reprocessing procedures because it is a single-use device, the applicant referenced an FDA Reprocessing Final Guidance document¹⁶ issued March 17, 2015. This FDA document provides guidance to medical device manufacturers on the complex activities involved in crafting and validating reprocessing instructions that ensure that the device can be used safely and for the purpose for which it is intended. The guidance document is limited to reusable medical devices and single-use medical devices that are initially supplied as non-sterile to the user and require the user to process the device prior to its use. In this guidance document, FDA identifies a subset of reusable medical devices (including bronchoscopes and accessories) that pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed and indicates design features which may pose a challenge to adequate reprocessing for arthroscopes, laparoscopic instruments, and electrosurgical instruments, and their respective accessories. However, the FDA guidance does not mention sterile, single-use medical devices in this document.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD reduces microbial transmission and infection because it is single-use, the applicant referenced an FDA safety notice¹⁷ issued on September 17, 2015 (2015 FDA safety notice). The FDA notice discussed the findings of an investigation into infections associated with reprocessed reusable

¹⁶ FDA Guidance March 17 2015 “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff”
<https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf>

¹⁷ FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. <https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647>

medical devices, including an analysis of Medical Device Reports (MDRs) submitted to FDA from manufacturers and health care facilities. The notice provided that between January 2010 and June 2015, FDA received 109 MDRs concerning infections or device contamination associated with flexible bronchoscopes. However, FDA noted that, when compared to the number of bronchoscopy procedures performed in the U.S. each year, this is considered a small number of MDRs. In 2014, FDA received 50 MDRs that mentioned infections or device contamination associated with reprocessed flexible bronchoscopes, which prompted additional investigation of this issue. FDA indicated that a small number of the reported infections were from persistent device contamination despite following the manufacturer's reprocessing instructions, however, most of the infections were the result of the failure to meticulously follow manufacturer instructions for reprocessing, or continued use of devices despite integrity, maintenance, and mechanical issues. FDA provides additional recommendations for health care facilities and staff that reprocess flexible bronchoscopes and patients considering bronchoscopy procedures, but does not reference single-use bronchoscopes in the notice.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD eliminates the need for continuous training of reprocessing staff, the applicant referenced a study by Châteauevieux et al.,¹⁸ which assessed the organizational and economic impacts of the introduction of a single-use flexible bronchoscope (FB) (Ambu® aScope™, versions 2 and 3) in comparison with a reusable FB (Pentax®) at the hospital level. The study took place between May 2016 and October 2016 in the Georges Pompidou European Hospital, an 800-bed university hospital in France. Châteauevieux et al. noted that the introduction of single-use FBs led to a more simplified process, less stress for medical and paramedical staff in emergency situations, teaching benefits, and easier management of transport, in comparison with reusable FBs.

¹⁸ Châteauevieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice*, 24(3), 528–535. <https://doi.org/10.1111/jep.12904>

However, the authors recommended limiting the use of single-use FBs to specific situations, and to prioritize the use of reusable devices for most of the bronchoscopies for cost savings.

The applicant referred to a meta study by Barron and Kennedy¹⁹ to support its claim that the use of Ambu® aScope™ 5 Broncho HD minimizes the risk of patient cross-contamination, ensuring that health care providers have taken optimal steps to safeguard their patients. Barron and Kennedy summarized the major advantages of single-use FBs over the standard reusable FBs in clinical scenarios. The authors noted that single-use FBs offer a safer alternative to standard reusable FBs in specific scenarios where reduced risk of cross infection was critical in the immunocompromised patient and in rare cases of prior contamination due to transmissible spongiform encephalopathies.

The applicant referred to a self-sponsored study²⁰ by Ofstead et al.²¹ in 2019, in support of its claim that the use of the Ambu® aScope™ 5 Broncho HD ensures a sterilized scope is available for each procedure while reusable endoscopes may not be sterile even if manufacturers' cleaning protocols are followed. The study first referenced Ofstead et al.'s 2017²² evaluation of the effectiveness of bronchoscope processing in three large hospitals where every bronchoscope had visible defects, protein was detected on 100 percent of high-level disinfected bronchoscopes, and bacteria or mold were found on 58 percent of the patient-ready bronchoscopes. Then, in 2019, Ofstead et al. conducted the study to determine the time and cost of acquiring, maintaining, and reprocessing bronchoscopes in four hospitals (two in the Midwest and two in the West Coast). Three hospitals had obtained single-use Ambu® bronchoscopes (2018, version unspecified) for procedures done in certain departments, after hours, or in emergency situations.

¹⁹ Barron, S. P., & Kennedy, M. P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy?. *Advances in therapy*, 37(11), 4538–4548. <https://doi.org/10.1007/s12325-020-01495-8>

²⁰ Ofstead et al. acknowledged that this study was supported by an unrestricted research grant from Ambu Inc. The study sponsor did not participate in designing the study, identifying sites, collecting data, compiling results, interpreting the findings, or writing this article.

²¹ Ofstead, C. L., Hopkins, K. M., Eiland, J. E., & Wetzler, H. P. Managing Bronchoscope Quality and Cost: Results of a Real-world Study. <https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf>

²² Ofstead CL, Quick MR, Wetzler HP, et al. Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. *Chest*. 2018;154(5):1024–34.

Per Ofstead et al. (2019), the cost for procedures with reusable bronchoscopes (\$281 to \$803) were comparable or higher than the cost of single-use bronchoscopes (\$220 to \$315), due to acquisition and maintenance of large inventories of bronchoscopes to ensure real-time availability for various hospital departments. Ofstead et al. (2019) suggested the use of single-use bronchoscopes and accessories for after hours and emergency situations and any procedures that do not require advanced bronchoscopy capabilities. Ofstead et al. (2019) summarized the steps that can be taken to reduce risks related to bronchoscope contamination and to focus on implementing quality management systems to improve personnel competence, bronchoscope inventory management, maintenance, reprocessing effectiveness, and storage. In addition to following manufacturer's steps for reprocessing the devices, Ofstead et al. (2019) suggest the use of single-use bronchoscopes and accessories for after hours and emergency situations and any procedures that do not require advanced bronchoscopy capabilities, which are currently available in the list of recommendations.

The applicant referenced a review article by Kovaleva et al.²³ in support of its claim that the Ambu® aScope™ 5 Broncho HD's single-use feature is free of biofilm from endoscope channels since routine cleaning procedures do not remove biofilm reliably from endoscope channels. This review presents an overview of the infections and cross-contaminations related to flexible gastrointestinal endoscopy and bronchoscopy and illustrates the impact of biofilm on endoscope reprocessing and post-endoscopic infection. Kovaleva et al. noted that the use of antibiofilm-oxidizing agents with an antimicrobial coating inside washer disinfectors could reduce biofilm build-up inside endoscopes and automated endoscope re-processors and decrease the risk of transmitting infections.²⁴ Per Kovaleva et al. while sterilization can be helpful to destroy microorganisms within biofilms, ethylene oxide sterilization may fail in the presence of

²³ Kovaleva, J., Peters, F. T., van der Mei, H. C., & Degener, J. E. (2013). Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clinical microbiology reviews*, 26(2), 231–254. <https://doi.org/10.1128/CMR.00085-12>

²⁴ Kovaleva, J., Peters, F. T., van der Mei, H. C., & Degener, J. E. (2013). Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clinical microbiology reviews*, 26(2), 231–254. <https://doi.org/10.1128/CMR.00085-12>

organic debris after an inadequate cleaning procedure before reprocessing of flexible endoscopes. There was no mention of single-use bronchoscopes in the study.

The applicant cited a self-sponsored, laboratory study by Kurman et al.,²⁵ in general support of its application. Kurman et al. evaluated and assessed four different manufacturers' single-use flexible bronchoscopes (SFB), including the nominated device and its prior model, against their reusable flexible bronchoscopes (RFB) on a cadaver (i.e., corpse) model, benchtop fixturing, and artificial plastic lung model. The study compared the Ambu® aScope™ 5 Broncho HD with four devices: (1) Olympus H-SteriScope; (2) Verathon BFLEX; (3) Boston Scientific Exalt-B; and (4) Ambu® aScope™ 4 Broncho (the prior model of the nominated device). The study concluded that the Ambu® aScope™ 5 Broncho HD has the highest overall performance, the highest overall rating for sampling, and highest maneuverability in difficult segmental airways among the comparator devices.

The applicant indicated that the Ambu® aScope™ 5 Broncho HD differs from these comparator devices as it is the only device that is compatible with argon gas plasma coagulation, cryotherapy, and laser, with an HD (1200x800) chip, has more degrees of articulation with tools, and provides image and video capture from the scope handle with multiple programmable functions including capture photo, start/end video, enable zoom, and initiate ARC. In addition, the applicant stated that the nominated device is superior to its earlier legally marketed device in terms of maneuverability into difficult segmental airways, overall performance, and overall sampling assessment. The applicant asserted that the nominated device differs from the predicate device due to a rotation mechanism on the handle and its superior articulation, which allow for more complicated procedures to be performed such as cryotherapy and coagulation. The applicant stated that the nominated device is equipped with an HD image chip and increased depth-of-field and field-of-view, which allow interventional pulmonologists to perform

²⁵ Kurman, J., Wagh, A., Benn, B., & Islam, S., (2023). A Comparison of Single-use Bronchoscopes and Reusable Bronchoscopes for Interventional Pulmonology Applications. Confidential. Ambu Inc., funded evaluation and testing.

inspections, biopsies, and debulking. The applicant also stated that the nominated device's programmable buttons allow for superior documentation than the earlier bronchoscope device.

We note that the nominated device was determined to be substantially equivalent to the earlier device that the applicant had previously legally marketed. The FDA 510(k) summary indicated that both devices share similar technological characteristics such as optical system, bending section, diameter of insertion cord and distal end, and insertion portion length. Furthermore, the 510(k) summary indicated that both have the same technical characteristics, which include maneuverable tip controlled by the user, flexible insertion cord, camera and LED light source at the distal tip, sterilized by ethylene oxide, single-use devices, ability for aspiration and sample collection in bronchoalveolar lavage, and bronchial wash procedures.

We note that in its application, the applicant provided a comparison of certain devices or device categories that it believed are most closely related or similar to the Ambu® aScope™ 5 Broncho HD. The applicant identified six reusable devices that it believed are most closely related: (1) Olympus Evis Exera Iii Bronchovideoscope Bf-h190; (2) Pentax EB-J10 Video Bronchoscope; (3) Fujifilm EB-580S Video Bronchoscope; (4) Olympus BF-Q190; (5) Olympus BF-1TH190; and (6) Olympus BF-XT190. According to the applicant, these devices are used during the same specific procedure(s) and/or services with which the Ambu® aScope™ 5 Broncho HD is used. The applicant stated that the Ambu® aScope™ 5 Broncho HD's single-use feature is unique among the comparators. According to the applicant, the single-use feature eliminates bronchoscope reprocessing. The applicant further submitted several articles reporting results on the prevalence of infection due to incomplete or inadequate processing for reusable bronchoscopes, which we summarize as follows. An article by Shimizu et al.²⁶ concluded that patients with larger lesions, presence of endobronchial lesions, histology of small-cell lung cancer, and advanced-disease stage tended to develop pulmonary infectious complications more

²⁶ Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. *Nagoya journal of medical science*, 82(1), 69–77. <https://doi.org/10.18999/nagjms.82.1.69>

often than other patients. A 2020 systematic literature review and meta-analysis by Travis et al.²⁷ reported an estimated average reusable FB cross-contamination rate of 8.69 percent \pm 1.86 (standard deviation [SD]) (95 percent confidence interval [CI]: 5.06–12.33 percent) among eight studies from the U.S. and four European countries. Travis et al.²⁸ attributed the infection rate to the differences in the study design and sampling methods, geography, low number of data points, clinical settings, and an aversion towards publishing negative findings among the eight studies. Furthermore, the applicant submitted a 2019 systematic review and cost-effective analysis by Mouritsen et al.,²⁹ which reported an average 2.8 percent cross-contamination rate from reusable, flexible bronchoscopes among 16 studies from the United Kingdom, U.S., France, Spain, Australia, and Taiwan. Mouritsen et al. identified that the single-use flexible bronchoscopes were cost effective and associated with a reduction of infection risk of approximately 1.71–4.07 percent compared with reusable flexible bronchoscopes. Lastly, the applicant again cited the meta study by Barron and Kennedy³⁰ referencing the findings from Ofstead et al.³¹, the review by Mouritsen et al., and the Emergency Care Research Institute’s (ECRI’s) report.³² Of note, ECRI highlighted the recontamination of flexible endoscopes due to mishandling or improper storage as one of the top 10 health technology hazards.

Based on the evidence submitted with the application, we note the following concerns:

We are concerned about whether the Ambu® aScope™ 5 Broncho HD can be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement. Four of the studies the

²⁷ Travis, H. S., Russell, R. V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention*, 17571774231158203.

²⁸ *Id.*

²⁹ Mouritsen, J. M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdady, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia*, 75(4), 529-540.

³⁰ Barron, S. P., & Kennedy, M. P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy?. *Advances in therapy*, 37(11), 4538–4548. <https://doi.org/10.1007/s12325-020-01495-8>

³¹ Ofstead CL, Quick MR, Wetzler HP, et al. Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. *Chest*. 2018;154(5):1024–34.

³² ECRI. Top 10 health technology hazards. Executive brief. Pennsylvania: ECRI Institute, Health devices; 2019. p. 2019.

applicant submitted, Châteauevieux et al.,³³ Barron and Kennedy,³⁴ Kurman et al.,³⁵ and Ofstead et al.,³⁶ investigated and provided data on the applicant's earlier models of the device, but did not provide comparisons to the nominated device. In addition, we note that the studies provided also did not compare the nominated device to an appropriate comparator such as a single-use bronchoscope from a different manufacturer or a standard reusable bronchoscope in a clinical setting. In addition, we note that the applicant's self-sponsored study by Kurman, et al.³⁷ was conducted in the laboratory (i.e., on cadaver, benchtop fixturing, and artificial plastic lung) and not in the clinical setting. 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.

Furthermore, we note that the Châteauevieux et al.³⁸ and Barron and Kennedy³⁹ studies suggested limiting the use of single-use bronchoscope device to specific situations (i.e., after hours or emergency), immunocompromised patients, and in rare cases of preventing prior contamination in the inpatient setting. We believe that further investigation with comparators in these specified cases would be particularly helpful to determine whether the device demonstrates

³³ Châteauevieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice*, 24(3), 528–535. <https://doi.org/10.1111/jep.12904>

³⁴ Barron, S. P., & Kennedy, M. P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy?. *Advances in therapy*, 37(11), 4538–4548. <https://doi.org/10.1007/s12325-020-01495-8>

³⁵ Kurman, J., Wagh, A., Benn, B., & Islam, S., (2023). A Comparison of Single-use Bronchoscopes and Reusable Bronchoscopes for Interventional Pulmonology Applications. Confidential. Ambu Inc., funded evaluation and testing.

³⁶ Ofstead, C. L., Hopkins, K. M., Eiland, J. E., & Wetzler, H. P. Managing Bronchoscope Quality and Cost: Results of a Real-world Study. <https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf>

³⁷ Kurman, J., Wagh, A., Benn, B., & Islam, S., (2023). A Comparison of Single-use Bronchoscopes and Reusable Bronchoscopes for Interventional Pulmonology Applications. Confidential. Ambu Inc., funded evaluation and testing.

³⁸ Châteauevieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice*, 24(3), 528–535. <https://doi.org/10.1111/jep.12904>

³⁹ Barron, S. P., & Kennedy, M. P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy?. *Advances in therapy*, 37(11), 4538–4548. <https://doi.org/10.1007/s12325-020-01495-8>

substantial clinical improvements over currently available treatments in the clinical setting where it is most likely to be used.

We note concern that the application and all the articles submitted as evidence of substantial clinical improvement discuss potential adverse events from reusable bronchoscope procedures, but do not directly show any clinical improvement that results from the use of the Ambu® aScope™ 5 Broncho HD. We note that Shimizu et al.,⁴⁰ Travis et al.,⁴¹ Barron and Kennedy,⁴² and Ofstead et al.⁴³ provided information about the risks associated with reprocessing reusable devices and reported mixed results.

We also note that the 2015 FDA safety notice⁴⁴ provided preliminary information regarding infections associated with the use of reprocessed flexible bronchoscopes, but did not discuss or recommend the use of disposable, single-use devices in the notice. Furthermore, we note the following concerns about studies on the prevalence of infection due to incomplete/inadequate reprocessing of reusable bronchoscopes. The studies authored by Châteauevieux et al.,⁴⁵ Shimizu et al.,⁴⁶ Travis et al.,⁴⁷ and Mouritsen et al.⁴⁸ have small sample

⁴⁰ Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. *Nagoya journal of medical science*, 82(1), 69–77. <https://doi.org/10.18999/nagjms.82.1.69>

⁴¹ Travis, H. S., Russell, R. V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention*, 17571774231158203.

⁴² Barron, S. P., & Kennedy, M. P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy?. *Advances in therapy*, 37(11), 4538–4548. <https://doi.org/10.1007/s12325-020-01495-8>

⁴³ Ofstead, C. L., Hopkins, K. M., Eiland, J. E., & Wetzler, H. P. Managing Bronchoscope Quality and Cost: Results of a Real-world Study. <https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf>

⁴⁴ FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. <https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647>

⁴⁵ Châteauevieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice*, 24(3), 528–535. <https://doi.org/10.1111/jep.12904>

⁴⁶ Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. *Nagoya journal of medical science*, 82(1), 69–77. <https://doi.org/10.18999/nagjms.82.1.69>

⁴⁷ Travis, H. S., Russell, R. V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention*, 17571774231158203.

⁴⁸ Mouritsen, J. M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia*, 75(4), 529-540.

sizes. Furthermore, the Barron and Kennedy,⁴⁹ Travis et al.,⁵⁰ and Mouritsen et al.⁵¹ studies used different study designs and sampling methodologies, or were performed in various clinical settings other than outpatient, which may affect the quality and reliability of the data provided in support of the applicant's assertions. 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 nominated device. We are seeking comments on the prevalence of infection due to incomplete/inadequate processing for bronchoscopes in the U.S. and whether single-use bronchoscopes reduce the infection rate in patients to identify the extent of the problem with existing technologies.

The applicant provided evidence which seemed to rely on indirect inferences from other sources of data. We question the relevance of the 2015 FDA safety notice⁵² to the nominated device because as stated above, the guidance applies to reprocessed flexible bronchoscopes broadly, but not to disposable, single-use devices comparable to the nominated device. We are concerned that many of the applicant's substantial clinical improvement claims rely on an assumption that inadequate reprocessing of reusable bronchoscopes is positively correlated with heightened risk of infection, providing studies with small sample sizes and other limitations as described above as their only support. We note that the applicant provided background information on the established reprocessing guidelines⁵³ for reusable devices; however, the existence of reprocessing guidelines does not provide evidence on the prevalence of infection rates, establish a relationship between infection risk and reprocessing procedures, or substantiate

⁴⁹ Barron, S. P., & Kennedy, M. P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy?. *Advances in therapy*, 37(11), 4538–4548. <https://doi.org/10.1007/s12325-020-01495-8>

⁵⁰ Travis, H. S., Russell, R. V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention*, 17571774231158203.

⁵¹ Mouritsen, J. M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdady, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia*, 75(4), 529-540.

⁵² FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. <https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647>

⁵³ FDA Guidance March 17 2015 “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff”

that single-use disposable scopes, or the nominated device specifically, would be a substantial clinical improvement over currently available treatments.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the substantial clinical improvement 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 be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Ambu® aScope™ 5 Broncho HD would be reported with HCPCS codes listed in Table 31.

TABLE 31: HCPCS CODES REPORTED WITH THE AMBU® ASCOPE™ 5 BRONCHO HD

HCPCS Code	Long Descriptor	SI	APC
31615	Tracheobronchoscopy through established tracheostomy incision	T	5162
31622	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing	J1	5153
31623	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with brushing or protected brushings	J1	5153
31624	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with bronchial alveolar lavage	J1	5153
31625	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with bronchial or endobronchial biopsy(s), single or multiple sites	J1	5153
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of fiducial markers, single or multiple	J1	5155
31628	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial lung biopsy(s), single lobe	J1	5154
31629	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial needle aspiration biopsy(s). Trachea, main stem and/or lobar bronchus(i)	J1	5154
31630	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with tracheal/bronchial dilation or closed reduction of fracture	J1	5154
31631	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of tracheal stent(s) (includes tracheal/bronchial dilation as required)	J1	5155
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (e.g., fibrin glue), if performed	J1	5155
31635	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of foreign body	J1	5153

HCPCS Code	Long Descriptor	SI	APC
31636	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of bronchial stent(s)(includes tracheal/bronchial dilation as required), initial bronchus	J1	5155
31638	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with revision of tracheal or bronchial stent inserted at previous session (includes tracheal/bronchial dilation as required)	J1	5155
31640	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with excision of tumor	J1	5154
31641	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with destruction of tumor or relief of stenosis by any method other than excision (e.g., laser therapy, cryotherapy)	J1	5154
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of catheter(s) for intracavitary radioelement application	J1	5153
31645	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with therapeutic aspiration of tracheobronchial tree, initial	J1	5153
31646	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with therapeutic aspiration of tracheobronchial tree, subsequent, same hospital stay	T	5152
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe	J1	5155
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of bronchial valve(s), initial lobe	J1	5154
31652	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration(s)/biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structures	J1	5154
31653	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration(s)/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stations or structures	J1	5154
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	J1	5155
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	J1	5155
31785	Excision of tracheal tumor or carcinoma; cervical	J1	5165
32400	Biopsy, pleura, percutaneous needle	J1	5072
32550	Insertion of indwelling tunneled pleural catheter with cuff	J1	5341
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	J1	5182
32552	Removal of indwelling tunneled pleural catheter with cuff	Q2	5181
32554	Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance	T	5181

HCPCS Code	Long Descriptor	SI	APC
31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with computer-assisted, image-guided navigation	**	N/A
31632	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial lung biopsy(s), each additional lobe (list separately in addition to code for primary procedure)	**	N/A
31633	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial needle aspiration biopsy(s), each additional lobe (list separately in addition to code for primary procedure)	**	N/A
31637	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, each additional major bronchus stented (list separately in addition to code for primary procedure)	**	N/A
31649	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure)	**	N/A
31654	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s)	**	N/A
31780	Excision tracheal stenosis and anastomosis; cervical	**	N/A
31781	Excision tracheal stenosis and anastomosis; cervicothoracic	**	N/A
31786	Excision of tracheal tumor or carcinoma; thoracic	**	N/A
32200	Pneumonostomy, with open drainage of abscess or cyst	**	N/A
32674	Thoracoscopy, surgical; with mediastinal and regional lymphadenectomy (List separately in addition to code for primary procedure)	**	N/A
32815	Open closure of major bronchial fistula	**	N/A

** Denotes a HCPCS code that was not evaluated for the cost criterion because the HCPCS code was not included in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPPS Addendum (87 FR 2060).

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 with comment period (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. For our calculations, we used APC 5152, which had a CY 2022 payment rate of \$383.33 at the time the application was received. 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 HCPCS code 31646 identified by the applicant had a device offset amount of \$0.00 at the time

the application was received. Accordingly, we are evaluating the cost significance requirements using \$0.00 as the appropriate device offset amount. According to the applicant, the cost of the Ambu® aScope™ 5 Broncho HD 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 estimated average reasonable cost of \$799.00 for the Ambu® aScope™ 5 Broncho HD is 208.44 percent of the applicable APC payment amount for the service related to the category of devices of \$383.33 ($(\$799.00/\$383.33) \times 100 = 208.44$ percent). Therefore, we believe the Ambu® aScope™ 5 Broncho HD 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). Given that there are no device-related costs in the APC payment amount, and the Ambu® aScope™ 5 Broncho HD has an estimated average reasonable cost of \$799.00, we believe that the Ambu® aScope™ 5 Broncho HD 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 the Ambu® aScope™ 5 Broncho HD and the portion of the APC payment amount for the device of \$0.00 exceeds the APC payment amount for the related service of \$799.00 by 208.44 percent ($((\$799.00 - \$0.00)/\$383.33) \times 100 = 208.44$ percent). Therefore, we believe that the Ambu® aScope™ 5 Broncho HD meets the third cost significance requirement.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(b) Praxis Medical CytoCore

Praxis Medical, LLC submitted an application for a new device category for transitional pass-through payment status for Praxis Medical CytoCore (CytoCore) for CY 2024. Per the applicant, CytoCore is a single-use disposable biopsy instrument. Per the applicant, at the time of biopsy, the motorized CytoCore device contains gears and an internal motor that spins a minimally invasive needle to increase cellular yields in fewer passes. The applicant further explained that CytoCore is vacuum-assisted and can easily be operated using one hand. According to the applicant, the primary use is for biopsy of any suspicious thyroid nodule.

The applicant stated that the CytoCore Biopsy Instrument device package includes: (1) five CytoCore Biopsy Instruments, each containing three luer adapters in a sterile pouch, a syringe-holding device, equipped with a scissor-slide mechanism for drawing back the syringe plunger to create suction, an internal motor that rotates a needle, and an internal alkaline type battery; (2) five 5-mL syringes; and (3) instructions for use (IFU) booklets. Per the applicant, the CytoCore is compatible with disposable needles of 22-to-25-gauge and 4-to-10-cm length that are intended for soft tissue biopsy procedures (needles are not included in the device package). The applicant further explained that only the CytoCore luer adapters and syringes provided by Praxis can be used on CytoCore and that the CytoCore luer adapters can only be used with the CytoCore Biopsy Instrument.

Per the applicant, the operator of CytoCore can direct the needle and draw back the plunger with only one hand, thereby diminishing the need to move the needle in an in-and-out motion to harvest cells. As with other types of biopsies, the sample collected can help make a diagnosis or rule out conditions such as cancer. The applicant claimed that CytoCore enables the physician to collect more cellular material in fewer passes and reduce the number of repeat

biopsies and surgeries related to inadequate cellular samples using the standard fine needle aspiration (FNA) biopsy. According to the applicant, CytoCore is designed to collect enough DNA for pathology to definitively rule in or out cancer and inform subsequent treatment at the time of the first biopsy. Per the applicant, studies report nondiagnostic rates for thyroid biopsies to be as high as 30 to 50 percent using standard FNA biopsy.

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 31, 2020, the applicant received 510(k) clearance from FDA for CytoCore for use as a device to hold a syringe for performing a biopsy of an identified mass with one hand. We received the application for a new device category for transitional pass-through payment status for CytoCore on August 31, 2022, which is within 3 years from the date of the initial FDA marketing authorization.

We are inviting public comments on whether CytoCore meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the applicant did not assert whether CytoCore is integral to the service provided. According to the applicant, CytoCore is used for one patient only. Per the applicant, CytoCore comes into contact with human tissue and is surgically inserted via the syringe attached to the motorized CytoCore device. Per the applicant, CytoCore is used with a 22-to-25-gauge standard fine needle (not included in the device package), which is inserted into human tissue to collect cellular samples. The applicant stated that the fine needle is attached to CytoCore, inserted into the nodule, and cellular material is collected through the needle into the syringe. The applicant further explained that the cellular material is visible in the hub of the needle or the luer adapter. However, we note that the motorized CytoCore device itself is not 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). Further, we note that according to the FDA 510(k) Summary and Indication for Use, CytoCore is

a device to hold a syringe for performing a biopsy of an identified mass with one hand and that the device never comes in contact with the patient. With respect to the exclusion criterion at § 419.66(b)(4), the applicant did not address whether CytoCore is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets. The applicant also did not address whether CytoCore is a supply or material furnished incident to a service. However, in the CY 2000 OPPS interim final rule with comment period (65 FR 67798, 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 surgically inserted or implanted via a natural or surgically created orifice, or inserted or implanted via 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. In the CY 2006 OPPS final rule with comment period (70 FR 68516, 70 FR 68629 and 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 are inviting public comments on whether CytoCore meets the exclusion criterion at § 419.66(b).

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 CytoCore as a motorized, single-use disposable biopsy instrument that contains gears and an internal motor that spins a minimally invasive needle during biopsy to increase cellular yields in fewer passes. Per the applicant, no previous device categories for pass-through payment have encompassed the device.

We have not identified an existing pass-through payment category that describes CytoCore. We are inviting public comment on whether CytoCore 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 the use of CytoCore results in substantial clinical improvement over existing technologies by: (1) reducing tissue trauma, bleeding; (2) increasing cellular harvest; (3) reducing passes required, clinical invasiveness; and

(4) reducing nondiagnostic biopsy results follow up. The applicant provided one article and one conference poster in support of these claims.

In support of the claims that using CytoCore reduced tissue trauma and/or bleeding, and that it increased cellular harvest, the applicant submitted a conference poster of a study performed to evaluate the consistency and diagnostic quality of cellular material obtained with a 22-to-25-gauge fine needle using CytoCore as compared to FNA without using CytoCore and to traditional core biopsy. In the study⁵⁴, samples utilizing FNA syringe (n=14) and core biopsy (n=12) were obtained and compared to biopsy samples obtained with CytoCore. The samples were analyzed in pathology separately for diagnostic adequacy. Using the Fisher exact test statistic, the study authors found no significant difference ($p < .05$) between FNA and CytoCore. Similarly, using the Fisher exact test statistic, the study authors found no significant difference ($p < .05$) between core biopsy and CytoCore. Specifically, the study authors reported that CytoCore was successful in obtaining a diagnosis in 78 percent of biopsies, which was unchanged from FNA; however, the authors reported that the cellular yield of samples obtained with CytoCore were superior to FNA biopsy samples. The study authors also reported that when compared to traditional core samples, CytoCore specimens were similar to traditional core biopsy in yielding a diagnosis, with CytoCore yielding a diagnosis 99 percent of the time and core biopsy 100 percent of the time. The authors concluded that CytoCore provides a reliably high amount of cellular material with significantly less tissue damage, which is especially useful for vascular tissue such as lymph nodes and breast tissue.

In support of the claims that using CytoCore reduces the number of passes required and the clinical invasiveness of a thyroid biopsy, and that it reduces nondiagnostic biopsy results and follow-up, the applicant provided an unpublished article that described the performance of

⁵⁴ Rey, E. Huber, J. Risam, R. Shahzad, R. Gonzalez, A. Acosta, A. (2022, April). Making the Diagnosis: Increasing the Cellular Yield of Pathology Samples Through a Motorized Rotating, Aspirating Device. Poster presented at the Daniel Manganaro Memorial 2022 Annual Scientific Poster Symposium, Elmira, NY. Retrieved from https://www.arnohealthgme.org/_files/ugd/c76666_083113203de449a8a6054cf7b81aac82.pdf

CytoCore on the number of passes required to obtain an adequate sample and diagnostic biopsy in comparison to using traditional ultrasound-guided FNA (US-FNA) biopsy rates reported in the literature.⁵⁵ The study authors performed a retrospective chart review of consecutive US-FNA thyroid biopsies performed with CytoCore between August 2020 and March 2021. The chart records included ultrasound and pathology data points, including exam code, name of operator, biopsy tool, number of passes required for adequacy, and pathological diagnosis using the Bethesda System for Reporting Thyroid Cytopathology. The authors stated that the study included a total of 100 FNA biopsies from 69 patients, and a total of nine different operators performed these biopsies. At the time of biopsy, most (88 percent) of the patients were women, and, on average, were 65 years of age at the time of biopsy. In addition, the study authors stated that the number of nodules biopsied ranged from one to three on average, but most patients (65 percent) had only one nodule biopsied. The operators' years of experience ranged from 4 to 39 years of practice, with most (76 percent) performed by an operator with 5 years of practice experience (the study authors noted that this operator was never the sole operator for the procedure). In addition, a cytotechnologist was present for all procedures and rapid on-site evaluation (ROSE) was done on the smears to determine if the sample met the criteria for adequacy. All biopsies were performed using a 25 gauge, 1 ½ inch BD™ needle attached to CytoCore. The Bethesda System classification categories include Category I (nondiagnostic), Category II (benign), Category III (atypia), Category IV (suspicious for neoplasm), Category V (suspicious for malignancy), and Category VI (malignant). The study authors defined determinant diagnoses as the sum total of biopsies classified in Categories II (benign) and IV (malignant). The authors compared their study results to 20 published articles with publication dates between 2012 and 2022 that reported results for thyroid US-FNA biopsy. The study used

⁵⁵ Authors unknown. Motorized rotating fine needle biopsy device reduces number of passes needed for cytological adequacy and improves diagnostic accuracy, not published; uses a retrospective study type

descriptive statistics (averages and frequencies) and a single sample proportion test to compare the adequacy of the biopsy sample for each pass and the percentage of nondiagnostic, indeterminant, and determinant diagnosis classifications to conventional US-FNA techniques results reported in literature. According to the study authors, the number of passes required to attain an adequate sample using CytoCore ranged from one to four and was statistically significantly lower than using conventional FNA technique as reported in the 20 articles. Specifically, to obtain an adequate sample of a thyroid nodule using CytoCore compared to the conventional FNA technique, 65 percent required only one pass compared to 36 percent, 93 percent required two or fewer passes compared to 60 percent, 97 percent required three or fewer passes compared to 72 percent, and 100 percent required four or fewer passes compared to 75 percent, respectively. The authors stated that restricting the analyses to only one nodule per patient did not result in a change in significance. In addition, the authors stated that for their study group, pathology was able to make a determinant diagnosis (Category II and Category VI) for 91 percent of the samples. Specifically, of the 100 samples included in the study, 3 percent were nondiagnostic (Category I), 88 percent were benign (Category II), 4 percent were atypia (Category III), 2 percent were suspicious for neoplasm (Category IV), 0 percent were suspicious for malignancy (Category V), and 3 percent were malignant (Category VI). According to the authors, this was significantly better than the median nondiagnostic (Category I) and determinant diagnosis rates reported in the literature, 10% ($p=0.02$) and 65% ($p<0.001$), respectively. The rate of indeterminant classifications (Category III) was also lower in their study population but was not statistically significant ($p=0.17$). The study authors concluded that if their study sample of 100 thyroid biopsies using CytoCore had the same median results as FNA thyroid biopsies reported in the literature, an additional 11 patients would have a biopsy classified as Category I or Category III (nondiagnostic and atypia) and would have required at least one more US-FNA to make a diagnosis, and an additional four patients would have a biopsy classified as Category IV (suspicious neoplasm) and would have required a partial lobectomy to determine malignancy.

The study authors further concluded that in addition to the higher cost associated with additional biopsies and/or surgical intervention, there may be a greater impact on a patient's quality of life due to potential surgical complications, vocal cord palsy (VCP), lifetime hormonal replacement, and cosmetic scarring. Furthermore, the authors concluded that CytoCore resulted in more than a three-fold decrease in nondiagnostic (Category III) biopsies and significant increase in definitive diagnoses. The management of an initially indeterminant biopsy can range from a repeat US-FNA (Categories I and III) to lobectomy or thyroidectomy (Categories IV and V). The actual risk of malignancy can be as low as 1 percent to 15 percent for Categories I and III, but as high as 75 percent for Category V. Therefore, the authors concluded that initially indeterminant diagnosis can result in unnecessary procedures and increased costs for the healthcare system and patients for false positives, but for true malignancies, indeterminant biopsies could also delay diagnosis and treatment.

We note that the nominated device was determined to be substantially equivalent to a legally marketed device, the TAO Aspirator and Plastic Finger. The FDA 510(k) summary indicated that the devices share similar technological characteristics such as a device to hold a syringe for performing fine needle aspiration, a needle is connected to the syringe and inserted into a lesion, and a syringe plunger is retracted to create suction. The FDA 510(k) summary indicated that CytoCore differs in that a battery powers a motor that rotates the needle. In addition, the applicant provided a comparison of certain devices that it believed are most closely related or similar to CytoCore. Specifically, the applicant identified two devices with related HCPCS procedure codes that it believes are most closely related to CytoCore: (1) HCPCS code 10005 (fine needle aspiration biopsy, including ultrasound guidance, first lesion) and the Benton [sic] Dickinson™ (BDTM) device; and (2) HCPCS code 60100 (biopsy thyroid, percutaneous core needle) and the BioPince device. According to the applicant, the BDTM is a single-use 25-gauge 1-inch basic needle with no syringe and is the standard fine needle used most often in thyroid biopsy procedures. In contrast, the applicant stated that CytoCore is a motorized vacuum

assisted device that applies vacuum during biopsy and rotates the [fine] needle. Per the applicant, BioPince is a full core firing biopsy device with a 16-to-18-gauge needle, and it is not recommended for head/neck biopsies due to sensitive structures in the head/neck area (e.g., nerves, carotid, vessels, trachea). The applicant further explained that medical society guidelines, including those of the American Thyroid Association (ATA), recommend fine needle aspiration for biopsy of thyroid nodules. In contrast, the applicant stated that CytoCore is designed to obtain core comparable specimens, but using the safe fine needle (25-to-22-gauge), obviating the need for this more invasive procedure for thyroid biopsies.

Based on the evidence submitted, we note the following concerns: The first study is an undated conference poster presentation and it is not clear whether it has been submitted for publication in a peer-reviewed journal. We also have concerns with the generalizability and validity of the findings. The authors did not report their sampling methodology used to obtain the study samples, calling into question the validity of the comparison groups and any inferences made. In addition, the authors did not describe how they addressed important confounding variables that may affect the quality of the biopsy specimen (e.g., ultrasound guided, nature, and location of nodule biopsied), calling into question whether the FNA and core biopsy samples can validly be compared to CytoCore biopsy samples. The study used small sample sizes, a sample of 14 biopsies for the comparison to FNA and a sample of 12 biopsies for the comparison to core biopsies, within one radiology department location, limiting the generalizability of the findings. In addition, it is not clear that the study is limited to thyroid biopsies and the authors did not report any information on patient characteristics (e.g., age or sex) or the nature of the nodule. Furthermore, the study authors reported that there was no significant difference in obtaining a diagnosis between CytoCore and FNA, and CytoCore and core biopsy, which calls into question any claim of the superiority (versus equivalency) of the CytoCore biopsy samples. The study authors reported that the cellular yield of samples obtained with CytoCore were overall superior to FNA biopsy samples, but the metrics to evaluate this and whether this difference was

statistically significant were not reported. We note that we are unable to determine the validity of this finding. We also note that, as presented in the poster, the study authors presented two different rates of diagnosis when using CytoCore with no explanation. Specifically, the study authors stated that CytoCore was able to obtain a successful diagnosis in 78 percent of biopsies when compared to FNA and in 99 percent of biopsies when compared to core biopsy. Additionally, the purpose of the study did not include an evaluation of whether CytoCore reduced trauma or increased cellular harvest, but rather sought to evaluate the consistency and diagnostic quality of cellular material obtained with CytoCore using a 22-to-25-gauge fine needle compared to traditional core biopsy. The study authors did not present metrics that might be used to evaluate the amount of trauma as a result of the biopsy procedures (e.g., bleeding or bruising after the biopsy procedures). We note that we are unable to determine the validity of this finding (i.e., using CytoCore compared to core biopsy reduces tissue damage).

The second document submitted with the application as evidence of substantial clinical improvement is an article that is undated and does not list the authors or location of the study. The applicant did not provide any further details regarding the status of the article. The study authors did not use a direct comparison group; rather, they compared their study results to those found in published literature. The paper did not describe the approach used to select the articles used to compare the performance of CytoCore and there is no indication that a systematic literature review was conducted. We note that we are not able to determine if the literature reported rates included in the study are representative of FNA thyroid biopsy results. Similarly, beyond selecting articles that reported US-FNA thyroid biopsies, the paper did not describe whether the study authors assessed the quality of the study designs in the selected literature. We note the paper did not control for confounding factors the study authors stated may impact the adequacy of a biopsy sample, including the skill and knowledge of the person performing the biopsy, the preparation of the specimens, and the nature of the nodule (e.g., size, composition, vascularity). Similarly, we note the study authors did not account for other important potential

confounders including the skill and knowledge of the pathologist and having a cytotechnologist present to perform ROSE on the specimens during the biopsy.

We further note that none of the evidence submitted by the applicant provides conclusive evidence that the use of CytoCore reduces tissue trauma and/or bleeding, increases cellular yield, reduces the number of passes required or clinical invasiveness, or reduces the number of nondiagnostic biopsy results or follow-up. 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 CytoCore demonstrates substantial clinical improvement over existing technologies.

Finally, we are concerned that CytoCore may not demonstrate that it substantially improves the diagnosis or treatment of an illness when compared to the benefits of other available treatments. CytoCore was determined to be substantially equivalent to a legally marketed device, the TAO Aspirator and Plastic Finger, which received 510(k) clearance on December 9, 1997. The FDA 510(k) summary for CytoCore indicated that the devices share similar technological characteristics. In fact, the FDA 510(k) summary indicated that CytoCore differs only in that a battery powers a motor that rotates the needle, while the TAO Aspirator is moved manually in an in-and-out motion. In addition, while the applicant distinguishes CytoCore from a comparator device, BioPince, it is our understanding that BioPince is a large gauge full core firing biopsy device that is not recommended for use in the head/neck, the anatomic region for which CytoCore has primary use, according to the application. Therefore it remains unclear how such a comparison with BioPince supports the argument of substantial clinical improvement.

We are inviting public comments on whether CytoCore meets the substantial clinical improvement 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 CytoCore would be reported with HCPCS codes in Table 32.

TABLE 32: HCPCS CODES REPORTED WITH CYTOCORE

HCPCS Code	Long Descriptor	SI	APC
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	T	5071
10006	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion (List separately in addition to code for primary procedure)	**	**
60100	Biopsy thyroid, percutaneous core needle	T	5071

** Denotes a HCPCS code that was not evaluated for the cost criterion because the HCPCS code was not included in Addendum P to the CY 2022 OPSS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPSS Addendum (87 FR 2060)..

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 with comment period (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. For our calculations, we used APC 5071, which had a CY 2022 payment rate of \$635.54 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 10005 had a device offset amount of \$0.89 at the time the application was received.⁵⁶ According to the applicant, the cost of the CytoCore is \$175.00.

⁵⁶ We note that the applicant selected a value of \$32.16 for the device offset amount. However, the value selected is inconsistent with the device offset amount related to HCPCS 10005 in APC 5071 found in Addendum P to the CY 2022 OPSS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPSS Addendum

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 estimated average reasonable cost of \$175.00 for CytoCore is 27.54 percent of the applicable APC payment amount for the service related to the category of devices of \$635.54 ($(\$175.00/\$635.54) \times 100 = 27.54$ percent). Therefore, we believe CytoCore 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 \$175.00 for CytoCore is 19,662.92 percent of the cost of the device-related portion of the APC payment amount for the related service of \$0.89 ($(\$175.00/\$0.89) \times 100 = 19,662.92$ percent). Therefore, we believe that CytoCore 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 \$175.00 for CytoCore and the portion of the APC payment amount for the device of \$0.89 is 27.40 percent of the APC payment amount for the related service of \$635.54 or ($((\$175.00-\$0.89)/\$635.54) \times 100 = 27.40$ percent). Therefore, we believe that CytoCore meets the third cost significance requirement.

(87 FR 2060). We selected the value of \$0.89, which we believe is the accurate value. Based on our initial assessment for this proposed rule, using the device offset amount of \$0.89 would result in CytoCore meeting the cost significance requirement.

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

(c) EchoTip®

Cook Medical submitted an application for a new device category for transitional pass-through payment status for the EchoTip® Insight Portosystemic Pressure Gradient Measurement System® (EchoTip®) for CY 2024. According to the applicant, EchoTip® is used in the diagnosis and management of patient populations with chronic liver diseases (CLDs), and especially with non-alcoholic fatty liver Disease (NAFLD). The applicant stated that EchoTip® directly measures pressures in the hepatic and portal venous vasculatures and is used in conjunction with an ultrasound endoscope. The applicant provided that a physician measures the portosystemic pressure gradient via endoscopic ultrasound guidance, a curvilinear array echoendoscope is advanced to the stomach, and the portal and hepatic veins are visualized under ultrasound guidance. A 25-gauge needle (which is prepared prior to the procedure by attaching it to connection tubing and a disposable transducer) is advanced through the echoendoscope which then punctures the hepatic vein through the liver parenchyma, and a pressure measurement is obtained. Per the applicant, a total of three measurements are obtained, after which the needle is retracted in the scope and the echoendoscope is repositioned for portal vein access. The needle is then advanced to the portal vein where another set of three pressure measurements is obtained. The portosystemic pressure gradient is calculated by determining the difference between the two averaged measurements.

According to the applicant, EchoTip® is a single-use, disposable device comprised of the EchoTip® Insight Needle, a connecting tube, and a Compass CT transducer. EchoTip® is supplied with a 10 ml syringe. Once assembled, EchoTip® is used with an ultrasound endoscope and directly measures pressures in the hepatic and portal venous vasculatures. The EchoTip® Insight Needle is stainless steel, has a handle and protective outer sheath, and attaches to the

accessory channel of the endoscope. The polyethylene connecting tube consists of a 90 cm tube, a female luer fitting, a male luer fitting, and a stopcock. The connecting tube is used to attach the transducer to the needle handle. The stopcock is used to aid priming of the assembled components. The Compass CT transducer is a self-calibrating disposable pressure transducer with integrated digital display. EchoTip[®] is intended for direct measurement and monitoring of physiological pressure, including during the infusion of fluids and therapeutic and diagnostic agents.

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 November 20, 2019, FDA granted De Novo classification for EchoTip[®] as a device to directly measure pressures in the hepatic and portal venous vasculatures and is used in conjunction with an ultrasound endoscope. We received the application for a new device category for transitional pass-through payment status for the EchoTip[®] on June 29, 2022, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comment on whether the EchoTip[®] meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the applicant stated that EchoTip[®] is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. According to the applicant, the hepatic vein and portal vein are punctured through the liver parenchyma to obtain pressure measurements.

We are inviting public comment on whether EchoTip[®] meets the integral part of the service criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant claimed that EchoTip[®] meets the device eligibility requirements because it is not equipment, 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 comment on whether EchoTip® 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 EchoTip® as the only device authorized by the FDA with an indication to directly access and measure pressure in the hepatic and portal venous vasculatures in conjunction with an ultrasound endoscope. Per the applicant, FDA established there is no recognized predicate product, or other similar approved device with a similar mechanism of action. Per the applicant, no previous device categories for pass-through payment have encompassed EchoTip® and there are no similar device categories. Upon review, it does not appear that there are any existing pass-through payment categories that might apply to EchoTip®.

We are inviting public comment on whether EchoTip® 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 EchoTip® represents a substantial clinical improvement over existing technologies in the diagnosis and management of chronic liver disease because: (1) Endoscopic ultra-sound-guided direct portal-systemic pressure gradient measurement (EUS-PPG)-guided measurement is clinically safer and more accurate than the current standard transjugular endovascular indirect measurement, referred to as the hepatic venous pressure gradient (HVPG); (2) EUS-PPG is technically feasible and superior to HVPG; (3) EUS-PPG has benefits in non-cirrhotic patients; and (4) EUS-PPG has utility in the evaluation of ESRD patients and kidney transplant candidacy. The applicant provided four articles specifically for the purpose of addressing the substantial clinical improvement criterion claims. The applicant also included one background article that discussed social determinants of health and disparities in liver disease.⁵⁷

In support of the first claim, the applicant submitted an article on a prospective, single-armed, single-academic center study.⁵⁸ Patients with suspected liver disease or cirrhosis were enrolled prospectively from 2020 to 2021. EUS-PPG was measured by calculating the difference between the mean portal pressure and the mean hepatic vein pressure. PH was defined as PPG >5 mm Hg and clinically significant PH as PPG <10 mm Hg. The primary outcomes were procedural technical success rate and correlation of EUS-PPG with fibrosis stage obtained from concurrent EUS-guided liver biopsy sampling and the correlation of EUS-PPG with patients' imaging, clinical, and laboratory findings. The secondary outcome was occurrence of procedural adverse events. EUS-PPG measurement was successful in 23 patients, leading to a technical success rate of 96 percent. The authors reported that there was no statistically significant correlation between the fibrosis stage on histology and measured PPG (P=.559). According to the authors, this did not change after excluding three patients without established chronic liver disease from the

⁵⁷ Kardashian, A., Wilder, J., Terrault, N. Price, J. (2021). Addressing Social Determinants of Liver Disease During the COVID-19 Pandemic and Beyond: A Call to Action. *Hepatology* 73 (2): 811-820.

⁵⁸ Hajifathalian, K., Westerveld, D., Kaplan, A. et. al. (2022). Simultaneous EUS-guided portosystemic pressure measurement and liver biopsy sampling correlate with clinically meaningful outcomes. *Gastrointestinal Endoscopy* 95(4): 703-710

analysis. The authors reported that one patient experienced a mild adverse event with postprocedural abdominal pain resulting in an emergency department visit. The authors also reported that five patients (28 percent) received oral acetaminophen in the post anesthesia care unit for mild abdominal pain after the procedure, which resolved in all cases before discharge without the need for further pharmacotherapy.

In support of its second claim, the applicant submitted a single-center retrospective study on patients with various CLDs undergoing EUS-PPG and EUS-guided liver biopsy (EUS-bx) to assess correlation with histological hepatic fibrosis stage and various clinical, laboratory, endoscopic and imaging variables indicative of advanced liver disease.⁵⁹ Cases with EUS-PPG were identified at the University of California Irvine, a tertiary endoscopy center, between January 2014 and March 2020. Three different ways of evaluating the EUS-PPG outcomes were assessed: (1) success rate of the EUS-PPG measurement; (2) performance; and (3) safety profile. The primary outcome evaluated was the association between EUS-PPG and the presence of histologic liver fibrosis, stage ≥ 3 . EUS-PPG procedures were successfully completed in all 64 cases. On multivariate analysis, EUS-PPG ≥ 5 mmHg was significantly associated with fibrosis stage ≥ 3 on EUG-liver biopsy (LR 27.0, 95% CI = 1.653–360.597, $p = 0.004$), independent from C-cirrhosis, clinical portal hypertension, thrombocytopenia, splenomegaly, aspartate aminotransferase to platelet ratio index score > 2 , and fibrosis-4 score > 3.25 . There were six complications in total, including abdominal pain ($n = 3$) and sore throat ($n = 3$). The authors reported that there were no subjects who had post-EUS-PPG emergency room (ER) visits or hospital admissions.

In support of its third claim, the applicant submitted a review of endoscopic ultrasound guided interventions. The article⁶⁰ discussed the diagnosis and treatment of portal hypertension

⁵⁹ Choi, A., Chang, K., Samaransena, J. et. al. (2022). Endoscopic Ultrasound-Guided Porto-systemic Pressure Gradient Measurement Correlates with Histological Hepatic Fibrosis. *Digestive Diseases and Sciences*. <https://doi.org/10.1007/s10620-022-07418-7>

⁶⁰ Rudnick, S., Conway, J., Russo, M. (2021). Current state of endohepatology: Diagnosis and treatment of portal hypertension and its complications with endoscopic ultrasound. *World Journal of Hepatology* 13 (8): 887-895.

and treatment of gastric varices (GV) and compared liver biopsy, HVPG, and EUS-PPG. With respect to the utility of HVPG, the authors explained that in the absence of fibrosis/nodules (i.e., cirrhosis) the pressure equalizes throughout the interconnected sinusoidal network, and results in minimal gradient (i.e., normal; up to 4 mmHg). Thus, according to the authors, HVPG does not provide useful information regarding prehepatic or presinusoidal portal hypertension (PH) (i.e., non-cirrhotic causes of PH). In comparison, EUS-guided portal pressure gradient (PPG) measurements employ a direct sampling technique. Thus, the study authors found direct measurement of the portal vein pressure could be considered the gold standard because it is not an estimate of sinusoidal pressure as is HVPG. The difference in the mean measurement of these pressures is termed the PPG which is analogous to the HVPG, with the caveat that direct portal vein measurement also allows for the assessment of prehepatic/presinusoidal PH; a limitation of the transjugular approach. The study authors cited a study by Huang et al.⁶¹ that used a porcine animal model with a novel EUS-guided system which included a manometer attached to a 25-gauge fine needle aspiration (FNA) needle for directly measuring pressures in the hepatic and portal veins. The purpose of this animal study was to assess clinical feasibility and assess correlation with the standard of care: HVPG measurement through transjugular approach. The study authors further cited a pilot study involving 28 patients between the age of 18-75 years with a history of liver disease or suspected cirrhosis that underwent EUS-PPG measurements using the technique and equipment in the animal study. The portal vein and hepatic vein were targeted via a transgastric–transduodenal approach (inferior vena cava (IVC) was substituted for hepatic vein when not technically feasible). The technical success rate of EUS-PPG measurement was 100 percent without any adverse events. The study authors concluded that EUS-PPG measurement was a safe and feasible alternative to HVPG measurement.

⁶¹ Huang JY, Samarasena JB, Tsujino T, Chang KJ. EUS-guided portal pressure gradient measurement with a novel 25-gauge needle device versus standard transjugular approach: a comparison animal study. *Gastrointest Endosc* 2016; 84: 358-362 [PMID: 26945557 DOI: 10.1016/j.gie.2016.02.032]

In support of its fourth claim, the applicant submitted a letter in which the author described a retrospective, single-center study to determine feasibility, safety, and utility of EUS-PPG using EUS-liver biopsy as comparison in patients with end stage renal disease (ESRD) and suspected portal hypertension.⁶² According to the letter author, the purpose of the study was to investigate the use of EUS-PPG to assess pressure and the recommendation to decide between kidney transplant (KT) or combined liver KT. According to the letter author, the study suggested that new endoscopic and EUS findings were discovered with successful/reproducible EUS-PPG in 10 out of 11 (91 percent) subjects. The author stated there were no significant adverse events such as bleeding related to venous punctures, transfusions, or EUS-PPG-related hospitalizations. The author referenced conclusions from the study citing the need for further studies correlating EUS-PPG with wedged hepatic vein pressure gradient (WHVPG), assess patient experience, and analyze cost/benefit of one-stop versus piecemeal procedures. It is also noted in the letter that WHVPG may not always be feasible in ESRD patients due to catheter-related suprapubic thromboses. We note that this source did not include the original retrospective study, only a letter referencing it and highlighting its potential value to further research.

Based on the evidence submitted with the application, we note the following concerns: a lack of direct comparison of EUS-PPG with HVPG and non-invasive methods, a lack of consistent correlation with liver biopsy, the reliance on non-peer reviewed studies, and small sample sizes.

In the first two claims, the applicant asserted EUS-PPG is clinically safer and more accurate than HVPG and technically superior to HVPG. However, the applicant did not directly

⁶² Rubin, R, Mehta, M., Rossi, A., Joeslon, D., Shrestha, R. (2021). Letter to the Editor: Endoscopic ultrasound guided portal-systemic pressure gradient measurement to determine candidacy for kidney transplant alone versus combined liver kidney transplant in patients with advanced fibrosis or cirrhosis. *Transplant International* 2021 (34): 2903-2904.

compare EUS-PPG and HVPG. The Hajifathalian et. al. study⁶³, which supported the first claim, stated EUS-PPG offers an alternative and potentially superior methodology to measure PPG regardless of liver disease etiology, without showing evidence of a direct comparison between EUS-PPG and HVPG. The Choi study⁶⁴, in support of the second claim, directly compared EUS-PPG with EUS-liver biopsy, but it did not compare EUS-PPG with HVPG. The authors cited the lack of direct comparison between EUS-PPG and HVPG as a limitation in the study. Further these two studies had small sample sizes and were conducted at a single site; the Hajifathalian et. al. study included 24 patients while the Choi study included 64 patients.

In addition, we note that the Hajifathalian et. al. study results did not achieve correlation with fibrosis stage obtained from concurrent EUS-guided liver biopsy sampling. According to the authors, there was no statistically significant correlation between the fibrosis stage on histology and measured PPG (P=.559). We are concerned that the lack of correlation would not support the claim that EUS-guided PPG measurement is more accurate than the current method using an indirect measurement with the use of HVPG.

In support of its fourth claim, we note the applicant relied on a letter to the editor that provides a study description rather than submitting the study directly as evidence for its claim.⁶⁵ In the enclosed letter, the author also noted that future studies are needed to correlate EUS-PPG with WHVPG. Lastly, the article the applicant provided in support of social determinants of health and disparities did not directly discuss the device. Additional supporting evidence, preferably published peer-reviewed clinical trials that show improved clinical outcomes would

⁶³ Hajifathalian, K., Westerveld, D., Kaplan, A. et. al. (2022). Simultaneous EUS-guided portosystemic pressure measurement and liver biopsy sampling correlate with clinically meaningful outcomes. *Gastrointestinal Endoscopy* 95(4): 703-710.

⁶⁴ Choi, A., Chang, K., Samaransena, J. et. al. (2022). Endoscopic Ultrasound-Guided Porto-systemic Pressure Gradient Measurement Correlates with Histological Hepatic Fibrosis. *Digestive Diseases and Sciences*. P.7. <https://doi.org/10.1007/s10620-022-07418-7>

⁶⁵ Rubin, R., Mehta, M., Rossi, A., Joeslon, D., Shrestha, R.. (2021). Letter to the Editor: Endoscopic ultrasound guided portal-systemic pressure gradient measurement to determine candidacy for kidney transplant alone versus combined liver kidney transplant in patients with advanced fibrosis or cirrhosis. *Transplant International* 2021 (34): 2903-2904.

help with our assessment of whether EchoTip[®] demonstrates substantial clinical improvement over existing technologies.

We are inviting public comment on whether EchoTip[®] meets the substantial clinical improvement 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 EchoTip[®] would be reported with HCPCS codes listed in Table 33.

TABLE 33: HCPCS CODES REPORTED WITH ECHOTIP[®]

HCPCS Code	Long Descriptor	SI	APC
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

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 with comment period with comment period (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. For our calculations, we used APC 5302, which had a CY 2022 payment rate of \$1658.81 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level

(81 FR 79657). HCPCS code 43238 had a device offset amount of \$19.08 at the time the application was received.⁶⁶ According to the applicant, the cost of the EchoTip[®] is \$1965.00.

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 estimated average reasonable cost of \$1,965.00 for EchoTip[®] is 118.46 percent of the applicable APC payment amount for the service related to the category of devices of \$1,658.81 ($(\$1,965.00/\$1658.81) \times 100 = 118.46$ percent). Therefore, we believe EchoTip[®] 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 \$1,965.00 for EchoTip[®] is 10,298.74 percent of the cost of the device-related portion of the APC payment amount for the related service of \$19.08 ($(\$1,965.00/\$19.08) \times 100 = 10298.74$). Therefore, we believe that EchoTip[®] 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 \$1,965.00 for EchoTip[®] and the portion of the APC payment amount for the device of \$19.08 is 117.31

⁶⁶ We note that the applicant selected a value of \$156.43 for the device offset amount. However, the value selected is inconsistent with the device offset amount related to HCPCS 43238 in APC 5302 found in Addendum P to the CY 2022 OPPTS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPPTS Addendum (87 FR 2060). We selected the value of \$19.08, which we believe is the accurate value. Based on our initial assessment for this proposed rule, using the device offset amount of \$19.08 would result in EchoTip[®] meeting the cost significance requirement.

percent of the APC payment amount for the related service of \$1658.81 ($((\$1965.00 - \$19.08)/\$1658.81) \times 100 = 117.31$ percent). Therefore, we believe that EchoTip[®] meets the third cost significance requirement.

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

(d) FLEX Vessel Prep[™] System

Venture Med Group, Inc. submitted an application for a new device category for transitional pass-through payment status for FLEX Vessel Prep[™] System (FLEX VP[™]) for CY 2024. Per the applicant, FLEX VP[™] is an endovascular, over-the-wire, retractable, sheathed catheter with a three-strut treatment element at the distal tip used to help resolve stenoses occluding vascular access in patients with End-Stage Renal Disease (ESRD) on hemodialysis. According to the applicant, FLEX VP[™] is used with percutaneous transluminal angioplasty (PTA) catheters and for the treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature. The applicant asserted that FLEX VP[™] consists of three integrated components: (1) control handle, which includes the flush and guidewire ports and sheath and treatment element actuators; (2) catheter shaft; and (3) treatment element, which includes three proximally mounted micro-surgical blades on protective skirts. The struts are radially opposed, and the proximal portion of each strut includes a micro-surgical blade. A radiopaque marker is located distally to assist in the positioning of the catheter.

According to the applicant, when deployed, FLEX VP[™]'s struts independently engage with neointimal hyperplastic stenoses occluding an arteriovenous fistula or graft used for hemodialysis. As the device is pulled back through the lesion, the blades create three continuous, parallel micro-incisions, approximately 250 microns in depth, along the lesion's entire length. The applicant provided that this is a non-balloon-based device where the struts exert a consistent force of approximately one atmosphere on the vessel wall. Per the applicant, additional micro-

incisions may be created by using several passes of the device. According to the applicant, the device breaks the lesion surface to facilitate the effectiveness of a percutaneous transluminal balloon angioplasty, which immediately follows use of the device in restoring patency to the vascular access.

The applicant asserted that the micro-incisions improve acute luminal gain and vessel compliance by releasing circumferential tension in the lesion. The applicant asserted that this preparation can help reduce vessel trauma and complications (including severe dissection and need for a bail-out stent) and the need for high pressure balloons (which risk barotrauma). Per the applicant, the interventionalist advances FLEX VP™ past the lesion, then unsheathes and expands the treatment element and slowly draws the catheter back, allowing each micro-surgical blade to simultaneously and independently engage with the lesion. This step produces three continuous, parallel micro-incisions along the lesion's length. According to the applicant, this process may be repeated several times; once the lesion is crossed on the first pass, the treatment element is re-sheathed, advanced again through the lesion, and rotated approximately 30 to 90 degrees. The treatment element is then re-deployed and the process is repeated.

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 11, 2020, the applicant received 510(k) clearance from FDA for FLEX VP™ for use with PTA catheters to facilitate dilation of stenoses in the femoral and popliteal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature. We received the application for a new device category for transitional pass-through payment status for FLEX VP™ on February 28, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comment on whether FLEX VP™ meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, FLEX VP™ is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied through an incision (for hemodialysis patients, the incision is in the wrist or arm area). FLEX VP™ is inserted through the incision over a guidewire until distal to the lesion to be treated and prior to the angioplasty procedure.

We are inviting public comment on whether FLEX VP™ meets the integral part of the service criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant claimed that FLEX VP™ meets the device eligibility requirements of § 419.66(b)(4) because it is not equipment, 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 comment on whether FLEX VP™ 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 FLEX VP™ as an endovascular, over-the-wire, retractable, sheathed catheter with a three-strut treatment element at the distal tip used to help resolve stenoses occluding vascular access in patients with ESRD on hemodialysis. Per the applicant, no previous device categories for pass-through payment have encompassed FLEX VP™ and there are no similar device categories. Upon review, it does not appear that there are any existing pass-through payment categories that might apply to FLEX VP™.

We are inviting public comment on whether FLEX VP™ 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 FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant stated that FLEX VP™ represents a substantial clinical improvement over existing technologies by: (1) improving clinical outcomes for the hemodialysis patient population with dysfunctional arteriovenous (AV) access; and (2) reducing the rate of device-related complications. The applicant cited two studies describing the findings of a single clinical trial specifically for the purpose of addressing the substantial clinical improvement criterion.

The first study presented findings 6 months after patients were treated with FLEX VP™ followed by balloon angioplasty (Aruny, et al.),⁶⁷ and the second study presented findings at 12 months post-treatment with FLEX VP™ followed by balloon angioplasty (author not identified in the manuscript for the 12-month follow up).⁶⁸ Both studies focused on results from methods used to show the durability of the treatments of blocked vascular accesses with FLEX VP™. The trial was a prospective, observational controlled clinical trial. A total of 148 lesions or blockages were treated with FLEX VP™ prior to a PTA in 114 subjects (the population was 53.5 percent

⁶⁷Aruny et al., Real-World Results of a Novel Vessel Preparation Device Prior to Balloon Angioplasty for Arteriovenous Access Repair in Diverse Populations on Dialysis, under review, JVA, Feb. 2023.

⁶⁸ Durability of Arteriovenous Access Repair Involving Vessel Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty; unpublished manuscript (no author identified).

female; 65.8 percent Black or African American (B/AA)), treated at eight clinical sites. All subjects were hemodialysis patients with vascular blockages. Of the 114 subjects, 104 patients had prior treatments to correct stenoses before enrolling in the trial. A primary endpoint was anatomic success, defined as angiographic confirmation of <30 percent residual stenosis post-procedure without adverse event. Additional assessments included dialysis circuit primary patency or vascular openness, clinical success and procedural success. The trial also measured the target lesion primary patency (TLPP) and freedom from target lesion restenosis (FFTLR) to determine if there is a decreased rate of subsequent therapeutic interventions. The two studies of the single clinical trial also examined the rate of device-related complications. No serious adverse events were reported initially (Aruny et al.), or in the 12-month follow-up (author not identified in the manuscript for the 12-month follow-up). The studies looked at differences in outcomes based on race and sex and found no significant differences. Per the applicant, the results suggest that FLEX VP™ followed by angioplasty can substantially reduce the number and burden of maintenance procedures for hemodialysis patients with arteriovenous fistula (AVF), arteriovenous graft (AVG), and AV disfunctions that cause cephalic arch stenoses.

In support of its first claim, that FLEX VP™ improves clinical outcomes for the hemodialysis patient population with dysfunctional AV access, the applicant asserted that FLEX VP™ decreased both the rates of therapeutic interventions and subsequent therapeutic interventions. The applicant provided the following evidence from the clinical trial and two studies. FLEX VP™ treatment prior to angioplasty benefits hemodialysis patients by improving the level of openness of blocked (or stenosed) arteriovenous access; a recurring issue that occurs because of the fistulas created to facilitate hemodialysis. The use of FLEX VP™ also allows the site with prior blockage (also known as lesions) to stay opened for a longer period of time, reducing the frequency of future angioplasty procedures. The applicant discussed how the initial study (Aruny et al.), found that patients treated with FLEX VP™ prior to PTA (FLEX+PTA) had 6 months TLPP of 63.7 percent openness, versus the 15.6 percent to 50.5 percent rates of

vascular openness after PTA alone observed in other publications. This study also presented results for FFTLR, a calculation to determine an average number of days of durability of the percentage of the patency or lesion openness reported; for the overall hemodialysis population studied it was 206.7 days. The applicant also described results for patients with only AVFs or AVGs. For FLEX+PTA in AVF patients, TLPP was 70.6 percent and FFTLR was 219.7 days. For FLEX+PTA in AVG patients, TLPP was 46.6 percent and FFTLR was 173.9 days. Confirmation of reliability of the findings was shown by dialysis access circuit primary patency: 54.3 percent (AVF 54.1 percent; AVG 47.4 percent). According to the applicant, results of dialysis access circuit primary patency derived from the literature with only angioplasty performed ranged from 0 percent to 48 percent. The applicant also presented results 12 months post-treatment (author not identified in the manuscript for the 12-month follow up) supporting the durability of the FLEX+PTA. Per the applicant, results generally accord with Aruny et al.'s 6-month results and exceed PTA-only results from the literature. Overall, TLPP was 45.7 percent (versus 62.2 percent at 6 months) and FFTLR was 250.9 days (versus literature (PTA only), 131.4 days). Per the applicant, this result suggests that compared to the durability of PTA only, FTA+PTA would result in a lower frequency of treatments to remove stenosis in overall hemodialysis patients. For AVFs, TLPP was 47.4 percent (versus 67.5 percent at 6 months); FFTLR was 258.5 days (versus literature, 156.9 days). For AVGs, TLPP was 43.8 percent (versus 52.4 percent at 6 months); FFTLR was 239.4 days (versus literature, 76.6 days). Overall, 12 months circuit primary patency was 36.5 percent (versus 54.3 percent at 6 months).⁶⁹

In further support of the applicant's first claim, the applicant presented results from the clinical trial comparing B/AA patients to non-B/AA patients. In support of FLEX VP™ prior to PTA improving clinical outcomes for B/AA hemodialysis patient population with dysfunctional AV access, the applicant discussed the initial Aruny et al. study, in which B/AA patients had

⁶⁹ Durability of Arteriovenous Access Repair Involving Vessel Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty; unpublished manuscript (no author identified).

better results with FLEX VP™ intervention than did non-B/AA patients. The B/AA cohort (65.8 percent of sample) had TLPP of 63.76 percent versus 58.8 percent for the non-B/AA cohort after treatment with FLEX+PTA. FFTLR was 207.8 days for B/AA versus 192.2 days for non-B/AA. For B/AA patients with cephalic arch lesions, TLPP was 78.6 percent versus 58.3 percent for non-B/AA. The applicant asserted that these results were achieved despite pre-existing disparities in patient's experience with AV access care. B/AA patients had more years since they started hemodialysis ($p<0.01$), suggesting a possibility of increased severity or complexity of lesions in the B/AA patients.⁷⁰ The applicant also presented results 12 months post-treatment.⁷¹ In terms of B/AA patient outcomes comparable to the overall sample, the B/AA cohort (65.8 percent of sample) had TLPP of 45.9 percent versus 45.7 percent overall patients and FFTLR was 257.8 days for B/AA versus 250.9 days overall patients. In B/AA patients with cephalic arch lesions, TLPP was 71.8 percent versus 59.7 percent overall patients.

Furthermore, in support of the applicant's first claim, the applicant provided the following evidence from the clinical trial. In support of FLEX VP™ improving clinical outcomes for a female hemodialysis patient population with dysfunctional AV access, the applicant stated that in the initial Aruny et al. study, females differed from males significantly in their pre-existing experiences with AV care. Female patients had more years since they started hemodialysis ($p<0.01$) and since AV access creation ($p<0.01$) and more prior AV access interventions ($p<0.05$); according to the applicant, this potentially suggests that female patients are more prone to complexity of lesions or recurrence of stenosis. However, no statistically significant differences in results of TLPP and FFTLR measures at 6 months post treatment were observed between females and males treated with FLX VP™ followed by PTA. Therefore,

⁷⁰ Aruny et al., Real-World Results of a Novel Vessel Preparation Device Prior to Balloon Angioplasty for Arteriovenous Access Repair in Diverse Populations on Dialysis, under review, JVA, Feb. 2023.

⁷¹ Durability of Arteriovenous Access Repair Involving Vessel Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty; unpublished manuscript (no author identified).

females receiving a FLEX VP™ intervention prior to PTA achieved results comparable to males, notwithstanding pre-existing disparities.⁷²

In further support of the applicant's first claim, the applicant explained that cephalic arch (CA) stenoses are notoriously difficult to treat effectively and have some of the worst results in dialysis access results and recurrence of the lesions in a short amount of time. The applicant explained that complications are also high. In this sample, the target stenosis was in the CA in 25/114 patients (21.9 percent). TLPP following FLEX+PTA at 6 months (Aruny et al.) was 70.6 percent overall patients, and 76.8 percent in the B/AA cohort. According to the applicant comparable figures in the literature ranged from 0 percent to 51.6 percent. Access dialysis circuit primary patency gathered from the literature for PTA only was 66.4 percent for CA cases.⁷³ The applicant also presented results 12-month post-treatment (author not identified in the manuscript for the 12-month follow up). TLPP for these patients following FLEX+PTA at 12 months was 59.7 percent for overall patients and 71.8 percent in the B/AA cohort. According to the applicant, comparable figures in the clinical literature ranged from 0 percent to 33.9 percent and access dialysis circuit primary patency was 55.3 percent for CA cases.⁷⁴

In support of the applicant's second claim, the applicant asserted that no serious adverse events were reported from the initial study (Aruny et al.). Five procedural complications and one dissection related to the FLEX VP™ device were recorded. Three dissections were associated with PTA.⁷⁵ The applicant also presented results 12 months post-treatment (author not identified in the manuscript for the 12-month follow-up), noting that no serious adverse events were reported during 12-month follow-up.

⁷² Aruny et al., Real-World Results of a Novel Vessel Preparation Device Prior to Balloon Angioplasty for Arteriovenous Access Repair in Diverse Populations on Dialysis, under review, JVA, Feb. 2023.

⁷³ Aruny et al., Real-World Results of a Novel Vessel Preparation Device Prior to Balloon Angioplasty for Arteriovenous Access Repair in Diverse Populations on Dialysis, under review, JVA, Feb. 2023

⁷⁴ Durability of Arteriovenous Access Repair Involving Vessel Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty; unpublished manuscript (no author identified).

⁷⁵ Aruny et al., Real-World Results on a Novel Vessel Preparation Device Prior to Balloon Angioplasty for Arteriovenous Access Repair in Diverse Populations on Dialysis, under review, JVA, Feb. 2023.

According to the applicant, these findings confirm the safety record for FLEX VP™, which is better when compared to the Journal of Vascular and Interventional Radiology (JVIR) Quality Improvement Guidelines thresholds for AVF and AVG. According to the applicant, in the literature, up to 15% cephalic arch lesions result in vessel rupture and about 12% of PTAs in B/AA patients are reported to result in major complications.⁷⁶

Ultimately, the applicant concluded that FLEX VP™ is safe and effective, notably in patients with AVGs and those with CA stenoses, and furthermore, despite observed differences in time since hemodialysis onset, clinical success was similar across sex and race, suggesting an opportunity to enhance health equity.⁷⁷ The applicant also added that FLEX VP™, when used with PTA, provides sustained clinical improvement over existing technologies by increasing the patency and time to reintervention of PTA procedures in AVFs and AVGs at 12 months (author not identified in the manuscript for the 12-month follow-up), while reducing the potential for serious complications, such as perforations and vessel rupture. Favorable results at 6 months for the B/AA cohort reported in Aruny et al.'s article were sustained in the 12 month results. Further, according to the applicant, the use of FLEX VP™ offers the prospect of improved treatment of unresponsive or difficult to treat stenosis in the cephalic arch.⁷⁸

Based on the evidence submitted in the application, we note the following concerns: The applicant presented two studies (Aruny et al. [a 6-month follow up], and an unpublished manuscript which did not identify an author [12-month follow up] submitted with the application) that are based on a single clinical trial of 114 patients followed for 12 months. Per the applicant, the results from the 6-months follow up are not yet published, and the results from 12-months post-treatment are also unpublished and only available at the FLEX VP™ registry.

⁷⁶ Durability of Arteriovenous Access Repair Involving Vessel Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty; unpublished manuscript (no author identified).

⁷⁷ Aruny et al., Real-World Results of a Novel Vessel Preparation Device Prior to Balloon Angioplasty for Arteriovenous Access Repair in Diverse Populations on Dialysis, under review, JVA, Feb. 2023

⁷⁸ Durability of Arteriovenous Access Repair Involving Vessel Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty; unpublished manuscript (no author identified).

Therefore, we note that the evidence presented on benefits to patients in hemodialysis is not peer-reviewed and this may reduce the strength of the evidence presented and the opinion of peers on study quality. 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. We also note that, due to the clinical trial design, there is insufficient data on the impact of angioplasty with the drug-coated balloon option. The drug in these balloons may play a role in the improvement of patency or openness durability and additional studies to strengthen the initial observations presented by the applicant would be helpful.

Lastly, we note the applicant did not show a clear crosswalk of findings or data in terms of device-related complications (including dissection and embolectomy) observed in the trial and compared to those referenced in literature. For example, procedural complications and dissection were mentioned in the FLEX VP™ group while rupture and major complications were mentioned in the literature. The clinical trial results presented one dissection attributed to FLEX VP™ after 148 lesions were treated with FLEX VP™ plus PTA. Per the applicant, there are approximately 732,000 interventions per year in the U.S. to maintain lifesaving arteriovenous access and FLEX VP™ could be potentially used in a fraction of those; this increases the concern for frequency of complications and therefore, additional studies may be needed to strengthen the second substantial clinical improvement claim.

We are inviting public comment on whether FLEX VP™ meets the substantial clinical improvement 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 FLEX VP™ would be reported with HCPCS codes listed in Table 34.

TABLE 34: HCPCS CODES REPORTED WITH FLEX VP™

HCPCS Code	Long Descriptor	SI	APC
36902	Introduction of catheters, dialysis circuit, with transluminal balloon angioplasty	J1	5192
36903	Introduction of catheters, dialysis circuit, with transcatheter placement of intravascular stent and all angioplasty	J1	5193
36905	Percutaneous transluminal mechanical thrombectomy, dialysis circuit, with transluminal balloon angioplasty	J1	5193
36906	Percutaneous transluminal mechanical thrombectomy, dialysis circuit, with transcatheter placement of intravascular stent and all angioplasty	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 with comment period (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. For our calculations, we used APC 5192, which had a CY 2022 payment rate of \$5,061.89 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 36902 had a device offset amount of \$1,271.04 at the time the application was received.⁷⁹

According to the applicant, the cost of FLEX VP™ is \$1,995.00.

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 estimated average

⁷⁹ We note that the applicant selected a value of \$1391.99 for the device offset amount. However, the value selected is inconsistent with the device offset amount related to HCPCS 36902 in APC 5192 found in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPPS Addendum (87 FR 2060). We selected the value of \$1271.04, which we believe is the accurate value. Based on our initial assessment for this proposed rule, using the device offset amount of \$1271.04 would result in FLEX VP™ meeting the cost significance requirement.

reasonable cost of \$1,995.00 for FLEX VP™ is 39.41 percent of the applicable APC payment amount for the service related to the category of devices of \$5,061.89 ($(\$1,995.00/\$5,061.89) \times 100 = 39.41$ percent). Therefore, we believe FLEX VP™ 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 \$1,995.00 for FLEX VP™ is 156.96 percent of the cost of the device-related portion of the APC payment amount for the related service of \$1,271.04 ($(\$1,995.00/\$1,271.04) \times 100 = 156.96$ percent). Therefore, we believe that FLEX VP™ 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 \$1,995.00 for FLEX VP™ and the portion of the APC payment amount for the device of \$1,271.04 is 14.30 percent of the APC payment amount for the related service of \$5,061.89 ($((\$1,995.00 - \$1,271.04)/\$5,061.89) \times 100 = 14.30$ percent). Therefore, we believe that FLEX VP™ meets the third cost significance requirement.

We are inviting public comment on whether FLEX VP™ 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 OPSS, 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 OPSS/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 listed below. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPSS/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 OPSS 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 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy--which includes the three criteria listed previously--to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Device-Intensive Procedure Policy for CY 2019 and Subsequent Years

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:

(a) 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

(b) 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 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's

claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

As we indicated in the CY 2019 OPPTS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850, or electronically at outpatientpps@cms.hhs.gov. Additional information can be submitted prior to issuance of an OPPTS/ASC proposed rule or as a public comment in response to an issued OPPTS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

The full listing of the proposed CY 2024 device-intensive procedures can be found in Addendum P to this proposed rule (which is available via the internet on the CMS website). Further, our claims accounting narrative contains a description of our device offset percentage

calculation. Our claims accounting narrative for this proposed rule can be found under supporting documentation for the CY 2024 OPPTS/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 OPPTS/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 OPPTS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPTS/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 that are assigned to a device-intensive APC. In the CY 2016 OPPTS/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 OPPTS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPTS/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 OPPTS/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 2023 OPSS/ASC final rule with comment period (87 FR 71830), we described a commenter’s concern about the potentially inadequate payment rate for APC 5495 (Level 5 Intraocular Procedures) and their recommendation that we use our equitable adjustment authority to limit the potential reduction in the CY 2023 APC payment rate by applying a 10 percent cap on the reduction in relative weights for Low Volume APCs in CY 2023. While we did not accept the commenter’s recommendation to limit a Low Volume APC’s decline in relative weight to no more than 10 percent, we stated we would continue to monitor the costs and payment rates for procedures assigned to Low Volume APCs to determine if additional changes or refinements to our current policy are needed.

In our review of claims data for CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), we noticed unusual coding, charge, and cost data in the claims data from CY 2017, CY 2018, CY 2019, and CY 2021. Some claims did not report the correct device code – HCPCS code C1840 (Lens, intraocular (telescopic)) – and such claims had substantially lower cost than claims that reported the correct device code. In particular, claims that reported the correct device code had an average device cost of \$15,030.04, while claims that did not report the correct device code had an average device cost of \$430.72. The vast majority of claims for CPT code 0308T in our 4-year analysis did report the correct device code; however, the limited number of claims that either reported the wrong procedure code or reported the wrong device code had an outsized impact on the APC payment rate because of the very low volume of claims for this APC. Because payment stability for this Low Volume APC relies so critically on accurate reporting of the procedure’s associated costs, we believe this APC would benefit from a procedure-to-device edit – a claims processing edit that requires a certain device code to be included on the claim when hospitals report a specific procedure code. The procedures associated with the Level 5 Intraocular APC, which we

propose to reassign to a new Level 6 Intraocular APC (APC 5496) in section III.E of this proposed rule, describe the implantation of a specific device codes:

- CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) describes the implantation of device HCPCS code C1840 (Lens, intraocular (telescopic));
- 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) describes the implantation of device HCPCS code C1839 (Iris prosthesis);
- CPT code 0617T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens) describes the implantation of device HCPCS code C1839 (Iris prosthesis); or
- CPT code 0618T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange) also describes the implantation of device HCPCS code C1839 (Iris prosthesis).

We propose to establish a procedure-to-device edit for the four aforementioned 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. While some interested parties have previously recommended in past rulemaking that we reestablish all of our previous procedure-to-device edits, we do not expect to extend this policy beyond the procedures assigned to APC 5496 (Level 6 Intraocular Procedures). We continue to rely on hospitals' accurate reporting and believe our current device edits policy of requiring device-intensive procedures to be subject to an additional device reporting edit has improved our ratesetting for hospital outpatient department procedures without placing an undue burden on hospitals. However, we believe this APC represents a unique situation – the APC (which was the Level 5 Intraocular APC in previous years) has 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. We believe requiring a procedure-to-device edit for procedures assigned to the APC 5496 (Level 6 Intraocular Procedures), would not be administratively burdensome to hospitals given the low volume of services associated for this APC and will have a meaningful and significant impact on the payment rate for this APC and the stability of the payment rate in the future.

We are soliciting comments on 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.

4. Adjustment to OPSS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPSS 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 2024.

V. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biologicals. Throughout the 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 the proposed rule includes (but is not necessarily limited to) a “biological product” or a “biologic” as defined under section 351 of the PHS Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. “Current” refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain “new” drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is “not insignificant” in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as “drugs.” As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B. Proposed CY 2024

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).⁸⁰

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 OPDS, 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 the 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/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>.

The pass-through application and review process for drugs and biologicals is described on our website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.

2. Transitional Pass-Through Payment Period for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

⁸⁰ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

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 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 2023

There are 43 drugs and biologicals for which pass-through payment status expires by December 31, 2023, as listed in Table 35. These drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2020 through December 31, 2023. 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 radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); 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 2024), as discussed further in section V.B.1 of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we provide separate payment at the applicable ASP methodology-based payment amount (which is generally ASP plus 6 percent), as discussed further in section V.B.2 of this proposed rule.

TABLE 35: DRUGS AND BIOLOGICALS FOR WHICH PASS - THROUGH PAYMENT STATUS WILL END BY DECEMBER 31, 2023

CY 2023 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0179	Injection, brolocizumab-dbl, 1 mg	G	9340	04/01/2020	03/31/2023
J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
J0791	Injection, crizanlizumab-tmca, 1 mg	G	9359	04/01/2020	03/31/2023
J1201	Injection, cetirizine hydrochloride, 1 mg	G	9361	04/01/2020	03/31/2023

CY 2023 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	Injection, luspatercept aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J1738	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
J3032	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023
J3241	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354	07/01/2020	06/30/2023
J7402	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5118	Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg	G	9348	07/01/2020	06/30/2023
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023
A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	9370	10/01/2020	09/30/2023
C9067	Gallium ga-68, dotatoc, diagnostic, 0.01 mCi	G	9323	10/01/2020	09/30/2023
J7351	Injection, bimatoprost, intracameral implant, 1 microgram	G	9351	10/01/2020	09/30/2023

CY 2023 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj	G	9378	10/01/2020	09/30/2023
J9227	Injection, isatuximab-irfc, 10 mg	G	9377	10/01/2020	09/30/2023
J9281	Mitomycin pyelocalyceal instillation, 1 mg	G	9374	10/01/2020	09/30/2023
J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	G	9376	10/01/2020	09/30/2023
J9318	Injection, romidepsin, non-lyophilized, 0.1 mg	G	9428	10/01/2020	09/30/2023
Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	G	9382	10/01/2020	09/30/2023
Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	G	9349	10/01/2020	09/30/2023
Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381	10/01/2020	09/30/2023
A9592	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9383	01/01/2021	12/31/2023
J0699	Injection, cefiderocol, 10 mg	G	9380	01/01/2021	12/31/2023
J1427	Injection, viltolarsen, 10 mg	G	9386	01/01/2021	12/31/2023
J1437	Injection, ferric derisomaltose, 10 mg	G	9388	01/01/2021	12/31/2023
J1554	Injection, immune globulin (Asceniv), 500 mg	G	9392	01/01/2021	12/31/2023
J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384	01/01/2021	12/31/2023
J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387	01/01/2021	12/31/2023
J9223	Injection, lurbinectedin, 0.1 mg	G	9389	01/01/2021	12/31/2023
J9316	Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg	G	9390	01/01/2021	12/31/2023

CY 2023 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9349	Injection, tafasitamab-cxix, 2 mg	G	9385	01/01/2021	12/31/2023
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9391	01/01/2021	12/31/2023

4. Proposed Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Expiring in CY 2024

We propose to end pass-through payment status in CY 2024 for 25 drugs and biologicals. These drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2021, and January 1, 2022, are listed in Table 36. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2024, 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).⁸¹ The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status, 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 2024 and subsequent years, we propose to continue to pay for pass-through drugs and biologicals using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP. This payment rate is generally ASP plus 6 percent, equivalent to the payment

⁸¹ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>

rate these drugs and biologicals would receive in the physician's office setting in CY 2024. We note that, under the OPD fee schedule, separately payable drugs assigned to an APC are generally payable at ASP plus 6 percent. Therefore, we propose that a \$0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2024 OPDS, and in subsequent years, 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 also proposed to be the same payment rate, which is generally ASP plus 6 percent, is \$0. We propose that this policy and the other policies proposed in this section would apply in both CY 2024 and subsequent years as they have been our longstanding policies under the OPDS. Therefore, we do not believe the policies need to be re-proposed annually and should apply for subsequent years until such time as we propose to change them.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we propose that their pass-through payment amount would be equal to a payment rate calculated using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP. This proposed payment rate would generally be ASP plus 6 percent for CY 2024 and subsequent years, 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 as described in section V.A.6 of this proposed rule. We propose this policy because, 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 propose to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2024 and subsequent years 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 OPPTS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2024 and subsequent years, consistent with our CY 2023 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to 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 OPPTS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2024 or subsequent years, we propose 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 propose to provide pass-through payment at WAC plus 3 percent (consistent with our policy in section V.B.2.b 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.b of this proposed rule). If WAC information also is not available, we propose to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We refer readers to Table 36 below for the list of drugs and biologicals with pass-through payment status expiring during CY 2024.

TABLE 36: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING IN CY 2024

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0224	J0224	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass- Through Payment Effective Date	Pass- Through Payment End Date
J7212	J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024
Q5122	Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	03/31/2024
A9593	A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409	07/01/2021	06/30/2024
A9594	A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410	07/01/2021	06/30/2024
J0741	J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414	07/01/2021	06/30/2024
J1305	J1305	Injection, evinacumab-dgnb, 5mg	G	9416	07/01/2021	06/30/2024
J1426	J1426	Injection, casimersen, 10 mg	G	9412	07/01/2021	06/30/2024
J1448	J1448	Injection, trilaciclib, 1mg	G	9415	07/01/2021	06/30/2024
J9247	J9247	Injection, melphalan flufenamide, 1mg	G	9417	07/01/2021	06/30/2024
J9348	J9348	Injection, naxitamab-gqgk, 1 mg	G	9408	07/01/2021	06/30/2024
J9353	J9353	Injection, margetuximab- cmkb, 5 mg	G	9418	07/01/2021	06/30/2024
Q2054	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 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass- Through Payment Effective Date	Pass- Through Payment End Date
		dose preparation procedures, per therapeutic dose				
Q5123	Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	G	9411	07/01/2021	06/30/2024
J1823	J1823	Injection, inebilizumab-cdon, 1 mg	G	9394	10/01/2021	09/30/2024
J2406	J2406	Injection, oritavancin (kimyrsa), 10 mg	G	9427	10/01/2021	09/30/2024
J9061	J9061	Injection, amivantamab-vmjw, 10 mg	G	9432	10/01/2021	09/30/2024
J9272	J9272	Injection, dostarlimab-gxly, 100 mg	G	9431	10/01/2021	09/30/2024
J9359	J9359	Injection, loncastuximab tesirine-lpyl, 0.075 mg	G	9205	10/01/2021	09/30/2024
Q2055	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	A9595	Piflufolastat f-18, diagnostic, 1 millicurie	G	9430	01/01/2022	12/31/2024
J0219	J0219	Injection, avalglucosidase alfa-ngpt, 2 mg	G	9433	01/01/2022	12/31/2024
J0491	J0491	Injection, anifrolumab-fnia, 1 mg	G	9434	01/01/2022	12/31/2024

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9021	J9021	Injection, asparaginase, recombinant, (rylaze), 0.1 mg	G	9437	01/01/2022	12/31/2024
J9071	J9071	Injection, cyclophosphamide, (auromedics), 5 mg	G	9203	01/01/2022	12/31/2024

5. Proposed Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Continuing through CY 2024

We propose to continue pass-through payment status in CY 2024 for 42 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2022, and April 1, 2023, are listed in Table 37. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that would continue after December 31, 2024, are assigned status indicator “G” in Addenda A and B to this proposed rule (which are available on the CMS website).⁸²

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 2024 and subsequent years, we propose to continue 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 2024. We propose that a \$0 pass-through payment amount would be paid for pass-through drugs and

⁸² <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

biologicals that are not policy-packaged as described in section V.B.1.c of this proposed rule under the CY 2024 OPPTS and in subsequent years, because the difference between the amount authorized under section 1842(o) of the Act, which would generally be ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which would also generally be ASP plus 6 percent, is \$0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we propose that their pass-through payment amount would 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 2024, minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6 of this proposed rule). We propose this policy because, 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 propose to continue to update pass-through payment rates on a quarterly basis on our website during CY 2024, and in subsequent years, 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 OPPTS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2024 and subsequent years, consistent with our CY 2023 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to 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 2024, 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.b of this proposed rule), the equivalent payment provided to 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.b 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. We propose that the other policies proposed in this section would apply in both CY 2024 and subsequent years as they have been our longstanding policies under the OPPS. Therefore, we do not believe the policies need to be re-proposed annually and should apply for subsequent years until such time as we propose to change them.

The drugs and biologicals that we propose would have pass-through payment status expire after December 31, 2024, are shown in Table 37.

TABLE 37: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING AFTER CY 2024

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 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
C9092	J3299	Injection, triamcinolone acetonide, suprachoroidal (xipere), 1 mg	G	9358	04/01/2022	03/31/2025

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9093	J2779	Injection, ranibizumab, via sustained release intravitreal implant (susvimo), 0.1 mg	G	9439	04/01/2022	03/31/2025
C9091	J9331	Injection, sirolimus protein-bound particles, 1 mg	G	9241	04/01/2022	03/31/2025
C9090	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 dose preparation procedures, per therapeutic dose	G	9498	07/01/2022	06/30/2025
J1302	J1302	Inj, 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	Inj, tebentafusp-tebn, 1 mcg	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

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J2777	J2777	Inj, 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
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, (ciplA), 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

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9144	C9144	Injection, bupivacaine (posimir), 1 mg	G	9106	04/01/2023	03/31/2026
C9145	C9145	Injection, aprepitant, (aponvie), 1 mg	G	9107	04/01/2023	03/31/2026
C9146	C9146	Injection, mirvetuximab soravtansine-gynx, 1 mg	G	9109	04/01/2023	03/31/2026
C9147	C9147	Injection, tremelimumab-actl, 1 mg	G	9110	04/01/2023	03/31/2026
C9148	C9148	Injection, teclistamab-cqyv, 0.5 mg	G	9111	04/01/2023	03/31/2026
C9149	C9149	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

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q5128	Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg	G	9117	04/01/2023	03/31/2026
Q5130	Q5130	Injection, pegfilgrastim-pbbk (flyntra), biosimilar, 0.5 mg	G	9118	04/01/2023	03/31/2026

6. Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packaged into APC Groups

Under the regulation at 42 CFR 419.2(b)(15), nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged in the OPDS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Also, under the regulation at 42 CFR 419.2(b)(16), nonpass-through drugs and biologicals that function as supplies in a surgical procedure are packaged in the OPDS. This category includes skin substitutes and other surgical-supply drugs and biologicals. Finally, under the regulation at 42 CFR 419.2(b)(4), anesthesia drugs are packaged in the OPDS. As described earlier, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for policy-packaged drugs, biologicals, and radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. This amount reflecting the portion of the APC payment associated with predecessor products is called the payment offset.

The payment offset policy applies to all policy-packaged drugs, biologicals, and radiopharmaceuticals. For a full description of the payment offset policy as applied to policy-packaged drugs, which include diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes, we refer readers to the discussion in the CY 2016 OPSS/ASC final rule with comment period (80 FR 70430 through 70432). For CY 2024 and subsequent years, as we did in CY 2023, we propose to continue to apply the same policy-packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. We propose that these policies would apply in both CY 2024 and subsequent years as they are our longstanding policies under the OPSS, and we do not believe they need to be re-proposed annually. Instead, we believe they should apply for subsequent years until such time as we propose to change them or until such time as the APCs to which a payment offset may be applicable for certain products change. The APCs to which a payment offset may be applicable for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes are identified in Table 38.

TABLE 38: APCs TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2023

CY 2023 APC	CY 2023 APC Title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services
5592	Level 2 Nuclear Medicine and Related Services
5593	Level 3 Nuclear Medicine and Related Services
5594	Level 4 Nuclear Medicine and Related Services
Contrast Agent	
5571	Level 1 Imaging with Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services
5593	Level 3 Nuclear Medicine and Related Services
Skin Substitute	
5054	Level 4 Skin Procedures
5055	Level 5 Skin Procedures

We propose to continue to post annually on our website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/Annual-Policy-Files.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html) a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through payment device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

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 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at \$135 for CY 2023 (87 FR 71960 through 71961).

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 2024 and round the resulting dollar amount (\$138.44) 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 IHS Global, Inc. 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 OPBS methodology, we propose a packaging threshold for CY 2024 of \$140.

b. Packaging of Payment for HCPCS Codes that Describe Certain Drugs, Certain Biologicals, and Certain Therapeutic Radiopharmaceuticals Under the Cost Threshold (“Threshold-Packaged Drugs”)

To determine the proposed CY 2024 packaging status for all nonpass-through drugs and biologicals 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 2022 and were paid (via packaged or separate payment) under the OPBS. We used data from CY 2022 claims processed through June 30, 2022, 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 2024: anesthesia drugs; 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.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2024, we use the methodology that was described in detail in the CY 2006 OPBS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPBS final rule with comment period

(70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate based on the ASP methodology, which is generally ASP plus 6 percent (which is the payment rate we proposed for separately payable drugs and biologicals) for CY 2024, as discussed in more detail in section V.B.2.b of this proposed rule) to calculate the CY 2024 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2022 (data that were used for payment purposes in the physician's office setting, effective April 1, 2023) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2024 we propose to use payment rates based on the ASP data from the fourth quarter of CY 2022 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 2024 OPPS/ASC proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2023. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2022 hospital claims data to determine their per day cost.

We propose to package items 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. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2022 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)⁸³ for proposed payment in CY 2024.

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

⁸³ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

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 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 and biologicals in this proposed rule, we propose to use ASP data from the fourth quarter of CY 2022, 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, 2023, along with updated hospital claims data from CY 2022. 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 2023. 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, 2023. These payment rates would then be updated in the January 2024 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2024. For items that do not currently have an ASP-based payment rate, we calculated their mean unit cost from all of the CY 2022 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 therapeutic radiopharmaceuticals in this OPPS/ASC proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for the final rule with comment period. Under such circumstances, we propose to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2024 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2023. These established policies have not changed for many years and are the same as described in the

CY 2016 OPPTS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2024 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 and biologicals that were paid separately in CY 2023 and that are proposed for separate payment in CY 2024, and that then have per day costs equal to or less than the CY 2024 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2024 final rule, would continue to receive separate payment in CY 2024.

- HCPCS codes for drugs and biologicals that were packaged in CY 2023 and that are proposed for separate payment in CY 2024, and that then have per day costs equal to or less than the CY 2024 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2024 final rule, would remain packaged in CY 2024.

- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2024 but that then have per-day costs greater than the CY 2024 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2024 final rule, would receive separate payment in CY 2024.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPTS, 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 OPSS 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, 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 that at § 419.2(b)(14). As we stated in the CY 2015 OPSS/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, 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 2024.

For CY 2024, 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 2022 claims data and our pricing information, which is based on the ASP methodology, which is 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 2022 claims data to make the proposed packaging determinations for these drugs: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg); HCPCS code J1850 (Injection, kanamycin sulfate, up to 75 mg); 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 2024 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 2024 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 2024 is displayed in Table 39.

TABLE 39: HCPCS CODES TO WHICH THE CY 2024 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2024 HCPCS Code	CY 2024 Long Descriptor	CY 2024 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
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
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	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

CY 2024 HCPCS Code	CY 2024 Long Descriptor	CY 2024 Status Indicator (SI)
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
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

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 taking into account 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 take into account 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 take into account the findings of the MedPAC study.⁸⁴

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

⁸⁴ 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.

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 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 OPSS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPSS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPSS/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 2023.

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 OPPTS, 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 OPPTS. 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 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.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule (available on the CMS website⁸⁵), which illustrate the proposed CY 2024 payment based on the ASP methodology for separately payable nonpass-through drugs and biologicals and the ASP methodology for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2023, or WAC, AWP, or mean unit cost from CY 2022 claims data and updated cost report information available for this CY 2024 OPPTS/ASC

⁸⁵ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

proposed rule. In general, these published payment rates are not the same as the actual January 2024 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2024 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2023 (July 1, 2023, through September 30, 2023) will be used to set the payment rates that are released for the quarter beginning in January 2024 in December 2023. In addition, payment rates for drugs and biologicals in Addenda A and B to this proposed rule, for which there was no ASP, WAC, or AWP information available for April 2023, are based on mean unit cost in the available CY 2022 claims data. If new pricing information becomes available for payment for the quarter beginning in January 2024, we will price payment for these drugs and biologicals based on their newly available information. Finally, there may be drugs and biologicals that have ASP, WAC, or AWP information available for the CY 2024 OPPS/ASC proposed rule (reflecting April 2023 ASP data) that do not have ASP, WAC, or AWP information available for the quarter beginning in January 2024. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2022 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2024 payment purposes and are only illustrative of the CY 2024 OPPS payment methodology using the most recently available information at the time of issuance of this proposed rule.

For CY 2024, we are not proposing any changes to our policies for payment for separately payable drugs and biologicals; and we are continuing 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).

We are, however, proposing to amend the regulation text to reflect our longstanding policies for calculating the Medicare program payment and copayment amounts for separately payable drugs and biologicals by adding a new paragraph (d) to § 419.41.

b. Biosimilar Biological Products

(1) Provisions of the Inflation Reduction Act Relating to Biologicals

The Inflation Reduction Act (Pub. L. 117-169, August 16, 2022) (hereinafter referred to as “IRA”) contains two provisions that affect payment limits for biosimilar biological products (hereinafter referred to as “biosimilars”): section 11402 of the IRA amends the payment limit for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data is not available. Section 11403 of the IRA makes changes to the payment limit for certain biosimilars with an ASP that is not more than the ASP of the reference biological for a period of 5 years. We implemented section 11403 of the IRA under program instruction^{86,87}, as permitted under section 1847A(c)(5)(C) of the Act.

Section 11402 of the IRA amended section 1847A(c)(4) of the Act by adding subparagraph (B), which limits the payment amount for biosimilars during the initial period described in section 1847A(c)(4)(A). The provision requires that for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data is not available, the payment limit for the biosimilar is the lesser of (1) an amount not to exceed 103 percent of the WAC of the biosimilar or the Medicare Part B drug payment methodology in effect on November 1, 2003, or (2) 106 percent of the lesser of the WAC or ASP of the reference biological, or in the case of a selected drug during a price applicability period, 106 percent of the maximum fair price of the reference biological. We refer readers to the CY 2024 PFS proposed rule for the discussion of the proposed changes to the regulation at § 414.904 to codify section 11402 of the IRA.

Section 11403 of the IRA amended section 1847A(b)(8) of the Act by establishing a temporary payment increase for qualifying biosimilar biological products (hereinafter referred to as “qualifying biosimilars”) furnished during the applicable 5-year period.⁸⁸ Section 1847(b)(8)(B)(iii) of the Act defines “qualifying biosimilar biological product” as a biosimilar

⁸⁶ <https://www.cms.gov/files/document/r11496cp.pdf>.

⁸⁷ <https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice>.

⁸⁸ <https://www.congress.gov/bill/117th-congress/house-bill/5376/text?q=%7B%22search%22%3A%5B%22inflation+reduction+act%22%2C%22inflation%22%2C%22red%22%2C%22act%22%5D%7D&r=1&s=1>

biological product (as described in section 1847A(b)(1)(C) of the Act) with an ASP (as described in section 1847A(b)(8)(A)(i) of the Act) less than the ASP of the reference biological for a calendar quarter during the applicable 5-year period. Section 11403 of the IRA requires that a qualifying biosimilar be paid at ASP plus 8 percent of the reference biological'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. We refer readers to the CY 2024 PFS proposed rule for the discussion of the proposed changes to the regulations at §§ 414.902 and 414.904 to codify section 11403 of the IRA.

Section 1833(t)(14)(A)(iii) of the Act provides for payment of separately covered outpatient drugs (SCODs), and currently, CMS pays under the OPSS for SCODs consistent with the payment methodology set forth in section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). Through rulemaking, CMS adopted a policy to apply the statutory default payment methodology to separately payable drugs and biologicals that are not SCODs (70 FR 68715 through 68716). Under this authority, the payment rate for SCODs and applicable separately payable drugs and biologicals is determined in accordance with sections 1842(o) and 1847A of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). Because our current policy is to pay for separately payable drugs and biologicals at payment amounts determined under section 1847A, we propose that, for a separately payable biosimilar that is new for purposes of section 1847A(c)(4)(A), the OPSS payment amount would be the amount determined under section 1847A, subject to the payment limit in section 1847A(c)(4)(A). We also propose that, for a separately payable biosimilar that meets the

definition of a “qualifying biosimilar biological product” for purposes of section 1847A(b)(8)(B)(iii) of the Act, the OPSS payment amount for the biosimilar would be the amount determined under section 1847A, subject to the temporary payment increase under section 1847A(b)(8)(B)(iii). We propose to codify OPSS payment for biosimilars consistent with sections 1847A(c)(4)(A) and 1847A(b)(8)(B)(iii) by adding new paragraphs (f) and (g) to the regulation at § 419.41. The proposed regulation text cross-references the regulation text included in the PFS proposed rule, which proposes to codify the requirements in sections 1847A(c)(4)(A) and 1847A(b)(8)(B)(iii). We refer readers to the PFS proposed rule for more information about those proposed regulations.

(2) Proposal to Except Biosimilars from the OPSS Packaging Threshold When Their Reference Biologicals Are Separately Paid

Medicare Part B spending for biologicals and biosimilars has significantly outpaced the spending for non-biologic drugs for the past 16 years. According to a 2020 report from the Assistant Secretary for Planning and Evaluation (ASPE), the spending for biologicals and biosimilars represented 77 percent of Medicare Part B prescription drug spending in CY 2017.⁸⁹ In a 2020 MedPAC report, the top 10 Part B drugs based on spending were all biologicals, and spending on them in the HOPD represented 39 percent of total HOPD drug spending in CY 2019.⁹⁰ Although Part B drug spending for biologicals and biosimilars has grown tremendously in the past 16 years, we also recognize that there is evidence that the entry of

⁸⁹ Assistant Secretary for Planning and Evaluation. “Medicare Part B Drugs: Trends in Spending and Utilization, 2006-2017.” November, 2020. Available at <https://aspe.hhs.gov/sites/default/files/private/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf>

⁹⁰ Medicare Payment Advisory Commission. July 2021 Data Book: Health Care Spending and the Medicare Program. July 2021. Available at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/data-book/july2021_medpac_databook_sec.pdf

biosimilars into the market has contributed to lower aggregate spending for the Medicare program.⁹¹

Congress has made legislative changes related to payment for biosimilars. First, it amended the Social Security Act to provide for payment of biosimilars in the Affordable Care Act (ACA) and more recently, in the IRA, to update payment for certain biosimilars. In particular, section 3139 of the ACA amended section 1847A(b) by adding a new paragraph (8), which provides that the payment amount for a biosimilar biological product is the biosimilar's ASP and 6 percent of the reference biological's ASP.⁹² And as explained previously, section 11402 of the IRA changed the payment limit for biosimilars during the initial period when ASP data is not available and section 11403 of the IRA temporarily increased the payment limit for certain biosimilars.

Our overarching policy goal is to create incentives for efficiency and selection of the least costly products while still meeting a beneficiary's clinical needs and to protect the long-term solvency of the Part B Trust Fund. When we established a policy to pay for biosimilars, we intended to promote the use of biosimilars as a less expensive alternative to their reference biologicals. For CY 2016 and CY 2017, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPSS/ASC final rule with comment period (82 FR 59351), we explained that, consistent with our established OPSS drug, biological, and radiopharmaceutical payment policy, HCPCS coding for biosimilar biological products will be based on policy established under the CY 2018 PFS final rule with comment period (82 FR 53182 to 53187),

⁹¹ Medicare Payment Advisory Commission. July 2022 Data Book: Health Care Spending and the Medicare Program. July 2022. Available at https://www.medpac.gov/wp-content/uploads/2022/07/July2022_MedPAC_DataBook_Sec10_v2_SEC.pdf

⁹² <https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf>

where CMS finalized a policy to implement separate HCPCS codes for biosimilar biological products. We also clarified that all biosimilar biological products will be eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

Our threshold packaging policy's intent is to create incentives for efficiency, but we have concerns that packaging biosimilars when the reference biological or other marketed biosimilars are separately paid may create financial incentives for providers to select more expensive, but clinically similar, products. In most cases, a biosimilar either has pass-through status or is separately payable. However, there have been a few instances where biosimilars are packaged. For example, in CY 2021, we noted that HCPCS code Q5105 (Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for esrd on dialysis), 100 units), was on pass-through status through September 2021. HCPCS code Q5105 is a biosimilar for HCPCS code Q4081 (injection, epoetin alfa, 1000 units (for esrd on dialysis)) and HCPCS code Q4081 is currently packaged under the OPPS. After HCPCS code Q5105's pass-through status expired, payment for HCPCS code Q5105 was packaged because its per day cost fell below our packaging threshold of \$130 for CY 2021. In CY 2023, payment for HCPCS code Q5101 (Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram) is packaged because its per day cost fell below our packaging threshold of \$135 for CY 2023. HCPCS code Q5101 is the biosimilar for HCPCS code J1442 (Injection, filgrastim (g-csf), excludes biosimilars, 1 microgram), which is currently separately payable with a status indicator "K."

Packaging payment for both of these biosimilars is consistent with our policy since CY 2018 to subject non-pass through biosimilars to the OPPS threshold-packaging policy. However, we believe this policy may create incentives to use the more expensive reference product or biosimilars that are separately payable, as hospitals would be paid less for using the threshold-packaged biosimilar. For example, the CY 2023 threshold packaging of the biosimilar described by HCPCS code Q5101 (Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram) may have created a financial incentive for providers to select the separately paid reference biological or the

separately paid filgrastim biosimilar over the packaged filgrastim biosimilar, which is inconsistent with our policy goal of encouraging efficiency and promoting use of biosimilars as lower cost alternatives to their reference biologicals. Accordingly, for CY 2024, we propose to except biosimilars from the OPSS threshold packaging policy when their reference biologicals are separately paid, meaning we would pay separately for these biosimilars even if their per-day cost is below the threshold packaging policy. We believe the threshold packaging exception for biosimilars when their reference biologicals are separately paid would preserve our policy intent to promote biosimilar use as a lower cost alternative to higher cost reference biologicals.

In addition, if a reference product's per-day cost falls below the threshold packaging policy, we propose that all the biosimilars related to the reference product would be similarly packaged regardless of whether their per-day costs are above the threshold. This would allow for consistent treatment of similar biological products in the unusual circumstance in which a biosimilar is priced above the reference biological. For the purpose of identifying biosimilar(s) related to a reference biological product, we would rely on the product's FDA approval under section 351(k) of the Public Health Service Act. For example, filgrastim-sndz (Zarxio), filgrastim-aafi (Nivestym), and filgrastim-ayow (Releuko) are biosimilars related to filgrastim (Neupogen).⁹³

(3) Comment Solicitation on Packaging Policy for Reference Biologicals and Biosimilars

While we have proposed to except threshold packaging of biosimilars when their reference biologicals are separately paid in this proposed rule, we are also soliciting comment on the packaging of payment for a reference biological and its biosimilar(s) into the payment for the associated service or procedure when the per-day cost of the reference biological, or any of its biosimilar(s), is less than or equal to the applicable OPSS drug packaging threshold. While both our proposed policy and the policy described by this comment solicitation share the goal of consistent treatment of similar biologic products, the method to achieve that goal differs. Our

⁹³ <https://purplebooksearch.fda.gov/results?query=filgrastim&title=Zarxio>

proposed policy would result in biosimilars being paid separately if their reference biologic is paid separately, whereas here we seek comment on a policy that would result in packaged payment for a biologic if the reference biologic or any of its biosimilars have per day costs below the drug packaging threshold.

For example, for purposes of this comment solicitation, if a biosimilar's per-day cost is above the threshold and separately paid but its reference product is packaged, the biosimilar (and all its related biosimilar(s)) would be packaged.

Additionally, we seek comment on other ways to structure payment for biologicals and biosimilars that would encourage efficiency while maintaining beneficiary access.

3. 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, we are continuing this payment policy for therapeutic radiopharmaceuticals in CY 2024. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP methodology (ASP, WAC, and AWP) information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. The rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals. Therefore, we are paying for all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP plus 6 percent (or applicable WAC or AWP amount) 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 OPPS/ASC final rule with comment period (74 FR 60520 through 60521).

Consistent with the policy we adopted for CY 2023 and subsequent years, for CY 2024 we will rely on the most recently available mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP methodology (ASP, WAC, and AWP) data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP methodology (ASP, WAC, and AWP) information is unavailable. For a complete history of the OPPS payment policy for therapeutic 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).

The proposed CY 2024 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B of this proposed rule (which are available on the CMS website).⁹⁴

4. Payment for Blood Clotting Factors

For CY 2023, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (87 FR 71969 through 71970). That is, for CY 2023, we provided payment for blood clotting factors under the OPPS at ASP plus 6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices or other settings for which Medicare makes payment under Part B, a furnishing fee is also applied to the payment. The CY 2023 updated furnishing fee was \$0.250 per unit.

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal for CY 2023 and subsequent years to pay for blood clotting factors at ASP plus

⁹⁴ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

6 percent, consistent with our payment policy for other nonpass-through, separately payable drugs and biologicals, and to pay an updated furnishing fee. Our policy to pay a furnishing fee for blood clotting factors under the OPSS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPSS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPSS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the PFS and OPSS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, 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 for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on our website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>.

5. 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. For CY 2024, we will continue to use the same payment policy as in CY 2023 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPSS hospital claims data. 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 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 1 day in the hospital outpatient setting and utilized the ASP methodology to determine their proposed payment status indicators. We refer readers to Table 40 below for the proposed CY 2024 status indicator for each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data which are also listed in Addendum B to this proposed rule, which is available on the CMS website.⁹⁵

TABLE 40: DRUGS AND BIOLOGICALS WITHOUT OPPS CLAIMS DATA

CY 2024 HCPCS Code	CY 2024 Long Descriptor	Proposed CY 2024 Status Indicator	Proposed CY 2024 APC
90378	Respiratory syncytial virus monoclonal antibody, recombinant, for intramuscular use, 50 mg, each	K	9003
A9604	Samarium SM-153 lexidronam, therapeutic, per treatment dose, up to 150 millicuries	K	1295
C9488	Injection, conivaptan hydrochloride, 1 mg	K	9488
J0470	injection, dimercaprol, per 100 mg	K	9039
J0691	Injection, lefamulin, 1 mg	K	
J0800	injection, corticotropin, up to 40 units	K	9040
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)	N	9202
J1426	Injection, casimersen, 10 mg	G	9412
J1427	Injection, viltolarsen, 10 mg	K	9386
J1429	Injection, golodirsen, 10 mg	K	9356
J1458	injection, galsulfase, per 5 mg	K	
J1551	Injection, immune globulin (cutaquist), 100 mg	K	9007
J1554	Injection, immune globulin (asceniv), 500 mg	K	9392
J1632	Injection, brexanolone, 1mg	K	9333
J1951	Injection, leuprolide acetate for depot suspension (fensolvi), 1 mg	K	9419

⁹⁵ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	K	9197
J3485	injection, zidovudine, 10 mg	E2	
J7181	Factor XIII (antihemophilic factor, recombinant), Tretten, per i.u.	K	
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	K	9468
J7332	Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg	K	
J8705	Topotecan, oral, 0.25 mg	K	
J9019	Injection, asparaginase (erwinaze), 1,000 iu	K	9289
J9210	Injection, emapalumab-lzsg, 1 mg	K	9310
J9348	Injection, naxitamab-gqgk, 1 mg	G	9408
Q0222	Injection, bebtelovimab, 175 mg	K	9401
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	K	9035
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	K	9391
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

6. Proposed OPPS Payment Methodology for 340B Purchased Drugs and Biologicals

a. Overview

Under the OPPS, we generally set payment rates for separately payable drugs and biologicals under section 1833(t)(14)(A) of the Act. Section 1833(t)(14)(A)(iii)(II) of the Act provides that, if hospital acquisition cost data is not available, the payment amount is the average price for the drug in a year established under section 1842(o) of the Act, which cross-references section 1847A of the Act, which generally sets a default rate of ASP plus 6 percent for certain drugs and biologicals. The provision also provides that the average price for the drug or

biological in the year as established under section 1847A of the Act is calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). As described below, beginning in CY 2018, the Secretary adjusted the 340B drug payment rate to ASP minus 22.5 percent to approximate a minimum average discount for 340B drugs and biologicals, which was based on findings of the GAO⁹⁶ and MedPAC⁹⁷ that 340B hospitals were acquiring drugs and biologicals at a significant discount under HRSA's 340B Drug Pricing Program. We direct readers to the CY 2018 OPPTS/ASC final rule with comment period for a more detailed discussion of the 340B drug payment policy (82 FR 52493 to 52511).

This policy has been the subject of extensive litigation, including before the Supreme Court of the United States. On June 15, 2022, the Supreme Court held in *American Hospital Association v. Becerra*, 142 S. Ct. 1896, that if CMS has not conducted a survey of hospitals' acquisition costs, it may not vary the payment rates for outpatient prescription drugs by hospital group. While the Supreme Court's decision addressed payment rates for CYs 2018 and 2019, it had implications for subsequent payment rates. Therefore, for CY 2023, we finalized a policy to revert to the default payment rate, which is generally ASP plus 6 percent, for 340B acquired drugs and biologicals and finalized a policy to pay for 340B acquired drugs and biologicals no differently than we pay for drugs and biologicals that are not acquired through the 340B program. We also finalized a budget neutrality adjustment to the CY 2023 OPPTS conversion factor of 0.9691 percent rather than the 0.9596 percent adjustment we had proposed. This adjustment offset the prior increase of 3.19 percent that was applied to the conversion factor when we implemented the 340B payment policy in CY 2018 in a budget neutral manner and

⁹⁶ Government Accountability Office. "Medicare Part B Drugs: "Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals." June 2015. Available at <https://www.gao.gov/assets/gao-15-442.pdf>.

⁹⁷ Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at <https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program-pdf/>.

ensured the CY 2023 conversion factor was equivalent to the conversion factor that would be in place if the 340B drug payment policy had never been implemented.

After the publication of the proposed CY 2023 OPSS rule, on September 28, 2022, the District Court issued a final judgment vacating the 340B reimbursement rate for the remainder of 2022, which the District Court explained would automatically reestablish the default rate for 340B-acquired drugs and biologicals. The agency took the necessary steps, including issuing instructions to Medicare contractors and updating drug payment files, to implement that September 28, 2022 decision and has since paid the default rate, which is generally ASP plus 6 percent, for 340B acquired drugs and biologicals.⁹⁸

b. Payment for 340B Drugs and Biologicals in CYs 2018 through 2022

For full descriptions of our OPSS payment policy for drugs and biologicals acquired under the 340B program beginning in CY 2018, we refer readers to the CY 2018 OPSS/ASC final rule with comment period (82 FR 59353 through 59371); the CY 2019 OPSS/ASC final rule with comment period (83 FR 59015 through 59022); the CY 2021 OPSS/ASC final rule with comment period (85 FR 86042 through 86055); the CY 2022 OPSS/ASC final rule with comment period (86 FR 63640 through 63649); and the CY 2023 OPSS/ASC final rule with comment period (87 FR 71970 through 71976).

In July, 2023, CMS published a proposed rule, referred to as “remedy proposed rule” to address the reduced payment amounts to 340B hospitals under the reimbursement rates in the final OPSS rules for CYs 2018 through 2022 and to comply with the statutory requirement to maintain budget neutrality under the OPSS. The remedy proposed rule does not propose changes to our CY 2024 OPSS drug payment policy nor the CY 2024 OPSS conversion factor, but it does propose changes to the calculation of the OPSS conversion factor beginning in CY 2025. We believe our proposed remedy rule is consistent with the Supreme Court’s decision in *American*

⁹⁸ Vacating Differential Payment Rate for 340B-Acquired Drugs in 2022 Outpatient Prospective Payment System Final Rule with Comment Period. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>

Hospital Association and the District Court’s remand order. We refer readers to the 340B remedy proposed rule for a full description of this proposed remedy policy as well as for when comments are due to that proposed rule. This document can be found in the **Federal Register** and on the CMS website.⁹⁹

c. CY 2024 Proposed 340B Drug Payment Policy

For CY 2024, consistent with our policy finalized for CY 2023, we propose to continue to pay the statutory default rate, which is generally ASP plus 6 percent, for 340B acquired drugs and biologicals. The payment for 340B acquired drugs and biologicals will not differ from the payment rate for drugs and biologicals not acquired through the 340B program. We believe this policy is appropriate given the Supreme Court decision discussed previously.

In the CY 2023 OPPTS/ASC final rule with comment period, we maintained the requirement that 340B hospitals report the “JG” (*Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes*) or “TB” (*Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities*) modifiers to identify drugs and biologicals acquired through the 340B Program for informational purposes (87 FR 71974). We explained that we believed maintaining both modifiers would reduce provider burden compared to shifting to a single modifier, as all providers can continue utilizing the modifier (either “JG” or “TB”) that they had been using for the previous five calendar years. On December 20, 2022, we issued “Part B Inflation Rebate Guidance: Use of 340B Modifiers,” which, in accordance with section 1847A(i) of the Act, requires all 340B covered entities, including hospital-based and non-hospital-based entities, to report the applicable modifier for separately payable drugs and biologicals acquired through the 340B Program.¹⁰⁰ Section 1847A(i) of the Act, as added by the Inflation Reduction Act, requires the Secretary to establish a Part B inflation rebate by manufacturers of certain single source

⁹⁹ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>

¹⁰⁰ <https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf>.

drugs and biologicals with prices increasing faster than the rate of inflation. Section 1847A(i)(3)(B)(ii)(I) of the Act specifically excludes units of drugs and biologicals for which the manufacturer provides a discount under the 340B program from the units of drugs and biologicals for which a manufacturer otherwise may have a Part B inflation rebate liability. Effective implementation of the Part B inflation rebate requires CMS to identify units of drugs and biologicals acquired through the 340B Program so they can be subtracted from the total number of otherwise rebatable units as applicable. This guidance explained that the “JG” and “TB” modifiers provide an existing mechanism to identify drugs and biologicals acquired through the 340B Program that is familiar to most 340B covered entities paid under the OPSS, and stated that it did not change the requirements in the CY 2023 OPSS/ASC final rule with comment period (i.e., that 340B covered entity hospitals should continue to use the modifiers they used previously to identify 340B drugs and biologicals). For claims with dates of service beginning no later than January 1, 2024, the guidance instructed all 340B covered entities to report the appropriate modifier, including those not currently reporting the “JG” or “TB” modifier, such as Ryan White clinics and hemophilia clinics, which should report the “JG” modifier on separately payable Part B claim lines for drugs and biologicals acquired through the 340B Program.

Although we stated in the CY 2023 OPSS/ASC final rule with comment period and in the “Part B Inflation Rebate Guidance: Use of 340B Modifiers” that hospital-based 340B covered entities should continue to use the modifier they used previously (either the “JG” or “TB” modifier), we now believe utilizing a single modifier will allow for greater simplicity, especially because both modifiers are used for the same purpose: to identify separately payable drugs and biologicals acquired under the 340B Program. Requiring hospitals to report a single modifier would allow CMS to continue to identify and exclude 340B-acquired drugs and biologicals from the definition of units for the purpose of Part B inflation rebate liability, while eliminating the need to use two modifiers for the same purpose. Additionally, we believe this proposal would

lessen the burden on providers as they would only have to report one modifier for all scenarios in which a 340B drug is acquired. Accordingly, we propose that all 340B covered entity hospitals paid under the OPSS would report the “TB” modifier effective January 1, 2025, even if the hospital previously reported the “JG” modifier.

The “JG” modifier would remain effective through December 31, 2024. Hospitals that currently report the “JG” modifier could choose to continue to use it in CY 2024 or choose to transition to use of the “TB” modifier during that year. Beginning on January 1, 2025, the “JG” modifier would be deleted and hospitals would be required to report drugs and biologicals acquired through the 340B program using the “TB” modifier. Additionally, beginning January 1, 2025, we would revise the “TB” modifier descriptor (*Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities*) to no longer include “...for select entities” as all entities would report this modifier after this date. We note that this proposal, if finalized, would update the December 20, 2022, guidance titled “Part B Inflation Rebate Guidance: Use of the 340B Modifiers.”¹⁰¹ Additionally, CMS plans to further update this guidance to align the modifier requirements for 340B covered entity providers and suppliers not paid under the OPSS with proposed modifier requirement changes for 340B covered entity hospitals paid under the OPSS.

For more information on the Medicare Part B inflation rebate program, please visit [“Inflation Rebates in Medicare.”](#)

7. High Cost/Low Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPSS/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

¹⁰¹ <https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf>

methodology that divides the skin substitutes into a high-cost group and a low-cost group, to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66886), we stated that skin substitutes are best characterized as either surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical devices and supplies.

Skin substitutes assigned to the high-cost group are described by 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 code 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 code 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 2023, the payment rate for APC 5053 (Level 3 Skin Procedures) was \$580.95, the payment rate for APC 5054 (Level 4 Skin Procedures) was \$1,725.86, and the payment rate for APC 5055 (Level 5 Skin Procedures) was \$3,253.04. This information is also available in Addenda A and B of the CY 2023 final rule with comment period (87 FR 71748) (the final rule and Addenda A and B are available on the CMS website (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>)).

We have continued the high cost/low cost categories policy since CY 2014, and we propose to continue it for CY 2024. 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 OPPTS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPTS/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 OPPTS/ASC final rule with comment period (80 FR 70434 through 70435). Beginning in CY 2016 and in subsequent years, 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); 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 2024

For CY 2024, 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 2022 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 2024 MUC threshold is \$47 per cm² (rounded to the nearest \$1) and the proposed CY 2024 PDC threshold is \$817 (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 2024, as we did for CY 2023, 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 was assigned to the high-cost group in CY 2023 would be assigned to the high-cost group for CY 2024, regardless of whether it exceeds or falls below the CY 2024 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 2024, 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 existing 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 41 includes the proposed CY 2024 cost category assignment for each skin substitute product.

TABLE 41: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH-COST AND LOW-COST GROUPS FOR CY 2024

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
A2001	Innovamatrix ac, per sq cm	High	High
A2002	Mirragen adv wnd mat per sq	High	High

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 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
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	Low	High
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
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	Transcyte, 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
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sq cm	High	High

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
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*
Q4210	Axolotl graf dualgraf 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	Low
Q4217	Woundfix biowound plus xplus	High	High
Q4218	Surgicord per sq cm	Low	High
Q4219	Surgigraft dual per sq cm	High*	High*
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	Low
Q4222	Progenamatrix, per sq cm	High	High*
Q4224	Hhfl0-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
Q4228	Bionextpatch, per sq cm	Low	Low
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	Low	High
Q4253	Zenith amniotic membrane psc	Low	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
Q4262	Dual layer impax, per sq cm	Low	Low
Q4263	Surgraft tl, per sq cm	Low	Low

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
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	Low
Q4269	Surgraft xt per sq cm	Low	Low
Q4270	Complete sl per sq cm	Low	Low
Q4271	Complete ft per sq cm	Low	Low

* These products do not exceed either the MUC or PDC threshold for CY 2024 but are assigned to the high-cost group because they were assigned to the high-cost group in CY 2023.

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. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, has been 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 has been promoting 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 new costs into the payment system that were not accounted for in the historical claims data.

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 OPPTS/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). A 2016 report from the National Academies of Sciences, Engineering, and Medicine anticipated the conversion of Tc-99m production from non-HEU sources would be completed at the end of 2019.¹⁰² However, the Secretary of Energy issued a certification effective January 2, 2020, stating that there continued to be an insufficient global supply of molybdenum-99 (Mo-99), which is the source of Tc-99m, produced without the use of HEU, available to satisfy the domestic U.S. market (85 FR 3362). The January 2, 2020 certification was to remain in effect for up to 2 years.

The Secretary of Energy issued a new certification regarding the supply of non-HEU-sourced Mo-99 effective January 2, 2022 (86 FR 73270). This certification 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. The Department of Energy also expected that the last HEU reactor that produces Mo-99 for medical providers in the United States would finish its conversion to a non-HEU reactor by December 31, 2022. In CY 2019, we stated that we would reassess the non-HEU incentive payment policy once conversion to non-HEU sources is closer to completion or has been completed (83 FR 58979). There is now a sufficient supply of non-HEU-sourced Mo-99 in the United States, and there is no available supply of HEU-sourced Mo-99 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

¹⁰² National Academies of Sciences, Engineering, and Medicine. 2016. Molybdenum-99 for Medical Imaging. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/23563>.

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 OPSS, diagnostic radiopharmaceuticals are packaged into the cost of the associated diagnostic imaging procedure no matter the per day cost of the radiopharmaceutical. 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 OPSS generally is from 2 years prior to the payment year.

As we explained in the CY 2023 OPSS/ASC final rule with comment period (87 FR 71987), the claims data we would use to set payment rates for CY 2024 (likely CY 2022 claims data) contain 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.

This policy was based on the Secretary of Energy's certification that the last HEU reactor that produces Mo-99 for medical providers in the United States would finish its conversion to a non-HEU reactor by December 31, 2022, and that all Tc-99m used for radiopharmaceuticals in

2023 would be produced from non-HEU sources. However, we understand that the conversion of the last HEU reactor that produces Tc-99m to a non-HEU reactor 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.

We believe that extending the additional \$10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2025 rather than the end of CY 2024, as we previously finalized, would ensure adequate payment for non-HEU-sourced Tc-99m now that the conversion from HEU-sourced Tc-99m to non-HEU-sourced Tc-99m is complete. Starting in CY 2026, the Medicare claims data utilized to set payment rates (likely CY 2024 claims data) will only include claims for diagnostic radiopharmaceuticals that utilized non-HEU-sourced Tc-99m, which means the data will more closely reflect the cost of the Tc-99m diagnostic radiopharmaceuticals that will be used by providers in CY 2026. As a result, there will no longer be a need for the additional \$10 add-on payment for CY 2026 or future years.

We propose to continue the additional \$10 payment through December 31, 2025, as beginning in CY 2026, the Medicare claims data used to set payment rates will reflect the full cost of non-HEU-sourced Tc-99m.

C. Requirement in the Physician Fee Schedule CY 2024 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 2024 PFS proposed rule includes proposals to operationalize section 90004 of the Infrastructure Act, including a proposal that impacts hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Similar to our CY 2023 notice in the OPPI/ASC proposed rule (87 FR 71988), we want to ensure interested parties are aware of these proposals and know to refer to the Physician Fee Schedule (PFS) proposed rule for a full description of the proposed policy. Interested parties are asked to submit comments on any proposals related to implementation of section 90004 of the Infrastructure Act on the CY 2024 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2024 PFS final rule with comment period. We note that this same notice appears in section XIII.D.3 of this proposed rule.

VI. Proposed Estimate of OPPI 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 OPPI 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 2024 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 2024. 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 2023 or beginning in CY 2024. The sum of the proposed CY 2024 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2024 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 proposed 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 2024, 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 2024, and therefore our estimate of drug and biological pass-through payment for CY 2024 for this group of items is \$100 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, propose that all of these policy-packaged drugs and biologicals with pass-through payment status would generally be paid at ASP plus 6 percent, like other pass-through drugs and biologicals, for CY 2024, less the policy-packaged drug APC offset amount described below. Our estimate of passthrough payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2024 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 passthrough 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 2024. 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 2023 or beginning in CY 2024. The sum of the CY 2024 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2024 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending for CY 2024

For CY 2024, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2024, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2023

(87 FR 719889). 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 2024, there are 7 active categories for CY 2024. The active categories are described by HCPCS codes C1747, C1761, C1826, C1827, C1831, C1832, and C1833. Based on the information from the device manufacturers, we estimate that HCPCS code C1747 will cost \$37.5 million in pass-through expenditures in CY 2024, HCPCS code C1761 will cost \$19.6 million in pass-through expenditures in CY 2024, HCPCS code C1826 will cost \$7.4 million in pass-through expenditures in CY 2024, HCPCS code C1827 will cost \$28.8 million in pass-through expenditures in CY 2024, HCPCS code C1831 will cost \$163,436 in pass-through expenditures in CY 2024, HCPCS code C1832 will cost \$37,603 in pass-through expenditures in CY 2024, and HCPCS code C1833 will cost \$281,238 in pass-through expenditures in CY 2024. Therefore, we propose an estimate for the first group of devices of \$93.7 million.

In estimating our proposed CY 2024 pass-through spending for device categories in the second group, we included: 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 2024; additional device categories that we estimated could be approved for pass-through status after the development of this proposed rule and before January 1, 2024; and contingent projections for new device categories established in the second through fourth quarters of CY 2024. For CY 2024, we propose to use the general methodology described in the CY 2008 OPPI/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPI experience in approving new pass-through device categories. For this proposed rule, the proposed estimate of CY 2024 pass-through spending for this second group of device categories is \$40.4 million.

To estimate proposed CY 2024 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 2024, we propose to use the CY 2022 Medicare hospital outpatient claims data regarding their utilization, information provided in the respective pass-through applications, other historical hospital claims data, pharmaceutical industry information, and clinical information regarding these drugs and biologicals to project the CY 2024 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 continue to have pass-through payment status in CY 2024, we estimate the pass-through payment amount as the difference between ASP plus 6 percent and the payment rate for non pass-through drugs and biologicals that will be separately paid. Because we propose to apply a payment rate of ASP plus 6 percent to 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 2024 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP plus 6 percent (or WAC plus 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, which we estimate for CY 2024 for the first group of policy-packaged drugs to be \$90 million.

To estimate proposed CY 2024 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 2023, 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, 2024, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2024), 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 2024 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 2024 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 2024 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2024 would be approximately \$234.1 million (approximately \$134.1 million for device categories and approximately \$100 million for drugs and biologicals) which represents 0.26 percent of total projected OPSS payments for CY 2024 (approximately \$88.6 billion). Therefore, we estimate that pass-through spending in CY 2024 would not amount to 2.0 percent of total projected OPSS CY 2024 program spending.

VII. Proposed OPSS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2024, 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 OPSS/ASC final rule with comment period (80 FR 70448). We also propose to continue our payment policy for critical care services for CY 2024. For a description of this policy, we refer readers to the CY 2016 OPSS/ASC final rule with comment period

(80 FR 70449), and for the history of this payment policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043).

As we stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63663), the volume control method for clinic visits furnished by non-excepted off-campus provider-based departments (PBDs) applies for CY 2023 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 2023 and beyond. The PFS-equivalent rate for CY 2024 is 40 percent of the proposed OPPS payment. Under this policy, these departments will be paid approximately 40 percent of the OPPS rate for the clinic visit service in CY 2024.

In the CY 2023 OPPS/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 Physician Fee Schedule-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this policy, we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051). For CY 2024, 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 proposed payment for partial hospitalization services as well as intensive outpatient services. Since CY 2000, Medicare has paid for partial hospitalization services under the OPPS. Beginning in CY 2024, as authorized by section 4124 of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-328), Medicare will begin paying

for intensive outpatient services furnished by hospital outpatient departments, community mental health centers, federally qualified health centers and rural health clinics. Additional background on the partial hospitalization and intensive outpatient benefits is included in the following paragraphs.

A. Partial Hospitalization

1. Background

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. 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 OPPTS 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 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B of the CY 2011 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 OPSS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPSS/ASC proposed rule (78 FR 43621 through 43622) and CY 2015 OPSS/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 OPPTS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016, 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 CY 2017 OPPTS/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 OPPTS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680, respectively).

In the CYs 2018 and 2019 OPPTS/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 OPPTS/ASC final rule with comment period (84 FR 61352).

In the CY 2020 OPPTS/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 OPSS, 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, so long as the location meets all conditions of participation to the extent not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. In the CY 2023 OPSS/ASC final rule (87 FR 72247), we confirmed these provisions as final, including that they apply 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 OPSS/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 OPSS/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).

Section 4124(a) of Division FF of the CAA, 2023 amends section 1861(ff)(1) of the Act to modify the definition of partial hospitalization services furnished on or after January 1, 2024. Specifically, section 4124(a) of the CAA, 2023 amends section 1861(ff)(1) of the Act by adding to the current definition that partial hospitalization services are “for an individual determined (not less frequently than monthly) by a physician to have a need for such services for a minimum of 20 hours per week.” We discuss these revisions to the definition of partial hospitalization services in the following section, section VIII.A.2, of this proposed rule.

2. Revisions to PHP Physician Certification Requirements

As amended by section 4124(a) of the CAA, 2023, section 1861(ff)(1) requires that a physician determine that each patient needs a minimum of 20 hours of PHP services per week, and this determination must occur no less frequently than monthly. We propose to codify this requirement in regulation as an additional requirement for the physician certification applicable for PHP services that we would add to § 424.24(e)(1)(i). We are not proposing any changes to the existing physician certification requirements for PHP, including that the patient would require inpatient hospitalization if they did not receive PHP services, which would remain at § 424.24(e)(1)(i).

Existing regulations at § 410.43 set forth conditions and exclusions that apply for partial hospitalization services. Under § 410.43(a)(3), partial hospitalization services are services that are furnished in accordance with a physician certification and plan of care as specified under § 424.24(e). Additionally, current patient eligibility criteria at § 410.43(c)(1) state that partial hospitalization programs are intended for patients who require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care. Because partial hospitalization services are already required to be furnished in accordance with a physician certification and plan of care, we believe it is appropriate to include this 20-hour minimum weekly requirement as a physician

certification requirement at § 424.24(e)(1)(i). We note that we do not believe this proposed change to the regulation would create a new requirement for PHPs from a practical perspective, as the change to the definition of partial hospitalization services made by the CAA, 2023 is consistent with the longstanding 20-hour minimum weekly regulatory requirement at § 410.43(c)(1) that Medicare has applied to PHP.

We propose to modify the regulation at § 424.24(e)(1)(i) to require the physician certification for PHP services include a certification that the patient requires such services for a minimum of 20 hours per week. Current regulations at § 424.24(e)(3)(ii) require an initial recertification after 18 days, with subsequent recertifications of PHP services no less frequently than every 30 days. We believe this interval is consistent with the CAA, 2023 requirement that the physician's determination of the need for PHP services at least 20 hours per week must occur no less frequently than monthly.

B. Intensive Outpatient Program Services

1. Establishment of Intensive Outpatient Services Benefit by Section 4124 of the CAA, 2023

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. Section 4124(b)(1)(A) of the CAA, 2023 amended section 1832(a)(2)(J) of the Act to add intensive outpatient services to the scope of covered benefits provided by CMHCs, and section 4124(b)(1)(B) amended section 1861(s)(2)(B) to add intensive outpatient services to the definition of "medical and other health services", specifically, as a service furnished "incident to a physicians' services."

Intensive outpatient services are furnished under an intensive outpatient program (IOP). Similar to PHP, an IOP is a distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders. Generally speaking, an IOP is thought to be less intensive than a PHP, and the statutory definition of IOP services

reflects this difference in intensity. Specifically, section 4124(b)(2)(B) of the CAA, 2023 amended section 1861(ff) of the Act to add a new paragraph (4) to define the term “intensive outpatient services” as having the same meaning as “partial hospitalization services” in paragraph (1). In particular, intensive outpatient services are the items and services described in paragraph (2) prescribed by a physician for an individual determined (not less frequently than once 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 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. For patients of an IOP, section 1835(a)(2)(F)(i) of the Act does not apply, that is, individuals receiving IOP would not require inpatient psychiatric care in the absence of such services. Lastly, section 4124(b)(2)(B) of the CAA, 2023 further added to section 1861(ff)(4)(C), which cross-references paragraph (3), that an IOP is a program furnished by a hospital to its outpatients, or by a community mental health center (CMHC), a Federally qualified health center (FQHC), or 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 4124(c) of the CAA, 2023 amends section 1834 of the Act by adding a new paragraph (5) to subsection (o) and a new paragraph (3) to subsection (y), which include special payment rules for intensive outpatient services furnished in FQHCs and RHCs, which are discussed in greater detail in section VIII.F of this proposed rule.

This proposed rule includes proposals to establish payment and program requirements for the IOP benefit in all of the above-described settings. Section VIII.B.2 of this proposed rule discusses the proposed scope of benefits for IOP services, and section VIII.B.3 of this proposed rule discusses proposed physician certification requirements. Section VIII.C of this proposed

rule discusses proposed coding and billing for both PHP and IOP services under the OPSS beginning in CY 2024. Section VIII.D of this proposed rule discusses the proposed payment methodology. Section VIII.E of this proposed rule discusses proposed outlier policy for CMHCs. Section VIII.F of this proposed rule discusses proposed payment for IOP in FQHCs and RHCs, and Section VIII.G of this proposed rule discusses proposed payment for IOP in Opioid Treatment Programs (OTPs).

2. IOP Scope of Benefits

Section 1861(ff)(2) of the Act describes the items and services available under the IOP benefit. These items and services include: individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered); individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; and such other items and services as the Secretary may provide (excluding meals and transportation) that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish, taking into account accepted norms of medical practice and the reasonable expectation of patient improvement.

Consistent with the statutory definition of intensive outpatient services under section 1861(ff)(2) of the Act, we propose to add regulations at 42 CFR 410.44 to set forth the conditions and exclusions that would apply for intensive outpatient services. Consistent with the existing regulations for partial hospitalization services, we propose to require that intensive outpatient services must be furnished in accordance with a physician certification and plan of care. However, where partial hospitalization requires the physician to certify that the services are instead of inpatient hospitalization, intensive outpatient program services are not intended for those who otherwise need an inpatient level of care. That is, section 1861(ff)(4)(A) of the Act, as added by section 4124 of the CAA, 2023, states that for intensive outpatient services, section 1835(a)(2)(F)(i) shall not apply. As further discussed in section VIII.B.3 of this proposed rule, we propose to add language to the regulation at § 424.24(d), which is currently reserved, that would set forth the physician certification and plan of care requirements for intensive outpatient services.

Additionally, we propose to revise 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 OPSS. We propose to create 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 propose to revise § 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. We discuss these proposed changes in the following paragraphs.

a. Proposed Definition of Intensive Outpatient Services

We propose the following definition at § 410.2 for intensive outpatient services:

Intensive outpatient services means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in § 410.44. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization. We note that the proposed definition for intensive outpatient services is consistent with the statutory requirements of section 1861(ff)(3)(A), which apply to both IOP and PHP services. Accordingly, the proposed definition is largely consistent with the existing regulatory definition of partial_hospitalization services. However, in accordance with section 1861(ff)(4)(A) of the Act, as added by the CAA, 2023, we are including a clarification in the regulatory definition of “intensive outpatient services” that they are not required to be provided in lieu of inpatient hospitalization. We are including this clarification in order to more clearly differentiate between the definitions of partial hospitalization and intensive outpatient at § 410.2.

The conditions and exclusions for partial hospitalization services are included in the regulation at § 410.43. We propose that the conditions and exclusions for intensive outpatient services would be included in new regulations at § 410.44.

At new § 410.44, we propose to establish regulatory language for intensive outpatient services that is consistent with the existing language for partial hospitalization conditions and exclusions and the statutory definition of intensive outpatient services. Specifically, under § 410.44(a) we propose that IOP services are services that: (1) are reasonable and necessary for the diagnosis or active treatment of the individual's condition; (2) are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; (3) are furnished in accordance with a physician certification and plan of care as specified under new regulations at § 424.24(d); and include any of the services listed in § 410.44(a)(4).

Under § 410.44(a)(4), we include a list of the types of services that we propose would be covered as intensive outpatient services:

- Individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State law.

- Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484 of this chapter.

- Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients.

- Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29.

- Individualized activity therapies that are not primarily recreational or diversionary.

- Family counseling, the primary purpose of which is treatment of the individual's condition.

- Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.

- Diagnostic services.

The proposed list at § 410.44(a)(4) is based on the list of items and services described in section 1861(ff)(2) of the Act. We note that 1861(ff)(2) of the Act also provides that intensive outpatient services may include such other items and services as the Secretary may provide (but in no event to include meals and transportation). As discussed in section VIII.C of this proposed rule, we solicit comments on whether additional codes should be added to the list of services recognized as appropriate for PHP and IOP.

We further note that both the statute at section 1861(ff)(2)(C) of the Act and our proposed regulation at § 410.44(a)(4)(iii) refer to “trained psychiatric nurses, and other staff trained to work with psychiatric patients.” Under our longstanding policy for partial hospitalization services, we have considered nurses and other staff trained to work with patients within their state scope of practice who are receiving treatment for substance use disorder (SUD) to be included under this statutory definition and the regulatory definition of PHP at § 410.43(a)(4). We have heard from interested parties that there could be a misconception that Medicare does not cover PHP for the treatment of SUD. We are clarifying that, in general, notwithstanding the requirement that PHP services are provided in lieu of inpatient hospitalization, Medicare covers PHP for the treatment of SUD, and we consider services that are for the treatment of SUD and behavioral health generally to be consistent with the statutory and regulatory definition of PHP. We are taking this opportunity to clarify that the terms “trained psychiatric nurses, and other staff trained to work with psychiatric patients,” as used in § 410.43(a)(4) and § 410.44(a)(4) would include trained SUD nurses and other staff trained to work with SUD patients. Under § 410.44(b), we propose that the following services are separately covered and not paid as intensive outpatient services: (1) physician services; (2) physician assistant services; (3) nurse practitioner and clinical nurse specialist services; (4) qualified psychologist services; and (5) services furnished to residents of a skilled nursing facility (SNF). We note that these proposed exclusions are consistent with the services excluded from payment as partial hospitalization program services at § 410.43(b). The services listed under §§ 410.43(b) and 410.44(b) would be paid under the applicable systems for such services.

Lastly, under § 410.44(c), we propose to establish patient eligibility criteria for intensive outpatient services. Specifically, we propose that intensive outpatient services are intended for patients who: (1) require a minimum of 9 hours per week of therapeutic

services as evidenced in their plan of care; (2) are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment; (3) do not require 24-hour care; (4) have an adequate support system while not actively engaged in the program; (5) have a mental health diagnosis; (6) are not judged to be dangerous to self or others; and (7) have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program.

We note that these proposed patient eligibility criteria at § 410.44(c) are consistent with the existing partial hospitalization patient eligibility criteria at § 410.43(c). With respect to the proposed criterion of a “mental health diagnosis”, we are clarifying that a mental health diagnosis would include SUD and behavioral health diagnoses generally under both the existing partial hospitalization regulation at § 410.43(c)(5) and the proposed intensive outpatient services regulation at § 410.44(c)(5). As discussed earlier in this section, this inclusion of SUD and behavioral health diagnoses as among the patient eligibility criteria for PHP services is consistent with our longstanding policy. However, we have noted that interested parties have raised concerns that this policy may not be clear. Therefore, we are clarifying that the term “mental health diagnosis” as used at both §§ 410.43(c)(5) and 410.44(c)(5) would include SUD and behavioral health diagnoses.

b. Coverage of IOP as Medical and Other Health Services Paid under Part B

We propose to amend the regulation at § 410.10(c) to add a reference to “intensive outpatient services” to the list of services that are covered as medical and other health services under Part B, when furnished as hospital or CAH services incident to a physician’s professional services. We believe this is consistent with section 1861(s)(2)(B) of the Act, as amended by section 4124(b)(1)(B) of the CAA, 2023 to include “intensive outpatient services” under the definition of medical and other health

services; specifically, hospital services incident to a physicians' services. We note that the services described at § 410.10(c) are furnished by a hospital or CAH. Accordingly, we propose conforming changes to the regulations at §§ 410.27(a)(2) and paragraph (e) introductory text to include references to intensive outpatient services.

c. Technical Changes to Codify Requirements for IOP at CMHCs

We propose technical changes to the regulations at 42 CFR Parts 488 and 489.

First, we propose to add the statutory basis for IOP at CMHCs at § 488.2. The proposed technical revision would add section 1832(a)(2)(J) of the Act, which sets forth the statutory basis of intensive outpatient services provided by CMHCs at § 488.2.

We also propose to revise the provision at 42 CFR 489.2(c)(2) so that CMHCs may enter into provider agreements to furnish intensive outpatient services. We propose to revise the current requirement that allows for CMHCs to enter into provider agreements only for the provision of partial hospitalization services. The proposed revisions to this provision would allow CMHCs to enter into provider agreements only to furnish partial hospitalization services and intensive outpatient services.

d. Technical Changes to Codify Coverage of IOP at CMHCs

We propose several technical changes and additions to the regulations at §§ 410.2, 410.3, 410.111, and 410.150.

First, we propose to revise the definition of "Community Mental Health Center (CMHC)" at § 410.2 to refer to intensive outpatient services. Specifically, we propose to revise the regulation to state that a CMHC is an entity that provides day treatment or other partial hospitalization services or intensive outpatient services, or psychosocial rehabilitation services. Second, we propose to revise the definition of "Participating" at § 410.2 to refer to intensive outpatient services as services that CMHCs can provide. Specifically, we propose that "Participating" refers to a CMHC that has in effect an agreement to participate in Medicare, but only for the purposes of providing partial hospitalization services and intensive outpatient

services. We are clarifying that this proposed definition would allow a CMHC to be considered a participating provider of both partial hospitalization services and intensive outpatient services, but would not require a CMHC to provide both types of services in order to be considered participating.

In addition, we propose to revise the scope of benefits provision at § 410.3(a)(2) to provide that the covered services for which the Medicare Part B supplementary medical insurance (SMI) program helps pay include partial hospitalization services and intensive outpatient services provided by CMHCs. We believe these proposed changes are consistent with the scope of benefits provision at section 1832(a)(2)(J) of the Act, as amended by section 4124(b)(1)(A) of the CAA, 2023 to include intensive outpatient services, as well as the proposed CMHC conditions of participation at § 485.918(b)(1)(iii). We refer readers to section XVII.B.5 of this proposed rule for discussion on the proposed amendments to regulations at § 485.918(b)(1)(iii).

In addition, subpart E of § 410 includes requirements for Community Mental Health Centers (CMHCs) Providing Partial Hospitalization Services. We propose to modify the Subpart E heading to include a reference to intensive outpatient services as well. Under subpart E, we propose to add a new § 410.111 to set forth Requirements for coverage of intensive outpatient services furnished in CMHCs. We propose that Medicare Part B would cover IOP services furnished by or under arrangements made by a CMHC if the CMHC has in effect a provider agreement and the services are prescribed by a physician and furnished under the general supervision of a physician, and subject to the proposed physician certification and plan of care requirements under § 424.24(d).

Additionally, we propose to revise § 410.150(b)(13) to include a reference to intensive outpatient services. Specifically, we propose that payment would be made to a CMHC on an individual's behalf for partial hospitalization services or intensive outpatient services furnished by or under arrangements made by the CMHC.

Lastly, we propose to amend § 419.21(c) to refer to intensive outpatient services provided by CMHCs as services for which payment is made under the OPSS. This proposed amendment would be consistent with current regulations at § 419.21(c), which include partial hospitalization services provided by CMHCs. We note that further discussion of our proposed payment methodology under the OPSS for intensive outpatient services is found in section VIII.D of this proposed rule.

e. Exclusion of Intensive Outpatient Services from the Outpatient Mental Health Treatment Limitation

Section 1833(c)(2) of the Act, as amended by section 4124(b)(3) of the CAA, 2023, excludes intensive outpatient services that are not directly provided by a physician from the term “treatment” for the purposes of the outpatient mental health treatment limitation under section 1833(c)(1) of the Act, similar to partial hospitalization services. Accordingly, we propose to amend the regulations at § 410.155(b)(2)(iii) to state that intensive outpatient services not directly provided by a physician are not subject to the outpatient mental health treatment limitation.

3. IOP Certification and Plan of Care Requirements

Section 4124(b)(2)(B) of the CAA, 2023 amended section 1861(ff) of the Act by adding a new paragraph (4) to define intensive outpatient services as the items and services prescribed by a physician for an individual determined (not less frequently than once every other month) by a physician to have a need for such services for a minimum of 9 hours per week. This certification must occur no less frequently than once every other month, and there is no requirement to certify that IOP patients would need inpatient hospitalization if they did not receive such services, which is required for PHP patients.

We propose to codify the content of the certification and plan of treatment requirements for intensive outpatient services at § 424.24(d). Specifically, we propose

to mirror the PHP content of certification and plan of care treatment requirements at § 424.24(e), with the following exceptions: require the content of certification to include documentation that the individual requires such services for a minimum of 9 hours per week (with no requirement for the patient to need inpatient psychiatric care if the IOP services were not provided). The physician's certification of the patient's need for either IOP or PHP services should be based on the physician's determination of the patient's needs and whether the patient meets the IOP or PHP patient eligibility criteria under § 410.44(c) or § 410.43(c), respectively. We note that the physician's certification should certify the patient's need for either IOP or PHP, and that patients participating in an IOP or PHP should not be under any other IOP or PHP plan of care for the same date of service. The patient's individualized plan of treatment should address all of the conditions that are being treated by the IOP or PHP.

Additionally, we propose to require in the regulation at § 424.24(d)(3)(ii) that the recertification of IOP services occur no less frequently than every 60 days. We believe the IOP recertification timing of no less frequently than every 60 days is consistent with the requirement in the statute that an individual be determined by a physician to have a need for IOP services "not less frequently than once every other month" because the minimum number of days for two consecutive months is 59 days. We believe that a consistent 60-day interval would be the most appropriate way to implement the statutory recertification requirement for IOP.

We are soliciting public comments on whether it would be appropriate to consider finalizing a shorter interval for the first recertification and for subsequent recertification for IOP patients. For example, we request comments on whether we should consider requiring an initial recertification by the 30th day of IOP services, and no less frequently than every 60 days thereafter. We request that commenters provide as

much detail as possible about the rationale for a shorter recertification interval, if appropriate.

Lastly, we would make conforming changes to § 424.24(b) to add a reference to paragraph (d)(1) in the list of paragraphs that specify the content for which physician certification is required for medical and other health services furnished by providers (and not exempted under § 424.24(a)) which are paid for under Medicare Part B.

C. Coding and Billing for PHP and IOP Services under the OPSS

We considered the similarities between the types of items and services covered by both PHP and IOP, and the larger continuum of care, when developing the proposed list of services that we believe would appropriately identify the range of services that IOPs provide to Medicare beneficiaries. Since the statutory definitions of both IOP and PHP generally include the same types of items and services covered, 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.

Currently, hospital outpatient departments use condition code 41 to indicate that a claim is for partial hospitalization services. CMHCs do not currently use a condition code on the bill type used—that is, 76X—to indicate that a claim is for partial hospitalization services, because they are only considered a provider of services for partial hospitalization; and therefore, partial hospitalization services are identified by the 76X bill type. In order to differentiate between IOP and PHP for billing purposes, the National Uniform Billing Committee (NUBC) has approved a new condition code, condition code 92, to identify intensive outpatient claims. Therefore, we propose to require hospitals and CMHCs to report condition code 92 on claims to indicate that a claim is for intensive outpatient services. We propose to continue to require hospitals to report condition code 41 for partial hospitalization claims. Additionally, because

CMHCs would be permitted to provide both PHP and IOP beginning January 1, 2024, we also propose to require CMHCs to report condition code 41 for partial hospitalization claims. We believe that this requirement would better allow us to identify which claims are for PHP and which are for IOP. We are soliciting comment on these proposed reporting requirements for PHP and IOP.

Under current policy, PHPs submit claims with HCPCS codes to identify the services provided during each PHP day. Therefore, we worked in conjunction with physicians to develop a proposed consolidated list of all HCPCS codes that we believe would appropriately identify the full range of services that both IOPs and PHPs provide to Medicare beneficiaries. For reference, Table 42 includes the current list of HCPCS codes that are recognized for PHP payment. For CY 2024, we propose to add certain codes to the list, change the descriptions of other codes, and remove one code from the list. The list of proposed consolidated HCPCS codes is included in Table 43.

We recognize that the level of intensity of mental health services 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 would ensure a smooth transition for patients when a change in the intensity or 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. Therefore, we propose to add several HCPCS codes to the list in Table 43 that are currently recognized as mental health codes under the OPPS, but are not recognized for PHP payment.

TABLE 42: CURRENT HCPCS APPLICABLE FOR PHP

HCPCS	Short Descriptor
90785	Psytx complex interactive
90791	Psych diagnostic evaluation
90792	Psych diag eval w/med srvc
90832	Psytx pt&/family 30 minutes
90833	Psytx pt&/fam w/e&m 30 min
90834	Psytx pt&/family 45 minutes
90836	Psytx pt&/fam w/e&m 45 min
90837	Psytx pt&/family 60 minutes
90838	Psytx pt&/fam w/e&m 60 min
90845	Psychoanalysis
90846	Family psytx w/o patient
90847	Family psytx w/patient
90865	Narcosynthesis
90880	Hypnotherapy
96116	Neurobehavioral status exam
96130	Psychological testing evaluation by physician/qualified health care professional; first hour
96131	Psychological testing evaluation by physician/qualified health care professional; each additional hour
96132	Neuropsychological testing evaluation by physician/qualified health care professional; first hour
96133	Neuropsychological testing evaluation by physician/qualified health care professional; each additional hour
96136	Psychological/neuropsychological testing by physician/qualified health care professional; first 30 minutes
96137	Psychological/neuropsychological testing by physician/qualified health care professional; each additional 30 minutes
96138	Psychological/neuropsychological testing by technician; first 30 minutes
96139	Psychological/neuropsychological testing by technician; each additional 30 minutes
96146	Psychological/neuropsychological testing; automated result only
G0129	Partial hosp prog service
G0176	Opps/php;activity therapy
G0177	Opps/php; train & educ serv
G0410	Grp psych partial hosp 45-50
G0411	Inter active grp psych parti

We propose to maintain all of the codes in Table 42, except for one code. We propose to remove 90865 Narcosynthesis, because we do not believe this code is widely used in the provision of PHP, and we do not anticipate it would be widely used in the provision of IOP in the future. We propose that the HCPCS codes listed in Table 43 would be payable when furnished by PHPs or IOPs.

TABLE 43: PROPOSED HCPCS APPLICABLE FOR PHP AND IOP

HCPCS/CPT	Short Descriptor	Proposed Action
90785	Psytx complex interactive	
90791	Psych diagnostic evaluation	
90792	Psych diag eval w/med srvc	
90832	Psytx pt&/family 30 minutes	
90833	Psytx pt&/fam w/e&m 30 min	
90834	Psytx pt&/family 45 minutes	
90836	Psytx pt&/fam w/e&m 45 min	
90837	Psytx pt&/family 60 minutes	
90838	Psytx pt&/fam w/e&m 60 min	
90839	Psytx crisis initial 60 min	Add
90845	Psychoanalysis	
90846	Family psytx w/o patient	
90847	Family psytx w/patient	
90849	Multiple family group psytx	Add
90853	Group psychotherapy	Add
90865	Narcosynthesis	Remove
90880	Hypnotherapy	
90899	Psychiatric service/therapy	Add
96112	Devel tst phys/qhp 1st hr	Add
96116	Neurobehavioral status exam	
96130	Psychological testing evaluation by physician/qualified health care professional; first hour	
96131	Psychological testing evaluation by physician/qualified health care professional; each additional hour	
96132	Neuropsychological testing evaluation by physician/qualified health care professional; first hour	
96133	Neuropsychological testing evaluation by physician/qualified health care professional; each additional hour	
96136	Psychological/neuropsychological testing by physician/qualified health care professional; first 30 minutes	
96137	Psychological/neuropsychological testing by physician/qualified health care professional; each additional 30 minutes	
96138	Psychological/neuropsychological testing by technician; first 30 minutes	
96139	Psychological/neuropsychological testing by technician; each additional 30 minutes	
96146	Psychological/neuropsychological testing; automated result only	
96156	Hlth bhv assmt/reassessment	Add
96158	Hlth bhv ivntj indiv 1st 30	Add
96164	Hlth bhv ivntj grp 1st 30	Add
96167	Hlth bhv ivntj fam 1st 30	Add
97151	Bhv id assmt by phys/qhp	Add
97152	Bhv id suprt assmt by 1 tech	Add
97153	Adaptive behavior tx by tech	Add
97154	Grp adapt bhv tx by tech	Add
97155	Adapt behavior tx phys/qhp	Add
97156	Fam adapt bhv tx gdn phy/qhp	Add
97157	Mult fam adapt bhv tx gdn	Add
97158	Grp adapt bhv tx by phy/qhp	Add
G0129	PHP/IOP service	Update
G0176	Opps/php/IOP; activity thrpy	Update

HCPCS/CPT	Short Descriptor	Proposed Action
G0177	Opps/php/IOP; train & educ	Update
G0410	Grp psych PHP/IOP 45-50	Update
G0411	Interactive grp psyc PHP/IOP	Update
G0451	Development test interpt&rep	Add

We propose to add 18 codes to the list of recognized PHP/IOP codes, as shown in Table 43. These codes are currently recognized as mental health codes under the OPPTS, and we believe it would be appropriate to recognize them for PHP and IOP as well. Additionally, we propose to update the descriptions of five existing Level II HCPCS codes that are currently recognized for PHP to also refer to IOP.

As shown in Table 43, we propose to add CPT code 90853 Group psychotherapy to the list of service codes recognized for PHP and IOP. We believe there could be overlap between 90853 and two existing Level II HCPCS codes for PHP group psychotherapy, specifically G0410 and G0411. We are considering whether it would be appropriate to remove G0410 and G0411 from the list of recognized service codes for PHP and IOP, and retain only CPT code 90853. We are soliciting comments on this topic, and we are interested in hearing specific reasons commenters believe support either keeping G0410 and G0411 on the list or removing them. We are particularly interested in understanding whether it would be appropriate to maintain these codes on a temporary basis to provide a transition for existing PHPs that are using these codes.

We propose to use the list of HCPCS in Table 43 to determine the number of services per PHP or IOP day, and therefore to determine the APC per diem payment amount for each day, as discussed in section VIII.D of this proposed rule. In addition, as discussed in section VIII.D of this proposed rule, we propose to calculate the costs for 3-service and 4-service days based on the list of HCPCS in Table 43. We remind readers that currently, to qualify for payment at the applicable PHP APC (5853 or 5863) one service must be from the Partial Hospitalization Primary list. Table 44 identifies the

services that are currently included in the Partial Hospitalization Primary list and those which we propose to add based on our analysis of the services included on days with three and four services from the proposed list in Table 43. We propose to maintain this requirement for CY 2024 and subsequent years to qualify for payment at the PHP or IOP APC. Thus, we propose that to qualify for payment for an IOP APC, at least one service must be from the Partial Hospitalization and Intensive Outpatient Primary list. Specifically, we propose that to qualify for payment for the IOP APC (5851, 5852, 5861 or 5862) or the PHP APC (5853, 5854, 5863, or 5864) one service must be from the Partial Hospitalization and Intensive Outpatient Primary list.

TABLE 44: PROPOSED PARTIAL HOSPITALIZATION AND INTENSIVE OUTPATIENT PRIMARY SERVICES

HCPCS/CPT	Short Descriptor	Proposed Action
90832	Psytx pt&/family 30 minutes	
90834	Psytx pt&/family 45 minutes	
90837	Psytx pt&/family 60 minutes	
90845	Psychoanalysis	Add
90846	Family psytx w/o patient	
90847	Family psytx w/patient	
90853	Group psychotherapy	Add
90865	Narcosynthesis	Remove
90880	Hypnotherapy	
96112	Devel tst phys/qhp 1st hr	Add
96116	Neurobehavioral status exam	Add
96130	Psychological testing evaluation by physician/qualified health care professional; first hour	Add
96132	Neuropsychological testing evaluation by physician/qualified health care professional; first hour	Add
96136	Psychological/neuropsychological testing by physician/qualified health care professional; first 30 minutes	Add
96138	Psychological/neuropsychological testing by technician; first 30 minutes	Add
G0410	Grp psych partial hosp/IOP 45-50	Update
G0411	Inter active grp psych PHP/IOP	Update

In the future, in the event there are new codes that represent the PHP and IOP services described under § 410.43(a)(4) and § 410.44(a)(4), respectively, we propose that we would add such codes to Table 43 through sub-regulatory guidance, and that these codes would be payable when furnished by a PHP or IOP. We note that coding updates frequently occur outside of the standard rulemaking timeline. We propose 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 would identify codes to be added sub-regulatorily if a new code is cross-walked to a previously included code, or if the code descriptor is substantially similar to a descriptor for a code on the list or describes a service on the list. 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 invite public comment on the proposed consolidated list of HCPCS codes that would be payable when furnished in a PHP and IOP; and any additional codes that we should consider adding. Specifically, we are interested in hearing from commenters if there are any other existing codes that CMS should consider adding to the list, or new codes that CMS should consider creating, to describe specific services not appropriately described by the codes in Table 43. For example, we are particularly interested in and are soliciting comment on whether it would be appropriate to include caregiver-focused services in the list of recognized services for PHP and IOP. We have identified the following HCPCS codes describing services related to caregivers:

- 96202 multiple -family group behavior management/modification training for parents(s) guardians(s) caregivers(s) with a mental or physical health diagnosis, administered by a physician or other QHP without the patient present, face to face up to 60 minutes.

- 96203 each additional 15 minutes.
- 96161 administration of caregiver -focused health risk assessment instrument (that is, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument.
- 9X015 CAREGIVER TRAINING 1ST 30 MIN
- 9X016 CAREGIVER TRAINING EA ADDL 15
- 9X017 GROUP CAREGIVER TRAINING

We note that the CMHC conditions of participation at § 485.916(b) and (c) already include references to the role of caregivers in the development and implementation of the individualized treatment plan for PHP patients, and we refer readers to section XVII.B.4 of this proposed rule for discussion of proposed amendments to the regulations at § 485.916(d). We are soliciting comments on whether it would be appropriate to include costs for such services in the calculation of PHP and IOP per diem payment rates. We note that if we were to include such services, we believe it would be appropriate to exclude them from the determination of the number of services provided per day, but we could include such services in the calculation of cost per day for determining the PHP and IOP payment rates.

Additionally, we are soliciting comments on peer services, and whether these would be appropriate to include for PHPs and IOPs. Peer support workers are people who have been successful in the recovery process who help others experiencing similar situations. Through shared understanding, respect, and mutual empowerment, peer support workers help people become and stay engaged in the recovery process and reduce the likelihood of relapse. Peer support services can effectively extend the reach of treatment beyond the clinical setting into the everyday environment of those seeking a successful, sustained recovery process. Peer support workers typically engage in a wide range of activities, including: advocating for people in recovery; sharing resources and

building skills; building community and relationships; leading recovery groups; and mentoring and setting goals.¹⁰³ We are interested in information about any available codes that would appropriately describe such services.

In addition, we are soliciting comments on whether it would be appropriate to add services related to coordinating a patient's discharge from a PHP or IOP, or their transition from one level of care to another. We note that current regulations require physicians, hospitals, and CMHCs to address discharge planning for PHP patients, and we would propose the same requirements for IOP patients. Specifically, physician recertification requirements for PHP at § 424.24(e)(3)(iii)(C) state that the physician's recertification must address treatment goals for coordination of services to facilitate discharge from the partial hospitalization program. We propose the same requirement for IOP at § 424.24(d)(3)(iii)(C). Additionally, hospital CoPs at § 482.43, which apply to hospital outpatient departments providing PHP and IOP, and CMHC CoPs at § 485.914(e) require appropriate discharge planning to meet each patient's needs. We are soliciting comments on whether the codes proposed in Table 43 represent the services that PHPs and IOPs provide to support transition and discharge planning for their patients, or whether we should consider additional codes. We ask commenters to provide as much detail as possible about the nature of any additional services, and whether there are any existing codes that could describe such services.

Lastly, we note that our analysis of PHP claims showed that the provision of testing and diagnostic services is very low among PHPs, although such services are covered under the PHP benefit and we propose to include them in Table 43 and cover such services under the IOP benefit as well. We note that our analysis of non-PHP days with 3 and 4 services, which we believe could represent IOP days in the future, shows a higher provision of testing and diagnostic services than is found among PHP days. We

¹⁰³ <https://www.samhsa.gov/brss-tacs/recovery-support-tools/peers>

believe that testing and diagnostic services would be included as component services of PHPs and IOPs, and we are interested in information from the public about why PHPs are not more frequently billing for these services. In particular, we welcome information from commenters about whether there are specific challenges that PHPs face in providing these services, as well as whether there are different codes, other than those proposed in Table 43 that could better describe the testing and diagnostic services that are provided to PHP patients. In addition, we are interested in understanding whether these services are typically provided by an entity other than the PHP, such as by a referring provider.

D. Proposed Payment Rate Methodology for PHP and IOP

In summary, we propose for CY 2024 to revise our methodology for calculating PHP payment rates. We propose to establish 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 propose to calculate payment rates using the broader OPPS data set, instead of hospital-based PHP data only, because we believe using the broader OPPS data set would allow 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 propose to establish consistent coding and payment between the PHP and IOP benefits, we propose to consider all OPPS data for PHP days and non-PHP days that include 3 or more of the same service codes. We propose to establish four separate IOP APC per diem payment rates at the same rates we propose for 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).

1. Background

The standard PHP day is typically four services or more per day. We currently provide 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 OPPTS/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 OPPTS/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 who is transitioning 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.

2. Current Payment Rate Methodology for PHP

Since CY 2017, our longstanding policy has been to pay PHP on a per diem basis for days that include three or more PHP services, which are identified using a defined list of codes in the Healthcare Common Procedure Coding System (HCPCS). We currently (for CY 2023) utilize two separate PHP APC per diem payment rates: CMHC PHP APC 5853 (Partial Hospitalization (three or More Services Per Day)) using only CMHC data, and hospital-based PHP APC 8563 (Partial Hospitalization (three or More Services Per Day)) using only hospital-based PHP data.

Under longstanding OPPTS policy, the hospital-based PHP APC per diem payment amount is also applied as a daily mental health cap, which serves as an upper limit on payment per day for individual OPPTS mental health services. Under the current methodology, for

CY 2023, hospital-based PHPs are paid a per diem rate of \$268.22 for three or more PHP services per day, and CMHCs are paid a per diem rate of \$142.70 for three or more PHP services per day. We refer readers to the PHP ratesetting methodology described in section VIII.B.2 of the CY 2016 OPSS/ASC final rule with comment period (80 FR 70462 through 70466) for information on the current calculation of geometric mean per diem costs and payment rates for PHP APCs 5853 and 5863, and the CY 2017 OPSS/ASC final rule with comment period (81 FR 79680 through 79687) and the CY 2022 OPSS/ASC final rule with comment period (86 FR 63665 through 63666) for information on modifications incorporated into the PHP ratesetting methodology.

We note that under our current methodology, we have 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 are not including that discussion in this proposed rule. These PHP-specific data trims and exclusions addressed limitations as well as anomalies in the PHP data. However, as discussed in the following section, we propose 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 propose not to apply PHP-specific trims and data exclusions, but rather to apply the same trims and data exclusions consistent with the OPSS. Additional information about the data trims, data exclusions, and CCR adjustments applicable to the data used for this proposed rule can be found online at

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>).¹⁰⁴

3. Proposed CY 2024 Payment Rate Methodology for PHP and IOP

As noted previously, the CAA, 2023 established IOP within the continuum of care, and the statute makes reference to weekly hour requirements. Specifically, IOP patients are required to be certified by a physician as needing at least 9 hours of services per week; while PHP patients are required to be certified by a physician as needing at least 20 hours of services per week.

While no IOP benefit existed prior to the CAA, 2023, we note that the types of items and services included in IOP have been, and are, paid for by Medicare either as part of the PHP benefit or under the OPSS more generally. Additionally, prior to the CAA, 2023, CMS had begun gathering information from interested parties on IOP under Medicare. In the CY 2023 OPSS/ 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.

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 believe it is appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP for CY 2024. At this time, although PHP claims can be specifically identified, there is no specific identifier or billing code to indicate IOP

¹⁰⁴ Click on the link labeled “CY 2024 OPSS/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 “2024 NPRM OPSS Claims Accounting (PDF)”.

services. However, hospitals are permitted to furnish and bill for many of these services as outpatient services under the OPSS. Thus, we analyzed a broader set of data that includes 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 propose to set IOP payment rates at the same rates as PHP. The primary goal in developing the proposed payment rate methodology for IOP and PHP services is to pay providers an appropriate amount relative to the patients' needs, and to avoid cost inversion in future years.

For CY 2024, we propose 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, a change from the current methodology of using only PHP data. We believe using the broader OPSS data set would allow us to capture data from claims not identified as PHP, but that include the service codes and intensity required for a PHP day. The larger data set would expand the sample size to allow for more precise rate calculations. In addition, we propose to calculate the 3 services per day and 4 services per day PHP rates for CMHCs and hospital-based programs separately. We propose to set IOP payment rates for 3 services per day and 4 services per day equal to the PHP payment rates.

We also propose to set payment rates for IOP APCs at amounts equal to the payment rates for PHP APCs. We believe setting the IOP payment rates equal to the PHP payments would be appropriate because IOP is a newly established benefit, and we do not have definitive data on utilization. However, 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 believe it is appropriate to pay the same per diem rates for IOP and PHP services unless future data analysis supports calculating rates independently.

For beneficiaries in a PHP or IOP, we propose applying 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 we note would be a departure from our current policy. Under our current policy, we do not make payment for any PHP days with fewer than three services, and we have heard from interested parties that this policy could discourage treatment of PHP patients when, due to extenuating circumstances, they cannot complete a full day. We believe that paying for a day with three or fewer services would allow us to more easily monitor the actual utilization of services, particularly IOP. Specifically, we believe utilizing 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) for days with three or fewer service would accommodate occasional instances when a patient is unable to complete a full day of PHP or IOP. We expect that days with fewer than three services would be very infrequent, and we intend to monitor the provision of these days among providers and individual patients.

Additionally, we propose that the 3 service per day hospital-based PHP APC per diem payment amount for APC 5863 would also be applied as the daily mental health cap, which serves as the upper limit on payment per day for individual OPPS mental health services. We believe setting the 3 service per day hospital-based PHP APC per diem payment amount as the daily mental health cap is appropriate because currently the daily mental health cap is equal to the payment amount for hospital-based PHP APC 5863, which is payment for 3 or more services per day. Therefore, consistency with the current daily mental health cap would be maintained. Additionally, PHP is meant to be the most intensive mental health services program, requiring inpatient care if PHP is not received, and the daily mental health cap is not expected to reach such level of intensity. We believe applying the 3 service per day hospital-based PHP APC per diem payment amount for APC 5863 as the daily mental health cap would preserve the difference of intensity between PHP and individual OPPS mental health services to not incentivize one over the other. We note that the proposed CY 2024 payment amount for APC

5863 would be comparable to the CY 2023 payment amount for APC 5863, which is currently applied as the daily mental health cap.

Lastly, we note that section 4124(c) of the CAA, 2023 requires that the payment amount for intensive outpatient services furnished in FQHCs and RHCs be equal to the payment amount that would have been paid for the same service furnished by a hospital outpatient department, thus establishing site-neutral payment for hospital outpatient departments, FQHCs, and RHCs. The CAA, 2023 is silent with respect to the payment methodology for IOP services provided by CMHCs. Based on our analysis of CMHC costs, we continue to observe that CMHCs incur significantly different costs than hospitals in the provision of PHP services, and we anticipate that in the future there will be significant differences between CMHCs' and hospitals' costs of furnishing IOP services as well. We believe it is appropriate to continue to recognize the differences in cost structures for different providers of PHP. This is of particular importance not only to the Medicare program, but also for the Medicare beneficiaries that CMHCs serve, who incur a 20 percent copay on all PHP services under Part B. Therefore, we propose to continue calculating CMHC payment rates based solely on CMHC claims, but we are also considering whether establishing a site-neutral payment for all providers of IOP using data from all providers of IOP would be more appropriate in an effort to increase access to mental health services. In order to inform public awareness, we have calculated combined payment rates by using the broader OPSS data from both hospitals and CMHCs to estimate the costs associated with providing days with three and four services from the list of services in Table 43. These alternative cost calculations are found in Table 46 in section VIII.D.3.b of this proposed rule. We are soliciting comments on whether this approach would be more appropriate to consider for establishing payment beginning in CY 2024. Specifically, we are interested in any information from commenters on how IOPs may structure their service days, and how the differences in cost structures of CMHCs might affect a site-neutral payment for IOP services. We are also soliciting comments on any ways IOP days could differ from PHP days, and considerations that could

affect payment. The following paragraphs describe our data analysis, and proposals for PHP and IOP APCs beginning in CY 2024.

a. Proposed PHP APC Changes and Effects on Geometric Mean Per Diem Costs

For CY 2024 and subsequent years, we propose a revision to our existing methodology to calculate the CMHC and hospital-based PHP geometric mean per diem costs to incorporate the larger data set under the OPSS, including PHP and non-PHP hospital claims for mental health services. We propose to use the latest available CY 2022 claims data, and CY 2021 cost data. This proposal is consistent with the overall proposed use of cost data for the OPSS, which is discussed in section II.A.1.a. of this proposed rule. In addition, we propose to establish four separate PHP APC per diem payment rates: two for CMHCs (APC 5853 and APC 5854) and two for hospital-based PHPs (APC 5863 and APC 5864). Following this proposed methodology, we propose to use the geometric mean per diem cost of \$97.59 for CMHCs providing 3-service days (APC 5853), and the geometric mean per diem cost of \$153.09 for CMHCs providing 4-service days (APC 5854), as the basis for developing the CY 2024 CMHC PHP APC per diem rates. Additionally, we propose to use the geometric mean per diem cost of \$284.00 for hospital-based providers providing 3-service days (APC 5863), and the geometric mean per diem cost of \$368.18 for hospital-based providers providing 4-service days (APC 5864) as the basis for developing the CY 2024 hospital-based PHP APC per diem rates. Lastly, we propose to establish four separate IOP APC per diem payment rates: two for CMHCs (APC 5851 and APC 5852 for 3-service days and 4-service days, respectively) and two for hospital-based IOPs (APC 5861 and APC 5862 for 3-service days and 4-service days, respectively) using the same above 3-service day and 4-service day geometric mean per diem costs proposed for the PHP APC per diem rates.

b. Development of the PHP and IOP APC Geometric Mean Per Diem Costs

The types of items and services paid as PHP (and that will be paid as IOP) can also be provided outside of those benefits by hospitals; therefore, we sought to understand the costs of

those services in our preliminary analysis to consider options for the proposed payment rates for IOP services. In preparation for CY 2024, in collaboration with physicians, we developed a consolidated list of all HCPCS codes that would be appropriate for identifying IOP and PHP services for analytic purposes. We refer readers to section VIII.C of this proposed rule for more detailed information on the proposed consolidated list of HCPCS codes applicable for IOP and PHP services.

We conducted a preliminary ratesetting analysis of all CMHC and hospital claims for patients that had 9 or more hours of behavioral health services per week. We then identified IOP as weeks with between 9 and 19 hours of services, and PHP as weeks with 20 hours or more of services. The relationship we observed between cost per day and cost per week suggests that typical IOP days include about three services, and typical PHP days include about four services, which as we noted previously, is also consistent with the typical service intensity for PHP.

Next, with this data set, we calculated the proposed payment rates for hospital-based providers based on costs for days with three services and days with four services using the data from all OPSS claims for hospitals, and calculated the proposed payment rates for CMHCs based on costs for days with three services and days with four services using only the data from CMHC claims. As discussed in section VIII.B.1.a of the CY 2022 OPSS/ASC final rule with comment period (86 FR 63666 through 63668), the costs for CMHC service days are calculated using cost report information from HCRIS. Although we anticipate that IOP weeks would generally include 9-19 hours of services and PHP weeks would generally include 20 or more hours of services, we did not restrict the data for this analysis by weekly hours. Because IOP is a new benefit, we do not have definitive data on utilization. However, if IOP utilization is similar to the data we analyzed for beneficiary weeks with 9 to 19 hours of mental health services, then we expect that IOP days will mostly include three services or fewer, but may sometimes include four or more. Given the uncertainty about how IOPs will structure their service days in the future, we believe it

is appropriate to propose 3-service day and 4-service day APCs for IOP with payment rates that are the same as the rates for the 3-service day and 4-service day APCs we propose for PHP.

We analyzed all CMHC and hospital claims data under the OPPS used to set proposed rates for this CY 2024 proposed rule as described earlier in this section of this proposed rule. We identified all patient days that included three or more services from the list in Table 43. As discussed in section VIII.D.3 of this proposed rule, we propose to calculate PHP payment rates for days with three services and days with four services, and we propose to utilize these proposed PHP payment rates for the proposed IOP APCs as well. We propose to calculate separate rates for hospitals and CMHCs.

c. Proposed CY 2024 PHP and IOP APC Geometric Mean Per Diem Costs

Following this proposed structure, the calculated CY 2024 PHP geometric mean per diem cost for all CMHCs for providing 3 services per day is \$97.59, which we propose to use for calculating the payment rate for the 3-service day APC, CMHC APC 5853. The calculated CY 2024 geometric mean per diem cost for all CMHCs for providing four or more services per day is \$153.09, which we propose to use for calculating the payment rate for the 4-service day APC, CMHC APC 5854. As noted, the calculated CY 2024 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide 3 services per service day is \$284.00, which we propose to use for calculating the payment rate for the 3-service day hospital-based PHP APC 5863. The calculated CY 2024 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide 4 services per day is \$368.18, which we propose to use for calculating the payment rate for the 4-service day hospital-based PHP APC 5864.

Similarly, the calculated CY 2024 IOP geometric mean per diem cost for all CMHCs for providing 3 services per day is \$97.59, which we propose to use for calculating the payment rate for the 3-service day APC, CMHC APC 5851. The calculated CY 2024 geometric mean per diem cost for all CMHCs for providing 4 or more services per day is \$153.09, which we propose

to use for calculating the payment rate for the 4-service day APC, CMHC APC 5852. The calculated CY 2024 hospital-based IOP APC geometric mean per diem cost for hospital-based IOP providers that provide 3 services per service day is \$284.00, which we propose to use for calculating the payment rate for the 3-service day hospital-based IOP APC 5861. The calculated CY 2024 hospital-based IOP APC geometric mean per diem cost for hospital-based IOP providers that provide 4 services per day is \$368.18, which we propose to use for calculating the payment rate for the 4-service day hospital-based IOP APC 5862.

We intend to monitor the provision of services in both PHP and IOP programs to better understand utilization patterns, and propose to set equal payment rates for PHP and IOP services until actual IOP utilization data becomes available for CY 2026 ratesetting, at which point we anticipate reevaluating our payment rate methodology if necessary.

In addition, we are soliciting comments on the service mix used to develop the per diem amounts for both PHP and IOP. We are interested in whether the proposed approach is appropriate, and any feedback commenters have on the service mix provided within each program.

The proposed CY 2024 PHP geometric mean per diem costs are shown in Table 45 and are used to derive the proposed CY 2024 PHP APC per diem rates for CMHCs and hospital-based PHPs. As stated in section VIII.D.3 of this proposed rule, we propose to use the same 3-service day and 4-service day geometric mean per diem PHP costs for the CY 2024 CMHC and hospital-based IOP APCs. The proposed CY 2024 PHP and IOP APC per diem rates are included in Addendum A to this proposed rule (which is available on our website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>) and in Table 45.

TABLE 45: PROPOSED CY 2024 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2024 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	\$97.59
5852	Intensive Outpatient (4 or more services per day) for CMHCs	\$153.09
5853	Partial Hospitalization (3 services per day) for CMHCs	\$97.59
5854	Partial Hospitalization (4 or more services per day) for CMHCs	\$153.09
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	\$284.00
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	\$368.18
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	\$284.00
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	\$368.18

Alternatively, as discussed earlier in this section, we are considering establishing combined payment rates for hospitals and CMHCs based on the calculated costs per day for days with 3 services and 4 or more services, using all OPPS claims. These alternative CY 2024 PHP geometric mean per diem costs are shown in Table 46.

TABLE 46: ALTERNATIVE CY 2024 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

<u>Group Title</u>	<u>Alternative PHP and IOP APC Geometric Mean Per Diem Costs</u>
Partial Hospitalization (three services per day)	\$281.48
Partial Hospitalization (four services per day)	\$316.63
Intensive Outpatient (three services per day)	\$281.48
Intensive Outpatient (four services per day)	\$316.63

E. Proposed Outlier Policy for CMHCs

For CY 2024, we propose to update 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 intensive outpatient services. These topics are discussed in more detail. We refer readers 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 noted a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Therefore, beginning in CY 2004, 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. This separate outlier threshold for CMHCs resulted in \$1.8 million in outlier payments to CMHCs in CY 2004 and \$0.5 million in outlier payments to CMHCs in CY 2005 (82 FR 59381). In contrast, in CY 2003, more than \$30 million was paid to CMHCs in outlier payments (82 FR 59381).

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 estimated CMHC per diem payments and outlier payments for this proposed rule by using the most recent available utilization and charges from CMHC claims, updated CCRs, and the proposed payment rates for PHP APCs 5853 and 5854. We recognize that CMHCs would be permitted to provide and bill for IOP beginning in CY 2024, and would be paid under IOP APCs

5851 and 5852. However, we have not included estimates of utilization for these APCs, because the latest available claims from CY 2022 do not reflect the provision of IOP services. For increased transparency, we are providing a more detailed explanation of the existing calculation process for determining the CMHC outlier percentages. To calculate the CMHC outlier percentage, we follow three steps:

- Step 1: We multiply the OPPS outlier threshold, which is 1.0 percent, by the total estimated OPPS Medicare payments (before outliers) for the prospective year to calculate the estimated total OPPS outlier payments:

$$(0.01 \times \text{Estimated Total OPPS Payments}) = \text{Estimated Total OPPS Outlier Payments.}$$

- Step 2: We estimate CMHC outlier payments by taking each provider's estimated costs (based on their allowable charges multiplied by the provider's CCR) minus each provider's estimated CMHC outlier multiplier threshold (we refer readers to section VIII.C.3 of the CY 2022 OPPS/ASC proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the total of CMHC PHP APC and CMHC IOP payment rates. If the provider's costs exceed the threshold, we multiply that excess by 50 percent, as described in section VIII.E.3 of this proposed rule, to determine the estimated outlier payments for that provider. CMHC outlier payments are capped at 8 percent of the provider's estimated total per diem payments (including the beneficiary's copayment), as described in section VIII.E.5 of this proposed rule, so any provider's costs that exceed the CMHC outlier cap will have its payments adjusted downward. After accounting for the CMHC outlier cap, we sum all of the estimated outlier payments to determine the estimated total CMHC outlier payments.

(Each Provider's Estimated Costs - Each Provider's Estimated Multiplier Threshold) = A.
If A is greater than 0, then $(A \times 0.50) = \text{Estimated CMHC Outlier Payment (before cap)} = B$. If B is greater than $(0.08 \times \text{Provider's Total Estimated Per Diem Payments})$, then cap adjusted B = $(0.08 \times \text{Provider's Total Estimated Per Diem Payments})$; otherwise, B = B. Sum (B or cap-adjusted- B) for Each Provider = Total CMHC Outlier Payments.

- Step 3: We determine the percentage of all OPPS outlier payments that CMHCs represent by dividing the estimated CMHC outlier payments from Step 2 by the total OPPS outlier payments from Step 1: (Estimated CMHC Outlier Payments / Total OPPS Outlier Payments).

We propose to continue to calculate the CMHC outlier percentage according to previously established policies. However, beginning in CY 2024, CMHCs will be permitted to provide and bill for intensive outpatient services for Medicare patients. Therefore, we propose to expand the calculation of the CMHC outlier percentage to include PHP and IOP, because we anticipate that total payments will increase for CMHCs in CY 2024. We propose to maintain our current methodology for calculating the CMHC outlier percentage, but to apply it to payments for IOP services as well as PHP services beginning in CY 2024. Therefore, based on our CY 2024 payment estimates, including our estimates of both PHP and IOP services, CMHCs are projected to receive 0.01 percent of total hospital outpatient payments in CY 2024, excluding outlier payments. We propose to designate approximately less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs. This percentage is based upon the formula given in Step 3.

3. Cutoff Point and Percentage Payment Amount

As 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. For example, for CY 2018, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeded 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853 [0.50 x (CMHC Cost – (3.4 x APC 5853 rate))]. This same policy was also reiterated in the CY 2019 OPSS/ASC final rule with comment period (83 FR 58996 through 58997), CY 2020 OPSS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPSS/ASC final rule with comment period (85 FR 86082 through 86083), the CY 2022 OPSS/ASC final rule with comment period (86 FR 63670), and the CY 2023 OPSS/ASC final rule with comment period (87 FR 72004). For CY 2024, we propose to continue to pay for partial hospitalization services that exceed 3.4 times the proposed CMHC PHP APC payment rate at 50 percent of the CMHC PHP APC geometric mean per diem costs over the cutoff point. In addition, we propose to extend this policy to intensive outpatient services. That is, for CY 2024, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APCs 5853 or 5854 exceeds 3.4 times the payment rate for the APC (either CMHC APC 5853 or 5854), the outlier payment would be calculated as:

$[0.50 \times (\text{CMHC cost} - (3.4 \times (\text{PHP APC payment})))]$.

Similarly, if a CMHC's cost for intensive outpatient services paid under CMHC IOP APCs 5851 or 5852 exceeds 3.4 times the payment rate for the APC (either CMHC APCs 5851 or 5852), the outlier payment would be calculated as:

$[0.50 \times (\text{CMHC cost} - (3.4 \times (\text{IOP APC payment})))]$.

4. Outlier Reconciliation

In the CY 2009 OPSS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPSS outlier payments. We addressed vulnerabilities in the OPSS outlier payment system that

led to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service, but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2023 OPPS/ASC and CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680).

We propose to continue these policies for partial hospitalization services provided through PHPs for CY 2024. In addition, since CMHCs will be permitted to provide and bill for intensive outpatient services for Medicare patients we propose to extend these policies to include intensive outpatient services in order to encompass the full scope of services that CMHCs will be permitted to furnish. The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold and whose overall ancillary CCRs change by plus or minus 10 percentage points or more, are subject to outlier reconciliation, pending approval of the CMS Central Office and Regional Office (as established in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68596 through 68599)). We note that the current threshold for outlier reconciliation for hospitals is \$500,000, and there is no threshold for CMHCs (that is, all outlier payments are subject to reconciliation for CMHCs whose overall ancillary CCRs change by plus or minus 10 percentage points or more). The policy also includes provisions related to CCRs and to calculating the time value of money for reconciled outlier payments due to or due from Medicare, as detailed in the CY 2009 OPPS/ASC final rule with comment period and in the Medicare Claims Processing Manual (73 FR 68595 through 68599 and Medicare Claims Processing Internet Only Manual, Chapter 4, Section 10.7.2 and its subsections, available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf>).

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. In the CY 2020 OPPTS/ASC final rule with comment period (84 FR 61351), we finalized a proposal to continue this policy in CY 2020 and subsequent years. We propose to maintain the 8 percent outlier payment cap for CY 2024 and apply it to both PHP and IOP payments. We note that the 8 percent would be calculated as 8 percent of total per diem PHP and IOP payments for CY 2024. As discussed earlier in this proposed rule, beginning in CY 2024, CMHCs will be permitted to provide and bill for intensive outpatient services for Medicare patients. Therefore, we propose to expand the calculation of the CMHC outlier cap to include both PHP and IOP, because we anticipate that total payments will increase for CMHCs in CY 2024. Therefore, we propose to calculate the 8 percent outlier payment cap for each CMHC in a way that would encompass the full scope of services that CMHCs will be permitted to furnish in CY 2024.

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 2023, CMHC PHP APC 5853 is the only APC for which CMHCs may receive payment under the OPPTS, and is for providing a defined set of services that are relatively low cost when compared to other OPPTS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APC 5853, it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPTS/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 OPPTS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPTS/ASC final rule with comment period (85 FR 86083), the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63508), and the CY 2023 OPPTS/ASC final rule with comment period (87 FR 72004). We propose to continue this policy for CY 2024 and not set a fixed-dollar threshold for the CMHC PHP APCs (5853 or 5854) or IOP APCs (5851 or 5852).

F. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. Statutory Background

The Rural Health Clinic Services Act of 1977 (Public Law 95-210, December 13, 1977), amended the Act by enacting section 1861(aa)(1) of the Act to extend Medicare and Medicaid entitlement and payment for primary and emergency care services furnished at a rural health clinic (RHC) by physicians and certain nonphysician practitioners, and for services and supplies incidental to their services. "Nonphysician practitioners" included nurse practitioners and physician assistants. (Subsequent legislation extended the definition of covered RHC services to include the services of clinical psychologists, clinical social workers, certified nurse midwives,

marriage and family therapist, and mental health counselors). The statutory payment requirements for RHC services are set forth at section 1833(a)(3) of the Act, which states that RHCs are paid reasonable costs, less the amount a provider may charge as described in clause of section 1866(a)(2)(A) of the Act, but in no case may the payment exceed 80 percent of such costs.

Section 4161 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508, November 5, 1990) (OBRA 90) established Federally Qualified Health Centers (FQHCs) in 1990 to be effective beginning on October 1, 1991. The law mandated that FQHCs furnish services that are typically furnished in an outpatient setting.

Section 1861(aa)(3) of the Act extends Medicare and Medicaid entitlement and payment for those services defined as RHC services under section 1861(aa)(1) of the Act, preventive services defined under section 1861(ddd)(3) of the Act, and preventive primary health services that a center is required to provide under section 330 of the Public Health Service Act furnished at a FQHC. Section 1861(aa)(4) of the Act describes the statutory requirements that FQHCs must meet to qualify for Medicare payment. Section 10501(i)(3)(A) of the Affordable (Pub. L. 111-148) added section 1834(o) of the Act to establish a new system of payment for the costs of FQHC services under Medicare Part B (Supplemental Medical Insurance) based on prospectively set rates. Section 1834(o)(2)(A) of the Act, the FQHC prospective payment system (PPS) was effective beginning on October 1, 2014. In addition, section 10501(i)(3)(B) of the Affordable Care Act added section 1833(a)(1)(Z) to the Act to specify that Medicare payment for FQHC services under section 1834(o) of the Act shall be 80 percent of the lesser of the actual charge or the amount determined under section 1834(o) of the Act.

Regulations pertaining to RHC and FQHC benefits are codified at 42 CFR part 405 subpart X.

b. Medicare Part B Payment of RHC and FQHC Services

As provided in 42 CFR part 405, subpart X of our regulations, RHC and FQHC visits generally are face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, CNMs, clinical psychologists (CPs), and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient in an area with a shortage of home health agencies. We note, effective January 1, 2024, marriage and family therapist and mental health counselor services are considered RHC services in accordance with section 1861(aa)(1)(B) of the Act as amended by section 4121(b) of CAA, 2023, which is incorporated into FQHC services through section 1861(aa)(3)(A) of the Act. In the CY 2024 PFS proposed rule, we propose to codify payment for MFTs and MHCs at § 405.2411. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

Section 130 of the Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), updated section 1833(f) of the Act by restructuring the payment limits for RHCs beginning April 1, 2021. As of April 1, 2021, all RHCs are subject to payment limits on the all-inclusive rate (AIR), and this limit will be determined for each RHC in accordance with section 1833(f) of the Act. RHCs generally are paid an AIR for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount.

FQHCs were paid under the same AIR methodology until October 1, 2014. Subsequently, FQHCs began to transition to the FQHC PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care. RHCs and FQHCs are required to file a cost report annually to determine their payment rate, which reflects adjustments for GME payments, bad debt, and influenza, pneumococcal and COVID-19 vaccines and covered monoclonal antibody products used as pre-exposure prophylaxis prevention of COVID-19 and their administration.

There are additional payments for non-face-to-face services for care management services including chronic care management (CCM), principal care management (PCM), chronic pain management (CPM), general behavior health integration (GBHI), psychiatric collaborative care model (CoCM), and virtual communications (§ 405.2464(c)).

Additionally, for FQHCs, § 405.2462(d) describes a "grandfathered tribal FQHC" as a FQHC that is operated by a tribe or tribal organization under the ISDEAA; was billing as if it were a provider-based to an Indian Health Service (IHS) hospital on or before April 7, 2000 and is not currently operating as a provider-based department of an IHS hospital. We refer to these tribal FQHCs as "grandfathered tribal FQHCs" to distinguish them from freestanding tribal FQHCs that are currently being paid the lesser of their charges or the adjusted national FQHC

PPS rate, and from provider-based tribal clinics that may have begun operations subsequent to April 7, 2000.

Under the authority in section 1834(o) of the Act to include adjustments determined appropriate by the Secretary, we revised §§ 405.2462 and 405.2464 to pay these grandfathered tribal FQHCs on the Medicare outpatient per visit rate as set annually by the IHS, and not the FQHC PPS payment rates (80 FR 71089). Such payment rates for outpatient medical care (also referred to as outpatient hospital services) furnished by the IHS and tribal facilities is set annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 248 and 249(b)) (Pub. L. 83–568 (42 U.S.C. 2001(a)), and the IHClA, based on the previous year cost reports from Federal and tribal hospitals. The outpatient per visit rate is only applicable for those IHS or tribal facilities that meet the definition of a provider-based department as described at § 413.65(m), or a “grandfathered” tribal FQHC as described at § 405.2462(d)(1). There is a higher outpatient per visit rate for IHS and tribal Medicare visits in Alaska and a lower general outpatient per visit rate for IHS/tribal Medicare visits in the lower 48 States (IHS does not operate any hospitals or facilities in Hawaii or the territories, and thus, no rates are set in those localities). For CY 2023, the outpatient per visit rate for Medicare visits in Alaska is \$801 and \$620 in the lower 48 States.¹⁰⁵

2. Establishment of Intensive Outpatient Services Benefit by Section 4124 of the CAA, 2023

a. Section 4124 of the Consolidated Appropriations Act of 2023

As discussed in section VIII.B.1 of this proposed rule, section 4124 of Division FF of the CAA, 2023, entitled “Ensuring Adequate Coverage of Outpatient Mental Health Services Under the Medicare Program,” established Medicare coverage for intensive outpatient program (IOP) services furnished by a hospital to its outpatients, or by a community mental health center (CMHC)), a FQHC or a RHC, as a distinct and organized intensive ambulatory treatment service

¹⁰⁵ <https://www.govinfo.gov/content/pkg/FR-2023-02-27/pdf/2023-03896.pdf>

offering less than 24-hour daily care in a location other than an individual's home or inpatient or residential setting, effective January 1, 2024.

An IOP is a distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness, which includes, but is not limited to conditions such as depression, schizophrenia, and substance use disorders. Generally speaking, an IOP is thought to be less intensive than a partial hospitalization program (PHP).

This new provision mandated several changes to the RHC and FQHC policies, including scope of benefits and services, certification and plan of care requirements, and special payment rules for IOP services in RHCs and FQHCs, all of which are discussed in the paragraphs below.

3. IOP Scope of Benefits and Scope of Services in RHC and FQHC Settings

a. Background

As described in section 1861(aa) of the Act and codified under §§ 405.2411 and 405.2446, the current scope of benefits for RHC and FQHC services are those services covered in a RHC, FQHC, or other outpatient setting, including a patient's place of residence, or a Medicare-covered Part A skilled nursing facility (SNF) when provided by a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or a clinical social worker. RHC/FQHC services may also be covered for individuals who have elected hospice when provided by an RHC/FQHC physician, nurse practitioner, or physician assistant employed or under contract with the RHC or FQHC at the time the services are furnished, who has been designated by the patient as his or her attending physician. Starting January 1, 2024, services of a marriage and family therapist (MFT) or mental health counselor (MHC) are covered under RHC/FQHC services if such MFT or MHC is employed or under contract with the RHC or FQHC at the time the services are furnished.

As defined in § 405.2415, RHCs and FQHCs furnish physicians' services; services and supplies "incident to" the services of physicians: Nurse practitioner (NP), physician assistant (PA), certified nurse-midwife (CNM), clinical psychologist (CP), and clinical social worker

(CSW) services; and services and supplies incident to the services of NPs, PAs, CNMs, CPs, and CSWs. They may also furnish diabetes self-management training and medical nutrition therapy (DSMT/MNT), transitional care management (TCM) services, and in some cases, visiting nurse services furnished by a registered professional nurse or a licensed practical nurse.

Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHC and FQHC services also include certain preventive services when specified in statute or when established through the National Coverage Determination (NCD) process. RHCs and FQHCs are paid for the professional component of allowable preventive services when all of the program requirements are met and frequency limits (where applicable) have not been exceeded.

Section 4124(b)(4) of the CAA, 2023, amended section 1861(aa)(1) of the Act by adding subparagraph (D) to establish Medicare Part B coverage for IOP services as defined in section 1861(ff)(4) of the Act when these services are furnished by RHCs, which is incorporated for FQHCs by reference in section 1861(aa)(3)(A) of the Act, effective January 1, 2024. Section 1861(ff)(2) of the Act describes the items and services available under the PHP and IOP benefits. These items and services include: individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered); individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the

individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; and such other items and services as the Secretary may provide (excluding meals and transportation) that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish, taking into account accepted norms of medical practice and the reasonable expectation of patient improvement.

To be consistent with the scope of benefits required for IOP services, we propose to adopt the same standards for IOP services furnished in RHCs and FQHCs as described in section VIII.B.2 "IOP Scope of Benefits" of this proposed rule. Specifically, this would include individual and group therapy, occupational therapy, drugs and biologicals furnished for therapeutic purposes, which cannot be self-administered, family counseling, beneficiary education, and diagnostic services. In order to expand access to behavioral health treatment for Medicare beneficiaries and to ensure continuity of care for IOP services to best meet patient needs, we propose to make conforming regulatory changes to applicable RHC and FQHC regulations at 42 CFR part 405, subpart X, specifically,

- At § 405.2401, Scope and definitions, we propose to amend the section to add IOP services.
- At § 405.2411, Scope of benefits, we propose to amend the section to include IOP services.
- At § 405.2446, Scope of services, we propose to amend this section to include IOP services.

b. Certification and Plan of Care Requirements for IOPs in RHC and FQHC Settings

Section 4124(b)(2)(B) of the CAA, 2023 amended section 1861(ff) of the Act to add paragraph (4) to define intensive outpatient services as the items and services prescribed by a physician for an individual determined (not less frequently than once 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) (that is, an outpatient program of mostly mental health related services and therapies provided by a hospital or CMHC on an outpatient basis) under the supervision of a physician. The services must be provided 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. For patients of an IOP, section 1835(a)(2)(F)(i) of the Act does not apply, that is, individuals receiving IOP would not require inpatient psychiatric care in the absence of such services.

In order to be consistent with physician certification and plan of care requirements required for IOP furnished in different care settings, we propose to adopt the same standards for RHCs and FQHCs providing such services as described in section VIII.B.3 "IOP Certification and Plan of Care Requirements" of this proposed rule. Specifically, this would require physicians to certify that an individual needs IOP services for a minimum of 9 hours per week and no more than 19 hours per week, as set out in section 4124 of CAA, 2023. This certification would require documentation to include that the individual requires such services for a minimum of 9 hours per week; require the first certification as of the 30th day of IOP services; and require that the certification of IOP services occur no less frequently than every other month. Accordingly, we propose to revise our regulations at 42 CFR part 405, subpart X to specify that for the purpose of furnishing IOP services RHCs and FQHCs must similarly meet the certification and plan of care requirements at proposed § 424.24(d).

Lastly, we propose to establish the same patient eligibility criteria for intensive outpatient services as described in proposed § 410.44(c). Specifically, we propose that intensive outpatient services are intended for patients who: (1) require a minimum of 9 hours per week of therapeutic services as evidenced in their plan of care; (2) are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment; (3) do not require 24-hour care; (4) have an adequate support system while not actively engaged in the program; (5) have a mental health diagnosis; (6) are not judged to be dangerous to self or others; and (7) have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program.

4. Special Payment Rules for Intensive Outpatient Services

Under Medicare Part B, payment to RHCs for services (defined in § 405.2411) furnished to beneficiaries is made on the basis of an all-inclusive payment methodology subject to a maximum payment per-visit and annual reconciliation. Our regulations at § 405.2470 provide that RHCs are required to submit cost reports to allow the Medicare Administrative Contractor (MAC) to determine payment in accordance with 42 CFR part 405, subpart X, and instructions issued by CMS. The beneficiary is responsible for the Medicare Part B deductible and coinsurance amounts. Section 1866(a)(2)(A)(ii) of the Act and implementing regulations at § 405.2410(b) establish beneficiary coinsurance at an amount not to exceed 20 percent of the clinic's reasonable charges for covered services.

Under Medicare Part B, FQHCs are paid under the FQHC PPS for services (defined in § 405.2446) furnished to beneficiaries. The statutory payment requirements for FQHC services are set forth at section 1834(o) of the Act. In addition, section 1833(a)(1)(Z) to the Act requires Medicare payment for FQHC services, determined under section 1834(o) of the Act, to be 80 percent of the lesser of the actual charge or the amount determined under section 1834(o) of the Act. Under the FQHC PPS, FQHCs are paid based on the lesser of the FQHC's actual charge for the service or the PPS rate (§ 405.2462(g)(1)). The FQHC PPS rate is subsequently adjusted

for certain circumstances as described under § 405.2464(b)(2). The Medicare Part B deductible does not apply to FQHC services. The beneficiary is responsible for a coinsurance amount of 20 percent of the lesser of the FQHC's actual charge for the service or the adjusted PPS rate.

As we discuss in the CY 2021 PFS final rule (85 FR 84699 through 84710), the FQHC PPS base payment is annually increased by the percentage increase in the FQHC market basket, which reflects the operating and capital cost structures for freestanding FQHC facilities. Beginning with CY 2017, FQHC PPS payments were updated using a 2013-based FQHC market basket. A complete discussion of the 2013-based FQHC market basket can be found in the CY 2017 PFS final rule (81 FR 80393 through 80403). In the CY 2021 PFS final rule, we finalized the rebasing and revising of the FQHC market basket to reflect a 2017 base year. The 2017-based FQHC market basket is primarily based on Medicare cost report data for freestanding FQHCs for 2017, which are for cost reporting periods beginning on and after October 1, 2016, and prior to September 31, 2017. We explained that we used data from cost reports beginning in FY 2017 because these data were the latest available, complete data for calculating the major cost weights for the market basket at the time of rulemaking. We also explained that CMS updates the market basket periodically so that the cost weights reflect a current mix of goods and services purchased in providing FQHC services.

Seven FQHCs that have been determined to be grandfathered tribal FQHCs and due to this designation are paid based on the lesser of the outpatient per visit rate or their actual charges, as set out at §405.2462(f). As stated above, these grandfathered tribal FQHCs are paid the outpatient per visit rate for furnishing FQHC services.

In addition to the normal package of services, RHCs and FQHCs receive payment for certain additional services. In the CY 2022 PFS final rule (86 FR 65205 through 65206), we implemented section 132 of CAA, 2021, which amended section 1834(o) of the Act and added a new section 1834(y) to the Act, to provide statutory authority for FQHCs and RHCs, respectively, to receive payment for hospice attending physician services. In the CY 2023 PFS

final rule (87 FR 69463, 69737 through 69739) we implemented sections 304(b) and (c) of division P of the CAA, 2022 (Pub. L. 117–103, March 15, 2022). Those subsections modified sections 1834(y) and 1834(o)(4) of the Act, respectively, to delay in-person visit requirements in order to for RHCs and FQHCs to receive payment for mental health visits furnished via telecommunications technology.

Section 4124(c) of the CAA, 2023 further amended section 1834(o) of the Act and section 1834(y) of the Act, to provide special payment rules for both FQHCs and RHCs, respectively, for furnishing intensive outpatient services. Section 4124(c)(1) of the CAA, 2023 amended section 1834(o) of the Act to add a new paragraph (5)(A) to require that payment for IOP services furnished by FQHCs be equal to the amount that would have been paid under Medicare for IOP services had they been covered outpatient department services furnished by a hospital. In addition, section 4124(c)(2) of the CAA, 2023 amended section 1834(y) of the Act to add a new paragraph (3)(A) to require that payment for IOP services furnished by RHCs be equal to the amount that would have been paid under Medicare for IOP services had they been covered outpatient department services furnished by a hospital.

Section VIII.D.3 of this proposed rule discusses the proposed CY 2024 payment rate methodology for IOP. We propose to establish two IOP APC per diem payment rates for hospital-based IOPs (APC 5861 and APC 5862 for 3-service days and 4-service days, respectively). We believe that it is appropriate to provide a payment structure that supports beneficiaries in an IOP where the utilization is typically structured to be days with three or fewer services. Therefore, we propose that the rate determined for APC 5861 (Intensive Outpatient (3 services per day) for hospital-based IOPs) would be the payment rate for IOP services furnished in an RHC. For IOP services furnished in FQHCs, we propose that that payment is based on the lesser of a FQHC's actual charges or the rate determined for APC 5861. Additionally, we propose that grandfathered tribal FQHCs will continue to have their payment based on the outpatient per visit rate when furnishing IOP services. That is, payment is based on the lesser of

a grandfathered tribal FQHC's actual charges or the outpatient per visit rate. We propose to revise §§ 405.2410, 405.2462 and 405.2464 in the regulations to reflect the payment amount for IOP services and how the Medicare Part B deductible and coinsurance are applied.

We solicit comment on whether the payment rate for IOP services furnished in RHCs and FQHCs should be adjusted to reflect the variations in costs of furnishing services in different geographic areas and what approaches would be appropriate for determining the value of the adjustment. We also solicit comment on whether the hospital-based IOP APC 5862 for 4-service days would be appropriate for RHCs and FQHCs.

In section VIII.C of this proposed rule, we discuss coding and billing for PHP and IOP services under the OPSS. We explain that beginning January 1, 2024, the hospital outpatient department and CMHCs will be able to furnish items and services of both PHPs and IOPs. We state that we believe it is appropriate to align these programs by using a consolidated list of HCPCS codes would identify the full range of services that both IOPs and PHPs provide to Medicare beneficiaries for billing purposes. We explain that those settings paid under the OPSS and that can furnish either PHP or IOP when submitting a claim to CMS for payment would be required to report a new condition code 92 to differentiate between PHP and IOP.

While RHCs and FQHCs are not authorized to furnish PHP services, we propose to also require RHCs and FQHCs to report condition code 92 to identify intensive outpatient claims. Since RHCs and FQHCs are paid outside of the RHC AIR methodology and FQHC PPS, respectively, for IOP services we believe the condition code reporting approach would allow us to operationalize a 3 service per day payment amount using the final list of HCPCS codes used to identify the full range of services for IOP. The list of proposed HCPCS codes is included in Table 43. In addition, we propose to align with the requirement under the OPSS, which is in order to qualify for IOP payment, at least one service must be from the Intensive Outpatient Primary list. Table 44 identifies the proposed list of intensive outpatient primary services.

Section 4124(c)(1) of the CAA, 2023 amended section 1834(o) of the Act to add a new paragraph (5)(B) to require that costs associated with intensive outpatient services not be used to determine the amount of payment for FQHC services under the FQHC PPS. Likewise, section 4124(c)(2) of the CAA, 2023 amended section 1834(y) of the Act to add a new paragraph (3)(B) to require that costs associated with intensive outpatient services not be used to determine the amount of payment for RHC services under the methodology for all-inclusive rates (established by the Secretary) under section 1833(a)(3) of the Act. We propose conforming revisions under § 405.2468. In addition, conforming revisions will be made to the cost reporting instructions to account for these changes.

c. FQHC Supplemental Payments

As discussed in the May 2, 2014 final rule with comment period (79 FR 25461), section 1833(a)(3)(B)(i)(II) of the Act requires that FQHCs that contract with MA organizations be paid at least the same amount they would have received for the same service under the FQHC PPS. This provision ensures FQHCs are paid at least the Medicare amount for FQHC services. Therefore, if the MA organization contract rate is lower than the amount Medicare would otherwise pay for FQHC services, FQHCs that contract with MA organizations would receive a wrap-around payment from Medicare to cover the difference (see § 422.316). If the MA organization contract rate is higher than the amount Medicare would otherwise pay for FQHC services, there is no additional payment from Medicare. We believe that the special payment rule, is also included in the FQHC PPS rate as described in section 1834(o) of the Act and therefore, IOP services are included in the wrap-around payment. We propose to make revisions under § 405.2469 to reflect these changes.

5. Multiple Visits

a. Background

Currently, RHC and FQHC encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and a single location constitute a single visit, with the following exceptions:

- A patient has a medical visit and a mental health visit on the same day; or
- A patient has an initial preventive physical exam visit and a separate medical or mental health visit on the same day.

Since IOP services are behavioral health services, we do not believe it would be appropriate to pay for a mental health visit and IOP services on the same day. In the case of a medical visit, an encounter can include a medical visit and a mental health visit or a medical visit and IOP services. An encounter cannot include two mental health visits on the same day. As such, we propose to make amend § 405.2463(c) in the regulations to clarify that we will permit a mental health visit or IOP services on the same day as a medical visit.

6. Other Regulatory Updates

In addition to the regulatory changes described in this section of the rule, we propose a revision to § 405.2400 to reflect that 42 CFR part 405, Subpart X is based not only on the provisions of sections 1833, 1861(aa), 1834(o) of the Act but also the provisions under section 1834(y) of the Act. We believe we inadvertently did not revise the regulations when the CAA, 2021 amended section 1834 of the Act to add new paragraph (y), as we discuss in the CY 2022 PFS final rule (86 FR 65205 through 65206).

G. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act) (Pub. L. 115-271, October 24, 2018) established a new Medicare Part B benefit category for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In

the CY 2020 Physician Fee Schedule (PFS) final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We established new codes for and finalized bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. For CY 2024, we propose modifications to the regulations and policies governing Medicare coverage and payment for OUD treatment services furnished by OTPs in both this proposed rule as well as the CY 2024 PFS proposed rule.

2. Statutory Authority for Coverage of Opioid Use Disorder Treatment Services Provided by OTPs

Intensive outpatient programs (IOPs) [American Society of Addiction Medicine (ASAM) Level 2.1 of Care] are diverse and flexible programs that can provide both a step-up and step-down level of care for the treatment of substance use disorders. IOPs may offer a step-down level of care in cases where a patient has been stabilized in a hospital facility or residential treatment program but continues to need services to maintain or achieve further treatment progress. IOPs also offer a step-up level of care in cases where a patient may need a higher level of care that is more structured or intensive than what can be provided in a typical outpatient treatment setting that offers care on a less frequent basis.¹⁰⁶ IOPs can be housed in an OTP, specialty addiction treatment facility, community mental health center (CHMC), or another setting.¹⁰⁷ According to the National Substance Use and Mental Health Services Survey , as of

¹⁰⁶ <https://www.ncbi.nlm.nih.gov/books/NBK64088/>

¹⁰⁷ The ASAM National Guideline for the Treatment of Opioid Use Disorder (2020): https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/guidelines/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2

2021, approximately 557 OTPs offer IOP services nationwide (30.1 percent of SUD treatment facilities offering OTPs).¹⁰⁸ Section 4124 of the CAA, 2023, which was enacted on December 29, 2022, provides for Medicare coverage and payment for IOP services in HOPDs, CMHCs, RHCs, and FQHCs. However, section 4124 of the CAA, 2023 did not address coverage for IOP services furnished in OTP settings.

Section 1861(jjj)(1) of the Act defines Opioid Use Disorder (OUD) treatment services as items and services that are furnished by an OTP for the treatment of opioid use disorder, including FDA-approved opioid agonist and antagonist medications, dispensing and administration of such medications, substance use counseling, individual and group therapy, toxicology testing, and other items and services that the Secretary determines are appropriate (not including meals or transportation). For matters related to payment for OUD treatment services, section 1834(w) of the Act establishes that the Secretary shall pay bundled payments to OTPs when they furnish OUD treatment services to an individual during an episode of care. Section 1834(w)(2) of the Act states that for purposes of making payments to OTPs, the Secretary may establish one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine[s] appropriate. We interpret the statutory language at sections 1861(jjj) and 1834(w) of the Act to grant the Secretary authority to establish more than one bundled payment to OTPs for OUD treatment services furnished during an episode of care provided that the scope of services is medically reasonable and necessary for the treatment of OUD. In the CY 2020 PFS final rule (84 FR 62644), we finalized a definition of OUD treatment services as those items and services that are specifically enumerated in section

¹⁰⁸ Substance Abuse and Mental Health Services Administration, National Substance Use and Mental Health Services Survey (N-SUMHSS), 2021: Annual Detailed Tables. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2023. Weblink: https://www.samhsa.gov/data/sites/default/files/reports/rpt39450/2021%20N-SUMHSS%20Annual%20Detailed%20Tables_508_Compliant_2_8_2023.pdf

1861(jjj)(1) of the Act and finalized the weekly bundled payment for an episode of care. After considering public comments, under the discretion granted to the Secretary under section 1861(jjj)(1)(F) of the Act, we also included additional items and services, including intake activities and periodic assessments within the definition of OUD treatment services specified in 42 CFR 410.67(b) (84 FR 62634). In addition, under our authority under section 1834(w) to create one or more bundled payments, we finalized that we would utilize add-on codes as a way to operationalize the creation of more than one bundled payment by making payment adjustments to the weekly bundled payment for the additional items and services.

Furthermore, CMS aims to ensure that Medicare beneficiaries have appropriate access to high quality care for the treatment of OUD, and that services provided to treat SUD under the Medicare OTP benefit are consistent with the services that are available in other settings covered under Medicare Part B. For example, when CMS first established payment policy for OTPs under Medicare Part B in the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we considered the available benefits payable under Medicare at that time in determining what items to propose to include in the bundled payment for OUD treatment services furnished by OTPs. In light of new legislation (CAA, 2023) granting authority for Medicare payment of IOP services provided by other types of health care providers, we believe it is appropriate to revisit the range of services covered under the current benefit for OUD treatment services furnished by OTPs.

In the CY 2023 PFS proposed rule, we solicited comments on whether there is a gap in coding under the PFS or other Medicare payment systems that may be limiting access to needed levels of care for treatment of mental health or substance use disorder treatment for Medicare beneficiaries (87 FR 45943 through 45944). Specifically, we sought information on multiple issues, including whether there is a gap in coding under Medicare payment systems that may be limiting access to needed levels of care for treatment of SUD; the extent to which potential gaps would best be addressed by the creation of new codes or billing rules; additional information

related to IOP services, including their settings, scope and types of offered services, and practitioners involved; and, other relevant information to the extent it would inform our ability to ensure Medicare beneficiaries have access to this care. In response, many commenters noted that IOPs serve as a “step-up” level of care for individuals in need of more services/supports, close monitoring, and structured therapy, but who cannot stabilize at a lower level of care provided in an office setting. Commenters also noted that IOPs simultaneously serve as a “step-down” level of care for individuals who have more stabilized biomedical conditions and may no longer need to be hospitalized, but cannot be discharged safely. Commenters mentioned that IOPs are tailorable to patient characteristics and are often flexible in the length, frequency, and days of treatment, but that typically patients receive at least 9 hours a week of care. Moreover, commenters stated that IOPs may be provided at stand-alone IOP facilities, OTPs, partial hospitalization programs, residential treatment centers, detoxification centers, or within a private outpatient office setting. Commenters further encouraged CMS to allow coverage for IOP services across the full continuum of care settings, so that patients can receive the care they need in the setting that is most clinically appropriate. Furthermore, several commenters emphasized the importance of ensuring access to care for IOP services provided in OTP settings. For example, one commenter recommended “that CMS also consider whether the agency has regulatory authority to extend coverage of any new IOP billing codes to OTPs.” Other commenters also preferred the IOP payment methodology to be amenable and complementary to the weekly bundled payment of OTPs, including a building block methodology with drug and non-drug components, and add-on codes for greater clinical complexity. As a whole, commenters were very receptive to expanding access to IOP services in multiple settings of care, including within OTPs.

Addressing the opioid crisis by expanding coverage for quality treatment options and reducing barriers to care continues to remain a high priority for CMS. Across the U.S, the rates of OUD have increased more than threefold and opioid-related mortality has increased by almost

18 percent amongst older adults in the past decade.¹⁰⁹ From 2015-2019, nearly 1.7 million (3 percent of all) Medicare beneficiaries had a SUD, though only 11 percent of those beneficiaries received treatment for their condition in a given year.¹¹⁰ Among Medicare beneficiaries with a SUD, one-third reported that financial barriers were a reason for not receiving treatment. Research from ASPE indicates that health plans that offer coverage for a greater number of IOP services per enrollee experience higher rates of SUD treatment initiation and continued engagement within their enrollee populations.¹¹¹ This suggests that IOP services could result in an increased rate of SUD treatment initiation and continued engagement. Therefore, expanding access to IOP services in other settings and reducing financial barriers to access to IOP services through coverage could potentially increase the number of Medicare beneficiaries seeking and completing treatment for a SUD, including among Medicare beneficiaries who are members of populations that have historically been less likely to receive such treatment. Studies have shown that among individuals in need of SUD treatment, Hispanic, Black, and Asian populations are less likely to receive outpatient SUD treatment for their condition than their White counterparts, suggesting greater barriers to treatment access for these populations.¹¹² Other evidence indicates that Black Americans significantly underutilize specialty SUD treatment and are also less likely to complete their SUD treatment programs compared to White Americans, but these disparities are reduced when Black Americans have access to health insurance.¹¹³ This evidence suggests that financial barriers impede initiation and completion of SUD treatment; in turn, providing health insurance coverage for SUD treatment services (such as IOP services) may lessen the impact of these financial barriers for all Medicare beneficiaries, including those who are more likely to experience these barriers. Some evidence also shows that

¹⁰⁹ <https://www.sciencedirect.com/science/article/pii/S0749379721000921?via%3Dihub>

¹¹⁰ <https://doi.org/10.15585/mmwr.mm675152e1>

¹¹¹ <https://aspe.hhs.gov/sites/default/files/private/pdf/260791/BestSUD.pdf>

¹¹² <https://www.samhsa.gov/data/sites/default/files/reports/rpt35326/2021NSDUHSUChartbook102221B.pdf>

¹¹³ <https://www.sciencedirect.com/science/article/pii/S0376871619302443>

zip codes in the U.S. within which there is at least one OTP tend to have a higher proportion of residents who are minorities (Black and Hispanic) and a lower proportion of White residents, compared to zip codes in the U.S without any OTPs¹¹⁴, and surveys of services provided by OTPs demonstrate that the majority of OTPs (82.6 percent) conduct community outreach services to those in need of treatment for OUD.¹¹⁵ This suggests that OTPs may be uniquely positioned to reach minority populations in need of IOP services, which would improve their access to SUD treatment services. In addition, from 2015 to 2019 and prior to implementation of the OTP benefit, Medicare beneficiaries younger than 65 years old were more likely to receive SUD treatment than those aged 65 years old or greater, due to more beneficiaries over age 65 reporting they could not afford treatment or that the treatment was not covered by Medicare or other insurance.¹¹⁶ Even after implementation of the OTP benefit, eliminating health disparities in access to SUD treatment for this older age bracket remains a priority. Therefore, we believe that expanding access to coverage and payment under Medicare for IOP services provided by OTPs may have a meaningful and positive impact on health equity, including for Medicare beneficiaries that may face barriers in accessing treatment, such as racial/ethnic minorities and/or beneficiaries aged 65 or older. Lastly, CMS' Behavioral Health Strategy includes multiple stated goals and objectives to promote person-centered behavioral health care.¹¹⁷ Expanding access to coverage and payment under Medicare for IOP services provided by OTPs may help strengthen access to SUD prevention, evidence-based treatment, and recovery services, as well as advance the equity and quality of behavioral health services, which are consistent with the goals of CMS' Behavioral Health Strategy.

3. Proposal to Provide Coverage of IOP Services Furnished by OTPs

¹¹⁴ <https://pubmed.ncbi.nlm.nih.gov/36645315/>

¹¹⁵ https://www.samhsa.gov/data/sites/default/files/reports/rpt39450/2021%20N-SUMHSS%20Annual%20Detailed%20Tables_508_Compliant_2_8_2023.pdf

¹¹⁶ <https://www.sciencedirect.com/science/article/pii/S0749379722001040>

¹¹⁷ <https://www.cms.gov/cms-behavioral-health-strategy>

a. Proposal to Include IOP Services Furnished by OTPs in the Definition of Opioid Use Disorder Treatment Services

In recognition of the evidence provided in the discussion above, we understand that some Medicare beneficiaries may continue to face barriers in accessing treatment for their OUD.

Additionally, we note that many OTPs nationwide already provide IOP services and that IOP services can be effective in promoting greater treatment initiation and engagement, which may improve health outcomes. For these reasons, and in order to expand access to behavioral health treatment for Medicare beneficiaries with OUD and ensure continuity of care between different treatment settings and levels of care, CMS is proposing to establish payment under Part B for IOP services furnished by OTPs for the treatment of OUD for CY 2024 and subsequent years.

As explained previously, section 1861(jjj)(1) of the Act defines Opioid Use Disorder (OUD) treatment services as items and services that are furnished by an OTP for the treatment of opioid use disorder, including FDA-approved opioid agonist and antagonist medications, dispensing and administration of such medications, substance use counseling, individual and group therapy, toxicology testing, and other items and services that the Secretary determines are appropriate (not including meals or transportation). IOP services are intended to treat individuals with an acute mental illness and/or substance use disorder, including those with an OUD. We believe that IOP services are similar to the specific services enumerated in section 1861(jjj)(1) of the Act, and the services and intensity of care required to provide intensive outpatient services under Level 2.1 of the ASAM continuum of care are a step-up from the services within the existing OTP benefit. The ASAM criteria's strength-based multidimensional assessment takes into account a patient's needs, obstacles and liabilities, as well as their strengths, assets, resources, and support structure; this information is used to determine the appropriate level of care across a continuum.¹¹⁸ OTP services that are currently covered under the OTP benefit are at the Outpatient (Level 1) level of care, whereas IOP services are classified as Level 2.1 on

¹¹⁸ <https://www.asam.org/asam-criteria/about-the-asam-criteria>

ASAM's continuum of care. Individuals who meet the criteria for IOP services generally require more frequent and intensive services.

Because the Secretary has discretion under section 1861(jjj)(1)(F) of the Act to add other items and services furnished by an OTP for the treatment of OUD, as appropriate, we propose to add a new paragraph (ix) to § 410.67(b) defining a new category of services called "OTP intensive outpatient services" and incorporate OTP intensive outpatient services in the definition of OUD treatment services that are covered under the Part B OTP benefit. Specifically, we propose to define OTP intensive outpatient services as those services specified in proposed 42 CFR § 410.44(a)(4) when furnished by an OTP as part of a distinct and organized intensive ambulatory treatment program for the treatment of Opioid Use Disorder and that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. OTP intensive outpatient services are services that are reasonable and necessary for the diagnosis or active treatment of the individual's condition; are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and are furnished in accordance with a physician certification and plan of care. We propose that in order to qualify as "OTP intensive outpatient services," a physician must certify that the individual has a need for such services for a minimum of 9 hours per week and requires a higher level of care intensity compared to existing OTP services. The specific services that we propose would be considered OTP intensive outpatient services would include any of the following:

- Individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State law.
- Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484 of this chapter.

- Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients.

- Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29, excluding opioid agonist and antagonist medications that are FDA-approved for use in treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose.

- Individualized activity therapies that are not primarily recreational or diversionary.
- Family counseling, the primary purpose of which is treatment of the individual's condition.

- Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.

- Diagnostic services that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, with the exception of toxicology testing.

We propose to exclude FDA-approved opioid agonist or antagonist medications for the treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, specifically, methadone, buprenorphine, naltrexone and naloxone, from the definition of OTP intensive outpatient services because these medications are already included as part of the weekly bundled payment for an episode of care or as an adjustment to the bundled payment. However, we are soliciting comment on the types of drugs and biologicals that are furnished as part of an IOP program (for example, whether IOPs furnish drugs used for emergent interventions), and the extent to which these drugs overlap with medications included in the existing weekly bundles described by HCPCS codes G2067 through G2073 and/or add-on codes described by G2078 (take-home supply of methadone), G2079 (take-home supply of oral buprenorphine), G2215 (take-home supply of nasal naloxone), G2216 (take-home supply of injectable naloxone), and G1028 (take-home supply of nasal naloxone; 2-pack of 8mg per 0.1 mL nasal spray) This information will help to inform our consideration of the extent to which

the drugs and biologicals furnished as part of an IOP program would already be covered under the drug component of the weekly bundled payment and the existing add-on payments or would need to be reflected in the proposed IOP add-on payment adjustment discussed in the next section. Similarly, we propose to exclude toxicology testing from the types of diagnostic services that would be included in the definition of OTP intensive outpatient services because toxicology testing is already included within the definition of opioid use disorder treatment services and paid for as part of the weekly bundled payment for an episode of care.

b. Proposal to Establish a Weekly Payment Adjustment for IOP Services Furnished by OTPs

Section 1834(w)(2) of the Act provides discretion to implement one or more payment bundles based on the frequency, scope and characteristics of the individuals, and other factors as determined appropriate. Currently, ASAM classifies OTP services as outpatient treatment services (under Level 1 of the continuum of care), which are typically provided for less than 9 hours a week, or as a step down from intensive outpatient services, whereas intensive outpatient services (under Level 2.1 of the continuum of care) are typically provided for more than 9 hours a week and no more than 20 hours a week for adults with more severe needs than those for whom treatment provided according to Level 1 of the continuum of care is clinically appropriate.¹¹⁹ In order to appropriately reflect the more intensive treatment profile for those individuals receiving IOP services versus OTP services, we propose to establish a weekly payment adjustment via an add-on code for OTP intensive outpatient services, which is consistent with the weekly bundled payment structure under the existing Medicare OTP benefit. We believe that a code billed on a weekly basis may allow greater flexibility with respect to how IOP services are rendered and how service hours may be distributed over a given week to best meet patient needs. Under this proposal, we propose that an OTP could bill for the weekly add-on code for OTP intensive services in the same week for the same beneficiary as the existing coding describing a weekly OTP bundle, so long as all applicable billing requirements for each

¹¹⁹ <https://americanaddictioncenters.org/rehab-guide/asam-criteria-levels-of-care>

code are met. However, we note that under this proposal, each OTP intensive outpatient service must be medically reasonable and necessary and not duplicative of any service(s) for which OTPs received a bundled payments for an episode of care in a given week.

For OTP intensive outpatient services, we propose to permit OTPs to bill new HCPCS code GOTP1 (Intensive outpatient services; minimum of nine services over a 7-contiguous day period, which can include individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; List separately in addition to code for primary procedure.

We propose to value HCPCS code GOTP1 based on an assumption of a typical case of three IOP services furnished per day for approximately 3 days per week. In response to the comment solicitation on IOP services in the CY 2023 PFS proposed rule, many commenters stated that a typical IOP treatment plan requires at least 9 hours of skilled treatment services per week, which would follow both the treatment protocol advised by SAMHSA and ASAM level placement criteria.¹²⁰ Moreover, the definition of intensive outpatient services in section 4124(b)(2)(B) of the CAA, 2023 specifies that in community mental health centers, hospital-based IOPs, RHCs, and FQHCs, an individual in need of IOP services must be certified by a physician to have a need for such services for a minimum of 9 hours per week compared to a

¹²⁰ <https://www.ncbi.nlm.nih.gov/books/NBK64088/>

<https://store.samhsa.gov/product/TIP-47-Substance-Abuse-Clinical-Issues-in-Intensive-Outpatient-Treatment/SMA13-4182>

minimum of 20 hours per week in a partial hospitalization service treatment program. Thus, we believe that our assumption of 9 services rendered per week would be consistent with the minimum requirement in other care settings and existing clinical guidance. Therefore, we propose to calculate the payment rate for add-on code GOTP1 based on 9 services per week. We welcome comments on whether an assumption of 9 services per week is representative of the typical number of services furnished to patients with an OUD who receive IOP services at OTPs. We propose that by billing HCPCS code GOTP1, the OTP would be attesting to the fact that it has furnished at least nine services for that week that would otherwise qualify as OTP intensive outpatient services as discussed in section VIII.G.3.a of this proposed rule. We acknowledge that not all OTP intensive outpatient services will necessarily be 60 minutes in duration, or be a time-based service, therefore, we propose that furnishing nine OTP intensive outpatient services, regardless of the length of each service, would meet the threshold to bill for HCPCS code GOTP1. We note that this aspect of our proposal differs from the proposed requirement for physician certification, discussed in section VIII.G.3.c., Certification and Plan of Care Requirements for IOPs in OTP settings, of this proposed rule, pursuant to which a physician must certify that the individual requires nine hours of OTP intensive outpatient services, and not simply nine OTP intensive outpatient services.

Under this proposal to establish a weekly add-on payment for OTP intensive outpatient services, no single service may be counted more than once for the purpose of meeting the criteria for billing for any given code. In other words, the same service could not be used to qualify to bill both the weekly bundle and the add-on payment adjustment for OTP intensive outpatient services. Additionally, we recognize that some services furnished as part of OTP intensive outpatient services may be required multiple times a week (e.g, occupational therapy, patient education, family counseling, activity therapies) to meet individual patient needs and varying clinical complexity. Such services of the same type would be allowable to meet the minimum of 9 services per week, provided that all services are medically reasonable and necessary.

This proposal for the calculation of the payment rate for HCPCS code GOTP1 is similar to the payment methodology proposed for IOP services furnished in other settings. Please see a more detailed discussion regarding this payment methodology at section VIII.D “Proposed Payment Rate Methodology for PHP and IOP” of this proposed rule. We believe that calculating the payment rate for the proposed add-on payment adjustment for OTP intensive outpatient services based on the rate provided in a hospital setting would promote greater consistency, site neutrality, and parity with payment rates proposed for IOPs in a majority of other settings, including hospital-based IOPs, FQHCs, and RHCs.

Since IOP services have not been covered or paid under Medicare to date, CMS does not have direct data to estimate utilization and costs of IOP services. However, many of the items and services included in IOP services have been and are currently paid for by Medicare as part of the PHP benefit or under the OPSS more generally. Therefore, in our preliminary ratesetting exercise, we identified, in consultation with clinicians, a list of HCPCS codes for services that would be reasonably included as part of IOP services. Please see a more comprehensive list of these HCPCS codes used to inform the payment methodology during our preliminary ratesetting exercise in Table 43 within section VIII.C “Coding and Billing for PHP and IOP Services under the OPSS” of this proposed rule. The inclusion of many of these services was informed by comments we received in response to comment solicitations in the CY 2023 OPSS/ASC and PFS proposed rules. For example, some of these codes correspond to services for individual and group therapy, occupational therapy, individualized activity therapies, family counseling, and patient training and education.

For the majority of these identified HCPCS codes, the most recent utilization data available was for OPSS claims paid for dates of service in CY 2022, and the most recent cost data available was from the cost reports in CY 2021. Based on this cost and utilization data from CY 2021 and CY 2022, respectively, the estimated payment rate for 3-services per day based on APC 5861 (Intensive Outpatient (1-3 services) for Hospital-based IOPs) was \$280.80; 3 services

per day for 3 days a week would therefore be equal to \$842.40. Because we are proposing that OTP intensive outpatient services include individual and group therapy, which are also already included in the non-drug component of the OTP bundled payments for an episode of care, we propose to subtract the amount that corresponds to the individual and group therapy proposed rate in the non-drug component of the OTP bundled payment from our estimate of \$842.40 in order to establish the amount of the OTP intensive outpatient services add-on payment.

Specifically, in the CY 2020 PFS final rule (84 FR 62658), we finalized a building block methodology to calculate the rate for the non-drug component based on established non-facility rates for similar services under the Medicare PFS, the Medicare CLFS, and state Medicaid programs. For group therapy, we used CPT code 90853 (Group psychotherapy (other than of a multiple-family group)) as a reference code, which at the time of drafting the CY 2020 PFS final rule, in CY 2019, was assigned a non-facility rate of \$27.39. In order to account for the application of the annual update to the non-drug component, the adjusted amount for group psychotherapy is currently \$28.36. For individual therapy, in the CY 2023 PFS final rule (87 FR 69773), we finalized an update to the reference code used in the non-drug component to be based on the CY 2019 non-facility rate for CPT code 90834 (Psychotherapy, 45 minutes with patient), which was \$91.18, and which we adjusted to account for the application of the annual update in the intervening years, resulting in \$94.37. Therefore, we propose an add-on payment adjustment of approximately \$719.67 for HCPCS code GOTP1 ($\$842.40 - (\$28.36 + \$94.37)$). We seek comment on whether the proposed add-on payment adjustment accurately reflects the typical resource costs involved in furnishing IOP services at OTPs. We also seek comment on our proposal to adjust the proposed add-on payment adjustment to account for individual and group therapy included in the non-drug component of OTP bundled payments for an episode of care.

In accordance with the methodology used to update the payment rate for other services payable under the OTP benefit, we propose to apply an annual update based on the percentage increase in the Medicare Economic Index (MEI) to the payment rate HCPCS code GOTP1, as

described in § 414.30. Additionally, consistent with the methodology used to determine payment for non-drug services furnished under the OTP benefit, we propose to apply a geographic adjustment to the payment for HCPCS code G0TP1 based on the Geographic Adjustment Factor, as described in § 414.26. Furthermore, consistent with the policy that applies for other OUD treatment services furnished by OTPs, a beneficiary copayment amount of zero would apply for OTP intensive outpatient services. Lastly, we are also seeking comment on the impact this proposal may have on dually eligible individuals, specifically, the extent to which this expanded coverage and payment may supplant Medicaid coverage for dually eligible individuals, versus the extent to which it would supplement Medicaid if it were fundamentally different from what Medicaid covers in a given state.

We recognize that in this proposed rule, we propose to adopt per diem rates for IOP services furnished in other settings, including CMHCs, hospital-based settings, FQHCs, and RHCs, and that per diem rates are used in the payment methodology for IOP services in some state Medicaid programs. Therefore, we are also seeking comment on whether a daily per diem rate based on 3 service hours per day would be more appropriate for OTP settings, especially if one payment methodology over the other would be less disruptive to OTPs as it relates to coordination of benefits. Lastly, we are seeking feedback about the experiences of furnishing IOP services within OTP settings, including the extent to which it is similar to or different than furnishing IOP services in other settings. We believe this additional information may be helpful to understand the clinical complexity of patients enrolled in OTPs who are in need of IOP services for OUD and to compare the level of care and type of services that may supplement and/or exceed those ordinarily provided under the existing OTP benefit, in order to help inform potential future rulemaking on this topic.

We propose to add a new paragraph (iv) to § 410.67(d)(4)(i)(F) in order to describe the new adjustment to the bundled payment for OTP intensive outpatient services. Additionally, we propose to amend § 410.67(d)(4)(ii) to add that the payment amounts for OTP intensive

outpatient services will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26. Lastly, we propose to amend § 410.67(d)(4)(iii) to add that payment for OTP intensive outpatient services will be updated annually using the Medicare Economic Index described in § 405.504(d).

c. Certification and Plan of Care Requirements for IOPs in OTP settings

In order to be consistent with physician certification and plan of care requirements for IOP services furnished in other settings of care and to ensure, to the extent possible, that IOP services are only provided and paid for when medically necessary and appropriate for the beneficiary, we propose to adopt the same standards set forth in § 424.24(d)(1) through (3) for OTPs providing OTP intensive outpatient services (please see more detailed discussions of these proposed standards in section VIII.B.3, IOP Certification and Plan of Care Requirements, of this proposed rule. Specifically, under this proposal, a physician would be required to certify that an individual needs OTP intensive outpatient services for a minimum of 9 hours per week, which is consistent with treatment standards specified by SAMHSA and minimum hour standards described by ASAM's Level 2.1 of care for IOP services.¹²¹ This certification would require documentation in the patient's medical record to include that the individual requires such services for a minimum of 9 hours per week; require the first recertification as of the 30th day of IOP services; and require that the certification of IOP services occur no less frequently than every other month. Accordingly, we propose to revise § 410.67(c) of our regulations to add a paragraph (5) to specify that OTPs must furnish OTP intensive outpatient services consistent with the requirements regarding content of certification, plan of treatment requirements, and recertification requirements as set forth under proposed § 424.24(d)(1) through (3).

Regarding the recertification requirements, given that OTP services are billed on a weekly basis, we propose that the required recertification could occur any time during an episode

¹²¹ <https://www.ncbi.nlm.nih.gov/books/NBK64088/>

<https://store.samhsa.gov/product/TIP-47-Substance-Abuse-Clinical-Issues-in-Intensive-Outpatient-Treatment/SMA13-4182>

of care in which the 30th day from the start of IOP services (and every other month thereafter) falls. We note that in the CY 2020 PFS final rule (84 FR 62641), we defined an episode of care as a 1-week (contiguous 7-day) period at § 410.67(b). In the CY 2021 PFS final rule (85 FR 84691), we clarified that OTPs may choose to apply a standard billing cycle by setting a particular day of the week to begin all episodes of care, or they may choose to adopt weekly billing cycles that vary across patients, and we propose to adopt the same approach here. We welcome comments on these proposals.

We note that this proposal requires that the physician certify a need for at least 9 hours of services per week, which differs from our proposal that in order to bill for the add-on payment adjustment for OTP intensive outpatient services, the OTP must attest that it provided 9 such services to the beneficiary in a week. Given that services can vary in duration and that some services are not time-based, we believe it would be administratively simpler for OTPs to count the number of services furnished rather than to count the number of hours for purposes of billing the add-on payment adjustment for OTP intensive outpatient services. Additionally, as described in Section VIII.G.3.b., our proposed payment rate is based on the number of services furnished per day, rather than the number of hours, consistent with the proposals for IOP payment in other settings. In contrast, for the purposes of certification and plan of care requirements for IOPs in OTP settings, we believe that requiring a physician to certify that a beneficiary requires a minimum of 9 hours of services per week is consistent with existing clinical guidance describing the intensity of care for IOP services.¹²² Additionally, a minimum of 9 hours of services per week is consistent with proposals for the certification and plan of care requirements for IOPs in other care settings. We welcome comments on both of these proposals, including whether this distinction accurately reflects the practice patterns of OTPs furnishing IOP services.

d. Correction to the OTP Regulation Text

¹²² <https://www.ncbi.nlm.nih.gov/books/NBK64088/>

<https://store.samhsa.gov/product/TIP-47-Substance-Abuse-Clinical-Issues-in-Intensive-Outpatient-Treatment/SMA13-4182>

We also propose to correct a typographical error at § 410.67(d)(3), which currently states “At least one OUD treatment service described in paragraphs (b)(1) through (5) of this section must be furnished to bill for the bundled payment for an episode of care.” This provision should refer to paragraphs (i) through (v) of the definition of OUD treatment service in paragraph (b). Accordingly, we propose to correct this sentence to read, “At least one OUD treatment service described in paragraphs (i) through (v) of the definition of Opioid use disorder treatment service in paragraph (b) of this section must be furnished to bill for the bundled payment for an episode of care.”

H. Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

1. Background

In the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79727) in the discussion of the proposed implementation of section 603 of the Bipartisan Budget Act (BBA) of 2015 (Pub. L. 114–74, November 2, 2015), we established the PHP payment rate under the Medicare Physician Fee Schedule (MPFS) for nonexcepted off-campus PBDs as equivalent to the level of payment made to CMHCs for furnishing three or more PHP services per day. We noted that when a beneficiary received outpatient services in an off-campus department of a hospital, the total Medicare payment for those services is generally higher than when those same services are provided in a physician’s office. Similarly, when partial hospitalization services are provided in a hospital-based PHP, Medicare pays more than when those same services are provided by a CMHC. Our rationale for adopting the CMHC per diem rate for APC 5853 as the MPFS payment amount for nonexcepted PBDs providing PHP services was because CMHCs are freestanding entities that are not part of a hospital, but they provide the same PHP services as hospital-based PHPs. This is similar to the differences between freestanding entities paid under the MPFS that furnish other services also provided by hospital-based entities. Similar to other entities currently paid for their technical component services under the MPFS, we believe

CMHCs would typically have lower cost structures than hospital-based PHPs, largely due to lower overhead costs and other indirect costs such as administration, personnel, and security. We explained that we believe that paying for nonexcepted hospital-based partial hospitalization services at the lower CMHC per diem rate aligns with section 603 of the BBA of 2015, while also preserving access to PHP services.

2. Proposed Payment for PHP and IOP Furnished by Nonexcepted Off-Campus Hospital Outpatient Departments

As discussed in section VIII.D of this proposed rule, we propose to change our methodology for calculating PHP payment rates by establishing separate payment rates for 3-service and 4-service days. We also propose to establish IOP payment rates for 3-service and 4-service days beginning in CY 2024. Because CMHCs have different cost structures than hospitals, we propose to establish separate CMHC and hospital rates for 3-service and 4-service PHP and IOP days. We propose to utilize the CMHC rates for PHP and IOP as the payment rates for PHP and IOP services furnished by nonexcepted off-campus hospital outpatient departments. Specifically, we propose to utilize the separate CMHC rates for 3-service and 4-service PHP days as the MPFS rates, depending upon whether a nonexcepted off-campus hospital outpatient department furnishes 3 or 4 PHP services in a day. Similarly, we also propose 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.

As discussed in section VIII.D of this proposed rule, we are soliciting comment on our proposed payment rates for PHP and IOP services, as well as whether commenters believe it would be appropriate to consider establishing a combined rate for 3-service days in hospitals and CMHCs, and a combined rate for 4-service days in hospitals and CMHCs. We are considering whether it would be appropriate to apply a different methodology for calculating the PHP and IOP rates for nonexcepted off-campus hospital outpatient departments and we solicit comments

on alternative methodologies commenters believe would be appropriate. For example, we are considering whether it would be appropriate to apply the PFS Relativity Adjuster of 40 percent, which was established in the CY 2018 PFS rule (82 FR 53030) and which applies to most other nonexcepted OPSS services furnished by a nonexcepted off-campus hospital outpatient department. Depending on the comments we receive, we may finalize an alternative methodology such as the PFS Relativity Adjuster. We note that if we were to adopt such a methodology, we would apply it to both PHP and IOP services.

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 OPPI/ASC final rule with comment period (76 FR 74353), we assessed whether a procedure or service met these criteria to determine whether it should be removed from the IPO list and assigned to an APC group for payment under the OPPI 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 the following:

1. Most outpatient departments are equipped to provide the services to the Medicare population.

2. The simplest procedure described by the code may be furnished in most outpatient departments.
3. The procedure is related to codes that we have already removed from the IPO list.
4. A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
5. 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 met the longstanding criteria for removal from the IPO list and was 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 OPSS and review 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 for 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 CY 2024, we received several requests from interested parties recommending particular services to be removed from the IPO list. Following our clinical review, we did not find sufficient evidence that, using the five criteria listed above, these services meet the criteria to be removed from the IPO list for CY 2024. Therefore, we are not proposing to remove any services from the IPO list for CY 2024.

We propose to add nine services for which codes were newly created by the AMA CPT Editorial Panel for CY 2024 to the IPO list. These new services are described by the placeholder CPT codes X114T, 2X002, 2X003, 2X004, 619X1, 7X000, 7X001, 7X002, and 7X003, which will be effective on January 1, 2024. After clinical review of these services, we found that they require a hospital inpatient admission or stay and thus, we believe they are not appropriate for payment under the OPPS. We propose to assign these services to status indicator “C” (Inpatient Only) for CY 2024. Additionally, we propose to reassign CPT code 0646T from status indicator “E1” (not payable by Medicare) to “C,” effective CY 2024. The CPT codes, long descriptors, and the proposed CY 2024 payment indicators are displayed in Table 47.

Table 47 below contains the proposed changes to the IPO list for CY 2024. The complete list of codes describing services that are proposed to be designated as inpatient only services beginning in CY 2024 is also included as Addendum E to this proposed rule, which is available via the internet on the CMS website.

TABLE 47: PROPOSED CHANGES TO THE INPATIENT ONLY (IPO) LIST FOR CY 2024

CY 2024 CPT Code	CY 2024 Long Descriptor	Action	CY 2024 Proposed Status Indicator
X114T	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed	Add to the IPO list	C
2X002	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments	Add to the IPO list	C
2X003	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments	Add to the IPO list	C
2X004	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed	Add to the IPO list	C
619X1	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)	Add to the IPO list	C
7X000	Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic	Add to the IPO list	C
7X001	Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report	Add to the IPO list	C
7X002	placement, manipulation of transducer, and image acquisition only	Add to the IPO list	C
7X003	interpretation and report only	Add to the IPO list	C
0646T	Transcatheter tricuspid valve implantation (tvti)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	Add to the IPO list	C

C. Solicitation of Public Comments on the Services Described by CPT Codes 43775, 43644, 43645, and 44204

We are soliciting comments regarding whether the services described by CPT codes 43775 (Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)), 43644 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and roux-en-y gastroenterostomy (roux limb 150 cm or less)), 43645 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption), and 44204 (Laparoscopy, surgical; colectomy, partial, with anastomosis) are appropriate to be removed from the IPO list. At this time, we do not believe that we have adequate information to determine whether the services described by CPT codes 43775, 43644, 43645, and 44204 can be safely performed in the hospital outpatient department setting on the Medicare population. Therefore, we are specifically requesting information on evidence that these services can be performed safely on the Medicare population in the outpatient setting. We are also seeking public comments on whether the services described by CPT codes 43775, 43644, 43645, and 44204 specifically meet any of the five criteria to be removed from the IPO list mentioned above.

X. Proposed Nonrecurring Policy Changes

A. Supervision by Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists of Cardiac Rehabilitation, Intensive Cardiac Rehabilitation, and Pulmonary Rehabilitation Services Furnished to Hospital Outpatients

1. Background

Section 51008(a) of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115-123) amended section 1861(eee)(1) and (2) of the Act to revise the definitions of cardiac rehabilitation (CR) program and intensive cardiac rehabilitation (ICR) program, respectively, to provide that services these programs furnish can be under the supervision of a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS). Section 51008(b) of the BBA of 2018

amended section 1861(fff)(1) of the Act similarly to revise the definition of a pulmonary rehabilitation (PR) program to provide that PR services can be furnished under the supervision of these same types of practitioners. Section 51008(c) of the BBA of 2018 provides that these amendments apply to items and services furnished on or after January 1, 2024. Before the effective date of these amendments, only physicians could supervise services furnished as part of CR, ICR, and PR programs.

To implement these amendments, we propose in the CY 2024 PFS proposed rule to revise the regulations at 42 CFR 410.47 and 410.49, which describe the conditions of coverage for the CR, ICR and PR programs, to provide that physician assistants, nurse practitioners, and clinical nurse specialists can supervise CR, ICR and PR program services. Specifically, the CY 2024 PFS proposed rule proposes to amend §§ 410.47 and 410.49 to provide that supervision of pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation services can be provided by a physician, PA, NP, or CNS.

2. Proposed Conforming Revisions to § 410.27

Correspondingly, to implement the amendments to section 1861(eee)(1) and (2) and (fff) of the Act, and to be consistent with the proposed revisions to § 410.47 and § 410.49, we propose to make conforming revisions to § 410.27, which describes the conditions for coverage for therapeutic outpatient hospital or CAH services and supplies provided incident to a physician's or nonphysician practitioner's service.

Currently, § 410.27(a)(1)(iv)(B)(I) provides that for PR, CR, and ICR services, direct supervision must be furnished by a doctor of medicine or osteopathy as specified in §§ 410.47 and 410.49. We propose to delete the reference to a doctor of medicine or osteopathy and retain the cross-reference to §§ 410.47 and 410.49. As the text remaining following this deletion would consist solely of cross-references to the newly revised §§ 410.47 and 410.49, this would have the

effect of expanding who may provide supervision for CR, ICR and PR to include PAs, NPs, and CNSs for purposes of supervision of PR, CR, and ICR services under § 410.27.

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) to provide that, during a Public Health Emergency as defined in 42CFR 400.200, the presence of the physician for purposes of the direct supervision requirement for PR, CR, and ICR services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. Specifically, the required direct physician supervision can be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. We further amended § 410.27(a)(1)(iv)(D) 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 2022 PFS final rule, CMS added CPT codes 93797 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)) and 93798 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)) and HCPCS codes G0422 (Intensive cardiac rehabilitation; with or without continuous ecg monitoring with exercise, per session) and G0423 (Intensive cardiac rehabilitation; with or

without continuous ecg monitoring; without exercise, per session) to the Medicare Telehealth Services List on a Category 3 basis (86 FR 65055).

In order to effectuate a similar policy under the OPSS, where PR, CR, and ICR rehabilitation services could be furnished during the PHE to beneficiaries in hospitals under direct supervision of a physician where the supervising practitioner is immediately available to be present via two-way, audio/video communications technology, in the CY 2023 OPSS/ASC final rule with comment period, we finalized a policy to extend the revised definition of direct supervision to include the presence of the supervising practitioner through two-way, audio/video telecommunications technology until December 31, 2023 (87 FR 72019 through 72020). Under the telehealth flexibilities extended in the CAA, 2023, these services will remain on the Medicare Telehealth Services List through the end of CY 2024. In the interest of maintaining similar policies for direct supervision of PR, CR, and ICR under the OPSS and PFS, we propose to further revise § 410.27(a)(1)(iv)(B)(I) to allow for the direct supervision requirement for CR, ICR, and PR to include virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024 and extend this policy to the nonphysician practitioners, that is NPs, PAs, and CNSs, who are eligible to supervise these services in CY 2024. We are also soliciting comments on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the current or proposed extensions and what policies CMS could adopt to address those concerns if the policy were extended beyond 2023.

For the complete discussion of the proposed revisions to § 410.47 and § 410.49, we refer readers to the CY 2024 PFS proposed rule that is published elsewhere in the **Federal Register**.

B. Payment for Intensive Cardiac Rehabilitation Services (ICR) Provided by an Off-Campus, Non-Excepted Provider Based Department (PBD) of a Hospital

1. Background on Intensive Cardiac Rehabilitation

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275) made a number of changes to the Act related to coverage and payment for pulmonary and cardiac rehabilitation services furnished to beneficiaries with chronic obstructive pulmonary disease and certain other conditions, effective January 1, 2010. Specifically, section 144(a)(1)(A) of MIPPA amended section 1861(s)(2) of the Act by adding new subparagraphs (CC) and (DD) to provide for Medicare Part B coverage of items and services furnished under a cardiac rehabilitation (CR) program (as defined in a new section 1861(eee)(1) of the Act); a pulmonary rehabilitation (PR) program (as defined in a new section 1861(fff)(1) of the Act); and an intensive cardiac rehabilitation (ICR) program (as defined in a new section 1861(eee)(4) of the Act). The amendments made by section 144(a) of MIPPA provide for coverage of CR, PR, and ICR program services provided in a physician's office, in a hospital on an outpatient basis, and in other settings determined appropriate by the Secretary.

Section 144(a)(2) of MIPPA amended section 1848(j)(3) of the Act to provide for payment for services furnished in an ICR program under the PFS and also added a new paragraph (5) to section 1848(b) of the Act. Section 1848(b)(5)(A) requires the Secretary for ICR program services to substitute the Medicare OPD fee schedule amount established under the OPPS for cardiac rehabilitation (under HCPCS codes 93797 and 93798 for calendar year 2007, or any succeeding HCPCS codes for cardiac rehabilitation). For a full discussion of implementation of the MIPPA amendments related to coverage and payment for PR, CR, and ICR programs under the OPPS, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60566 through 60574).

2. Background on Section 603 of the Bipartisan Budget Act of 2015 and the PFS Relativity Adjuster

Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74) (BBA, 2015) (hereinafter referred to as “section 603”) amended section 1833(t) of the Act by adding a new clause (v) to paragraph (1)(B) and adding a new paragraph (21). As a general matter, under

sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid “under the applicable payment system” under Medicare Part B if the requirements for such payment are otherwise met. Section 603 amended section 1833(t)(1)(B) of the Act by adding a new clause (v), which excludes from the definition of “covered OPD services” applicable items and services (defined in paragraph (21)(A) of the section) that are furnished on or after January 1, 2017, by an off-campus PBD, as defined in paragraph (21)(B) of the section.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719), we adopted a number of policies to implement section 603. Broadly, we: (1) defined applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and services will instead be made under the applicable payment system designated under section 1833(t)(21)(C) of the Act; (2) defined off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) established policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. To do so, we finalized policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the OPPS; established the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBDs and for the items and services furnished by such excepted off-campus PBDs); and described the applicable payment system for nonexcepted items and services (generally, the PFS).

To effectuate payment for nonexcepted items and services, in the CY 2017 interim final rule with comment period (81 FR 79720 through 79729), we established a new set of payment

rates under the PFS that reflected the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS specific to the nonexcepted off-campus PBDs of a hospital. Specifically, we established a PFS Relativity Adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD in order to calculate payment rates under the PFS. The PFS Relativity Adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the nonexcepted items and services furnished in nonexcepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. Nonexcepted items and services furnished by nonexcepted off-campus PBDs are generally paid under the PFS at the applicable OPPS payment rate adjusted by the PFS Relativity Adjuster of 40 percent (that is, 60 percent less than the OPPS rate) (82 FR 53030).

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79719 and 79725), we created modifier “PN” to collect data for purposes of implementing section 603 but also to trigger payment under the newly adopted PFS-equivalent rates for nonexcepted items and services. Nonexcepted off-campus PBDs bill for nonexcepted items and services on the institutional claim utilizing modifier “PN” to indicate that an item or service is a nonexcepted item or service.

For a full discussion of our initial implementation of section 603, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with comment period (79720 through 79729). For a detailed discussion of the current PFS Relativity Adjuster related to payments under section 603, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 52356 through 52637) and the CY 2019 PFS final rule with comment period (82 FR 59505 through 59513).

3. Proposal to Modify Claims Processing of HCPCS Codes G0422 and G0423 to Address an Unintended Payment Disparity Caused by Application of the PFS Relativity Adjuster to ICR Services Furnished by Off-Campus Non-Excepted PBDs Hospitals

Since 2010, ICR services provided in the physician’s office have been paid at 100 percent of the OPPS rate for CR services as required by 1848(b)(5). Since 2017, ICR services provided by an off-campus, non-excepted PBD of a hospital have been paid at the above-described “PFS-equivalent” rate through application of the PFS Relativity Adjuster, which was 50 percent of the OPPS rate in CY 2017 and 40 percent of the OPPS rate in CY 2018 and thereafter, consistent with the above-described implementation of section 603.

This has produced an outcome inconsistent with the text of section 1848(a)(5)(A) and at odds with the intent of section 603, which was to remove the significant disparity in payment rates for the same services depending on whether they were furnished in a physician’s office or an off-campus, non-excepted PBD of a hospital. When the PFS Relativity Adjuster was implemented in 2017, payment for the ICR service provided in a physician’s office and a PBD of an off-campus, non-excepted hospital was already the same pursuant to section 1848(b)(5)(A), which explicitly requires ICR services provided in a physician’s office to be paid at the OPPS rate for cardiac rehabilitation. Consequently, application of the 40 percent PFS Relativity Adjuster to payment for ICR provided by an off-campus, non-excepted PBD has resulted in an unintended reimbursement disparity between the two sites of the service, as shown in Table 48.

TABLE 48: 2023 REIMBURSEMENT FOR HCPCS CODES G0422 AND G0423 UNDER THE OPPS ON-CAMPUS RATE, OPPS NON-EXCEPTED RATE AND PFS RATE

HCPCS Code	2023 OPPS On-Campus Rate	2023 OPPS Non-Excepted Rate	2023 Medicare PFS Payment Rate
G0422 (intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session)	\$120.47	\$48.03	\$120.47
G0423 (intensive cardiac rehabilitation; with or without continuous ECG monitoring without exercise, per session)	\$120.47	\$48.03	\$120.47

This disparity creates a significant barrier to beneficiary access to an already underutilized service. To eliminate this unintended outcome and for consistency with the requirement in section 1848(b)(5)(A) of the Act to substitute the OPPS rate for CR services for the PFS rate for ICR services, we propose to pay for ICR services provided by an off-campus, non-excepted provider-based department of a hospital at 100 percent of the OPPS rate for CR services (which is also 100 percent of the PFS rate) rather than at 40 percent of the OPPS rate. Effective January 1, 2024, we propose to exclude ICR from the 40 percent Relativity Adjuster policy at the code level by modifying the claims processing of HCPCS codes G0422 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session) and G0423 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring without exercise, per session) so that 100 percent of the OPPS rate for CR is paid irrespective of the presence of the “PN” modifier (signifying a service provided in a non-excepted off-campus provider-based department of a hospital) on the claim. We solicit comment on whether there are other services for which the OPPS rate is unconditionally used under the PFS, such that these services should be treated similarly for purposes of payment to off-campus, non-excepted provider-based departments of hospitals.

C. OPPS Payment for Specimen Collection for COVID–19 Tests

In the May 8th, 2020 COVID–19 interim final rule with comment period titled “Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program”, we created a new E/M code to support COVID–19 testing during the PHE: HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars–cov–2) (coronavirus disease [covid–19]), any specimen source) (85 FR 27604). In our review of available HCPCS and CPT codes for the May 8th, 2020 COVID–19 IFC, we did not identify a prior code that explicitly described the exact services of symptom assessment and specimen collection that HOPDs were undertaking to

facilitate widespread testing for COVID-19. We believed that HCPCS code C9803 was necessary to meet the resource requirements for HOPDs to provide extensive testing for the duration of the COVID–19 PHE. This code was created only to meet the need of the COVID–19 PHE and we stated that we expected to retire this code at the conclusion of the COVID–19 PHE (85 FR 27604).

We assigned HCPCS code C9803 to APC 5731—Level 1 Minor Procedures effective March 1, 2020 for the duration of the COVID–19 PHE. In accordance with Section 1833(t)(2)(B) of the Act, APC 5731—Level 1 Minor Procedures contains services similar to HCPCS code C9803. APC 5731—Level 1 Minor Procedures has a payment rate of \$24.96 for CY 2023. HCPCS code C9803 was also assigned a status indicator of “Q1.” The Q1 status indicator indicates that the OPSS will package services billed under HCPCS code C9803 when billed with a separately payable primary service in the same encounter. When HCPCS code C9803 is billed without another separately payable primary service, we explained that we will make separate payment for the service under the OPSS. The OPSS also makes separate payment for HCPCS code C9803 when it is billed with a clinical diagnostic laboratory test with a status indicator of “A” on Addendum B of the OPSS. On May 11, 2023, the COVID-19 PHE concluded.¹²³ As stated above, we created HCPCS code C9803 to meet the need of the COVID-19 PHE and the resource requirements for HOPDs during the PHE, and planned to retire the code following the conclusion of the PHE. While the code will remain active for the remainder of CY 2023 for technical reasons, we do not believe it is necessary for the code remain active in CY 2024 now that the PHE has concluded. Therefore, we propose to delete HCPCS code C9803 effective January 1, 2024. We solicit comment on our proposal to delete this code for CY 2024.

¹²³ <https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html>

D. Remote Services

1. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

In the CY 2023 OPSS final rule with comment period (87 FR 72012 through 72017), we finalized creation of three HCPCS C-codes to describe mental health services furnished by hospital staff to beneficiaries in their homes through communications technology. See Table 49 for the C-code numbers and their descriptors.

TABLE 49: C-CODE NUMBERS AND LONG DESCRIPTORS

HCPCS Code	Long Descriptor
C7900	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 15-29 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7901	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 30-60 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7902	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service (List separately in addition to code for primary service)

When we created HCPCS codes C7900 through C7902, we did not specify whether they should be used for individual or group services, preferring to keep the coding more general while we gathered information about the use of these new codes. However, we have heard from interested parties that, in instances when a beneficiary is receiving multiple units of group therapy a day, it is administratively burdensome to report and document each unit of time using multiple codes. Instead, interested parties requested that we create a single, untimed code that can be reported when a beneficiary receives multiple hours of group therapy per day. In order to reduce administrative burden and enhance access to these services, we propose to create a new, untimed, HCPCS C-code describing group therapy. Please see Table 50 for the proposed C-code and long descriptor.

TABLE 50: PROPOSED C-CODE NUMBER AND LONG DESCRIPTOR

HCPCS	Long Descriptor
C79XX	Group psychotherapy service for diagnosis, evaluation, or treatment of a mental health or substance use disorder provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service

As we stated in the CY 2023 OPSS final rule with comment period, when beneficiaries are in their homes and not physically within the hospital, the hospital is not accruing all the costs associated with an in-person service; and the full OPSS rate would not accurately reflect these reduced costs. We believe that the costs associated with hospital clinical staff remotely furnishing a mental health service to a beneficiary who is in their home using communications technology more closely resembles the PFS payment amount for similar services when performed in a facility, which reflects the time and intensity of the professional work associated with performing the mental health service but does not reflect certain practice expense costs, such as clinical labor, equipment, or supplies (87 FR 72015).

In keeping with that methodology, we propose to assign HCPCS code C79XX to an APC based on the facility payment amount for a clinically similar service, CPT code 90853 (Group psychotherapy (other than of a multiple-family group)) under the PFS. See Table 51 for the proposed SI and APC assignments and payment rates for HCPCS code C79XX.

TABLE 51: PROPOSED CY 2023 SI, APC ASSIGNMENT, AND GEOMETRIC MEAN COST FOR HCPCS CODE C97XX

HCPCS	Short Descriptor	Proposed SI	Proposed Proxy Service	PFS Facility Rate	Proposed APC	APC GMC
C79XX	HOPD mntl hlt, grp	S	90853	\$23.38	5821	\$28.62

We seek comment on whether HCPCS code C79XX sufficiently describes group psychotherapy to the extent that group psychotherapy would no longer be reported with HCPCS codes C7900-C7902, in which case we would need to refine the code descriptors for HCPCS codes C7900-C7902 to stipulate that they are solely for services furnished to an individual

beneficiary. Alternatively, we are seeking comment on whether or there are circumstances where interested parties believe it would be appropriate to bill for group services using HCPCS codes C7900-C7902. We also seek comment on any further refinements to the code descriptors, valuation, or billing guidance.

We have also heard from interested parties that there is confusion about the presence of the word “initial” in the descriptors for HCPCS codes C7900 and C7901 and that this is preventing billing for remote behavioral health services furnished subsequent to either the first 15 to 29 minutes or 30 to 60 minutes. In order to facilitate accurate billing, regardless of whether the remote mental health service is being furnished as an initial or subsequent service, we propose to revise the code descriptors to remove the word “initial.” We also propose to revise the descriptor for HCPCS code C7902 to limit billing with HCPCS code C7901. See Table 52 for revised code descriptors.

TABLE 52: PROPOSED DESCRIPTORS FOR HCPCS CODES C9700 AND C9701

HCPCS	Proposed Long Descriptor
C7900	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, 15-29 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7901	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, 30-60 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7902	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service (List separately in addition to HCPCS code C9701)

2. Periodic In-Person Visits

In the CY 2023 OPSS 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 Consolidated Appropriations Act (CAA), 2023, (Pub. L. 117-328) 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. As previously stated, we believe it is important to maintain consistent requirements for these policies across payment systems; therefore we propose to delay the in-person visit requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025.

3. Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy when Furnished by Hospital Staff to Beneficiaries in Their Homes Through Communication Technology

The CAA, 2023 extended most flexibilities for Medicare telehealth services, including retention of physical and occupational therapists and speech-language pathologists as telehealth distant site practitioners, through the end of CY 2024. In the CY 2024 PFS proposed rule, we propose to continue to make payment for outpatient therapy (physical therapy, occupational therapy, and speech-language pathology) services, Diabetes Self-Management Training, and Medical Nutrition Therapy when furnished via telehealth by qualified employed staff of institutional providers through the end of CY 2024. We note that this proposal includes outpatient therapy, DSMT, and MNT services furnished via telehealth by staff of hospital outpatient departments. For further discussion, please see the CY 2024 PFS proposed rule.

E. OPSS Payment for Dental Services

1. Background

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to “the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth” as “dental services.”) In the CY 2023 Physician Fee Schedule (PFS) final rule (87 FR 69663), we explained that we believe there are instances where dental services are so integral to other medically necessary services that they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to the clinical success of an otherwise covered medical service, and therefore, are instead substantially related and integral to that primary medical service. To provide greater clarity to our current policies and respond to issues raised by interested parties, in the CY 2023 PFS final rule, we 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, and substantially related and integral to the clinical success of, other covered medical services (hereafter in this discussion,

“inextricably linked to other covered services”); (2) clarification and codification of certain longstanding Medicare FFS payment policies for inextricably linked dental 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; (4) for CY 2024, that Medicare Part A and B payment can be made for certain dental services inextricably linked to Medicare-covered services for treatment of head and neck cancers; and (5) beginning for CY 2023, the establishment of a process to submit for our consideration and review additional dental services that are inextricably linked to other covered medical services (87 FR 69670 through 69671). The CY 2023 PFS final rule specified that Medicare payment for these dental services may be made regardless of whether the services are furnished in an inpatient or outpatient setting. We direct readers to the CY 2023 PFS final rule (87 FR 69663 through 69688) for a full discussion of these policies as well as to the CY 2024 PFS proposed rule for proposals related to dental services.

In the CY 2023 PFS final rule, CMS identified various examples of HCPCS codes, mostly Current Dental Terminology (CDT®) codes, that could be used to describe the types of dental services identified in the CY 2023 PFS final rule for which Medicare payment can be made when coverage and payment policy requirements are met (87 FR 69667). We refer readers to the PFS Relative Value Files that are released quarterly on the CMS website for a comprehensive list of HCPCS codes, including D-codes, that may be payable under the PFS, available at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files>.

The policies adopted in the CY 2023 PFS final rule allow payment for certain dental services performed in outpatient settings. However, the current dental codes assigned to APCs for CY 2023 do not fully describe the dental services that may be inextricably linked to covered medical services and payable under Medicare Part B. Specifically, for the OPFS for CY 2023, only 57 CDT codes are assigned to APCs and payable under the OPFS when coverage and

payment conditions are met. In addition to the small number of CDT codes assigned to APCs for CY 2023, there is also a limited number of CPT codes that may describe dental services, including CPT code 41899 (Unlisted px dentalvlr strux), that are currently assigned to APCs and payable under the OPSS.

In the CY 2023 OPSS/ASC final rule with comment period, we created HCPCS code G0330 to describe facility services for dental rehabilitation procedure(s) furnished to patients who require monitored anesthesia (e.g., general, intravenous sedation (monitored anesthesia care)) and use of an operating room. We finalized this code based on extensive public comments expressing the need for a coding and payment mechanism to improve access to covered dental procedures under anesthesia, especially dental rehabilitation procedures, an issue that commenters to the CY 2023 OPSS proposed rule explained is caused by barriers to securing sufficient operating room time to furnish these services. We further noted that HCPCS code G0330 must only be used to describe facility fees for dental rehabilitation services that meet Medicare payment and coverage requirements as interpreted in the CY 2023 PFS final rule. We explained that HCPCS code G0330 cannot be used to describe or bill the facility fee for noncovered dental professional services. We assigned HCPCS code G0330 to APC 5871 (Dental Procedures) for CY 2023. We direct readers to the CY 2023 OPSS/ASC final rule with comment period for a full discussion on HCPCS code G0330 (87 FR 71882 through 71883). For CY 2024, we do not propose to change the APC assignment for HCPCS code G0330. However, we refer readers to the section XIII of this proposed rule for a proposal regarding payment for HCPCS code G0330 under the ASC payment system.

2. Proposed OPSS Payment for Additional Dental Codes Beginning in CY 2024

To ensure that dental services can be paid under the OPSS when consistent with the policies and clarifications included in the CY 2023 PFS final rule, we propose to assign additional dental codes to APCs for CY 2024. Specifically, for CY 2024, we propose to assign 229 additional dental codes to clinical APCs to enable them to be paid for under the OPSS when

payment and coverage requirements are met. Assigning additional dental codes to clinical APCs would result in greater consistency in Medicare payment for different sites of service and help ensure patient access to dental services for which payment can be made when performed in the hospital outpatient setting.

Prior to detailing our proposals, we note two things for readers' awareness. First, OPSS payment will only be made for a dental code that we propose to assign to an APC for CY 2024 if it is among the types of dental services for which payment can be made as described in the regulation at § 411.15(i)(3)(i). As we have consistently stated in past rules (87 FR 71879) and quarterly change requests to assign new codes to APCs (see, e.g., Pub 100-04 Medicare Claims Processing, Transmittal 11937), 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. 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 a dental service assigned to an APC when the appropriate MAC determines that the service meets the relevant conditions for coverage and payment.

Second, we anticipate that we would continue to assess our policies for OPSS payment for dental services in future rulemaking. We believe that as we collect claims data, gather input from the public and interested parties, and learn more about the services performed in the HOPD setting, we will be able to make more informed decisions regarding payment rates, APC assignments, and status indicators for dental services.

The dental services for which we propose APC assignments in this proposed rule are those dental services described in the CY 2023 PFS final rule for which Medicare Part B payment can be made when they are inextricably linked to other covered services. Based on the dental services identified in that final rule, we generated a list of codes that describe those

services for which we believe we need to propose APC assignments to ensure payment is available under the OPSS. To generate this list, we reviewed the dental codes that were specifically listed as examples of payable dental services in the CY 2023 PFS final rule (87 FR 69676). We also reviewed the clinical vignettes provided in the CY 2023 PFS final rule to identify whether there are other dental codes in addition to the dental code examples already identified for which we should propose APC assignments.

The CY 2023 PFS final rule amended § 411.15(i)(3)(i) to allow for payment under Medicare Part A and Part B for dental services, furnished in an inpatient or outpatient setting, that are inextricably linked to, and substantially related and integral to the success of, certain other covered medical services, including, but not limited to: (1) dental or oral examination as part of a comprehensive workup prior to a Medicare covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; and the necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the organ transplant, cardiac valve replacement, or valvuloplasty procedure; (2) reconstruction of a dental ridge performed as a result of, and at the same time as, the surgical removal of a tumor; (3) the stabilization or immobilization of teeth in connection with the reduction of a jaw fracture, and dental splints only when used in conjunction with covered treatment of a covered medical condition such as dislocated jaw joints; and (4) the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease. For CY 2024, we established that Medicare Parts A and B payment may also be made for dental services, such as dental examinations, including necessary treatments, performed as part of a comprehensive workup prior to treatment for head and neck cancers. We include a proposal in the CY 2024 PFS proposed rule to codify this example under § 411.15(i)(3)(i). We identified dental services described in the regulation at § 411.15(i)(3)(i) and those that may be part of a comprehensive workup prior to treatment for head and neck cancers that could be payable under the OPSS if payment and coverage requirements are met. For example, consistent with § 411.15(i)(3)(A), which describes dental or

oral examinations as part of a comprehensive workup prior to a Medicare covered organ transplant, cardiac valve replacement, or valvuloplasty procedure, we identified several codes describing dental examinations for which we propose APC assignments (e.g., D0120, D0140, D0150, D0160, D0170, D0180, D0191, D0171). Section 411.15(i)(3)(C) describes services for the stabilization or immobilization of the teeth in connection with the reduction of a jaw fracture, and dental splints only when used with a covered treatment of a covered medical condition. We identified an additional 16 dental codes (e.g., D7670-D7671; D4322; D5988) that we believe identify these services and for which we propose APC assignments.

While it is appropriate for CMS to assign certain dental codes to APCs for payment under the OPSS, we do not believe that every dental code should be assigned to an APC and made payable under the OPSS. For instance, there are services described by CDT codes that may already be described by existing CPT codes assigned to clinical APCs. When this is the case, we propose that HOPDs would use the existing CPT codes to bill for the services performed. We also are not proposing APC assignments for all dental codes, even if they describe dental services that are payable consistent with the policies and clarifications included in the CY 2023 PFS final rule. This is because under our regulation at 42 CFR 419.22, the following services are not paid under the OPSS (except when packaged as part of a bundled payment): physician services that meet the requirements of 42 CFR 415.102(a); nurse practitioner or clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act; physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act; and services of an anesthetist as defined in § 410.9. We note that dentists are considered physicians for purposes of Medicare payment policy, including this regulation. There are a number of existing CDT codes that describe the professional services of dentists that could be paid under the PFS (e.g., D9990-D9997), but that we do not believe are appropriate for payment under the OPSS. Therefore, we do not propose to assign CDT codes that describe professional services of dentists and other dental professionals to clinical APCs.

Finally, there are dental codes that we believe would not meet our current interpretation of dental services that may be inextricably linked to other covered medical services. For instance, there are CDT codes that describe removable prosthodontic procedures, including codes that describe complete or partial denture procedures (e.g., D5110; D5120; D5211-D5214). Because denture procedures are not covered medical procedures under Medicare, we are not proposing to assign any dental codes describing denture procedures to clinical APCs.

In sum, in consultation with medical experts, we identified 229 dental codes as appropriate for payment under the OPSS when relevant conditions for payment and coverage are met. In addition to the dental codes already assigned to APCs, we propose to assign the 229 additional dental codes listed in Table 53 below to various clinical APCs for CY 2024:

TABLE 53: DENTAL CODES PROPOSED FOR ASSIGNMENT TO CLINICAL APCS IN CY 2024

HCPCS Code	Description
D0120	Periodic oral evaluation
D0140	Limit oral eval problm focus
D0160	Extensv oral eval prob focus
D0170	Re-eval,est pt,problem focus
D0180	Comp periodontal evaluation
D0191	Assessment of a patient
D0171	Re-eval post-op visit
D1110	Dental prophylaxis adult
D7950	Mandible graft
D7340	Vestibuloplasty ridge extens
D7350	Vestibuloplasty exten graft
D7485	Surg reduct osseoustuberosit
D7310	Alveoplasty w/ extraction
D7311	Alveoloplasty w/extract 1-3
D7510	I&d abscc intraoral soft tiss
D7473	Remove torus mandibularis
D7472	Removal of torus palatinus
D7520	I&d abscess extraoral
D7521	Incision/drain abscess extra
D7511	Incision/drain abscess intra
D7550	Removal of sloughed off bone
D7460	Rem nonodonto cyst to 1.25cm
D7461	Rem nonodonto cyst > 1.25 cm
D7272	Tooth transplantation
D7270	Tooth reimplantation
D7670	Closd rductn splint alveolus
D7671	Alveolus open reduction

HCPCS Code	Description
D7770	Open reduc compd alveolus fx
D7771	Alveolus clsd reduc stblz te
D7874	Tmj arthroscopy disc reposit
D7922	Place intra-socket bio dress
D4323	Splint extra-coronal
D4322	Splint intra-coronal
D5988	Surgical splint
D2140	Amalgam one surface permanen
D2150	Amalgam two surfaces permane
D2160	Amalgam three surfaces perma
D2161	Amalgam 4 or > surfaces perm
D2330	Resin one surface-anterior
D2331	Resin two surfaces-anterior
D2332	Resin three surfaces-anterio
D2335	Resin 4/> surf or w incis an
D2390	Ant resin-based cmpst crown
D2391	Post 1 srfc resinbased cmpst
D2392	Post 2 srfc resinbased cmpst
D2393	Post 3 srfc resinbased cmpst
D2394	Post >=4srfc resinbase cmpst
D2410	Dental gold foil one surface
D2420	Dental gold foil two surface
D2430	Dental gold foil three surfa
D2510	Dental inlay metallic 1 surf
D2520	Dental inlay metallic 2 surf
D2530	Dental inlay metl 3/more sur
D2542	Dental onlay metallic 2 surf
D2543	Dental onlay metallic 3 surf
D2544	Dental onlay metl 4/more sur
D2610	Inlay porcelain/ceramic 1 su
D2620	Inlay porcelain/ceramic 2 su
D2630	Dental onlay porc 3/more sur
D2642	Dental onlay porcelin 2 surf
D2643	Dental onlay porcelin 3 surf
D2644	Dental onlay porc 4/more sur
D2650	Inlay composite/resin one su
D2651	Inlay composite/resin two su
D2652	Dental inlay resin 3/mre sur
D2662	Dental onlay resin 2 surface
D2663	Dental onlay resin 3 surface
D2664	Dental onlay resin 4/mre sur
D2710	Crown resin-based indirect
D2712	Crown 3/4 resin-based compos
D2720	Crown resin w/ high noble me
D2721	Crown resin w/ base metal
D2722	Crown resin w/ noble metal
D2740	Crown porcelain/ceramic
D2750	Crown porcelain w/ h noble m
D2751	Crown porcelain fused base m

HCPCS Code	Description
D2752	Crown porcelain w/ noble met
D2753	Crown porc fused to titanium
D2780	Crown 3/4 cast hi noble met
D2781	Crown 3/4 cast base metal
D2782	Crown 3/4 cast noble metal
D2783	Crown 3/4 porcelain/ceramic
D2790	Crown full cast high noble m
D2791	Crown full cast base metal
D2792	Crown full cast noble metal
D2794	Crown-titanium
D2799	Interim crown
D2990	Resin infiltration of lesion
D2910	Recement inlay onlay or part
D2915	Recement cast or prefab post
D2920	Re-cement or re-bond crown
D2921	Reattach tooth fragment
D2929	Prefab porc/ceram crown pri
D2928	Prefab porc/cer crown perm
D2930	Prefab stnlss steel crwn pri
D2931	Prefab stnlss steel crown pe
D2932	Prefabricated resin crown
D2933	Prefab stainless steel crown
D2934	Prefab steel crown primary
D2940	Protective restoration
D2941	Int therapeutic restoration
D2949	Restorative foundation
D2950	Core build-up incl any pins
D2951	Tooth pin retention
D2952	Post and core cast + crown
D2953	Each addtnl cast post
D2954	Prefab post/core + crown
D2957	Each addtnl prefab post
D2955	Post removal
D2960	Labial veneer resin direct
D2961	Labial veneer resin indirect
D2962	Labial veneer porc indirect
D2971	Add proc construct new crown
D2975	Coping
D2980	Crown repair
D2981	Inlay repair
D2982	Onlay repair
D2983	Veneer repair
D1354	Int caries med app per tooth
D4210	Gingivectomy/plasty 4 or mor
D4211	Gingivectomy/plasty 1 to 3
D4212	Gingivectomy/plasty rest
D4230	Ana crown exp 4 or> per quad
D4231	Ana crown exp 1-3 per quad
D4240	Gingival flap proc w/ planin

HCPCS Code	Description
D4241	Gngvl flap w rootplan 1-3 th
D4245	Apically positioned flap
D4249	Crown lengthen hard tissue
D4261	Osseous surg 1 to 3 teeth
D4265	Bio mtrls to aid soft/os reg
D4266	Guided tiss regen resorbble
D4267	Guided tiss regen nonresorb
D4274	Mesial/distal wedge proc
D4275	Non-auto graft 1st tooth
D4276	Con tissue w pedicle graft
D4277	Soft tissue graft firsttooth
D4278	Soft tissue graft addl tooth
D4283	Auto tissue graft addl tooth
D4285	Non-auto graft addl tooth
D4341	Periodontal scaling & root
D4342	Periodontal scaling 1-3teeth
D4346	Scaling gingiv inflammation
D4355	Full mouth debridement
D4381	Localized delivery antimicro
D4910	Periodontal maint procedures
D4920	Unscheduled dressing change
D4921	Gingival irrigation per quad
D4999	Unspecified periodontal proc
D3110	Pulp cap direct
D3120	Pulp cap indirect
D3220	Therapeutic pulpotomy
D3221	Gross pulpal debridement
D3222	Part pulp for apexogenesis
D3230	Pulpal therapy anterior prim
D3240	Pulpal therapy posterior pri
D3310	End thxpy, anterior tooth
D3320	End thxpy, premolar tooth
D3330	End thxpy, molar tooth
D3331	Non-surg tx root canal obs
D3332	Incomplete endodontic tx
D3333	Internal root repair
D3346	Retreat root canal anterior
D3347	Retreat root canal premolar
D3348	Retreat root canal molar
D3351	Apexification/recalc initial
D3352	Apexification/recalc interim
D3353	Apexification/recalc final
D3355	Pulpal regeneration initial
D3356	Pulpal regeneration interim
D3357	Pulpal regeneration complete
D3410	Apicoectomy – anterior
D3421	Root surgery premolar
D3425	Root surgery molar
D3426	Root surgery ea add root

HCPCS Code	Description
D3428	Bone graft peri per tooth
D3429	Bone graft peri each addl
D3430	Retrograde filling
D3431	Biological materials
D3432	Guided tissue regeneration
D3450	Root amputation
D3470	Intentional replantation
D3471	Surg rep root res anterior
D3472	Surg rep root res premolar
D3473	Surg rep root res molar
D3501	Surg exp root surf anterior
D3502	Surg exp root surf premolar
D3503	Surg exp root surf molar
D3910	Isolation- tooth w rubb dam
D3911	Intraorifice barrier
D3920	Tooth splitting
D3921	Decor or submerg erupt tooth
D3950	Canal prep/fitting of dowel
D0210	Intraor comprehensive series
D0220	Intraoral periapical first
D0230	Intraoral periapical ea add
D0273	Bitewings - three images
D0310	Dental saliography
D0320	Dental tmj arthrogram incl i
D0321	Other tmj images by report
D0322	Dental tomographic survey
D0330	Panoramic image
D0340	2d cephalometric image
D0350	Oral/facial photo images
D0364	Cone beam ct capt & interp
D0365	Cone beam ct interprete man
D0366	Cone beam ct interprete max
D0367	Cone beam ct interp both jaw
D0368	Cone beam ct interprete tmj
D0369	Max mri capture & interprete
D0370	Max ultrasound capt & interp
D0371	Sialoendoscopy capt & interp
D0380	Cone beam ct capture limited
D0381	Cone beam ct capt mandible
D0382	Cone beam ct capt maxilla
D0383	Cone beam ct both jaws
D0384	Cone beam ct capture tmj
D0385	Max mri image capture
D0386	Max ultrasound image capture
D0701	Pano radio image
D0702	2d cephal radio image
D0703	2d oral/facial photo image
D0705	Extra oral post radio image
D0706	Intraoral occlus radio image

HCPCS Code	Description
D0707	Intraoral periap radio image
D0708	Intraoral bite radio image
D0709	Intraoral comp image capture
D0393	Trtmnt simulation 3d image
D0394	Digital sub 2 or more images
D0395	Fusion 2 or more 3d images

We request comments on the list of 229 dental codes that we propose to assign to APCs for OPPS payment for CY 2024. We also request comments on any additional dental codes that may fall within the scope of dental services for which payment is permitted as explained in the CY 2023 PFS final rule and provided in § 411.14(i)(3)(i), and for which payment should be made available under the OPPS when payment and coverage requirements are met.

3. Proposed APC Assignments for Additional Dental Codes

In accordance with section 1833(t)(2)(B) of the Act, services classified within each APC must be comparable clinically and with respect to the use of resources. Accordingly, when considering the appropriateness of an APC assignment for a code, we consider the clinical characteristics and resource costs of the service described by the code compared to other services in a clinical APC.

Consistent with our existing processes, we were able to crosswalk many of the dental codes to existing CPT codes assigned to APCs for purposes of assessing clinical similarity. For instance, we crosswalked certain tissue graft procedures (e.g., D4270) to CPT code 41870 (gum graft). Because both are surgical procedures where gum tissue near the area of recession is used to cover and protect the exposed tooth root, the codes are clinically similar and we believe are appropriate for grouping within the same clinical APC (i.e., APC 5163 (Level 3 ENT Procedures)). We also found clinical similarities between several dental imaging services and the services assigned to the various levels of the Imaging without Contrast APC series (i.e., APCs 5521 (Level 1, Imaging without Contrast); 5522 (Level 2, Imaging without Contrast); and 5523 (Level 3, Imaging without Contrast)). For example, we crosswalked D0210 (Intraor

complete film series) to CPT code 70320 (Full mouth x-ray of teeth) and therefore propose to assign D0210 to APC 5523 based on the crosswalk analysis.

With regard to resource similarity, because the 229 dental codes we propose to assign to APCs for CY 2024 were not previously paid under the OPSS, we do not have existing claims information to inform proposed APC placements based on resource costs. We considered gathering cost information from several non-Medicare data sources to aid in assigning the dental codes to APCs. For instance, we considered requesting cost information from the Department of Veterans Affairs (VA). However, the VA's dental reimbursement rates are proprietary and are not publicly available.

We also considered requesting data from State Medicaid agencies but found the available data too inconsistent and limited to be useful given that payment rates vary between states. Additionally, not every State Medicaid Agency provides the same dental benefits, so not every state would have cost information for each of the dental codes we propose for OPSS payment. Lastly, while many State Medicaid Agencies provide robust information on the dental benefits covered for Medicaid beneficiaries in their state, the fee schedules published by State Medicaid Agencies most likely include payments to practitioners only and would not be informative for our purposes of assigning payment rates under the OPSS.

Finally, we considered analyzing private insurance claims from third-party databases but determined that the cost information available would also not be relevant for OPSS ratesetting. For example, because most dental services covered by private insurance are provided in the office setting, there is a very limited number of claims that would be relevant for OPSS ratesetting purposes. Of the limited dental claims performed in the hospital setting, we learned that many of the dental services are performed in combination with several other services; therefore, it would be extremely difficult to isolate the facility fee payment for the dental services performed.

Although specific cost information is informative for making proposed APC assignments, it is not essential. For example, each quarter, after consultation with clinical experts, CMS assigns new CPT codes for which no cost information is available to APCs using crosswalk code analyses. Similar to our process for assigning new codes to APCs, we used a crosswalk code analysis and consulted with clinical experts to propose appropriate APC assignments for the 229 dental codes. In our conversations with the clinical experts, we discussed the clinical aspects of each dental service and learned about the resources, including supplies, used to perform each dental service, in order to more accurately identify crosswalk codes and propose APC assignments for them. We solicit comments regarding the proposed APC assignments for the dental codes for CY 2024. We refer readers to Addendum B to this proposed rule for the proposed CY 2024 APC assignments and associated payment rates for the dental codes. Addendum B is available via the Internet on the CMS website.

4. Proposed Packaged Payment and Associated Status Indicators for Dental Codes

For CY 2024, we propose to package payments for dental services when they are performed with another covered dental or medical service to promote clinical resource efficiencies, a strategic goal of the OPSS. Given our understanding of the nature of dental practice and in consultation with our clinical experts, we believe packaged payments are appropriate for dental services paid under the OPSS. We are aware that it is common for several dental services to be performed together, or alongside other medical services, and submitted on one claim. Unlike medical specialties where often only one procedure is performed at a time, it is our understanding that it is common for a patient to undergo several surgical and non-surgical dental procedures on multiple teeth in one day, or for dental services to be performed contemporaneously with other medical services. For example, there are several non-invasive, non-surgical dental services, including a dental exam or X-ray, which would most likely be performed together with other more invasive dental services in the HOPD setting, rather than on their own. Because a dental exam or X-ray is likely to be performed in addition to other more

invasive dental services in the HOPD setting, we believe packaging payment for dental codes describing dental exams and X-rays (e.g., D0380-D0386) when performed with another service is appropriate and would further our strategic goal of encouraging hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. We also are aware that there are several dental services that are performed as part of a primary service, and therefore, we believe would also result in resource efficiencies if paid under the OPSS as a packaged payment. For example, CDT codes D3110 (pulp cap-direct (excluding final restoration)) and D3120 (pulp cap-indirect (excluding final restoration)) are typically performed as part of a restorative procedure (e.g., a crown or amalgam). Thus, we believe it is appropriate to propose to package payment for CDT codes D3110 and D3120 with payment for the associated restorative procedures.

We believe our proposal to package payment for dental services under the OPSS is consistent with existing packaging payment principles in the OPSS. The OPSS regularly 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. We believe applying these principles to the furnishing of dental services in the OPSS is appropriate and would incentivize clinical resource efficiencies.

In addition to proposing to package payment for dental services to promote clinical resource efficiencies, there are also several dental services that would nevertheless be packaged under our regulation at 42 CFR § 419.2(b). For example, payment for dental services described by add-on codes, like CDT code D2953 (each addtln cast post) would be packaged under the OPSS consistent with § 419.2(b)(18). Therefore, we propose to package payment for CDT code D2953 with the procedures with which it is performed. We refer readers to the regulation at § 419.2(b) for a full list of items and services for which payment is packaged or conditionally packaged.

For CY 2024, we propose packaging payment for dental services under the OPSS by assigning the dental codes to packaged status indicators. We believe there are clinical resource efficiencies to be gained by packaging payments rather than separately paying for each dental service performed. We refer readers to Addendum B to this proposed rule for the proposed CY 2024 status indicators for the dental codes. Addendum B is available via the Internet on the CMS website. For more information on all of the proposed status indicators for CY 2024, including explanations of the payment status for each proposed status indicator, we refer readers to Addendum D1 to this proposed rule.

5. Summary of OPSS Dental Proposal and Requests for Comments

In summary, we propose to assign an additional 229 dental codes describing various dental services to APCs for CY 2024. We are requesting comments on the list of codes we have identified for APC assignment and payment under the OPSS, including whether any of the 229 dental codes do not meet the requirements for payment for dental services included in the CY 2023 PFS final rule and regulation at § 411.15(i)(3)(i). Additionally, we are requesting comments on the proposed APC assignments for the dental codes for CY 2024. Finally, we propose to make packaged payments for dental services under the OPSS by assigning the dental codes describing those dental services to packaged status indicators. We believe packaging payment for dental services will incentivize clinical resource efficiencies, and we request comments on our proposal.

F. Use of Claims and Cost Report Data for CY 2024 OPSS and ASC Payment System

Ratesetting Due to the PHE

As described in section I.A of this proposed rule, section 1833(t) of the Act requires the Secretary to annually review and update the payment rates for services payable under the Hospital OPSS. Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually and to revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) of the Act 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.

When updating the OPSS payment rates and system for each rulemaking cycle, we primarily use two sources of information: the outpatient Medicare claims data and Healthcare Cost Report Information System (HCRIS) cost report data. The claims data source is the Outpatient Standard Analytic File, which includes final action Medicare outpatient claims for services furnished in a given calendar year. For the OPSS ratesetting process, our goal is to use the best available data for ratesetting to accurately estimate the costs associated with furnishing outpatient services and to set appropriate payment rates. Ordinarily, the best available claims data are the data from 2 years prior to the calendar year that is the subject of rulemaking. For the CY 2024 OPSS/ASC proposed rule ratesetting, the best available claims data would typically be the CY 2022 calendar year outpatient claims data processed through December 31, 2022. The cost report data source is typically the Medicare hospital cost report data files from the most recently available quarterly HCRIS file as we begin the ratesetting process. The best available cost report data used in developing the OPSS relative weights would ordinarily be from cost reports beginning three fiscal years prior to the year that is the subject of the rulemaking. For CY 2024 OPSS ratesetting, that would be cost report data from HCRIS extracted in December 2022, which would contain many cost reports ending in FY 2020 and 2021 based on each hospital's cost reporting period.

As discussed in the CY 2022 OPSS/ASC final rule with comment period, the standard hospital data we would have otherwise used for purposes of CY 2022 ratesetting included significant effects from the COVID-19 PHE, which led to a number of concerns with using this data for CY 2022 ratesetting (86 FR 63751 through 63754). In section X.E of the CY 2022 OPSS/ASC proposed rule (86 FR 42188 through 42190), we noted a number of changes in the CY 2020 OPSS claims data we would ordinarily have used for ratesetting, likely as a result of the PHE. These changes included overall aggregate decreases in claims volume (particularly

those associated with visits); significant increases in HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims; and increases in certain PHE-related services, such as HCPCS code C9803, which describes COVID-19 specimen collection, and services assigned to APC 5801 (Ventilation Initiation and Management). As a result of the effects we observed from COVID-19 PHE-related factors in our claims and cost report data, as well as the increasing number of Medicare beneficiaries vaccinated against COVID-19, which we believed might make the CY 2022 outpatient experience closer to CY 2019 rather than CY 2020, we believed that CY 2020 data were not the best overall approximation of expected outpatient hospital services in CY 2022. Instead, we believed that CY 2019 data, as the most recent complete calendar year of data prior to the COVID-19 PHE, were a better approximation of expected CY 2022 hospital outpatient services. Therefore, in the CY 2022 OPPS/ASC final rule with comment period, we established a policy of using CY 2019 claims data and cost reports prior to the PHE in ratesetting for the CY 2022 OPPS with certain limited exceptions, such as where CY 2019 data were not available (86 FR 63753 through 63754).

For the CY 2023 OPPS proposed rule ratesetting, we conducted a review similar to the one we conducted for the CY 2022 OPPS ratesetting to determine the degree to which the effects of the COVID-19 PHE had continued or subsided in our claims data as well as what claims and cost report data would be appropriate for CY 2023 OPPS ratesetting. In general, we saw that the PHE had limited effect on the service and aggregate levels of volume as well as changes in the site of service of care, suggesting that, while clinical and billing patterns had not quite returned to their pre-PHE levels, they were beginning to do so.

For the CY 2023 OPPS/ASC final rule, while the effects of the COVID-19 PHE remained at both the aggregate and service levels for certain services, as discussed in that final rule with comment period (87 FR 48795 through 48798) and in FY 2023 IPPS proposed rule (87 FR 28123 through 28125), we recognized that future COVID-19 variants may have potentially varying effects. Therefore, we explained that we believed it was reasonable to

assume that there would continue to be some effects of the COVID-19 PHE on the outpatient claims that we use for OPSS ratesetting, similar to the CY 2021 claims data. As a result, we proposed and finalized the use of CY 2021 claims for CY 2023 OPSS ratesetting.

We also used cost report data for the CY 2023 OPSS/ASC final rule (87 FR 72021) from the same set of cost reports we originally used in the CY 2021 OPSS/ASC final rule for ratesetting, which included cost reporting periods beginning in CY 2018 in most cases. We typically would have used the most updated available cost reports available in HCRIS in determining the CY 2023 OPSS/APC relative weights, which would have included cost reports with reporting periods that overlap with parts of CY 2020. However, noting that we observed significant impact at the service level when incorporating these cost reports into ratesetting and the effects on billing/clinical patterns, we finalized a policy to continue to use the same set of cost reports that we used in developing CY 2022 OPSS ratesetting.

For CY 2024 OPSS rulemaking, we continue to observe some differences at the aggregate and service level volumes in the CY 2022 claims data, relative to the pre-PHE period. However, we believe that it is reasonable to assume that there will be minor variations as a result of the COVID-19 PHE in claims data we use for ratesetting for the foreseeable future. As we have found that the effects are less pronounced, even relative to CY 2021 claims data used in CY 2023 OPSS ratesetting, we anticipate that most of the changes we observe represent a moderate continued return to pre-PHE volume and ongoing changes in clinical practice. As a result, we believe the CY 2022 claims data are appropriate for setting CY 2024 OPSS rates.

For CY 2024, we also evaluated the impact of using our standard update for cost reports. If we were to resume our typical process of using the most updated cost reports available, we would predominantly use cost report data from CY 2021, with some portion of the cost reports including cost reporting periods from prior years. While there are some differences compared to pre-PHE data, we generally observed limited impacts. Similar to the claims data approach, we believe it is reasonable to assume there will continue to be a limited influence of the COVID-19

PHE on the cost report data. However, as we continue to receive more updated cost report data, we believe that data will better reflect changes in provider charge and cost reporting structures. Given these factors, we believe that using the most recent cost report data available and resuming our regular cost report update process is appropriate for CY 2024 OPPS ratesetting.

As a result of our expectation that the CY 2022 claims that we would typically use are appropriate for establishing the CY 2024 OPPS rates, we propose to use the CY 2022 claims for the CY 2024 OPPS/ASC ratesetting process. In addition, we propose to resume our typical cost report update process of including the most recently available cost report data (primarily including cost reports with cost reporting periods including CY 2021). For the reasons previously discussed, we are generally not proposing any modifications to our usual OPPS ratesetting methodologies with regards to the use of updated claims and cost report data to account for the impact of COVID-19 on the ratesetting data.

G. Comment Solicitation on Payment for High-Cost Drugs Provided by Indian Health Service and Tribally-Owned Facilities

In the CY 2000 Final Rule (65 FR 18433), CMS implemented the prospective payment system for hospital outpatient services furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Act. In this rule, we noted that the Outpatient Prospective Payment System (OPPS) applies to covered hospital outpatient services furnished by all hospitals participating in the Medicare program with a few exceptions. We identified one of these exceptions as “outpatient services provided by hospitals of the Indian Health Service (IHS).” While we stated that these services would “continue to be paid under separately established rates which are published annually in the **Federal Register**,” we indicated that our intent was “to develop a plan that will help these facilities transition to the [O]PPS and will consult with the IHS to develop this plan.” In the CY 2002 Final Rule (66 FR 59855), we finalized our revision to § 419.20 (Hospitals subject to the hospital outpatient prospective payment system) by adding paragraph (b)(4) specifying that hospitals of the IHS are excluded from the OPPS. However, we reiterated

that this exclusion would only be in place until we developed a plan to include IHS hospitals under the OPPTS.

In the intervening years, IHS and tribally-owned 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. Due to the higher cost of living in Alaska, separate rates are calculated for Alaska and the lower 48 States. For CY 2023, the Medicare Outpatient per Visit Rate for the lower 48 States is \$654 and \$862 for Alaska.

IHS and tribally-owned 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 tribally-owned facilities appear to be well served by the AIR, there are specialty facilities where the AIR might not be an adequate representation of the Medicare share of costs. If providing a drug or service costs a specialty facility exponentially more than the payment they receive through the AIR, it may not be financially feasible for these facilities to provide that drug or service. For example, the cost of providing expensive cancer drugs or oncology services could greatly exceed payment a specialty IHS 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 tribally-owned hospital outpatient specialty programs currently in operation and provide less incentive to IHS hospitals and tribally-owned facilities not currently offering specialty services to begin doing so.

Consequently, we seek comment on a number of potential policies to address payment to IHS and tribally-owned facilities for certain high-cost drugs and services. We are seeking comment on whether Medicare should pay separately for high-cost drugs provided by IHS and tribally-owned facilities. We would like input on:

- What universe of drugs would be appropriate for separate payment? How could CMS maintain that list and add or remove drugs from it?

- Would paying separately for all drugs over a certain cost threshold be easier to operationalize than paying separately for a specified list of drugs, while achieving the same policy objective? If so, what would be an appropriate cost threshold and how should it be updated?

- What would be the appropriate payment rate for any separately paid drugs? How should these rates be updated and should these rates be updated on an annual basis?

- Would the standard OPPS Average Sales Price (ASP) plus 6 percent payment methodology rate be too high of a payment rate if tribal and IHS facilities are able to acquire drugs at a discounted rate through the Federal Supply Schedule? Would a payment rate equivalent to the acquisition cost of the drug through the Federal Supply Schedule be a more appropriate approximation of the cost of these drugs?

- Should IHS remove the cost of any separately paid drugs from the calculation of the AIR? If the cost of these drugs was not removed from the AIR, would the government be paying twice for these drugs?

- How would IHS and tribally-owned facilities bill for separately paid drugs? Could they use the UB-04 form like standard OPPS hospitals?

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. We seek comment on whether an outlier policy might be an appropriate mechanism for addressing high-cost drugs and services provided by IHS and tribally-owned facilities.

We welcome input from interested parties on these policy ideas and any additional payment approaches that would enhance our ability to provide equitable payment for high-cost drugs and services provided by IHS and tribally-owned facilities.

XI. Proposed CY 2024 OPPS Payment Status and Comment Indicators

A. Proposed CY 2024 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 OPSS. They indicate whether a service represented by a HCPCS code is payable under the OPSS or another payment system and whether particular OPSS policies apply to the code.

For CY 2024, we propose to change the definition of status indicator “P” from “Partial Hospitalization” to “Partial Hospitalization or Intensive Outpatient Program” in order to account for the proposed payment of intensive outpatient services beginning January 1, 2024, as discussed in section VIII.B of this proposed rule. We are not proposing to make any other changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2023 OPSS/ASC final rule with comment period, which is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>.

We solicit public comments on the proposed definitions of the OPSS payment status indicators for 2024.

The complete list of proposed CY 2024 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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>.

The proposed CY 2024 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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

B. Proposed CY 2024 Comment Indicator Definitions

We propose to use four comment indicators for the CY 2024 OPSS. These comment indicators, “CH,” “NC,” “NI,” and “NP,” are in effect for CY 2023; and we propose to continue their use in CY 2024. The proposed CY 2024 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 request comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.
- “NI”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- “NP”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPSS comment indicators for CY 2024 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

We solicit public comments on our proposed definitions of the OPSS comment indicators for 2024.

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 2023 report.

A. OPSS Payment Rates Update

The March 2023 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 percent. We refer readers to the March 2023 report for a complete discussion of this recommendation.¹²⁴ We appreciate MedPAC’s recommendation and, as discussed further in section II.B of this proposed rule, we propose to increase the OPSS payment rates by the amount specified in current law.

B. Medicare Safety Net Index

The March 2023 MedPAC “Report to the Congress: Medicare Payment Policy,” recommended that Congress should begin a transition to redistribute disproportionate share hospital and uncompensated care payments through the Medicare Safety-Net Index (MSNI). Additionally, MedPAC recommended that Congress add \$2 billion to the MSNI pool of funds and distribute such funds through a percentage add-on to payments under the IPPS and OPSS.

In light of these recommendations, and in particular those concerning safety net hospitals, we look forward to working with Congress and seek comments on approaches CMS could take.

C. ASC Cost Data

In the March 2023 MedPAC “Report to the Congress: Medicare Payment Policy,” MedPAC reiterated its longstanding recommendation that Congress require ASCs to report cost

¹²⁴ Medicare Payment Advisory Committee. March 2023 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, p.57. Available at: <https://www.medpac.gov>.

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 allow CMS to examine whether an existing Medicare price index 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.¹²⁵

While we recognize that the submission of cost data could place additional administrative burden on most ASCs, and we are not proposing any cost reporting requirements for ASCs in this proposed rule, 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 index 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 2023 OPPS/ASC final rules with comment period

¹²⁵ Medicare Payment Advisory Committee. March 2023 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.163. Available at: https://www.medpac.gov/wp-content/uploads/2023/03/Ch5_Mar23_MedPAC_Report_To_Congress_SEC.pdf.

(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; and 87 FR 72054 through 72096).

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 OPSS 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 OPSS payment policies and we use quarterly change requests (CRs) to update services paid for under the OPSS. 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 OPSS/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 OPSS/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 OPPI/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 2024 OPPI/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 2024 OPPI/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2024 OPPI/ASC final rule with comment period (and responding to those comments in the CY 2025 OPPI/ASC final rule with comment period).

2. April 2023 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2023 update, there were no new CPT codes; however, there were several new Level II HCPCS codes. In the April 2023 ASC quarterly update (Transmittal 11927, dated March 24, 2023, CR 13143), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 54 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2023) of this proposed rule, lists the new Level II HCPCS codes that were implemented April 1, 2023. 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, 2023, 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 2024 (Including Surgical Procedures for Which Payment is Packaged),
- ASC Addendum BB: Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for CY 2024 (Including Ancillary Services for Which Payment is Packaged),
- ASC Addendum DD1: Proposed ASC Payment Indicators (PI) for CY 2024,
- ASC Addendum DD2: Proposed ASC Comment Indicators (CI) for CY 2024,
- ASC Addendum EE: Proposed Surgical Procedures to be Excluded from Payment in ASC for CY 2024, and
- ASC Addendum FF: Proposed ASC Device Offset Percentages for CY 2024
- Addendum O: Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-codes, and G-Codes Effective January 1, 2024

We are inviting public comments on the proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2023 through the quarterly update CRs, as listed in Table 54 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2023) of this proposed rule. We propose to finalize their payment indicators in the CY 2024 OPPS/ASC final rule with comment period.

**TABLE 54: NEW LEVEL II HCPCS CODES FOR ASC COVERED
ANCILLARY SERVICES EFFECTIVE APRIL 1, 2023**

CY2023 HCPCS Code	CY 2023 Long Descriptor
C9145	Injection, aprepitant, (aponvie), 1 mg
C9146	Injection, mirvetuximab soravtansine-gynx, 1 mg
C9147	Injection, tremelimumab-actl, 1 mg
C9148	Injection, teclistamab-cqyv, 0.5 mg
C9149	Injection, teplizumab-mzwv, 5 mcg
J0208	Injection, sodium thiosulfate, 100 mg
J0218	Injection, olipudase alfa-rpcp, 1 mg
J1449	Injection, eflapegrastim-xnst, 0.1 mg
J1747	Injection, spesolimab-sbzo, 1 mg
J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg
J9294	Injection, pemetrexed (hospira) not therapeutically equivalent to j9305, 10 mg
J9296	Injection, pemetrexed (accord) not therapeutically equivalent to j9305, 10 mg
J9297	Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg
Q4265	Neostim tl, per square centimeter
Q4266	Neostim membrane, per square centimeter
Q4267	Neostim dl, per square centimeter
Q4268	Surgraft ft, per square centimeter
Q4269	Surgraft xt, per square centimeter
Q4270	Complete sl, per square centimeter
Q4271	Complete ft, per square centimeter
Q5127	Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg
Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg
Q5130	Injection, pegfilgrastim-pbbk (fynetra), biosimilar, 0.5 mg

3. July 2023 HCPCS Codes Proposed Rule Comment Solicitation

In the July 2023 ASC quarterly update (Transmittal 12099, Change Request 13216, dated June 22, 2023), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 55 (New HCPCS Codes for Covered Surgical Procedures and Covered Ancillary Services Effective July 1, 2023) of this proposed rule, lists the new HCPCS codes that are effective July 1, 2023. 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, 2023, 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 55: NEW HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2023

CY2023 HCPCS Code	CY 2023 Long Descriptor
0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance
0797T	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; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0803T	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; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0809T	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intra-articular implant(s), including allograft or synthetic device(s)
C9151	Injection, pegcetacoplan, 1 mg
J1440	Fecal microbiota, live - jslm, 1 ml
J1576	Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1961	Injection, lenacapavir, 1 mg
J2329	Injection, ublituximab-xiiy, 1mg
J2427	Injection, paliperidone palmitate extended release (invega hafyera, or invega trinza), 1 mg
J7213	Injection, coagulation factor ix (recombinant), ixinity, 1 i.u.
J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg
J9058	Injection, bendamustine hydrochloride (apotex), 1 mg
J9059	Injection, bendamustine hydrochloride (baxter), 1 mg
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg

J9259	Injection, paclitaxel protein-bound particles (american reagent) not therapeutically equivalent to j9264, 1 mg
J9322	Injection, pemetrexed (bluepoint) not therapeutically equivalent to J9305, 10 mg
J9323	Injection, pemetrexed ditromethamine, 10 mg
J9347	Injection, tremelimumab-actl, 1 mg
J9350	Injection, mosunetuzumab-axgb, 1 mg
J9380	Injection, teclistamab-cqyv, 0.5 mg
J9381	Injection, teplizumab-mzwv, 5 mcg
Q5129	Injection, bevacizumab-adcd (vegzelma), biosimiliar, 10 mg

We are inviting 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, 2023, and July 1, 2023, through the quarterly update CRs, as listed in Tables 54 and 55. We propose to finalize the payment indicators in the CY 2024 OPPS/ASC final rule with comment period.

4. October 2023 HCPCS Codes Final Rule Comment Solicitation

For CY 2024, consistent with our established policy, we propose that the Level II HCPCS codes that will be effective October 1, 2023, would be flagged with comment indicator “NI” in Addendum BB to the CY 2024 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment status for CY 2023. We will invite public comments in the CY 2024 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2025 OPPS/ASC final rule with comment period.

5. January 2024 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 2024 OPPS/ASC final rule with comment period, January 2024 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2024, 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, 2024, 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 2024 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2025 OPPS/ASC final rule with comment period.

b. CPT Codes Proposed Rule Comment Solicitation

For the CY 2024 ASC update, we received the CPT codes that will be effective January 1, 2024, 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 2024 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 2024 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 2024 OPPS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code.” We intend to include the final CPT code numbers the CY 2024 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2024 payment indicators for the new Category I and III CPT codes that will be effective January 1, 2024. 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 2024 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, 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 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 56, 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 56: 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 2023	HCPCS (CPT and Level II codes)	April 1, 2023	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
July 2023	HCPCS (CPT and Level II codes)	July 1, 2023	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
October 2023	HCPCS (CPT and Level II codes)	October 1, 2023	CY 2024 OPPS/ASC final rule with comment period	CY 2025 OPPS/ASC final rule with comment period
January 2024	CPT Codes	January 1, 2024	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2024	CY 2024 OPPS/ASC final rule with comment period	CY 2025 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 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator “NP” is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator “NP” also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The “CH” comment indicator is used in Addenda AA and BB to the proposed rule (these addenda are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example, if an active HCPCS code is newly recognized as payable in ASCs or an active HCPCS code is discontinued at the end of the current calendar year. The “CH” comment indicators that are published in the final rule are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

In the CY 2021 OPPS/ASC final rule with comment period, we finalized the addition of ASC payment indicator “K5” – Items, Codes, and Services for which pricing information and

claims data are not available. No payment made. – to ASC Addendum DD1 (which is available via the Internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

b. Proposed ASC Payment and Comment Indicators for CY 2024

For CY 2024, 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 2024 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2024, compared to the CY 2023 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 this CY 2024 OPPS/ASC proposed rule.

For CY 2024, we propose to add two ASC payment indicators for new proposed dental codes. Section XIII.D of this proposed rule describes the proposed addition of dental codes to the ASC CPL and ancillary services list for CY 2024. We propose to add specific dental payment indicators for more streamlined claims processing of the new dental codes, as these codes would require different billing mechanisms than non-dental procedures currently on the CPL. Separate payment indicators would allow MACs to more quickly and easily distinguish how these codes need to be processed. Proposed ASC payment indicators “D1” and “D2” are for the new dental codes that would be paid in CY 2024 and subsequent calendar years and would be added to Addendum DD1 (which is available via the Internet on the CMS website) to indicate potentially payable dental services and procedures in the ASC setting. The first proposed payment indicator is “D1”— “Ancillary dental service/item; no separate payment made.” The “D1” indicator would indicate an ancillary dental procedure that would be performed integral to a separately payable dental surgical procedure with a payment indicator of “D2.” The second proposed payment indicator is “D2” – “Non office-based dental procedure added in CY 2024 or later.” The “D2” payment indicator would indicate a separately payable dental surgical procedure that would be

subject to the multiple procedure reduction, but would not be designated as an office-based covered surgical procedure. Section XIII.D.2 of this proposed rule describes how these payment indicators would be used in claims processing for dental services. We solicit comment on these proposed new payment indicators, including whether their descriptors are appropriate and any considerations interested parties believe we should take into account when structuring payment for the procedures for which we propose to use payment indicators D1 and D2.

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 2024 update.

C. 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 CY 2024 OPPTS/ASC proposed rule, we update the payment amounts for office-based procedures (payment indicators “P2,” “P3,” and “R2”) using the most recent available MPFS and OPPTS 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 OPPTS/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 OPPTS. Under the OPPTS, 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 OPPTS are always packaged (payment indicator “N1”) under the ASC payment system. Under the OPPTS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There is no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no

Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal – conditionally packaged in the OPPS (status indicator “Q2”) – we have continued to provide separate payment since CY 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2024

We propose to update ASC payment rates for CY 2024 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XIII.C.4 of this proposed rule. As the proposed OPPS relative payment weights are generally based on geometric mean costs, we propose that the ASC payment system will generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We propose to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators “A2” and “G2.”

We propose to calculate payment rates for office-based procedures (payment indicators “P2,” “P3,” and “R2”) and device-intensive procedures (payment indicator “J8”) according to our established policies and to identify device-intensive procedures using the methodology discussed in section XIII.C.4 of this proposed rule. Therefore, we propose to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2024 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We propose that payment for office-based procedures would be at the lesser of the proposed CY 2024 MPFS nonfacility PE RVU-based amount or the proposed CY 2024 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2023, for CY 2024, we propose to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators “Q1” and “Q2”) will be assigned the current ASC payment indicators associated with those procedures and will continue to be paid separately under the ASC payment system.

c. Proposed Payment for ASC Add-On Procedures Eligible for Complexity Adjustments under the OPPS

In this section, we discuss the policy to provide increased payment under the ASC payment system for combinations of certain “J1” service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

(1) OPPS C-APC Complexity Adjustment Policy

Under the OPPS, complexity adjustments are utilized to provide increased payment for certain comprehensive services. As discussed in section II.A.2.b of this proposed rule, we apply a complexity adjustment by promoting qualifying paired “J1” service code combinations or paired code combinations of “J1” services and add-on codes from the originating Comprehensive APC (C-APC) (the C-APC to which the designated primary service is first assigned) to the next higher paying C-APC in the same clinical family of C-APCs. A “J1” status indicator refers to a hospital outpatient service paid through a C-APC. We package payment for all add-on codes, which are codes that describe a procedure or service always performed in addition to a primary service or procedure, into the payment for the C-APC. However, certain combinations of primary service codes and add-on codes may qualify for a complexity adjustment.

We apply complexity adjustments when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule, as specified in section 1833(t)(2) of the Act and described in section III.A.2.b of this proposed rule,

in the originating C-APC. These paired code combinations that meet the frequency and cost threshold criteria represent those that exhibit materially greater resource requirements than the primary service. After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim that are either assigned to status indicator “J1” or add-on codes to determine if there are paired code combinations that meet the complexity adjustment criteria. Once we have determined that a particular combination of “J1” services, or combinations of a “J1” service and add-on code, represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, 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 2024, 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/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>).

(2) CY 2023 ASC Special Payment Policy for OPSS Complexity-Adjusted C-APCs

Comprehensive APCs cannot be adopted in the ASC payment system due to limitations of the ASC claims processing systems. Thus, we do not use the OPPS comprehensive services ratesetting methodology in the ASC payment system. Under the standard ratesetting methodology used for the ASC payment system, comprehensive “J1” claims that exist under the OPPS are treated the same as other claims that contain separately payable procedure codes. As comprehensive APCs do not exist under the ASC payment system, there is not a process similar to the OPPS complexity adjustment policy in the ASC payment system to provide higher payment for more complex code combinations. In the ASC payment system, when multiple procedures are performed together in a single operative session, most covered surgical procedures are subject to a 50-percent reduction for the lower-paying procedure (72 FR 66830). This multiple procedure reduction gives providers additional payment when they perform multiple procedures during the same session, while still encouraging providers to provide necessary services as efficiently as possible. Add-on procedure codes are not separately payable under the ASC payment system and are always packaged into the ASC payment rate for the procedure. Unlike the multiple procedure discounting process used for other surgical procedures in the ASC payment system, providers do not receive any additional payment when they perform a primary service with a service corresponding to an add-on code in the ASC payment system.

Before CY 2023 rulemaking, we received suggestions from commenters requesting that we explore ways to increase payment to ASCs when services corresponding to add-on codes are performed with procedures, as certain code combinations may represent increased procedure complexity or resource intensity when performed together. For example, in the CY 2022 OPPS/ASC final rule with comment period, one commenter suggested that we modify the device-intensive criteria to allow packaged procedures that trigger a complexity adjustment under the OPPS to be eligible for device-intensive status under the ASC payment system (86 FR 63775). Based on our internal data review and assessment at that time, our response to

that comment noted that we did not believe any changes were warranted to our packaging policies under the ASC payment system but that we would consider it in future rulemaking.

In the CY 2023 OPPS/ASC final rule, we evaluated the differences in payment in the OPPS and ASC settings for code pairs that included a primary procedure and add-on codes that were eligible for complexity adjustments under the OPPS and also performed in the ASC setting. When we compared the OPPS complexity-adjusted payment rate of these primary procedure and add-on code combinations to the ASC payment rate for the same code combinations, we found that the average rate of ASC payment as a percent of OPPS payment for these code combinations was significantly lower than 55 percent. We recognized that this payment differential between the C-APC-assigned code combinations eligible for complexity adjustments under the OPPS and the same code combinations under the ASC payment system could potentially create financial disincentives for providers to offer these services in the ASC setting, which could potentially result in Medicare beneficiaries encountering difficulties accessing these combinations of services in ASC settings. As noted above, our policy did not include additional payment for services corresponding to add-on codes, unlike our payment policy for multiple surgical procedures performed together, for which we provide additional payment under the multiple procedure reduction. However, these primary procedure and add-on code combinations that would be eligible for a complexity adjustment under the OPPS represented a more complex and costly version of the service, and we believed that providers not receiving additional payment under the ASC payment system to compensate for that increased complexity could lead to providers not being able to provide these services in the ASC setting, which could result in barriers to beneficiary access.

In order to address this issue, in the CY 2023 OPPS/ASC final rule (87 FR 72079 to 72080), we finalized a new ASC payment policy that would apply to certain code combinations in the ASC payment system where CMS would pay for those code combinations at a higher payment rate to reflect that the code combination is a more complex and costlier version of the

procedure performed, similar to the way in which the OPSS APC complexity adjustment is applied to certain paired code combinations that exhibit materially greater resource requirements than the primary service. We finalized adding new regulatory text at § 416.172(h) to codify this policy.

We finalized that combinations of a primary procedure code and add-on codes that are eligible for a complexity adjustment under the OPSS (as listed in OPSS Addendum J) would be eligible for this payment policy in the ASC setting. Specifically, we finalized that the ASC payment system code combinations eligible for additional payment under this policy would consist of a separately payable surgical procedure code and one or more packaged add-on codes from the ASC Covered Procedures List (CPL) and ancillary services list. Add-on codes were assigned payment indicator “N1” (Packaged service/item; no separate payment made), as listed in the ASC addenda.

Regarding eligibility for this special payment policy, we finalized that we would assign each eligible code combination a new C-code, which we will refer to as an “ASC complexity adjustment code,” that describes the primary and the add-on procedure(s) performed. C-codes are unique temporary codes and are only valid for claims for HOPD and ASC services and procedures. Under our policy, we add these ASC complexity adjustment codes to the ASC CPL and the ancillary services list, and when ASCs bill an ASC complexity adjustment code, they receive a higher payment rate that reflects that the code combination is a more complex and costlier version of the primary procedure performed. We anticipated that the ASC complexity adjustment codes eligible for this payment policy would change slightly each year, as the complexity adjustment assignments change under the OPSS; and we expect we would add new ASC complexity adjustment codes each year accordingly. In the CY 2023 OPSS/ASC final rule with comment period (87 FR 72079 to 72080), we finalized new ASC complexity adjustment codes to add to the ASC CPL, which were listed in the ASC addenda. We also finalized adding new regulatory text at § 416.172(h)(1), titled “Eligibility,” to codify this policy.

We finalized the following payment methodology for this policy, which we reflected in new § 416.172(h)(2), titled “Calculation of Payment.” The ASC complexity adjustment codes are subject to all ASC payment policies, including the standard ASC payment system ratesetting methodology, meaning, they are treated the same way as other procedure codes in the ASC setting. For example, the multiple procedure discounting rules would apply to the primary procedure in cases where the services corresponding to the ASC complexity adjustment code are performed with another separately payable covered surgical procedure in the ASC setting. We finalized using the OPSS complexity-adjusted C-APC rate to determine the ASC payment rate for qualifying code combinations, similar to how we use OPSS APC relative weights in the standard ASC payment system ratesetting methodology. Under the ASC payment system, we used the OPSS APC relative payment weights to update the ASC relative payment weights for covered surgical procedures since ASCs do not submit cost reports. We then scaled those ASC relative weights for the ASC payment system to ensure budget neutrality. To calculate the ASC payment rates for most ASC covered surgical procedures, we multiplied the ASC conversion factor by the ASC relative payment weight. A more detailed discussion of this methodology is provided in the in the CY 2008 OPSS/ASC final rule with comment period (72 FR 66828 through 66831).

We also finalized using the OPSS complexity-adjusted C-APC rate for each corresponding code combination to calculate the OPSS relative weight for each corresponding ASC complexity adjustment code, which we believed would appropriately reflect the complexity and resource intensity of these ASC procedures being performed together. For ASC complexity adjustment codes that are not assigned device-intensive status (discussed below), we multiply the OPSS relative weight by the ASC budget neutrality adjustment (or ASC weight scalar) to determine the ASC relative weight. We then multiply the ASC relative weight by the ASC conversion factor to determine the ASC payment rate for each ASC complexity adjustment code.

In short, we apply the standard ASC ratesetting process to the ASC complexity adjustment codes. We finalized adding new § 416.172(h)(2)(i) to codify this policy.

As discussed in section XIII.C.1.b of the CY 2023 OPPI/ASC final rule with comment period (87 FR 44708), certain ASC complexity adjustment codes under our policy may include a primary procedure that also qualifies for device-intensive status under the ASC payment system. For primary procedures assigned device-intensive status that are a component of an ASC complexity adjustment code created under this proposal, we believe it is appropriate for the ASC complexity adjustment code to retain the device-intensive status of the primary procedure as well as the device portion (or device offset amount) of the primary procedure and not the device offset percentage. For example, if the primary procedure has a device offset percentage of 31 percent (a device offset percentage of greater than 30 percent would be needed to qualify for device-intensive status) and a device portion (or device offset amount) of \$3,000, ASC complexity adjustment codes that included this primary procedure would be assigned device-intensive status and a device portion of \$3,000 to be held constant with the OPPI. We apply our standard ASC payment system ratesetting methodology to the non-device portion of the OPPI complexity-adjusted APC rate of the ASC complexity adjustment codes; that is, we apply the ASC budget neutrality adjustment and ASC conversion factor. We believe assigning device-intensive status and transferring the device portion from the primary procedure's ASC payment rate to the ASC complexity adjustment code's ASC payment rate calculation is consistent with our treatment of device costs and determining device-intensive status under the ASC payment system and is an appropriate methodology for determining the ASC payment rate. The non-device portion would be the difference between the device portion of the primary procedure and the OPPI complexity-adjusted APC payment rate for the ASC complexity adjustment code based on the ASC standard ratesetting methodology. Although this may yield results where the device offset percentage is not greater than 30 percent of the OPPI complexity-adjusted APC payment rate, we believe this is an appropriate methodology to apply where primary procedures assigned device-intensive

status are a component of an ASC complexity adjustment code. As is the case for all device-intensive procedures, we apply the ASC standard ratesetting methodology to the OPPS relative weights of the non-device portion for any ASC complexity adjustment code eligible for payment under this proposal. That is, we would multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate. We finalized adding new § 416.172(h)(2)(ii) to codify this policy.

In order to include these ASC complexity adjustment codes in the budget neutrality calculations for the ASC payment system, we estimated the potential utilization for these ASC complexity adjustment codes. We do not have claims data for packaged codes in the ASC setting because ASCs do not report packaged codes under the ASC payment system. Therefore, we finalized estimating CY 2023 ASC utilization based upon how often these combinations are performed in the HOPD setting. Specifically, we used the ratio of the primary procedure volume to add-on procedure volume from CY 2021 OPPS claims and applied that ratio against ASC primary procedure utilization to estimate the increased spending as a result of our proposal for budget neutrality purposes. We believed this method would provide a reasonable estimate of the utilization of these code combinations in the ASC setting, as it is based on the specific code combination utilization in the OPPS. We anticipated that we would continue this estimation process until we have sufficient claims data for the ASC complexity adjustment codes that can be used to more accurately calculate code combination utilization in ASCs, likely for the CY 2025 rulemaking.

For CY 2024, we propose to continue the special payment policy and methodology for OPPS complexity-adjusted C-APCs that was finalized in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080). The full list of the proposed ASC complexity adjustment codes for CY 2024 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-notices>. Because the complexity adjustment assignments change each year under the OPPS, 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 OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a universal Low Volume APC policy for CY 2022 and subsequent calendar years. Under our policy, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs to also apply to clinical and brachytherapy APCs. Specifically, a clinical APC or brachytherapy APC with fewer than 100 claims per year would be designated as a Low Volume APC. For items or services assigned to a Low Volume APC, we use up to four 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 four clinical APCs and five brachytherapy APCs as Low Volume APCs under the ASC payment system. The four clinical APCs and five brachytherapy APCs shown in Table 57 of this proposed rule met our criteria of having fewer than 100 single claims in the claims year (CY 2022 for this 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. Eight of the nine APCs were designated as low volume APCs in CY 2023. In addition, based on data for this CY 2024 OPSS/ASC proposed rule, APC 2642 (Brachytx, stranded, C-131) meets our criteria to be designated a Low Volume APC, and we propose to designate it as such for CY 2024.

TABLE 57: COST STATISTICS FOR PROPOSED LOW VOLUME APCS STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2024

APC	APC Description	CY 2022 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	Proposed CY 2024 APC Cost
2632	Iodine I-125 sodium iodide	0	---*	\$31.74	\$61.83	\$41.06	\$61.83
2635	Brachytx, non-str, HA, P-103	21	\$98.73	\$58.38	\$60.86	\$54.77	\$60.86
2636	Brachy linear, non-str, P-103	1	\$89.34	\$22.17	\$57.15	\$33.66	\$57.15
2642	Brachytx, stranded, C-131	76	\$99.92	\$79.90	\$100.65	\$79.90	\$100.65
2647	Brachytx, NS, Non-HDRIr-192	2	\$452.28	\$201.69	\$403.29	\$167.08	\$403.29
5244	Level 4 Blood Product Exchanges and Related Services	1	\$11,801.45	\$44,380.23	\$38,586.00	\$33,541.43	\$44,380.23
5494	Level 4 Intraocular Procedures	7	\$13,296.11	\$12,166.15	\$12,060.74	\$11,252.12	\$12,166.15
5495	Level 5 Intraocular Procedures	69	\$3,554.44	\$3,276.94	\$3,833.79	\$3,148.13	\$3,833.79
5496	Level 6 Intraocular Procedures	12	\$12,649.58	\$17,384.57	\$16,695.84	\$14,642.86	\$17,384.57

* For the CY 2024 OPSS/ASC proposed rule, there were no CY 2022 claims that contain the HCPCS code assigned to APC 2632 (HCPCS code A9527) that were available for CY 2024 OPSS/ASC 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 OPSS.

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 OPSS 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 OPSS.

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 OPPTS/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 OPPTS 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 OPPTS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPTS or, if OPPTS 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 OPPTS.

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 OPPTS. 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 OPSS 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 2024

We propose to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2024 OPPS and ASC payment rates and subsequent years' payment rates. We also propose to continue to set the CY 2024 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 2024 and subsequent years' payment rates.

Covered ancillary services and their proposed payment indicators for CY 2024 are listed in Addendum BB of this proposed rule (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS proposed rates (similar to our office-based payment policy), the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2024. For a discussion of the PFS rates, we refer readers to the CY 2024 PFS proposed rule, which is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

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 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 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 2024 Proposed Office-Based Procedures

In developing this CY 2024 OPSS/ASC 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 2022 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2023 of “G2” (Non office-based surgical procedure added in CY 2008 or later; payment based on OPSS 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 2022 OPPS/ASC final rule with comment period (86 FR 63769 through 63773).

In our CY 2022 OPPS/ASC final rule with comment period (86 FR 63770), we discussed that we, historically, review the most recent claims volume and utilization data and clinical characteristics for all covered surgical procedures that were assigned a payment indicator of “G2” for CY 2021. For the CY 2022 OPPS/ASC final rule with comment period, the most recent claims volume and utilization data was CY 2020 claims. However, given our concerns with the use of CY 2020 claims data as a result of the COVID-19 PHE as further discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), we adopted a policy to not review CY 2020 claims data and did not assign permanent office-based designations to covered surgical procedures that were assigned a payment indicator of “G2” in CY 2021 (86 FR 63770 through 63771).

As discussed further in section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682), in our review of the CY 2021 outpatient claims available for ratesetting for this CY 2023 OPPS proposed rule, we observed that many outpatient service volumes have partially returned to their pre-PHE levels; and it is reasonable to assume that there will continue to be some effects of the COVID-19 PHE on the outpatient claims that we use for OPPS ratesetting. As a result, we proposed to use the CY 2021 claims for CY 2023 OPPS ratesetting. Similarly, in the CY 2023 OPPS/ASC proposed rule (87 FR 44705 through 44708), we proposed to resume our historical practice and review the most recent claims and utilization data, in this case data from CY 2021 claims, for determining office-based assignments under the ASC payment system.

Our review of the CY 2022 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 2024 are listed in Table 58.

TABLE 58: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2024

CY 2023 CPT/HCPCS Code	Long Descriptor	CY 2023 ASC Payment Indicator	Proposed CY 2024 ASC Payment Indicator*
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	G2	P2*
38232	Bone marrow harvesting for transplantation; autologous	G2	R2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2024 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2024 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 2022 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.” As shown in Table 59, for four of the nine surgical procedures, there were greater than 50 claims available and the volume and utilization data indicated these four procedures were

performed predominantly in the office setting. Therefore, we propose to no longer designate the four procedures as temporarily office-based but to permanently designate these procedures as office-based and assign one of the office-based payment indicators, specifically “P2,” “P3,” or “R2.”

Additionally, for one of the nine surgical procedures, there were greater than 50 claims available; and the volume and utilization data indicated that this procedure – CPT code 64454 (Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed) – is not performed predominantly in the office setting. Therefore, as shown in Table 59, we propose to no longer designate this procedure as temporarily office-based. For CY 2024, we propose to assign this procedure a payment indicator of “G2” (Non office-based surgical procedure added in CY 2008 or later; payment based on OPFS relative payment weight).

TABLE 59: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED FOR CY 2024

CY 2023 CPT/HCPCS Code	Long Descriptor	CY 2023 ASC Payment Indicator	Proposed CY 2024 ASC Payment Indicator*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium, when performed, and intraoperative pachymetry, when performed	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound	R2	R2*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	G2
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2	P2*
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2	P2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2024 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2024 PFS proposed rule.

For four of the nine procedures that were designated as temporarily office-based in the CY 2023 OPPS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically “P2,” “P3,” or “R2,” there were fewer than 50 claims; therefore, there was an insufficient amount to determine if the office setting was the predominant setting of care for these procedures. Therefore, as shown in Table 60, we propose to continue to designate such procedures as temporarily office-based for CY 2024 and assign one of the office-based payment indicators.

For CY 2024, we propose to designate three new CY 2024 CPT codes for ASC covered surgical procedures as temporarily office-based – CPT placeholder codes 6X000, 64XX4, and X170T. After reviewing the clinical characteristics, utilization, and volume of related procedure codes or predecessor codes, we determined that the predecessor code for CPT placeholder code 6X000 (Suprachoroidal space injection of pharmacologic agent (separate procedure)) is CPT code 0465T (Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)), which was designated as an office-based procedure. Additionally, CPT placeholder code 64XX4 (Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator) is most similar to CPT code 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), which is also designated as temporarily office-based. Lastly, CPT placeholder code X170T (Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy) is most similar to CPT code 0101T (Extracorporeal shock wave involving musculoskeletal system, not otherwise specified) which is designated as an office-based surgical procedure. Therefore, as shown in Table 60, we propose to designate these three new CPT codes as temporarily office-based for CY 2024.

The procedures for which the proposed office-based designation for CY 2024 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>).

TABLE 60: PROPOSED CY 2024 PAYMENT INDICATORS FOR NEW AND EXISTING ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2023 CPT/HCPCS Code / CY 2024 Placeholder Code	Long Descriptor	Final CY 2023 ASC Payment Indicator	Proposed CY 2024 ASC Payment Indicator*
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	R2	R2*
6X000	Suprachoroidal space injection of pharmacologic agent (separate procedure)	NA	P3*
64XX4	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	NA	R2*
65785	Implantation of intrastromal corneal ring segments	P2	P3*
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*
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*
X170T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	NA	R2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2024 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2024 PFS proposed rule.

4. Device-Intensive ASC Covered Surgical Procedures

a. Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

b. CY 2024 Proposed Device Intensive Procedures

In the CY 2019 OPPS/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 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2 of the CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;

- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63773 through 63775), we modified our approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, we adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices if their

device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPSS. Second, we adopted a policy that if a procedure is assigned device-intensive status under the OPSS, 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 OPSS 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 would retain 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.

We are not proposing any changes related to designating surgical procedures as device-intensive under the ASC payment system for CY 2024.

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations, and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices. ASC payment is reduced by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the amount of the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC appends the HCPCS “FB” modifier on the line in the claim with the procedure to implant or insert the device. The contractor reduces payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

In the CY 2019 OPSS/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 OPSS/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 2024.

5. Requirement in the Physician Fee Schedule CY 2024 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 2024 PFS proposed rule includes proposals to operationalize section 90004 of the Infrastructure Act, including a proposal that impacts hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Similar to our CY 2023 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 2024 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 2024 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2024 PFS final rule with comment period. We note that this same notice appears in section V.C of this proposed rule.

6. Payment Amount and Beneficiary Coinsurance for Part B Rebatable Drugs

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169) was signed into law. Section 11101 of the IRA requires a Part B inflation rebate for a Part B rebatable drug if the Medicare payment amount, which is generally ASP plus 6 percent, if the drug rises at a rate that is faster than the rate of inflation. It also establishes changes to the Medicare payment rate and beneficiary coinsurance for such drugs under the ASC payment system. We refer the

reader to the discussion of this proposed policy and proposed changes to the regulatory text, which are discussed in further detail in section II.H.I of this proposed rule.

D. Proposed Additions to ASC Covered Surgical Procedures and Covered Ancillary Services

Lists

1. 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 OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

Section 416.166(c) sets out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening

in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15.

In the CY 2019 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.

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, CY 2022, and CY 2023 OPPTS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805, 87 FR 72068 through 72076).

2. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2024

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. In the CY 2023 OPPTS/ASC final rule with comment period, we received requests to add dental surgeries furnished in the ASC setting to the ASC CPL (87 FR 71882). In response to these public comments, we noted that if a dental service is covered under Medicare Part B and meets the criteria for the ASC CPL (set forth at 42 CFR 416.166), then it could be added to the ASC CPL, and that we would take additional dental procedures into consideration for future rulemaking. For CY 2024, we conducted a review of procedures that currently are paid under the OPPTS and

not included on the ASC CPL. We also assessed procedures against our regulatory safety criteria at § 416.166. Based upon this review, we propose to update the ASC CPL by adding 26 dental surgical procedures to the list for CY 2024, as shown in Table 61 below.

After reviewing the clinical characteristics of these procedures, as well as 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 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 2024.

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 OPSS, 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 2024 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>.

HCPCS code G0330 covers 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. While G0330 has a broader code descriptor than most of the dental codes proposed to be added to the ASC CPL, we propose to add G0330 to the ASC CPL. We also propose that it can only be billed when accompanied by at least one covered ancillary dental service on a specific and definitive list of CDT codes, which can be found in ASC Addendum BB with payment indicator “D1.”¹²⁶ Performance of at least one of these covered ancillary services is integral to each of the surgical procedures that correspond to G0330. For example, if a patient requires a full mouth debridement to enable a comprehensive periodontal evaluation and diagnosis on a subsequent visit, as described by covered ancillary code CDT code D4355, or to enable excision of a gum lesion, as described by CPT 41827, and this procedure needs to be performed under anesthesia due to patient-specific circumstances, the ASC would bill G0330 with covered ancillary code D4355 to perform the debridement under anesthesia or G0330 with covered ancillary code 41827 to perform the excision service under anesthesia. Additionally, as previously noted, when G0330 is billed on a claim, MACs would determine whether payment can be made for the procedure under § 411.15(i)(3), and whether the procedure was reasonable and medically necessary before providing payment for the procedure. This claims processing mechanism is discussed in further detail in the covered ancillary services section (section XIII.D.2 of this proposed rule). Procedures assigned to payment indicator “D2”, other than HCPCS code G0330, are not required to be billed with a covered ancillary procedure assigned to payment indicator “D1” in order to receive payment for the procedure.

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

¹²⁶ See section XIII.B.6.b for a detailed discussion of payment indicators “D1” and “D2.”

that the procedure is safe to be performed in the ASC setting for a typical Medicare beneficiary. We expect to continue to gradually expand the ASC CPL, as medical practice and technology continue to evolve and advance in future years. We encourage stakeholders 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.

TABLE 61: CY 2024 PROPOSED SURGICAL PROCEDURES FOR THE ASC CPL

CY 2024 CPT/HCPCS/CDT Code	CY 2024 Long Descriptor
D4210	Gingivectomy or gingivoplasty - four or more contiguous teeth or tooth bounded spaces per quadrant
D4211	Gingivectomy or gingivoplasty - one to three contiguous teeth or tooth bounded spaces per quadrant
D4212	Gingivectomy or gingivoplasty to allow access for restorative procedure, per tooth
D4260	Osseous surgery (including elevation of a full thickness flap entry and closure) - four or more contiguous teeth or tooth bounded spaces per quadrant
D4263	Bone replacement graft - retained natural tooth - first site in quadrant
D4270	Pedicle soft tissue graft procedure
D4273	Autogenous connective tissue graft procedure (including donor and recipient surgical sites) first tooth, implant, or edentulous tooth position in graft
D7111	Extraction, coronal remnants - primary tooth
D7140	Extraction – erupted tooth or exposed root (elevation and/or forcep removal)
D7210	Surgical removal of an erupted tooth requiring removal of bone and/or sectioning of tooth and including elevation of mucoperiosteal flap if indicated
D7220	Removal of impacted tooth – soft tissue
D7230	Removal of impacted tooth – partially bony
D7240	Removal of impacted tooth – completely bony
D7241	Removal of impacted tooth – completely bony, with unusual surgical complications
D7250	Surgical removal of residual tooth roots (cutting procedure)
D7270	Tooth reimplantation and/or stabilization of accidentally evulsed or displaced tooth
D7310	Alveoloplasty in conjunction with extractions - four or more teeth or tooth spaces, per quadrant
D7311	Alveoloplasty in conjunction with extractions - one to three teeth or tooth spaces, per quadrant

CY 2024 CPT/HCPCS/CDT Code	CY 2024 Long Descriptor
D7472	Removal of torus palatinus
D7473	Removal of torus mandibularis
D7510	Incision and drainage of abscess-intraoral soft tissue
D7511	Incision and drainage of abscess - intraoral soft tissue - complicated (includes drainage of multiple fascial spaces)
D7520	Incision and drainage of abscess-extraoral soft tissue
D7550	Partial ostectomy/sequestrectomy for removal of non-vital bone
D7950	Osseous, osteoperiosteal, or cartilage graft of the mandible or maxilla - autogenous or nonautogenous, by report
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

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 OPSS 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 2023, but will be packaged under the CY 2024 OPSS, we would also package the ancillary service under the ASC payment system for CY 2024 to maintain consistency with the OPSS. Comment indicator “CH” is used in Addendum BB (which is available via the Internet on the CMS website) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPSS treatment of the service for CY 2024.

In the CY 2022 OPSS/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 2024 can be found in section XIII.B of this proposed rule. All ASC covered ancillary services and their proposed payment indicators for CY 2024 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

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)*) is a proposed addition to the ASC CPL for CY 2024, as discussed in section XIII.D.1 of this proposed rule. In ASC Addendum BB, there is a specific and definitive list of covered ancillary dental services with proposed payment indicator of “D1.” For CY 2024, we propose that G0330 could only be billed with a covered ancillary procedure that has the proposed payment indicator of “D1,” indicating an ancillary dental service

or item with no separate payment made. This limitation would ensure that only covered ancillary services we have evaluated for safety in the ASC setting can be performed with G0330. While HCPCS code G0330 must be billed with a covered ancillary procedure with a proposed payment indicator of “D1”, these covered ancillary procedures can be billed with procedures other than G0330. When billed with procedures other than G0330, these procedures would be packaged in accordance with our policy for covered ancillary procedures. 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. More detail on the proposed ASC dental indicators can be found in section XIII.B.6 of this proposed rule.

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). Table 62 lists the five drugs that met our finalized criteria established in CY 2022 to receive separate payment under the ASC payment system when furnished in the ASC setting for CY 2023 as described in the CY 2023 final rule with comment period (86 FR 63496).

TABLE 62: SUMMARY OF FINALIZED PRODUCTS MEETING CMS’S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING POLICY FOR CY 2023

HCPCS Code	Brand Name	Long Descriptor	CY 2023 OPPS Status Indicator (SI)*	CY 2023 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
C9144	Posimir	Injection, bupivacaine (posimir), 1 mg	N	K2

*Please see the CY 2023 OPPS/ASC final rule with comment period addenda, specifically, the ASC Addenda BB for final applicable payment rates, OPPS Addenda D1 for final SI definitions, and ASC Addenda DD1 for final PI definitions. All are available via the internet on the CMS website.

2. Proposed CY 2024 Qualification Evaluation for Separate Payment of Non-Opioid Pain Management Drugs and Biologicals that Function as a Surgical Supply

As noted above, in the CY 2022 OPPS/ASC final rule with comment period, 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 drug packaging threshold beginning on or after January 1, 2022. For CY 2024, the OPPS drug packaging threshold is proposed to be \$140. For more information on the drug packaging threshold, see section V.B.1.a of this CY 2024 OPPS/ASC proposed rule.

In the CY 2023 OPPS/ASC final rule, 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 OPPS or ASC payment system under a policy other than the one specified in § 416.174.

The following sections include the non-opioid alternatives of which we are aware and our evaluations of whether these non-opioid alternatives meet the criteria established at § 416.174. We welcome stakeholder comment on these evaluations.

(a) Proposed Annual Eligibility Re-Evaluations of Non-Opioid Alternatives that Were Separately Paid in the ASC Setting During CY 2023

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). These drugs are described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0. mg*), HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), HCPCS code C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), and HCPCS code C9144 (*Injection, bupivacaine (posimir), 1 mg*)).

We re-evaluated these products outlined in the previous paragraph against the criteria specified in § 416.174, including the technical clarifications we proposed to that section, to determine whether they continue to qualify for separate payment in CY 2024. Based on our evaluation, we propose that the drugs described by HCPCS codes C9290, J1096, J1097, and C9089 continue to meet the required criteria and should receive separate payment in the ASC setting. We propose that the drug described by HCPCS code C9144 would not receive separate payment in the ASC setting under this policy, as this drug will be separately payable during CY 2024 under OPSS transitional pass-through status. Please see section V.A (OPSS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals) of this CY 2024 OPSS/ASC proposed rule for additional details on the pass-through status of HCPCS code C9144. We welcome comment on our evaluations below.

(b) Proposed Eligibility Evaluation for the Separate Payment of Exparel

Based on our internal review, we believe that Exparel, described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), meets the criteria described at § 416.174; and we propose to continue paying separately for it under the ASC payment system for CY 2024. Exparel was approved by the FDA with a New Drug Application (NDA #022496) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on October 28, 2011.¹²⁷ Exparel's FDA-approved indication is "in patients 6 years of age and older for single-dose infiltration to

¹²⁷ Exparel. FDA Letter. 28 October 2011.
https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/022496s000ltr.pdf.

produce postsurgical local analgesia” and “in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.”¹²⁸ No component of Exparel is opioid-based. Accordingly, we propose that Exparel meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Exparel exceeds the proposed \$140 per-day cost threshold. Therefore, we propose that Exparel meets the criterion described at § 416.174(a)(2). Additionally, Exparel will not have transitional pass-through payment status under § 419.64 in CY 2024, nor will it be otherwise separately payable in the OPSS or ASC payment system in CY 2024 under a policy other than the one specified in § 416.174. Therefore, we propose that Exparel meets the criteria in the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we believe that Exparel meets the criteria described at § 416.174; and we propose to continue making separate payment for it as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

(c) Proposed Eligibility Evaluation for the Separate Payment of Omidria

Based on our internal review, we believe that Omidria, described by HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), meets the criteria described at § 416.174(a), and we propose to continue paying separately for it under the ASC payment system for CY 2024. Omidria was approved by the FDA with a New Drug Application (NDA #205388) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on May 30, 2014.¹²⁹ Omidria’s FDA-approved indication is as “an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor indicated for: Maintaining pupil size by preventing intraoperative miosis; Reducing postoperative pain.”¹³⁰ No component of Omidria

¹²⁸ Exparel. FDA Package Insert. 22 March 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022496s0351bl.pdf.

¹²⁹ Omidria. FDA Letter. 30 May 2014.

https://www.accessdata.fda.gov/drugsatfda_docs/appltr/2014/205388Orig1s000ltr.pdf.

¹³⁰ Omidria. FDA Package Insert. December 2017.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s0061bl.pdf.

is opioid-based. Accordingly, we propose that Omidria meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Omidria exceeds the proposed \$140 per-day cost threshold. Therefore, we propose that Omidria meets the criterion described at § 416.174(a)(2). Additionally, we believe that Omidria will not have transitional pass-through payment status under § 419.64 in CY 2024, nor will it be otherwise separately payable in the OPSS or ASC payment system in CY 2024 under a policy other than the one specified in § 416.174. Therefore, we propose that Omidria meets the criteria in the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we propose that Omidria meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

(d) Proposed Eligibility Evaluation for the Separate Payment of Xaracoll

Based on our internal review, we believe Xaracoll, described by C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), meets the criteria described at § 416.174(a), and we propose to continue paying separately for it under the ASC payment system for CY 2023. Xaracoll was approved by the FDA with a New Drug Application (NDA # 209511) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on August 28, 2020.¹³¹ Xaracoll is “indicated in adults for placement into the surgical site to produce postsurgical analgesia for up to 24 hours following open inguinal hernia repair.”¹³² No component of Xaracoll is opioid-based. Accordingly, we propose that Xaracoll meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Xaracoll exceeds the proposed \$140 per-day cost threshold. Therefore, we propose that Xaracoll meets the criterion described at § 416.174(a)(2). Additionally, at this time we do not believe that Xaracoll will have

¹³¹ Xaracoll. FDA Letter. August 2020.

https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/209511Orig1s000ltr.pdf.

¹³² Xaracoll. FDA Labeling. August 2020.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209511s000lbl.pdf.

transitional pass-through payment status under § 419.64 in CY 2024, nor do we believe it will otherwise be separately payable in the OPPTS or ASC payment system under a policy other than the one specified in § 416.174. Therefore, we propose that Xaracoll meets the criteria in the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we propose that Xaracoll meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

(e) Proposed Eligibility Evaluation for the Separate Payment of Dextenza

Based on our internal review, we believe Dextenza, described by HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), meets the criteria described at § 416.174; and we propose to provide separate payment for it under the ASC payment system for CY 2024.

Dextenza was approved by the FDA with a New Drug Application (NDA # 208742) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on November 30, 2018.¹³³

Dextenza's FDA-approved indication is as "a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery" and "the treatment of ocular itching associated with allergic conjunctivitis."¹³⁴ No component of Dextenza is opioid-based. Accordingly, we propose that Dextenza meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Dextenza exceeds the proposed \$140 per-day cost threshold. Therefore, we propose that Dextenza meets the criterion described at § 416.174(a)(2). Additionally, we believe that Dextenza will not have transitional pass-through payment status under § 419.64 in CY 2024, nor do we believe it will otherwise be separately payable in the OPPTS or ASC payment system under a policy other than the one specified in

¹³³ Dextenza. FDA Letter. November 2018.
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208742Orig1s000Approv.pdf.

¹³⁴ Dextenza. FDA Labeling. October 2021.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s0071bl.pdf.

§ 416.174. Therefore, we propose that Dextenza meets the criteria in the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we propose that Dextenza meets the criteria described at §416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

(f) Proposed Eligibility Evaluation for the Separate Payment of Posimir

Based on our internal review, we do not believe that Posimir, described by HCPCS code C9144 (*Injection, bupivacaine (Posimir), 1 mg*), meets the criteria described at § 416.174(a); and we do not propose to continue paying separately for it under the ASC payment system for CY 2024. Posimir was approved by the FDA with a New Drug Application (NDA # 204803) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on February 1, 2021.¹³⁵ Posimir contains an amide local anesthetic and is indicated in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression.”¹³⁶

No component of Posimir is opioid-based. Accordingly, we propose that Posimir meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Posimir exceeds the proposed \$140 per-day cost threshold. Therefore, we propose that Posimir meets the criterion described at § 416.174(a)(2). However, Posimir will have transitional pass-through payment status under § 419.64 in CY 2024, and it will be otherwise separately payable in the OPPS or ASC payment system in CY 2024 under a policy other than the one specified in § 416.174. Therefore, we propose that Posimir does not meet the criteria at the regulation text at § 416.174(a)(3) and (4).

¹³⁵ Posimir. FDA Approval Letter. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/204803Orig1s000ltr.pdf.

¹³⁶ Posimir. FDA Package Insert. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204803Orig1s001lbl.pdf.

Based on the above discussion, we propose that Posimir does not meet the criteria in the regulation text at § 416.174(a)(3) and (4), and should not receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024. However, HCPCS code C9144 will continue to receive separate payment under its pass-through status as outlined in section V of this proposed rule.

Table 63 below lists the four drugs that we propose 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 for CY 2024.

TABLE 63: SUMMARY OF PRODUCTS PROPOSED TO MEET CMS'S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING POLICY FOR CY 2024

HCPCS Code	Brand Name	Long Descriptor	CY 2024 OPPS 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, OPPS Addenda D1 for SI definitions, and ASC Addenda DD1 for PI definitions. All are available via the internet on the CMS website.

3. Comment Solicitation on New Products that Meet the Criteria

We solicit comment on additional non-opioid pain management drugs and biologicals that function as surgical supplies that may meet the criteria specified in § 416.174 and qualify for separate payment under the ASC payment system. We encouraged commenters to include an explanation of how the drug or biological meets the eligibility criteria in § 416.174. If we find

that any additional drugs or biologicals described by commenters do satisfy the criteria established at § 416.174, we will finalize their separate payment status for CY 2024 in the ASC setting in the CY 2024 OPPS/ASC final rule with comment period.

F. Comment Solicitation on Access to Non-Opioid Treatments for Pain Relief Under the OPPS and ASC Payment System

1. Background on Access to Non-Opioid Treatments for Pain Relief

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

Paragraph (10) of section 1833(i) of the Act cross-references the OPPS provisions about the additional payment amount and payment limitation for non-opioid treatments for pain relief and applies them to payment under the ASC payment system. In particular, 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.

Because the additional payments are required to begin on January 1, 2025, we plan to include our proposals to implement the section 4135 amendments in the CY 2025 OPPS/ASC proposed rule. We specifically seek comment on the issues discussed in the following sections as well as comments on the implementation of all facets of this provision.

2. CY 2025 Comment Solicitation

a. Potential Qualifying Drugs, Biologicals, and Devices

In preparation for implementing section 4135 of the CAA, 2023, for CY 2025, we seek comment on any drug, biological, or medical device that a commenter believes would meet the definition of a non-opioid treatment for pain relief under section 1833(t)(16)(G)(iv) of the Act. We encourage commenters to submit appropriate FDA documentation, published peer-reviewed literature, or other evidence-based support, if applicable, to illustrate why the commenters believe the drug, biological, or medical device meets the definition of a non-opioid treatment for pain relief. For these products, we also solicit comment on appropriate codes and descriptors if no HCPCS codes currently exist for the product. We note that we will evaluate these products, including the information submitted by commenters, and propose additional payments, subject to the payment limitation, for those that meet the definition of a non-opioid treatment for pain relief in the CY 2025 OPPS/ASC rulemaking cycle, rather than during the CY 2024 OPPS/ASC final rule with comment period.

b. Evidence Requirement for Medical Devices

Section 1833(t)(16)(G)(iv)(II)(bb) of the Act specifies an additional requirement for medical devices to meet the definition of non-opioid treatment for pain relief. This section requires that a medical device demonstrate 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.

As the statute requires information from a clinical trial or data published in a peer-reviewed journal, we seek comment on the best way to obtain and evaluate that information. We also seek comment on how we should assess information from a clinical trial or data published in a peer-reviewed journal, including how to assess for conflicts of interest or integrity concerns, whether to focus on outcomes rather than surrogate endpoints, and whether to require that all decreases in opioid use be statistically and clinically significant compared to the usual standard of care (rather than placebo).

c. Amount of Payment

Section 1833(t)(16)(G)(ii)(I) of the Act states that, subject to the limitation in clause (iii), the amount of payment for a non-opioid treatment for pain relief that is a drug or biological product is the amount of payment for such drug or biological 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. As this language is very similar to the transitional pass-through language at section 1833(t)(6)(D)(i) of the Act, we anticipate implementing a similar payment methodology for drugs and biologicals under this future policy.

Section 1833(t)(16)(G)(ii)(II) of the Act states that the amount of payment for a non-opioid treatment for pain relief that is a medical device 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. As this language is very similar to the transitional pass-through language at section 1833(t)(6)(D)(ii) of the Act, we

anticipate implementing a similar payment methodology for medical devices under this future policy.

Section 1833(i)(10) of the Act provides that the same payment rate shall apply in the ASC setting as the rates described in section 1833(t)(16)(G)(ii) of the Act for hospital outpatient departments, subject to the limitation in section 1833(t)(16)(G)(iii) of the Act.

d. Payment Limitation

Section 1833(t)(16)(G)(iii) of the Act states that the additional payment amount specified in clause (ii), and as 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. We are seeking comment on how we should determine the OPD service or groups of services with which non-opioid treatments for pain relief are furnished for purposes of calculating the payment limitation for each treatment. Specifically, we seek comment on the scenarios outlined below. Additionally, we welcome other recommendations from interested parties consistent with the statutory requirements.

Scenario 1: Payment Limitation Based on the Top Five Services by Volume with Known Claims Data

As demonstrated in this example (Table 64), one possible approach is to use the top five services associated with a hypothetical drug, biological, or medical device, to determine the volume-weighted payment rate and the payment limit, based on the most recent claims data available. For the non-opioids that are currently separately paid, we predict that the majority of utilization is focused in the top five mostly frequently performed services, thus using the top five services would provide a representative estimate for the payment limit. However, we solicit comment on this prediction and welcome input from commenters if they believe another number

of procedures, or another metric, would be appropriate to determine the list of procedures in which the payment limitation would be calculated.

For this example, we would begin by identifying the top five services by volume that package this drug, biological, or device into their payment rate. Second, we would calculate the volume-weighted payment rate per claim, which would be \$700 in the example below. Third, we would apply the 18 percent payment limit per clinical dose, rather than per HCPCS dosage unit, which is \$126 in the case below. We would apply this payment limit to the clinical dose received by the beneficiary as the payment limit applies to the total amount of payment, rather than the HCPCS dosage unit payment, which may only represent a small fraction of the total amount of payment. This means that even if the non-opioid treatment for pain relief had an amount of additional payment under section 1833(t)(16)(G)(ii) of the Act that was greater than \$126 per dose, it would be limited to \$126 by 1833(t)(16)(G)(iii) of the Act. In this example, this non-opioid treatment for pain relief would not be subject to the threshold packaging policy in section V.B.1.a. of this proposed rule even though its payment falls below the proposed CY 2024 drug packaging threshold of \$140, per section 1833(t)(16)(G)(i) of the Act, and would also be

separately paid when used during a comprehensive APC (C-APC) procedure in the HOPD setting.

TABLE 64: Example of Payment Limitation Based on the Top Five Services by Volume

Service	Volume (claims)	Payment	Total Payment (volume * claims)	Volume Weighted Payment per claim (total payment / total volume)	Payment Limit
1	100	1000	100,000	$\frac{(100,000 + 4,000 + 1,000 + 1,000 + 1,000)}{100 + 20 + 10 + 10 + 10} = \700	$\$700 * 0.18 = \126
2	20	200	4,000		
3	10	100	1,000		
4	10	100	1,000		
5	10	100	1,000		

We welcome comments on this approach. We seek comment on whether utilizing the top five services by volume is an appropriate method by which to establish this payment limit. We also seek comment on additional methodologies, such as determining the payment limit based on the top 10 services by volume, by total payment rather than volume, or any number of services with more than a certain percentage of overall utilization, such as 10 percent.

Scenario 2: Payment Limit Without Claims Data

Additionally, we seek comment on the best approach for determining a payment limit, pursuant to section 1833(t)(16)(G)(iii) of the Act for drugs, biologicals, and devices when there are no known claims data, such as for newly FDA-approved and marketed products. CMS could propose the services with which a product would be expected to be furnished and would typically be packaged absent this policy during calendar year rulemaking, based on expected clinical use patterns. Determining the service, or group of services, to use to calculate the payment limit 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 make its determination of the service, or group of services, to use to calculate the payment

limit based on expected clinical use patterns. CMS could then adjust the services that are used to calculate the payment limit as claims data becomes available in subsequent years. We seek comment on this approach as well as other approaches of interest to commenters.

We welcome comment from interested parties on the implementation of all facets of section 4135. We will include proposals to implement the section 4135 amendments in the CY 2025 OPPTS/ASC proposed rule.

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.

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/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html>.

- We announce annually, in the proposed rule updating the ASC and OPPTS 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 OPPTS 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 2024

We did not receive any requests for review to establish a new NTIOL class for CY 2024 by March 1, 2023, the due date published in the CY 2023 OPSS/ASC final rule with comment period (87 FR 72091).

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 2024.

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 OPSS 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 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 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 unadjusted hospital wage indexes, which are updated yearly and are

used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. On February 28, 2013, OMB issued OMB Bulletin No. 13-01, 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 June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at:

<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf>.) In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13-01 for the IPPS hospital wage index beginning in FY 2015.

OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15-01, which provides updates to and supersedes OMB Bulletin No. 13-01 that was issued on February 28, 2013. OMB Bulletin No. 15-01 made changes that are relevant to the IPPS and ASC wage index. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79750) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at

<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf>.)

On August 15, 2017, OMB issued OMB Bulletin No. 17-01, which provided updates to and superseded OMB Bulletin No. 15-01 that was issued on July 15, 2015. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58864 through 58865) for a

discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at

<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf>.)

On April 10, 2018, OMB issued OMB Bulletin No. 18–03, which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. A copy of OMB Bulletin No. 18–03 may be obtained at <https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf>. A copy of OMB Bulletin No. 18–04 may be obtained at

<https://www.whitehouse.gov/wpcontent/uploads/2018/90/Bulletin-18-04.pdf>.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. (For a copy of this bulletin, we refer readers to the following website: <https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf>.)

The proposed CY 2024 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 13-01, 15-01, 17-01, 18-03, 18-04, and 20-01). We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where “contiguous” is defined as sharing a border). For example, for CY 2024, we are applying a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA).

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, we 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.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2024 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 2022 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 2024 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 2022, we propose to compare the estimated total payment using the CY 2023 ASC relative payment weights with the estimated total payment using the CY 2024 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2023 and CY 2024.

Additionally, in light of our policy to provide a higher ASC payment rate through the use of ASC complexity adjustment codes for certain primary procedures when performed with add-on packaged services, we incorporate estimated total spending and estimated utilization for these codes in our budget neutrality calculation. 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 proposed CY 2023 ASC complexity adjustment codes would be \$5 million in spending and we propose to incorporate this \$5 million in estimated CY 2023 total payments for the budget neutrality calculation of this proposed rule. For estimated CY 2024 total payments, we propose to incorporate the estimated total spending and estimated utilization related to our proposed CY 2024 ASC complexity adjustment codes. In this proposed rule, we estimate the additional CY 2024 spending related to our proposed ASC complexity adjustment codes will be \$5 million.

We propose to use the ratio of estimated CY 2023 to estimated CY 2024 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2024. The proposed CY 2024 ASC weight scalar is 0.8649. 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 2022 claims data to model our budget neutrality adjustment for CY 2024.

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 2024, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2022 claims data available and estimating the difference in total payment that would be created by introducing the proposed

CY 2024 ASC wage indexes. Specifically, holding CY 2022 ASC utilization, service-mix, and the proposed CY 2024 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2023 ASC wage indexes and the total adjusted payment using the proposed CY 2024 ASC wage indexes. 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 2023 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2024 ASC wage indexes and applied the resulting ratio of 1.0017 (the proposed CY 2024 ASC wage index budget neutrality adjustment) to the CY 2023 ASC conversion factor to calculate the proposed CY 2024 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 2024 was projected to be 0.2 percentage point, as published in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27005) based on IGI's 2022 fourth quarter forecast.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI-U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI-U in the absence of any update. Because the Secretary updates the ASC payment amounts

annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI-U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized a policy to apply the 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 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 this CY 2024 OPPS/ASC proposed rule, we propose to extend the 5-year interim period an additional 2 years, that is, through CY 2024 and CY 2025. We believe hospital outpatient and ASC utilization data from CYs 2023 and 2024 will enable us to more accurately analyze whether the application of the hospital market basket update to the ASC payment system had an effect on the migration of services from the hospital setting to the ASC setting. We propose to revise 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 propose to

revise 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 2024, in accordance with our proposed revisions to § 416.171(a)(2)(iii), (vi), and (viii)(B), we propose to utilize the hospital market basket update of 3.0 percent reduced by the productivity adjustment of 0.2 percentage point, resulting in a proposed productivity-adjusted hospital market basket update factor of 2.8 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to apply a 2.8 percent productivity-adjusted hospital market basket update factor to the CY 2023 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2024 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 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 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 0.2 percentage point productivity adjustment. Therefore, we propose to apply a 0.8 percent productivity-adjusted hospital market basket update factor to the CY 2023 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 2024 ASC update for the CY 2024 OPPS/ASC final rule with comment period.

For CY 2024, we propose to adjust the CY 2023 ASC conversion factor (\$51.854) by the proposed wage index budget neutrality factor of 1.0017 in addition to the productivity-adjusted hospital market basket update of 2.8 percent discussed above, which results in a proposed CY 2024 ASC conversion factor of \$53.397 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we propose to adjust the CY 2023 ASC conversion factor (\$51.854) by the proposed wage index budget neutrality factor of 1.0017 in addition to the quality reporting/productivity-adjusted hospital market basket update of 0.8 percent discussed above, which results in a proposed CY 2024 ASC conversion factor of \$52.358.

3. Display of the Proposed CY 2024 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 2024 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 2024 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 2024 Payment Weight” are the proposed relative payment weights for each of the listed services for CY 2024. 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 2024 payment rate displayed in the “Proposed CY 2024 Payment Rate” column, each ASC payment weight in the “Proposed CY 2024 Payment Weight” column was multiplied by the proposed CY 2024 conversion factor. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment. The proposed CY 2024 ASC conversion factor uses the CY 2024 productivity-adjusted hospital market basket update factor of 2.8 percent (which is equal to the proposed inpatient hospital market basket percentage increase of 3.0 percent reduced by the proposed productivity adjustment of 0.2 percentage point).

In Addendum BB, there are no relative payment weights displayed in the “Proposed CY 2024 Payment Weight” column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The “Proposed CY 2024 Payment” column displays the proposed CY 2024 national unadjusted ASC payment rates for all items and services. The proposed CY 2024 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 finalized to be excluded from payment in ASCs for CY 2024.

Addendum FF to this proposed rule displays the OPPS payment rate (based on the standard ratesetting methodology), 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 2024 for covered surgical procedures.

XIV. Hospital Outpatient Quality Reporting (OQR) Program Requirements, Proposals, and Requests for Comment

A. Background

We seek to promote higher quality, more efficient, and equitable healthcare for patients. Consistent with these goals, we have implemented quality reporting programs for multiple care settings, including the Hospital Outpatient Quality Reporting (OQR) Program for hospital outpatient care.

We refer readers to the CY 2011 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system final rule (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program. We refer readers to the CYs 2008 through 2023 OPPS/ASC final rules for detailed discussions of the regulatory history of the Hospital OQR Program (72 FR 66860 through 66875; 73 FR 68758 through 68779; 74 FR 60629 through 60656; 75 FR 72064 through 72110; 76 FR 74451 through 74492; 77 FR 68467 through 68492; 78 FR 75090 through 75120; 79 FR 66940 through 66966; 80 FR 70502 through 70526; 81 FR 79753 through 79797; 82 FR 59424 through 59445; 83 FR 59080 through 59110; 84 FR 61410 through 61420; 85 FR 86179 through 86187; 86 FR 63822 through 63875; and 87 FR 72096 through 72117).

We have codified certain requirements under the Hospital OQR Program at 42 CFR 419.46. We refer readers to section XIV.F of this proposed rule for a detailed discussion of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements.

B. Hospital OQR Program Quality Measures

1. Retention, Removal, Replacement, or Suspension of Quality Measures from the Hospital OQR Program Measure Set

We refer readers to § 419.46(i) for our policies regarding: (1) measure retention; (2) immediate measure removal; and (3) measure removal, suspension, or replacement through the rulemaking process. We propose to amend our immediate measure removal policy codified at § 419.46(i)(2) to replace references to “QualityNet” with “CMS-designated information system” or “CMS website,” and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

a. Proposed Removal of the Left Without Being Seen Measure Beginning with the CY 2024 Hospital OQR Reporting Period

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72088 through 72089) where we adopted the Left Without Being Seen (LWBS) measure beginning with the CY 2013 payment determination. The LWBS measure was initially endorsed by a consensus-based entity (CBE) in 2008. This process measure assesses the percent of patients who leave the emergency department (ED) without being evaluated by a physician, advanced practice nurse, or physician’s assistant. Our rationale for adopting the LWBS measure was that patients leaving without being seen was an indicator of ED overcrowding (75 FR 72089).

Endorsement of the measure was removed in 2012 because the measure steward did not choose to resubmit the measure to maintain endorsement. We continued to retain the LWBS measure because our data showed variation/gap in performance and improvement. However, over the last few years, our routine measure monitoring and evaluation indicated: (1) limited evidence linking the measure to improved patient outcomes; (2) that increased LWBS rates may reflect poor access to timely clinic-based care rather than intrinsic systemic issues within the

ED;¹³⁷ and (3) unintended effects on LWBS rates caused by other policies, programs, and initiatives may lead to skewed measure performance.^{138,139,140}

We recognize that LWBS performance issues could be due to inefficient patient flow in the ED for a variety of reasons or due to insufficient community resources, which result in higher ED patient volumes that lead to long wait times and patients deciding to leave without being seen. These patients' reasoning for visiting the ED is often not severe enough that they would want to wait if the ED is crowded. Additionally, we do not believe that the LWBS measure provides enough specificity to give value because it does not provide granularity for actionable meaningful data toward quality improvement.

We believe, based on these findings, that this measure meets the 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).

ED performance and care continues to be an important topic area of the Hospital OQR Program. We believe the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure (Median Time for Discharged ED Patients measure) is better for measuring ED performance and care. The Median Time for Discharged ED Patients measure, adopted for reporting in the Hospital OQR Program, provides more meaningful data compared to the LWBS measure because the measure presents more granular data on length of time of ED throughput. Additionally, the Median Time for Discharged ED Patients measure provides useful information to facilities for improvement efforts because the measure is stratified, showing the median time from ED departure for discharged ED patients in four different strata in the Hospital Outpatient

¹³⁷ Li DR, Brennan JJ, Kreshak AA, et al. (2019). Patients who leave the emergency department without being seen and their follow-up behavior: a retrospective descriptive analysis. *J Emerg Med*, 57(1), 106-13. <https://doi.org/10.1016/j.jemermed.2019.03.051>

¹³⁸ Allen L, Cong TG, & Kosali S. (2022). The Impact of Medicaid Expansion on Emergency Department Wait Times. *Health Services Research*, 57(2), 294–99. <https://doi.org/10.1111/1475-6773.13892>

¹³⁹ Roby N, Smith H, Hurdelbrink J, et al. (2022). Characteristics and Retention of Emergency Department Patients Who Left without Being Seen (LWBS). *Internal and Emergency Medicine*, 17(2),: 551–58. <https://doi.org/10.1007/S11739-021-02775-Z>

¹⁴⁰ Yoo MJ, Schauer SG, & Trueblood WE. (2022). 'Swab and Go' Impact on Emergency Department Left without Being Seen Rates." *The American Journal of Emergency Medicine*, 57(July): 164–65. <https://doi.org/10.1016/J.AJEM.2021.11.043>

Department (HOPD) setting. These improvement efforts by facilities could ultimately reduce the number of patients who leave without being seen.

Based on the above assessment and rationale, we believe the LWBS measure does not provide enough evidence to promote quality of care and improved patient outcomes to justify retaining the measure in the Hospital OQR Program. Therefore, we propose to remove the LWBS measure from the program beginning with the CY 2024 reporting period/CY 2026 payment determination.

We invite public comment on our proposal.

2. Modifications to Previously Adopted Measures

In this proposed rule, we propose to modify three previously adopted measures beginning with CY 2024 reporting period/CY 2026 payment determination: (1) COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure; (2) Cataracts: Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery measure; and (3) Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure.

a. Proposed Modification of the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

(1) Background

On January 31, 2020, the Secretary of the Department of Health and Human Services (HHS) declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–COV–2, a then novel coronavirus that causes a disease named “coronavirus disease 2019” (COVID–19).¹⁴¹ Subsequently, the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure was adopted across multiple quality reporting programs,

¹⁴¹ U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>

including the Hospital OQR Program (86 FR 63824 through 63833).¹⁴² COVID–19 has continued to spread domestically and around the world with more than 102.7 million cases and 1.1 million deaths in the United States alone as of February 13, 2023.¹⁴³ The Secretary renewed the PHE on April 21, 2020, and then every three months thereafter, with the final renewal on February 9, 2023.¹⁴⁴ The PHE expired on May 11, 2023; however, the public health response to COVID–19 remains a public health priority including vaccination efforts.¹⁴⁵

We stated in the CY 2022 OPPS/ASC final rule (86 FR 63825), and in our “Revised Guidance for Staff Vaccination Requirements,” that vaccination is a critical part of the nation’s strategy to effectively counter the spread of COVID–19.^{146,147,148} We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including the HOPD setting, to protect health care workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities. Studies indicate higher levels of population-level vaccine effectiveness in preventing COVID–19 infection among HCP and other frontline workers in multiple industries, with vaccines having a 90 percent effectiveness in preventing symptomatic and asymptomatic

¹⁴²The ASCQR Program (86 FR 63875 through 63833), the Hospital IQR Program (86 FR 45374 through 45382), the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the PPS-Exempt Cancer Hospital Quality Reporting Program (86 FR 45428 through 45434), the Long-Term Care Hospital Quality Reporting Program (86 FR 45438 through 45446), the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244 through 67248), and the Inpatient Rehabilitation Facility Quality Reporting Program (86 FR 42385 through 42396).

¹⁴³ Centers for Disease Control and Prevention. COVID Data Tracker. Accessed February 13, 2023. Available at: <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>

¹⁴⁴ U.S. Dept. of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. (2023). Renewal of Determination that a Public Health Emergency Exists. Available at: <https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx>

¹⁴⁵ U.S. Dept. of Health and Human Services. Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html>

¹⁴⁶ Centers for Medicare and Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: <https://www.cms.gov/files/document/qs0-23-02-all.pdf>

¹⁴⁷ Centers for Disease Control and Prevention. (September 24, 2021). Morbidity and Mortality Weekly Report (MMWR). Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID–19 Hospitalizations Among Adults Without Immunocompromising Conditions – United States, March–August 2021. Available at: https://cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w

¹⁴⁸ Centers for Medicare and Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: <https://www.cms.gov/files/document/qs0-23-02-all.pdf>

infection from December 2020 through August 2021.¹⁴⁹ Since the Food and Drug Administration (FDA) issued emergency use authorizations (EUAs) for selected initial and primary vaccines for adults, vaccines have been highly effective in real-world conditions at preventing COVID–19 in HCP with up to 96 percent efficacy for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID–19.^{150,151,152,153} Overall, data demonstrate that COVID–19 vaccines are effective and prevent severe disease, hospitalization, and death from COVID–19 infection.¹⁵⁴

When we adopted the COVID–19 Vaccination Coverage Among HCP measure in the CY 2022 OPPS/ASC final rule (86 FR 63875 through 63883), we acknowledged that the measure did not address booster shots for COVID-19 vaccination (86 FR 63881) though the FDA authorized, and the Centers for Disease Control and Prevention (CDC) recommended, additional doses and booster doses of the COVID-19 vaccine for certain individuals, particularly those who are immunocompromised due to age or condition or who are living or working in high-risk settings, such as HCP (86 FR 63881). However, we also stated that we believed the numerator of the measure was sufficiently broad to include potential future boosters as part of a “complete vaccination course” (86 FR 63881).

Since then, new variants of SARS–COV–2 have emerged around the world and within the United States. Specifically, the Omicron variant (and its related subvariants) is listed as a

¹⁴⁹ -Centers for Disease Control and Prevention. (August 27, 2021). Morbidity and Mortality Weekly Report (MMWR). Effectiveness of COVID-19 Vaccines in Preventing SARS-COV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance – Eight U.S. Locations, December 2020-August 2021. Available at: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm>

¹⁵⁰ Pilishivi T, Gierke R, Fleming-Dutra KE, et al. (2022). Effectiveness of mRNA Covid–19 Vaccine among U.S. Health Care Personnel. *New England Journal of Medicine*, 385(25), e90. <https://doi.org/10.1056/NEJMoa2106599>

¹⁵¹ Centers for Disease Control and Prevention. (2021). Morbidity and Mortality Weekly Report (MMWR). Monitoring Incidence of COVID–19 Cases, Hospitalizations, and Deaths, by Vaccination Status – 13 U.S. Jurisdictions, April 4-July 17, 2021. Available at: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm>

¹⁵² Centers for Medicare and Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: <https://www.cms.gov/files/document/qs0-23-02-all.pdf>

¹⁵³ Food and Drug Administration. (2020). FDA Takes Key Action in Fight Against COVID–19 By Issuing Emergency Use Authorization for First COVID–19 Vaccine. Available at: <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>

¹⁵⁴ McGarry BE, Barnett ML, Grabowski DC, et al. (2022). Nursing Home Staff Vaccination and Covid–19 Outcomes. *New England Journal of Medicine*, 386(4), 397-398. <https://doi.org/10.1056/NEJMc2115674>

variant of concern by the CDC because it spreads more easily than earlier variants.¹⁵⁵ Vaccine manufacturers have responded to the Omicron variant by developing bivalent COVID–19 vaccines, which include a component of the original virus strain to provide broad protection against COVID–19 and a component of the Omicron variant to provide better protection against COVID–19 caused by the Omicron variant.¹⁵⁶ Booster doses of the bivalent COVID–19 vaccine have proven effective at increasing immune response to SARS–COV–2 variants, including Omicron, particularly in individuals who are more than 6 months removed from receipt of their primary series.¹⁵⁷ These booster doses are associated with a greater reduction in infections among HCP and their patients relative to those who only received primary series vaccination, with a rate of breakthrough infections among HCP who received only the two-dose regimen of 21.4 percent compared to a rate of 0.7 percent among boosted HCP.^{158,159,160} Data from the existing COVID–19 Vaccination Coverage Among HCP measure demonstrate clinically significant variation in booster dose vaccination rates across HOPDs.

We believe that vaccination remains the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death. Given the availability of vaccine efficacy data, EUAs issued by the FDA for bivalent boosters, continued presence of SARS–COV–2 in the United States, and variance among rates of booster dose vaccination, it is important to modify the COVID–19 Vaccination Coverage Among HCP measure for HCP to receive primary series and booster vaccine doses in a timely manner per

¹⁵⁵ Centers for Disease Control and Prevention. (2021). Variants of the Virus. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html>

¹⁵⁶ Food and Drug Administration. (2022). COVID–19 Bivalent Vaccine Boosters. Available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccines>

¹⁵⁷ Chalkias S, Harper C, Vrbicky K, et al. (2022). A Bivalent Omicron-Containing Booster Vaccine against Covid–19. *New England Journal of Medicine*, 387(14), 1279-1291. <https://doi.org/10.1056/NEJMoa2208343>

¹⁵⁸ Prasad N, Derado G, Nanduri SA, et al. (May 2022). Effectiveness of a COVID–19 Additional Primary or Booster Vaccine Dose in Preventing SARS-CoV-2 Infection Among Nursing Home Residents During Widespread Circulation of the Omicron Variant - United States, February 14-March 27, 2022. *Morbidity and Mortality Weekly Report (MMWR)*. 71(18), 633-637. Available online at: <https://www.cdc.gov/mmwr/volumes/71/wr/mm7118a4.htm>

¹⁵⁹ Oster Y, Benenson S, Nir-Paz R, et al. (2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. *Clinical Microbiology and Infection*, 28(5), 735.e1-735.e3. <https://doi.org/10.1016/j.cmi.2022.01.019>

¹⁶⁰ Ibid.

CDC’s recommendation that bivalent COVID-19 vaccine booster doses might improve protection against SARS-CoV-2 Omicron sublineages.¹⁶¹

We propose to modify the COVID–19 Vaccination Coverage Among HCP measure to utilize the term “up to date” in the HCP vaccination definition. We also propose to update the numerator to specify the timeframes within which an HCP is considered up to date with CDC recommended COVID–19 vaccines, including booster doses, beginning with CY 2024 reporting period/CY 2026 payment determination for the Hospital OQR Program.

We note that as we stated in the CY 2022 OPPS/ASC final rule (86 FR 63877), the COVID–19 Vaccination Coverage Among HCP measure is a process measure that assesses HCP vaccination coverage rates and not an outcome measure for which hospitals are held responsible for a particular outcome. We propose to adopt the same modification to versions of the measure that we have adopted for other quality reporting programs.¹⁶²

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCPs in various settings and are reported via the CDC’s National Healthcare Safety Network (NHSN). We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63827 through 63828) for more information on the initial review of the measure by the Measure Applications Partnership (MAP).¹⁶³ We included an updated version of the measure on the Measures Under Consideration (MUC) list for the 2022-2023 pre-rulemaking cycle for consideration by the MAP. In December 2022, during the MAP’s Hospital Workgroup discussion, the workgroup stated that

¹⁶¹ Centers for Medicare and Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: <https://www.cms.gov/files/document/qs0-23-02-all.pdf>

¹⁶² The Hospital Inpatient Quality Reporting Program, the Long-Term Care Hospital Quality Reporting Program and the PPS-Exempt Cancer Hospital Quality Reporting Program (88 FR 27074) as well as the Inpatient Psychiatric Facility Quality Reporting Program (88 FR 21290), the Skilled Nursing Facility Quality Reporting Program (88 FR 21332), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244), and the Inpatient Rehabilitation Facility Quality Reporting Program (88 FR 20985).

¹⁶³ Interested parties convened by the consensus-based entity will provide input and recommendations on the Measures under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to <https://p4qm.org/PRMR-MSR> for more information.

the revision of the current measure captures up to date vaccination information in accordance with the CDC's updated recommendations for additional and booster doses since the measure's initial development. Additionally, the Hospital Workgroup appreciated that the re-specified measure's target population is broader and simplified from seven categories of HCP to four.¹⁶⁴ During the MAP's Health Equity Advisory Group review, the group highlighted the importance of COVID-19 vaccination measures and questioned whether the proposed revised measure excludes individuals with contraindications to FDA authorized or approved COVID-19 vaccines, and if the measure would be stratified by demographic factors. The measure developer confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator but stated that the measure would not be stratified since the data are submitted at an aggregate rather than an individual level. The MAP Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually.¹⁶⁵ We note that when reviewed by the MAP, reporting for contract personnel providing care or services not specifically included in the measure denominator was fully optional, whereas this reporting is now required to complete NHSN data entry, but is not included in the measure calculation.

The developer also noted that the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431).¹⁶⁶ We refer readers to sections XXIV.B and XXVI of this proposed rule for additional detail on the burden and impact of this proposal.

The proposed revised measure received conditional support for rulemaking from the MAP pending (1) testing indicating the measure is reliable and valid, and (2) endorsement by the CBE. The MAP noted that the previous version of the measure received endorsement from the

¹⁶⁴ Centers for Medicare & Medicaid Services. Pre-rulemaking MUC lists and map reports. The Measures Management System. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>

¹⁶⁵ Ibid.

¹⁶⁶ In previous years, we referred to the consensus-based entity (CBE) by corporate name. We have updated this language to refer to the CBE more generally.

CBE (CBE #3636)¹⁶⁷ and that the measure steward (CDC) intends to submit the updated measure for endorsement.¹⁶⁸

(a) Measure Specifications

This measure is calculated quarterly by averaging the hospital's most recently submitted and self-selected 1 week of data. The measure includes at least 1 week of data collection a month for each of the 3 months in a quarter. The denominator is calculated as the aggregated number of HCP eligible to work in the hospital for at least 1 day during the week of data collection, excluding denominator-eligible individuals with contraindications as defined by the CDC for all 3 months in a quarter.¹⁶⁹ Facilities report the following four categories of HCP to the NHSN:

- Employees: This includes all persons who receive a direct paycheck from the reporting facility (that is, on the facility's payroll), regardless of clinical responsibility or patient contact.)
- Licensed independent practitioners (LIPs): This includes only physicians (MD, DO), advanced practice nurses, and physician assistants who are affiliated with the reporting facility but are not directly employed by it (that is, they do not receive a paycheck from the reporting facility), regardless of clinical responsibility or patient contact.

Post-residency fellows are also included in this category if they are not on the facility's payroll.

- Adult students/trainees and volunteers: This includes medical, nursing, or other health professional students, interns, medical residents, or volunteers aged 18 or older who are

¹⁶⁷ Centers for Medicare and Medicaid Services. Measures Inventory Tool. Available at: <https://cmit.cms.gov/cmit/#/MeasureView?variantId=11670§ionNumber=1>

¹⁶⁸ The measure steward owns and maintains a measure while a measure developer develops, implements, and maintains a measure. In this case, the CDC serves as both the measure steward and measure developer. For more information on measure development, we refer readers to: Centers for Medicare and Medicaid Services (2023). Roles in Measure Development. Available at: <https://mmshub.cms.gov/about-quality/new-to-measures/roles>.

¹⁶⁹ Centers for Disease Control and Prevention. (2022). Contraindications and precautions. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications>

affiliated with the facility but are not directly employed by it (that is, they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact.

- Other contract personnel: Contract personnel are defined as persons providing care, treatment, or services at the facility through a contract who do not fall into any of the previously discussed denominator categories. This also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract. Facilities are required to enter data on other contract personnel for submission in the NHSN application, but data for this category are not included in the HCP COVID–19 Vaccine measure.¹⁷⁰

We are not proposing to modify the denominator exclusions. The numerator is calculated as the cumulative number of HCP in the denominator population who are considered up to date with CDC recommended COVID–19 vaccine. Guidance issued by the CDC defines the term “up to date” as meeting the CDC’s criteria on the first day of the applicable reporting quarter. The current definition of “up to date” can be found at:

<https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf>.

We propose that public reporting of the modified version of the COVID–19 Vaccination Coverage Among HCP for the Hospital OQR Program would begin with the Fall 2024 Care Compare refresh, or as soon as technically feasible.

(b) CBE Endorsement

The current version of the measure in the Hospital OQR Program received CBE endorsement (CBE#3636) on July 26, 2022.¹⁷¹ The measure steward (CDC) is pursuing endorsement for the modified version of this measure.

¹⁷⁰ For more details on the reporting of other contract personnel, we refer readers to the NHSN COVID–19 Vaccination Protocol, Weekly COVID–19 Vaccination Module for Healthcare Personnel available at: <https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf>

¹⁷¹ Centers for Medicare & Medicaid Services. Measure Specifications for Hospital Workgroup for the 2022 MUC List. Available at: <https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf>

(3) Data Submission and Reporting

We refer readers to the CY 2022 OPPTS/ASC final rule (86 FR 63879 through 63883) for information on data submission and reporting of this measure. While we are not proposing any changes to the data submission or reporting process, we propose that reporting of the updated, modified version of this measure would begin with the CY 2024 reporting period for the Hospital OQR Program. Under the data submission and reporting process, hospitals would collect the numerator and denominator for the COVID–19 Vaccination Coverage Among HCP measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personnel Safety (HPS) Component before the quarterly deadline to meet Hospital OQR Program requirements. If a hospital submits more than one week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, the third week data would be used. Each quarter, the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each hospital, which would be calculated by taking the average of the data from the three weekly rates submitted by the hospital for that quarter. CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC (86 FR 63878). We refer readers to section XV.B of this proposed rule for the same proposal for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.

We invite public comment on this proposal.

b. Proposed Modification of Survey Instrument Use for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Beginning with the Voluntary CY 2024 Reporting Period

(1) Background

In the CY 2014 OPPTS/ASC final rule (78 FR 75102 through 75103), we finalized the adoption of the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (the Cataracts Visual Function) measure, beginning with the CY 2014 reporting

period/CY 2016 payment determination. This measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function within 90 days following the cataract surgery via the administration of pre-operative and post-operative survey instruments (78 FR 75102). A “survey instrument” is an assessment tool that has been appropriately validated for the population for which it being used.¹⁷² For purposes of this proposed modification to the Cataracts Visual Function measure, the survey instruments we considered and propose assess the visual function of a patient pre- and post-operatively to determine whether the patient’s visual function changed within 90 days of cataract surgery. Currently, examples of survey instruments assessing visual function include, but are not limited to, the National Eye Institute Visual Function Questionnaire (NEI-VFQ), the Visual Function (VF-14), the modified (VF-8), the Activities of Daily Vision Scale (ADVS), the Catquest, and the modified Catquest-9. While the measure has been available for voluntary reporting in the Hospital OQR Program since the CY 2015 reporting period, a number of facilities have reported data consistently using the survey instrument-collection method of their choice (87 FR 72098). We refer readers to the Cataracts Visual Function measure’s Measure Information Form (MIF) and the Hospital OQR Program Specifications Manual for additional detail, which is available at: <https://qualitynet.cms.gov/outpatient/specifications-manuals>.

In the CY 2015 OPPTS/ASC final rule (79 FR 66947), we expressed concerns that clinicians’ use of varying survey instruments would lead to inconsistent measure results. However, a comparison study conducted of the 16 survey instruments that are currently accepted for use in collecting data for this measure by HOPDs found them to be scientifically valid, able to detect clinically important changes, and provide comparable results.¹⁷³ While all 16 survey

¹⁷² Centers for Medicare & Medicaid Services. (2023). Hospital OQR Specification Manual Version 16.0. Available at: <https://qualitynet.cms.gov/outpatient/specifications-manuals#tab1>

¹⁷³ McAlinden C, Gothwal VK, Khadka J, et al. (2011). A head-to-head comparison of 16 cataract surgery outcome questionnaires. *Ophthalmology*, 118(12), 2374–81. <https://doi.org/10.1016/j.ophtha.2011.06.008>

instruments demonstrate usefulness for detecting clinically important changes in cataract patients, some survey instrument's detection sensitivity scored higher than others.¹⁷⁴

Several commenters responding to the CY 2022 OPPI/ASC proposed rule (86 FR 63846) requested additional guidance from CMS regarding measure specifications and survey instruments. We agree that the use of survey instruments for the assessment of visual function pre- and post-cataract surgery should be clarified. The use of survey instruments should be standardized across HOPDs to minimize collection and reporting burden, as well as to improve measure reliability. We propose to clarify which specific survey instruments may be used for the assessment of visual function pre- and post- cataract surgery for the Cataracts Visual Function measure in both the Hospital OQR Program and the ASCQR Program, to ensure alignment of this measure's specifications across our quality reporting programs. Thus, we propose to limit the allowable survey instruments that an HOPD may use to assess changes in patient's visual function for the purposes of the Cataracts Visual Function measure to those listed below:

- The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25)
- The Visual Functioning Patient Questionnaire (VF-14)
- The Visual Functioning Index Patient Questionnaire (VF-8R)

(2) Considerations for the Standardization of Survey Instruments Assessing Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery

We took into consideration several factors when identifying which specific survey instruments would be acceptable for HOPDs to use when collecting data for the Cataracts Visual Function measure, such as comprehensiveness, validity, reliability, length, and burden. We believe that these three proposed survey instruments will allow HOPDs to select the length of the

¹⁷⁴ Ibid.

survey to be administered while ensuring adequate validity and reliability.^{175,176,177} All three of these proposed surveys are based upon the 51-item National Eye Institute Visual Function Questionnaire (NEI VFQ-51) survey instrument, which was the first survey instrument originally developed for assessing a patient’s visual function before and after cataract surgery. Each of the three proposed survey instruments have progressively fewer numbers of questions than the NEI VFQ-51: 25 questions for the NEI VFQ-25, 14 questions for the VF-14, and 8 questions for the VF-8R. Even with fewer numbers of questions, all three of the proposed survey instruments have been validated as providing results comparable to the NEI VFQ-51. In addition, all three of the proposed survey instruments are readily available for hospitals to access and use.

We propose to allow HOPDs to use the NEI VFQ-25 for administering and calculating the Cataracts Visual Function measure due to its comprehensiveness, its adequate validity and reliability, as well as its potential to reduce language barriers for patients. The NEI VFQ-25 is a shorter version of the NEI VFQ-51, being comprised of 25 items across 12 vision-specific domains (general health, general vision, ocular pain, near activities, distance activities, social functioning, mental health, role difficulties, dependency, driving, color vision, and peripheral vision).¹⁷⁸

The NEI VFQ-25, similar to the VF-14 and VF-8R, displays adequate reliability and validity.¹⁷⁹ The NEI VFQ-25 composite, near activities, and distance activities subscales demonstrated good internal consistency reliability, test-retest reliability, convergent validity, and

¹⁷⁵ Sivaprasad S, Tschosik E, Kapre A, et al. (2018). Reliability and construct validity of the NEI VFQ-25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. *American Journal of Ophthalmology*, 190, 1–8. <https://doi.org/10.1016/j.ajo.2018.03.006>

¹⁷⁶ Hecht I, Kanclerz P, & Tuuminen R. (2022). Secondary outcomes of Lens and cataract surgery: More than just “best-corrected visual acuity”. *Progress in Retinal and Eye Research*, 101150. <https://doi.org/10.1016/j.preteyeres.2022.101150>

¹⁷⁷ Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient’s visual function within 90 days following cataract surgery. Mdinteractive. Available at: https://mdinteractive.com/mips_measure/2023-mips-quality-measure-303

¹⁷⁸ U.S. Department of Health and Human Services. *Visual function questionnaire 25*. National Eye Institute. Available at: <https://www.nei.nih.gov/learn-about-eye-health/outreach-campaigns-and-resources/outreach-materials/visual-function-questionnaire-25>

¹⁷⁹ Sivaprasad S, Tschosik E, Kapre A, et al. (2018). Reliability and construct validity of the NEI VFQ-25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. *American Journal of Ophthalmology*, 190, 1–8. <https://doi.org/10.1016/j.ajo.2018.03.006>

known-groups validity.¹⁸⁰ Furthermore, the NEI VFQ-25's high internal consistency, indicates that items of the NEI VFQ-25 are highly related to each other and to the scale as a whole.¹⁸¹

In addition, the survey instrument is publicly available on the RAND website at no cost and has been translated to many languages, which is a valuable benefit for patients with limited English proficiency. The NEI VFQ-25 was chosen over other survey instruments to reduce potential language barriers, as, for example, the currently available Activities of Daily Vision Scale (ADVS) is dependent on English language skills.¹⁸² More information on the NEI VFQ-25 can be found at: https://www.rand.org/health-care/surveys_tools/vfq.html.

While the NEI VFQ-25 was shortened significantly from the original NEI VFQ-51, it has been criticized for its still lengthy test-time. However, our proposal to include this survey instrument in this measure's specifications allows for a more detailed assessment of cataract surgery outcomes, as it was designed to include questions which are most important for persons who have chronic eye diseases.¹⁸³ Further, if a hospital finds the NEI VFQ-25 particularly burdensome to administer, the hospital may choose from the other two survey instruments we propose for inclusion in this measure's specifications, as both of these have even fewer survey questions to administer.

We also propose to allow HOPDs to use the 14-item VF-14 and the 8-item VF-8R for administering and calculating the Cataracts Visual Function measure, which each can be administered in a shorter timeframe than the NEI VFQ-25 with high precision.^{184,185} Thus, the succinct formats of the VF-14 and VF-8R may ease HOPD's burden in administering the survey

¹⁸⁰ Ibid.

¹⁸¹ Ibid.

¹⁸² Mangione CM, Phillips RS, Seddon JM, et al. (1992). Development of the 'Activities of Daily Vision Scale'. A measure of visual functional status. *Med Care*, 30(12), 1111-1126. <https://doi.org/10.1097/00005650-199212000-00004>

¹⁸³ Hecht I, Kanclerz P, & Tuuminen R. (2022). Secondary outcomes of Lens and cataract surgery: More than just "best-corrected visual acuity." *Progress in Retinal and Eye Research*, 101150. <https://doi.org/10.1016/j.preteyeres.2022.101150>

¹⁸⁴ Ibid.

¹⁸⁵ Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Available at: https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303

instruments and potentially increase the rate of patient responses for this measure, as compared with other survey instrument options we considered. Therefore, we propose the VF-14 and VF-8R for this measure's data collection specifications because we believe these survey instruments achieve comparable results with the longer NEI VFQ-25 and NEI VFQ-51 survey instruments with substantially fewer questions to administer.

Furthermore, we propose inclusion of the VF-14 because currently it is the most commonly used survey instrument and we believe it would be beneficial to allow the majority of physicians who have already been using VF-14 to continue to have the option to do so.¹⁸⁶ The VF-14 is comprised of 14 items relating to daily living activities and function, such as reading, writing, seeing steps, stairs or curbs, and operating a motor vehicle.¹⁸⁷ Studies using this survey instrument generally report significant and clinically important improvement following cataract surgery.¹⁸⁸ The VF-14 additionally has achieved adequate reliability and validity, proving it to be a dependable survey instrument for cataract outcomes.^{189,190}

We propose the VF-8R as it is the most concise of the three survey instruments, while still achieving adequate validity and reliability.¹⁹¹ The VF-8R consists of questions related to reading, fine handwork, writing, playing board games, and watching television.¹⁹² Given its conciseness compared to the majority of currently available survey instruments and its adequate psychometric properties, we believe that the VF-8R would be beneficial for measuring cataract surgery outcomes without prompting further patient survey fatigue.¹⁹³

¹⁸⁶ Hecht, I., Kanclerz, P., & Tuuminen, R. (2022). Secondary outcomes of Lens and cataract surgery: More than just "best-corrected visual acuity." *Progress in Retinal and Eye Research*, 101150. <https://doi.org/10.1016/j.preteyeres.2022.101150>

¹⁸⁷ Ibid.

¹⁸⁸ Ibid.

¹⁸⁹ Ibid.

¹⁹⁰ Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Retrieved March 13, 2023, from https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303

¹⁹¹ Ibid.

¹⁹² Pre-Cataract Surgery – Visual Functioning Index (VF-8R) patient. (n.d.). <https://eyecaresite.com/wp-content/uploads/2020/02/Visual-Functioning-Index-Pre-Cat-SX.pdf>

¹⁹³ Ibid.

For these reasons, we believe that the NEI VFQ-25, VF-14, and VF-8R are the most appropriate survey instruments for HOPDs to use to assess a patient's visual function pre- and post-cataract surgery for purposes of calculating and submitting data for the Cataracts Visual Function measure in the Hospital OQR Program.

In response to commenters' concerns as summarized in the CY 2023 OPPTS/ASC final rule (87 FR 72097 through 72099) regarding the lack of specificity around survey instrument administration for the Cataracts Visual Function measure, we propose to limit the survey instruments that can be used to administer this measure, beginning with the voluntary CY 2024 reporting period, to these three survey instruments: (1) NEI VFQ-25; (2) VF-14; and (3) VF-8R. We believe the use of these three survey instruments to report data on the Cataracts Visual Function measure would allow for a more standardized approach to data collection. Having a limited number of allowable survey instruments would also address commenters' requests for additional guidance on survey instruments as well as improve measure reliability.

(3) Considerations for Data Collection Modes for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Beginning with the Voluntary CY 2024 Reporting Period

As summarized in the CY 2023 OPPTS/ASC final rule (87 FR 72104 through 72105), many commenters expressed concern about the high administrative burden of reporting the Cataracts Visual Function measure, as the measure uniquely requires coordination among clinicians of different specialties (that is, opticians and ophthalmologists). In an effort to decrease administrative burden surrounding in-office time constraints, we reiterate that, while we recommend the patient's physician or optometrist administer, collect, and report the survey instrument results to the HOPD, the survey instruments required for this measure can be administered by the HOPD itself via phone, by the patient via regular or electronic mail, or during clinician follow-up.

Scientific literature supports the conclusion that self-administered survey instruments produce statistically reliable results.^{194,195} Furthermore, scientific literature indicates that regular mail and electronic mail surveys respectively, are preferred by varying subgroups of patients. The inclusion of both options ensures that patients will be able to respond to surveys in their preferred format.^{196,197} These findings support the inclusion of varying survey instrument-collection methods for patient and provider convenience.

We invite public comment on this proposal.

c. Proposed Modification of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Denominator Change to Align with Current Clinical Guidelines Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

(1) Background

In 2019, colorectal cancer (CRC) accounted for the 4th highest rate of new cancer cases and the 4th highest rate of cancer deaths in the United States.¹⁹⁸ The American Cancer Society (ACS) estimates that in 2023, 153,020 individuals will be newly diagnosed with CRC and 52,550 individuals will die from CRC in the United States.¹⁹⁹ The CDC advises, “[c]olorectal cancer almost always develops from precancerous polyps (abnormal growths) in the colon or rectum. Screening tests can find precancerous polyps, so that they can be removed before they turn into cancer. Screening tests can also find colorectal cancer early, when treatment works

¹⁹⁴ Bhandari NR, Kathe N, Hayes C, & Payakachat N. (2018). Reliability and validity of SF-12V2 among adults with self-reported cancer. *Research in Social and Administrative Pharmacy*, 14(11), 1080–1084. <https://doi.org/10.1016/j.sapharm.2018.01.007>

¹⁹⁵ Stolwijk C, van Tubergen A, Ramiro S, et al. (2014). Aspects of validity of the self-administered comorbidity questionnaire in patients with ankylosing spondylitis. *Rheumatology*, 53(6), 1054–1064. <https://doi.org/10.1093/rheumatology/ket354>

¹⁹⁶ Kelfve S, Kivi M, Johansson B, & Lindwall M. (2020). Going web or staying paper? the use of web-surveys among older people. *BMC Medical Research Methodology*, 20(1), 252. <https://doi.org/10.1186/s12874-020-01138-0>

¹⁹⁷ Meyer VM, Benjamins S, Moumni ME, et al. (2020). Global overview of response rates in patient and health care professional surveys in surgery. *Annals of Surgery*, 275(1). <https://doi.org/10.1097/sla.0000000000004078>

¹⁹⁸ Centers for Disease Control and Prevention. (2022). Colorectal Cancer Statistics. Available at: <https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/>

¹⁹⁹ American Cancer Society. (2023). Cancer Facts & Figures 2023. Available at: <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2023-cancer-facts-figures.html>

best. Regular screening, beginning at age 45, is the key to preventing colorectal cancer and finding it early.”²⁰⁰

In May 2021, the United States Preventive Services Task Force (USPSTF) issued a revised Final Recommendation Statement on CRC Screening.²⁰¹ This replaced the prior USPSTF 2016 Final Recommendation Statement and included a number of updated policy recommendations based on new evidence and understandings of CRC and CRC screening. The USPSTF recommended that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of the previous recommendation of age 50.²⁰² In addition, multiple professional organizations, including the ACS, American Society of Colon and Rectal Surgeons, and the U.S. Multi-Society Task Force on Colorectal Cancer (which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy), recommend that people of average risk of CRC start regular screening at age 45.^{203,204,205} Based on the recent changes in clinical guidelines to begin CRC screening at age 45 instead of age 50, we propose to modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the Colonoscopy Follow-Up Interval) measure to follow these clinical guideline changes.

(2) Overview of Measure

We refer readers to the CMS Measures Inventory Tool and the Hospital OQR Program specification manual for more information on the Colonoscopy Follow-Up Interval measure,

²⁰⁰ Centers for Disease Control and Prevention. (2022). What Should I Know About Screening? Available at: https://www.cdc.gov/cancer/colorectal/basic_info/screening/index.htm

²⁰¹ US Preventive Services Task Force. (2021). Screening for Colorectal Cancer. *JAMA*, 325(19), 1965-1977. <https://doi.org/10.1001/jama.2021.6238>

²⁰² Ibid.

²⁰³ Wolf A, Fontham ETH, Church TR, et al. (2018). Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA. Cancer J. Clin.*, 2018(68), 250-281. <https://doi.org/10.3322/caac.21457>

²⁰⁴ American Society of Colon & Rectal Surgeons. Colorectal Cancer Screening and Surveillance Recommendations of U.S. Multisociety Task Force. Available at: <https://fascrs.org/healthcare-providers/education/clinical-practice-guidelines/colorectal-cancer-screening-and-surveillance-recom>

²⁰⁵ Patel SG, May FP, Anderson JC, Burke CA, et al. (2022). Updates on Age to Start and Stop Colorectal Cancer Screening: Recommendations From the U.S. Multi-Society Task Force on Colorectal Cancer. *The American Journal of Gastroenterology*, 117(1), 57-69. <https://doi.org/10.14309/ajg.0000000000001548>

including background on the measure and a complete summary of measure specifications.^{206,207}

Currently, the Colonoscopy Follow-Up Interval measure assesses the “percentage of patients aged 50 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.”²⁰⁸ We propose to amend the measure’s denominator language by replacing the phrase “aged 50 years” with the phrase “aged 45 years.” The measure denominator would be modified to “all patients aged *45 years to 75 years* receiving screening colonoscopy without biopsy or polypectomy” from “all patients aged *50 years to 75 years* receiving screening colonoscopy without biopsy or polypectomy.”²⁰⁹ We are not proposing any changes to the measure numerator, other measure specifications, exclusions, or data collection for the Colonoscopy Follow-Up Interval measure.

In the CY 2023 Physician Fee Schedule final rule (87 FR 69760 through 69767), we adopted the modified Colonoscopy Follow-Up Interval measure (which we propose here for the Hospital OQR Program) for the Merit-based Incentive Payment System (MIPS). We have considered the importance of aligning the minimum age requirement for CRC screening across quality reporting programs and clinical guidelines. As a result, we propose to modify the Colonoscopy Follow-Up Interval measure denominator to “all patients aged 45 to 75 years” for the Hospital OQR Program. We propose the modification of the Colonoscopy Follow-Up Interval measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

We invite public comment on this proposal.

²⁰⁶ Centers for Medicare & Medicaid Services. (2023). Measures Inventory Tool. Available at: <https://cmit.cms.gov/cmit/#/MeasureView?variantId=793§ionNumber=1>

²⁰⁷ Centers for Medicare & Medicaid Services. Qualitynet Home. Available at: <https://qualitynet.cms.gov/outpatient/specifications-manuals>

²⁰⁸ Centers for Medicare & Medicaid Services. (2023). Measures Inventory Tool. Available at: <https://cmit.cms.gov/cmit/#/MeasureView?variantId=793§ionNumber=1>

²⁰⁹ Ibid.

3. Proposed Adoption of New Measures for the Hospital OQR Program Measure Set

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus-based entities. We have noted in previous rulemaking, the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from CBE endorsement, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment (75 FR 72064).

Section 1890A of the Act requires that we establish and follow a pre-rulemaking process for selecting quality and efficiency measures for our programs, including taking into consideration input from multi-stakeholder groups. As part of this pre-rulemaking process, the CBE, with which we contract under section 1890 of the Act, convened these groups under the Measure Applications Partnership (MAP). The MAP is a public-private partnership created for the primary purpose of providing input to HHS on the selection of measures as required by section 1890(b)(7)(B) of the Act. We followed this pre-rulemaking process for the measures we propose for adoption for the Hospital OQR Program under this section of the proposed rule, as further detailed below.

In this proposed rule, we propose to: (1) re-adopt the original Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures with modification, beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (2) adopt the 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), beginning with the voluntary CYs 2025 and 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting

period/CY 2030 payment determination; and (3) adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults measure, beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. In this section of the proposed rule, we provide additional information on these measure adoption proposals.

a. Proposed Re-adoption with Modification of the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures Measure Beginning with the Voluntary CY 2025 Reporting Period Followed By Mandatory Reporting Beginning with the CY 2026 Reporting Period/CY 2028 Payment Determination

(1) Background

Hospital care has been gradually shifting from inpatient to outpatient settings.²¹⁰ Research indicates that volume of services performed in HOPDs will continue to grow, with some estimates projecting a 19 percent increase in patients between 2019 and 2029.²¹¹ In light of this trend, it has become even more important to track volume within HOPDs. Larger facility surgical procedure volume may be associated with better outcomes due to having characteristics that improve care, such as efficient team work and increased surgical experience, discussed in more detail below.²¹² Given the association between volume and outcomes, this information could provide valuable insight to patients when choosing a HOPD.

Although measuring the volume of procedures and other services has a long history as a quality metric, quality measurement efforts had moved away from collecting and analyzing data on volume because some considered volume simply a proxy for quality compared to directly measuring outcomes.²¹³ However, experts on quality and safety have recently suggested that

²¹⁰ Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3. Available at: https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf

²¹¹ Sg2. (2021). Sg2 Impact of Change Forecast Predicts Enormous Disruption in Health Care Provider Landscape by 2029. Available at: <https://www.sg2.com/media-center/press-releases/sg2-impact-forecast-predicts-disruption-health-care-provider-landscape-2029/>

²¹² Jha AK. (2015) Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015. <https://jamanetwork.com/channels/health-forum/fullarticle/2760155>

²¹³ Ibid.

while volume alone may not indicate or lead to better outcomes, it is still an important component of quality.^{214,215,216} Specifically, larger facility surgical procedure volume may be associated with better outcomes due to having characteristics that improve care.²¹⁷ For example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications.²¹⁸ This association between volume and patient outcomes may be attributable to greater experience or surgical skill, greater comfort with and, hence, likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure.

The Hospital OQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but it did so previously. We refer readers to the CY 2012 OPSS/ASC final rule (76 FR 74466 through 74468) where we adopted the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures (HOPD Procedure Volume) measure beginning with the CY 2014 payment determination. This structural measure of facility capacity collected surgical procedure volume data on nine categories of procedures frequently performed in the hospital outpatient setting: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, Skin, and Other.²¹⁹ We adopted the HOPD Procedure Volume measure based on evidence that the volume of surgical procedures, particularly of high-risk surgical procedures, is related to better patient

²¹⁴ Ibid.

²¹⁵ Shang M, Mori M, Gan G, et al. (2022). Widening volume and persistent outcome disparity in Valve Operations: New York Statewide Analysis, 2005-2016. *The Journal of Thoracic and Cardiovascular Surgery*, 164(6). <https://doi.org/10.1016/j.jtcvs.2020.11.098>

²¹⁶ Iwatsuki M, Yamamoto H, Miyata H, et al. (2018). Effect of hospital and surgeon volume on postoperative outcomes after distal gastrectomy for gastric cancer based on data from 145,523 Japanese patients collected from a nationwide web-based data entry system. *Gastric Cancer*, 22(1), 190–201. <https://doi.org/10.1007/s10120-018-0883-1>

²¹⁷ Jha AK. (2015) Back to the Future: Volume as a Quality Metric. *JAMA Forum Archive*. Published online June 10, 2015. <https://jamanetwork.com/channels/health-forum/fullarticle/2760155>

²¹⁸ Ibid.

²¹⁹ Centers for Medicare & Medicaid Services. (2016). Hospital Outpatient Specifications Manuals version 9.1. Available at: <https://qualitynet.cms.gov/outpatient/specifications-manuals#tab9>

outcomes, including decreased mortality (76 FR 74466).^{220,221} We further stated our belief that publicly reporting volume data would provide patients with beneficial information to use when selecting a care provider (76 FR 74467).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59429 through 59430), we removed the HOPD Procedure Volume measure, stating our belief at that time that there is a lack of evidence to support this specific measure's link to improved clinical quality. Although there is currently increased evidence of a link between patient volume and better patient outcomes, we previously stated that we believed that there was a lack of evidence that this link was reflected in the HOPD Procedure Volume measure. At the time, we stated that measuring the number of surgical procedures does not offer insight into the facilities' overall performance or quality improvement in regard to surgical procedures (82 FR 59429). Thus, we removed the HOPD Procedure Volume measure beginning with the CY 2020 payment determination based on 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).

In the CY 2023 OPPS/ASC proposed rule (87 FR 44730 through 44732), we stated that we have been considering re-adopting the HOPD Procedure Volume measure with modification for two reasons. First, since the removal of the HOPD Procedure Volume measure, scientific literature has concluded that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care.²²² Further supporting this position that volume metrics are an indicator of quality, one study found an inverse volume–mortality relationship related to

²²⁰ Saito Y, Tateishi K, Kanda M, et al. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association*, 11(6). <https://doi.org/10.1161/jaha.121.023805>

²²¹ Vemulapalli S, Carroll J, Mack, M, et al. (2019) Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. <https://doi.org/10.1056/NEJMsa1901109>

²²² Ogola GO, Crandall ML, Richter KM, & Shafi S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*, 85(3), 560–565. <https://doi.org/10.1097/TA.0000000000001985>

transfemoral transcatheter aortic-valve replacement (TAVR) procedures performed from 2015 through 2017.²²³ Second, as discussed above, the recent shift of more surgical procedures being performed in outpatient settings has placed greater importance on tracking the volume of outpatient procedures in different settings, including HOPDs. Given these developments, we believe that patients may benefit from the public reporting of facility-level volume measure data that reflect the procedures performed across hospitals, provide the ability to track volume changes by facility and procedure category, and can serve as an indicator for patients of which facilities are experienced with certain outpatient procedures.

In response to our request for comment in the CY 2023 OPPTS/ASC proposed rule (87 FR 44730 through 44732), regarding the potential re-adoption of the Hospital Outpatient Surgical measure, several commenters expressed concern that the burden of collecting and reporting data for the measure outweighs its value (87 FR 72104 through 72105). Before its removal from the Hospital OQR Program, the HOPD Procedure Volume measure was the only measure that captured facility-level volume within HOPDs and volume for Medicare and non-Medicare patients. As a result, the Hospital OQR Program currently does not capture surgical procedure volume in HOPDs. We recognize that we can determine facility volumes for procedures performed using Medicare Fee-For-Service (FFS) claims. However, the specifications for the HOPD Procedure Volume measure also include reporting data for non-Medicare patients; thus, relying solely on the use of Medicare FFS claims data to simplify reporting would limit a future volume measure to only the Medicare program payer, leading to an incomplete representation of procedural volume.²²⁴

In addition, in response to our request for comment in the CY 2023 OPPTS/ASC proposed rule (87 FR 44730 through 44732), some commenters expressed their belief that volume is not a

²²³ Vemulapalli S, Carroll J, Mack M, et al. (2019). Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. <https://doi.org/10.1056/NEJMsa1901109>

²²⁴ The specifications for the removed HOPD Procedure Volume measure are available in the Hospital Outpatient Specifications Manuals version 9.1 available at <https://qualitynet.cms.gov/outpatient/specifications-manuals#tab9>

clear indicator of care quality and therefore procedure volume data would not be useful to consumers (87 FR 72104 through 72105). However, many studies in recent years have shown that volume does serve as an indicator of quality of care.^{225,226} For example, studies published since the CY 2018 OPPI/ASC final rule found that patients at high volume hospitals for a specific procedure had lower rates of surgical site infections, complications, and mortality compared to patients at low-volume hospitals.^{227,228} We reiterate our belief, grounded in this published scientific literature, that volume metrics serve as an indicator of which facilities have experience with certain outpatient procedures and assist consumers in making informed decisions about where they receive care, acknowledging that many studies in recent years have shown that volume does serve as an indicator of quality of care.^{229,230}

(2) Overview of Measure

(a) Data Collection, Submission, Reporting, and Measure Specifications

The proposed HOPD Procedure Volume measure collects data regarding the aggregate count of selected surgical procedures. Most frequent outpatient procedures fall into one of eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.²³¹ For this proposed measure, data surrounding the top five most frequently performed procedures among HOPDs in each category would be collected and

²²⁵ Ogola, GO, Crandall, ML, Richter, KM, & Shafi, S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*, 85(3), 560–565. <https://doi.org/10.1097/TA.0000000000001985>

²²⁶ Vemulapalli S, Carroll J, Mack M, et al. (2019) Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. <https://doi.org/10.1056/NEJMsa1901109>

²²⁷ Mufarrih SH, Ghani MOA, Martins RS, et al. (2019) Effect of hospital volume on outcomes of total hip arthroplasty: a systematic review and metaanalysis. *J Orthop Surg Res* 14, 468. <https://doi.org/10.1186/s13018-019-1531-0>

²²⁸ Saito Y, Tateishi K, Kanda M, et al. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association*, 11(6). <https://doi.org/10.1161/jaha.121.023805>

²²⁹ Ogola GO, Crandall ML, Richter KM, Shafi, S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*, 85(3), 560–565. <https://doi.org/10.1097/TA.0000000000001985>

²³⁰ Vemulapalli S, Carroll J, Mack M, et al. (2019). Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. <https://doi.org/10.1056/NEJMsa1901109>

²³¹ Centers for Medicare & Medicaid Services. (2016). Hospital Outpatient Specifications Manuals version 9.1. Available at: <https://qualitynet.cms.gov/outpatient/specifications-manuals#tab9>

publicly displayed. The top five procedures in each category would be assessed and updated annually as needed to ensure data collection of most accurate and frequently performed procedures.²³²

We propose that hospitals would submit aggregate-level data through the CMS Web-based tool (currently, the Hospital Quality Reporting (HQR) system), consistent with what was required during the measure's initial adoption (76 FR 74467). Data received through the HQR system would then be publicly displayed on Care Compare or another CMS website. We refer readers to the CY 2009, CY 2014, and CY 2017 OPSS/ASC final rules (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures.

We propose to re-adopt the HOPD Procedure Volume measure with modification, with voluntary reporting beginning with the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. At the time of this measure's initial adoption in the CY 2012 OPSS/ASC final rule, (76 FR 74468) we finalized that HOPDs would report all-patient volume data with respect to the eight categories mentioned prior. In response to commenter concerns regarding potential difficulty detecting procedural volume differentiation among these broad based categories (76 FR 74467), the sole modification to this measure is that instead of collecting and publicly displaying data surrounding these eight broad categories, we would more granularly collect and publicly display data reported for the top five most frequently performed procedures among HOPDs within each category. We refer readers to the Center for Medicare and Medicaid Services Inventory Tool for more information on this measure: <https://cmit.cms.gov/cmit/#/>.

We also propose that HOPDs submit these data to CMS during the time period of January 1 through May 15 in the year prior to the affected payment determination year. For example, for the CY 2028 payment determination, the data submission period would be January 1, 2027 to

²³² Data source: Part A and B claims for Outpatient Hospitals for services January 1, 2022 - December 31, 2022.

May 15, 2027, covering the performance period of January 1, 2026 to December 31, 2026. We refer readers to section XIV.E.5 of this proposed rule for a more detailed discussion of the requirements for data submitted via a CMS Web-based tool. We previously codified our existing policies regarding data collection and submission under the Hospital OQR Program at § 419.46.

(b) Review by the Measure Applications Partnership (MAP)

The MAP conditionally supported the HOPD Procedure Volume measure for rulemaking, pending testing indicating that the measure is reliable and valid, and endorsement by the CBE.²³³ The MAP acknowledged that the measure reports the volume of procedures performed at HOPDs in select categories reflecting typical high-volume categories of procedures and stated that the measure would capture the volume for many procedures not currently monitored by the Hospital OQR Program measure set. Furthermore, the MAP expressed its belief that measuring the volume of procedures would relate to the program's goals of improving the safety and quality of outpatient procedures in HOPDs.²³⁴ The MAP added that electronic reporting of procedure volumes based on code lists should not be overly burdensome to hospitals, and the public reporting of specific procedure volumes may be useful to patients.²³⁵

The MAP described that there is a well-established positive correlation between the volume of procedures performed at a facility and the clinical outcomes resulting from that procedure. One systematic review highlighted by the MAP found a significant volume-outcome relationship in the vast majority (87 percent) of the 403 included studies.²³⁶ Furthermore, the MAP included a similar review in their analysis of the HOPD Procedure Volume measure that

²³³ Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>

²³⁴ Ibid.

²³⁵ Ibid.

²³⁶ Levaillant M, Marcilly R, Levaillant L, et al. (2021). Assessing the hospital volume-outcome relationship in surgery: A scoping review. *BMC Medical Research Methodology*, 21(1). [https://doi.org/10.1186/s12874-021-01396-](https://doi.org/10.1186/s12874-021-01396-6)

also focused on outpatient surgeries, which found a significant volume-outcome relationship across eight studies.²³⁷

The MAP stated that this measure addresses a national trend where even complex surgeries are moving from inpatient to outpatient settings, and that public reporting of this measure could help CMS and the public better understand possible quality differences between settings.²³⁸ The MAP reported that the HOPD Procedure Volume measure data from 2015 and 2016 demonstrates that the number of procedures performed by facilities in the 25th and 75th percentiles varied across the condition categories.²³⁹ These findings support our belief that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care.^{240,241}

In addition, the MAP noted the concurrent submission of MUC 2022-028: ASC Facility Volume Data on Selected Surgical Procedures for inclusion in the ASCQR Program. The MAP highlighted that the specifications of the volume measure proposal for the ASCQR Program are aligned with the volume measure we propose for the Hospital OQR Program and, therefore would facilitate comparisons of equivalent procedure volumes across ambulatory surgical centers (ASCs) and HOPDs, one of the key goals of the programs.²⁴²

²³⁷ Stanak M, & Strohmaier C. (2020). Minimum volume standards in day surgery: A systematic review. *BMC Health Services Research*, 20(1). <https://doi.org/10.1186/s12913-020-05724-2>

²³⁸ Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: <https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/>

²³⁹ Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>

²⁴⁰ Ogola GO, Crandall ML, Richter KM, & Shafi S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*, 85(3), 560–565. <https://doi.org/10.1097/TA.0000000000001985>

²⁴¹ Saito Y, Tateishi K, Kanda M, et al. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association*, 11(6). <https://doi.org/10.1161/jaha.121.023805>

²⁴² Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>

(c) Measure Endorsement

As discussed in the previous subsection of the proposed rule, the MAP reviewed and conditionally supported the HOPD Procedure Volume measure pending testing indicating the measure is reliable and valid, and endorsement by a national consensus-based entity as the measure was not submitted for endorsement. As we noted in previous rulemaking (75 FR 72064), the requirement that measures reflect consensus among affected parties can be achieved in ways other than from endorsement by a national consensus-based entity, including the measure development process, broad acceptance of the measure(s), use of the measure(s), and public comment.

We considered the MAPs recommendation and propose to adopt the measure because we did not find any other measures of procedure volume. Additionally, this measure was previously in the program with supporters of its use. Given the support from the MAP and feedback from public comment, as well as the increasing shift from inpatient to outpatient surgical procedures and evidence that volume metrics can promote higher quality healthcare for patients, we propose adoption of this measure in the Hospital OQR Program pending endorsement by a national consensus-based entity.

We invite public comment on this proposal.

b. Proposed Adoption of the 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) Beginning with Voluntary CYs 2025 and 2026 Reporting Periods Followed By Mandatory Reporting Beginning with the CY 2027 Reporting Period/CY 2030 Payment Determination

(1) Background

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257), we adopted the THA/TKA PRO-PM in the Hospital Inpatient Quality Reporting (IQR) Program beginning with voluntary FY 2025 and FY 2026 reporting periods, followed by mandatory reporting for eligible

elective procedures occurring July 1, 2024 through June 30, 2025 for the FY 2028 payment determination. In this proposed rule, we propose the adoption of the THA/TKA PRO-PM into the Hospital OQR Program using the same specifications as finalized for the hospital-level measure adopted into the Hospital IQR Program (87 FR 49246 through 49257), with modifications to include procedures performed in the HOPD setting.

Approximately six million adults aged 65 or older suffer from osteoarthritis in the United States.²⁴³ In 2013, there were approximately 568,000 hospitalizations billed to Medicare for osteoarthritis.²⁴⁴ Hip and knee osteoarthritis is one of the leading causes of disability among non-institutionalized adults,^{245,246} and roughly 80 percent of patients with osteoarthritis have some limitation in mobility.^{247,248} Elective THA and TKA are most commonly performed for degenerative joint disease or osteoarthritis, which affects more than 30 million Americans.²⁴⁹ THA and TKA offer the potential for significant improvement in quality of life by decreasing pain and improving function in a majority of patients, without resulting in a high risk of complications or death.^{250,251,252} However, not all patients experience benefit from these

²⁴³ Arthritis Foundation. (2018). Arthritis By the Numbers Book of Trusted Facts and Figures. Accessed March 8, 2019. Available at: <https://www.arthritis.org/getmedia/e1256607-fa87-4593-aa8a-8db4f291072a/2019-abtn-final-march2019.pdf>

²⁴⁴ Torio CM, & Moore BJ. (2016). National inpatient hospital costs: the most expensive conditions by payer, 2013. HCUP statistical brief #204. Healthcare Cost and Utilization Project (HCUP) Statistical Briefs. Rockville, MD, Agency for Healthcare Research and Quality. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK368492/>

²⁴⁵ Guccione AA, Felson DT, Anderson JJ, et al. (1994). The effects of specific medical conditions on the functional limitations of elders in the Framingham Study. *American journal of public health*, 84(3), 351–358. <https://doi.org/10.2105/AJPH.84.3.351>

²⁴⁶ Barbour KE, Helmick CG, Boring M, & Brady TJ. (2017). Vital Signs: Prevalence of Doctor-Diagnosed Arthritis and Arthritis-Attributable Activity Limitation - United States, 2013-2015. *MMWR Morbidity and mortality weekly report*, 66(9), 246–253. <https://doi.org/10.15585/mmwr.mm6609e1>

²⁴⁷ Michaud CM, McKenna MT, Begg S, et al. (2006). The burden of disease and injury in the United States 1996. *Population health metrics*, 4, 11. <https://doi.org/10.1186/1478-7954-4-11>

²⁴⁸ Theis KA, Murphy LB, Baker NA, & Hootman JM. (2019). When you can't walk a mile: Walking limitation prevalence and associations among middle-aged and older US adults with Arthritis: A cross-sectional, population-based study. *ACR Open Rheumatol*, 1(6), 350-358. <https://doi.org/10.1002/acr2.11046>

²⁴⁹ Centers for Disease Control and Prevention (CDC). Osteoarthritis (OA). Accessed March 8, 2019. Available at: <https://www.cdc.gov/arthritis/basics/osteoarthritis.htm>

²⁵⁰ Rissanen P, Aro S, Slati P, et al. (1995). Health and quality of life before and after hip or knee arthroplasty. *The Journal of arthroplasty*, 10(2), 169–175. [https://doi.org/10.1016/s0883-5403\(05\)80123-8](https://doi.org/10.1016/s0883-5403(05)80123-8)

²⁵¹ Ritter MA, Albohm MJ, Keating EM, et al. (1995). Comparative outcomes of total joint arthroplasty. *The Journal of arthroplasty*, 10(6), 737–741. [https://doi.org/10.1016/s0883-5403\(05\)80068-3](https://doi.org/10.1016/s0883-5403(05)80068-3)

²⁵² Sayah SM, Karunaratne S, Beckenkamp PR, et al. (2021). Clinical Course of Pain and Function Following Total Knee Arthroplasty: A Systematic Review and Meta-Regression. *J Arthroplasty*, 36(12), 3993-4002.e37. <https://doi.org/10.1016/j.arth.2021.06.019>

procedures.²⁵³ Many patients note that their pre-operative expectations for functional improvement have not been met.^{254,255,256,257} In addition, clinical practice variation has been well documented in the United States,^{258,259,260,261,262} readmission and complication rates vary across hospitals,²⁶³ and international experience documents wide hospital-level variation in patient-reported outcome measure results following THA and TKA.²⁶⁴

Due to the absence of recently conducted large scale and uniformly collected patient-reported outcome (PRO) data available from patients undergoing elective primary THA/TKA, we established an incentivized, voluntary PRO data collection opportunity within the Comprehensive Care for Joint Replacement (CJR) model to support measure development.²⁶⁵ Elective THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (such as pain, mobility, and quality of life) can be

²⁵³ National Joint Registry. National Joint Registry for England and Wales 9th Annual Report 2012. Available at: <https://www.hqip.org.uk/resource/national-joint-registry-9th-annual-report-2012/>

²⁵⁴ Suda AJ, Seeger JB, Bitsch RG, et al. (2010). Are patients' expectations of hip and knee arthroplasty fulfilled? A prospective study of 130 patients. *Orthopedics*, 33(2), 76–80. <https://doi.org/10.3928/01477447-20100104-07>

²⁵⁵ Ghomrawi HM, Franco Ferrando N, Mandl LA, et al. (2011). How Often are Patient and Surgeon Recovery Expectations for Total Joint Arthroplasty Aligned? Results of a Pilot Study. *HSS journal: The musculoskeletal journal of Hospital for Special Surgery*, 7(3), 229–234. <https://doi.org/10.1007/s11420-011-9203-6>

²⁵⁶ Harris IA, Harris AM, Naylor JM, et al. (2013). Discordance between patient and surgeon satisfaction after total joint arthroplasty. *The Journal of arthroplasty*, 28(5), 722–727. <https://doi.org/10.1016/j.arth.2012.07.044>

²⁵⁷ Jourdan C, Poiraudau S, Descamps S, et al. (2012). Comparison of patient and surgeon expectations of total hip arthroplasty. *PloS one*, 7(1), e30195. <https://doi.org/10.1371/journal.pone.0030195>

²⁵⁸ Roos EM. (2003). Effectiveness and practice variation of rehabilitation after joint replacement. *Current opinion in rheumatology*, 15(2), 160–162. <https://doi.org/10.1097/00002281-200303000-00014>

²⁵⁹ Anderson FA, Huang W, Friedman RJ, et al. (2012). Prevention of venous thromboembolism after hip or knee arthroplasty: findings from a 2008 survey of US orthopedic surgeons. *The Journal of arthroplasty*, 27(5), 659–666 e655. <https://doi.org/10.1016/j.arth.2011.09.001>

²⁶⁰ American Academy of Orthopaedic Surgeons. (2011). Preventing Venous Thromboembolic Disease in Patients Undergoing Elective Hip and Knee Arthroplasty: Evidence-Based Guideline and Evidence Report. https://www.aaos.org/globalassets/quality-and-practice-resources/vte/vte_full_guideline_10.31.16.pdf

²⁶¹ Pincus D, et al. (2020). Association Between Surgical Approach and Major Surgical Complications in Patients Undergoing Total Hip Arthroplasty. *JAMA*, 323(11), 1070-1076. <https://doi.org/10.1001/jama.2020.0785>

²⁶² Siebens HC, Sharkey P, Aronow HU, et al. (2016). Variation in Rehabilitation Treatment Patterns for Hip Fracture Treated With Arthroplasty. *PM&R*, 8(3), 191-207. <https://doi.org/10.1016/j.pmrj.2015.07.005>

²⁶³ Suter LG, Parzynski CS, Grady JN, et al. 2013 Measures Update and Specifications: Elective Primary Total Hip Arthroplasty (THA) AND/OR Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 2.0). March 2013. Available at: <http://qualitynet.org/>

²⁶⁴ Rolfson O. (2010). Patient-reported Outcome Measures and Health-economic Aspects of Total Hip Arthroplasty: A study of the Swedish Hip Arthroplasty Register. Accessed July 20, 2013. Available at: https://gupea.ub.gu.se/bitstream/handle/2077/23722/gupea_2077_23722_1.pdf?sequence=1

²⁶⁵ Centers for Medicare & Medicaid Services. Comprehensive Care for Joint Replacement Model. Available at: <https://innovation.cms.gov/innovation-models/cjr>

measured in a scientifically sound way,^{266,267} are influenced by a range of improvements in care,²⁶⁸ and demonstrate hospital-level variation even after patient case mix adjustment.^{269,270} Further, THA/TKA procedures are specifically intended to improve function and reduce pain, making PROs a meaningful outcome metric to assess.²⁷¹

In the CY 2021 OPSS/ASC final rule (85 FR 86146), we announced that THA and TKA procedures were removed from the Inpatient Only Procedures (IPO) list and added to the ASC covered procedures list (CPL).²⁷² As a result, the volume of THA and TKA procedures for Medicare beneficiaries aged 65 years and older have been increasing in outpatient settings.

We analyzed Part B Medicare FFS claims data for the number of HOPD claims with THA/TKA procedures during CY 2020, 2021, and 2022 (Table 65).

TABLE 65: Distribution of Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) claims per Outpatient Hospital CY 2020-2021

CY Year	CPT	CPT Description	#HOPDs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max
2020	27130	ARTH RP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	2341	13	30.26	43.81	1	394
2020	27447	ARTH RP KNE CONDYLE&PLATU MEDIAL&LAT COMPARTMENTS	2668	23	49.57	68.65	1	644
2020	27130 and 27447	All THA/TKA	2753	31	73.77	106.50	1	978

CY	CPT	CPT Description	#HOPDs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max
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²⁶⁶ Liebs TR, Herzberg W, Ruther W, et al. (2016). Quality-adjusted life years gained by hip and knee replacement surgery and its aftercare. *Archives of physical medicine and rehabilitation*, 97(5), 691–700.

<https://doi.org/10.1016/j.apmr.2015.12.021>

²⁶⁷ White D, & Master H. (2016). Patient Reported Measures of Physical Function in Knee Osteoarthritis. *Rheum Dis Clin North Am*, 42(2), 239–252. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4853650/>

²⁶⁸ Kim K, Anoushiravani A, Chen K, et al. (2019). Perioperative Orthopedic Surgical Home: Optimizing Total Joint Arthroplasty Candidates and Preventing Readmission. *Journal of Arthroplasty*, 34(7), S91–S96.

<https://doi.org/10.1016/j.arth.2019.01.020>

²⁶⁹ Bozic KJ, Grosso LM, Lin Z, et al. (2014). Variation in hospital-level risk-standardized complication rates following elective primary total hip and knee arthroplasty. *The Journal of Bone and Joint Surgery*, 96(8), 640–647.

<https://doi.org/10.2106/JBJS.L.01639>

²⁷⁰ Makela KT, Peltola M, Sund R, et al. (2011). Regional and hospital variance in performance of total hip and knee replacements: A national population-based study. *Annals of medicine*, 43(sup1), S31–S38.

<https://doi.org/10.3109/07853890.2011.586362>

²⁷¹ Liebs T, Herzberg W, Gluth J, et al. (2013). Using the patient’s perspective to develop function short forms specific to total hip and knee replacement based on WOMAC function items. *The Bone & Joint Journal*, 95(B), 239–243. <https://doi.org/10.1302/0301-620X.95B2.28383>

²⁷² Centers for Medicare & Medicaid Services. Ambulatory Surgical Center (ASC) Payment. Available at: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment>

2021	27130	ARTHRO ACETABULAR/PROX FEM PROSTHESIS REPLACEMENT	2619	18	37.80	53.19	1	540
2021	27447	ARTHRO KNE CONDYLE AND PLATAU MEDIAL AND LATERAL COMPARTMENTS	2901	30	60.75	86.08	1	1259
2021	27130 and 27447	All THA/TKA	2961	43	92.95	133.68	1	1400

CY	CPT	CPT Description	#HOPDs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max
2022	27130	ARTHRO ACETABULAR/PROX FEM PROSTHESIS REPLACEMENT	2756	21	42.09	63.69	1	1447
2022	27447	ARTHRO KNE CONDYLE AND PLATAU MEDIAL AND LATERAL COMPARTMENTS	3001	36	70.24	98.70	1	1625
2022	27130 and 27447	All THA/TKA	3070	51	106.45	157.11	1	3072

Data source: Part B outpatient claims January 1, 2020 - December 31, 2022 with a CPT code of 27130 or 27447. Claims indicating an ED visit are excluded.

In CY 2022 OPPS/ASC proposed rule (86 FR 42251 through 42252), we requested comment on the potential future adoption of the THA/TKA PRO-PM into the Hospital OQR Program. We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63896 through 63898) for a complete summary of feedback from interested parties.

Many commenters supported inclusion of the THA/TKA PRO-PM to the Hospital OQR Program as procedures move from inpatient to outpatient settings. Commenters noted it was important to monitor quality outcomes and publicly report results. Additionally, commenters stated that the measure is aligned with patient values, being presented in a manner that is easy to understand.

Other commenters did not support expansion of the measure to the Hospital OQR Program, and expressed concern with data collection burden, patient survey fatigue, and reporting thresholds. While we recognize that PRO based performance measures require providers to integrate data collection into clinical workflows, this integration provides opportunity for PROs to inform clinical decision-making and benefits patients by engaging them in discussions about potential outcomes. Furthermore, we do not expect this measure to contribute to survey fatigue as the PRO instruments used to calculate pre- and post-operative scores for this THA/TKA PRO-PM were carefully selected, with extensive input from interested

parties, to be low burden for patients. We refer readers to the CY 2022 OPPTS/ASC final rule (86 FR 63851 through 63854) for a complete summary of feedback.

We propose to adopt the THA/TKA PRO–PM into the Hospital OQR Program beginning with two voluntary reporting periods, followed by mandatory reporting. The first voluntary reporting period would begin with the CY 2025 reporting period for eligible elective outpatient procedures between January 1, 2025 through December 31, 2025, and the second would begin with the CY 2026 reporting period for eligible elective outpatient procedures between January 1, 2026 through December 31, 2026. Mandatory reporting would begin with the CY 2027 reporting period/CY 2030 payment determination for eligible elective outpatient procedures occurring January 1, 2027 through December 31, 2027, impacting the CY 2030 payment determination and subsequent years. Because this proposed measure requires collection of data during the 3-month pre-operative period and the greater than 1-year post-operative period, there is a delay between when the elective THA/TKA procedures actually occur, when the results would be reported under the Hospital OQR Program, and when payment determinations occur. Therefore, we propose a 3-year gap between the reporting period and the payment determination year (for example, CY 2027 reporting period for the CY 2030 payment determination) for the Hospital OQR Program. We refer readers to section XIV.E.7.a of this proposed rule for more information on the reporting requirements.

(2) Overview of Measure

(a) Data Collection, Submission, Reporting, and Measure Specifications

This measure reports the facility-level risk-standardized improvement rate (RSIR) in PROs following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older who were enrolled in Medicare FFS Part A and B for the 12 months prior to the date of the procedure and in Medicare Part A and B during the procedure. The measure includes only elective primary outpatient THA/TKA procedures (patients with fractures and revisions are not included) performed in HOPDs and does not include any inpatient procedures. The measure

excludes patients with staged procedures (multiple elective primary THA or TKA procedures performed on the same patient during distinct encounter) that occur during the measurement period and excludes discontinued procedures (that is, procedures that were started but not completed).²⁷³

Substantial clinical improvement is measured by achieving a pre-defined improvement in score on one of the two validated joint-specific PRO instruments measuring hip or knee pain and functioning: (1) The Hip Dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) for completion by THA recipients; or (2) the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients. Improvement is measured from the pre-operative assessment (data collected 90 to 0 days before surgery) to the post-operative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk-adjusted to account for differences in patient case-mix. The measure, as proposed, accounts for potential non-response bias through inverse probability weighting based on likelihood of response.

We refer readers to the FY 2023 IPPS/LTCH PPS final rule (FR 87 49246 through 49257), for more information on the development of the hospital-level THA/TKA PRO-PM, including background on the measure and a complete summary of measure specifications, data sources, and measure calculation.

For additional details regarding the measure specifications, we also refer readers to the Hip and Knee Arthroplasty Patient-Reported Outcomes file, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology>.

(i) Data Sources

²⁷³ U.S. Department of Health and Human Services. (2021). Hospital Outpatient Prospective Payment System (OPPS): Use of Modifiers –52, -73, and –74 for Reduced or Discontinued Services. Available at: <https://www.hhs.gov/guidance/document/hospital-outpatient-prospective-payment-system-opps-use-modifiers-52-73-and-74-reduced-or>

The THA/TKA PRO-PM uses four sources of data for the calculation of the measure: (1) PRO data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. As described in section XIV.B.3.b(1) of this proposed rule, the measure uses PRO data directly reported by the patient regarding their health, quality of life, or functional status associated with health care or treatment. These patient-reported data are collected by facilities pre-operatively and post-operatively, and limited patient-level risk factor data are collected with PRO data and identified in claims as detailed in this section of the proposed rule.²⁷⁴ The measure includes PRO data collected with the PRO instruments described in this section of the proposed rule, among them are two joint-specific PRO instruments—the HOOS, JR for completion by THA recipients and the KOOS, JR for completion by TKA recipients—from which scores are used to assess substantial clinical improvement. For risk-adjustment by pre-operative mental health score, HOPDs would submit one of two additional PRO instruments, all of the items in either the: (1) Patient-Reported Outcomes Measurement Information System (PROMIS)-Global Mental Health subscale; or (2) Veterans RAND 12-Item Health Survey (VR-12) Mental Health subscale. The risk model also includes a one-question patient-reported assessment of health literacy—the Single Item Literacy Screener questionnaire.

Furthermore, the following data would be collected for identification of the measure cohort, for risk-adjustment purposes, and for the statistical approach to potential non-response bias. Claims data billed under OPPS would be used to identify eligible elective primary outpatient THA/TKA procedures for the measure cohort to which submitted PRO data can be matched, and to identify additional variables for risk-adjustment and in the statistical approach to account for response bias, including patient demographics and clinical co-morbidities up to 12 months prior to surgery. The Medicare Enrollment Database (EDB) identifies Medicare FFS enrollment and patient-identified race, and the Master Beneficiary Summary File allows for

²⁷⁴ Higgins JP, Thomas J, Chandler J, et al. (2019). *Cochrane handbook for systematic reviews of interventions*. John Wiley & Sons. <https://doi.org/10.1002/9781119536604>

determination of Medicare and Medicaid dual eligibility enrollment status. Demographic information from the U.S. Census Bureau's American Community Survey allows for derivation of the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index score. Race, dual eligibility, and AHRQ SES Index score are used in the statistical approach to account for potential non-response bias in the outcome calculation. We refer readers to section XIV.B.3.b(2)(a)(iii) of this proposed rule for further details regarding the variables required for data collection and submission.

(ii) Measure Calculation

The HOPD facility-level THA/TKA PRO-PM result is calculated by aggregating all patient-level results across the facility. This measure would be calculated and presented as a RSIR, producing a performance measure per facility which accounts for patient case-mix, addresses potential non-response bias, and represents a measure of quality of care following elective primary outpatient THA/TKA. Response rates for PRO data would be calculated as the percentage of elective primary THA or TKA procedures performed at HOPDs for which complete and matched pre- and post-operative PRO data have been submitted, divided by the total number of eligible THA or TKA procedures performed at each facility.

(iii) Data Submission and Reporting

In response to feedback received from interested parties in the requests for comments (RFCs) on this measure in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45408 through 45414) and the CY 2022 OPPI/ASC proposed rule (FR 86 42251 through 42252) and the adoption of the measure in the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257), we propose to adopt the THA/TKA PRO-PM in the Hospital OQR Program utilizing flexible data submission approaches.

HOPDs would submit the following variables collected pre-operatively between 90 and zero days prior to the THA/TKA procedure for each patient: Medicare provider number; Medicare health insurance claim (HIC) number/Medicare beneficiary identifier (MBI); date of

birth; date of procedure; date of PRO data collection; procedure type; mode of collection; person completing the survey; facility admission date; patient reported outcome measure version; PROMIS Global (mental health subscale items) or VR-12 (mental health subscale items); HOOS, JR (for THA patients) or KOOS, JR (for TKA patients); Single-Item Health Literacy Screening (SILS2) questionnaire; BMI or weight (kg)/height (cm); chronic (≥ 90 day) narcotic use; total painful joint count (patient reported in non-operative lower extremity joint); and quantified spinal pain (patient-reported back pain, Oswestry index question^{275,276}).

HOPDs would submit the following variables collected post-operatively between 300 and 425 days following the THA/TKA procedure for each patient: Medicare provider number; Medicare HIC number/MBI; date of birth; procedure date, date of PRO data collection; procedure type; mode of collection; person completing the survey; facility admission date; KOOS, JR (TKA patients) or HOOS, JR (THA patients). The data submission period for the THA/TKA PRO-PM would also serve as the review and correction period. Data would not be able to be corrected following the submission deadline.

We propose a phased implementation approach for adoption of this measure to the Hospital OQR Program, with voluntary reporting periods in CYs 2025 and 2026 followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination.

Voluntary reporting prior to mandatory reporting would allow time for facilities to incorporate the THA/TKA PRO-PM data collection into their clinical workflows and is responsive to comments from interested parties, as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45408 through 45414) and FY 2023 IPPS/LTCH PPS final rule (FR 87 49246 through 49257). Following the two voluntary reporting periods, we propose mandatory reporting

²⁷⁵ Fairbank JC, & Pynsent PB. (2000). The Oswestry Disability Index. *Spine*. 25(22), 2940–52. <https://doi.org/10.1097/00007632-200011150-00017>

²⁷⁶ The Oswestry Disability Index is in the public domain and available for all hospitals to use.

of the THA/TKA PRO–PM beginning with the CY 2027 reporting period/CY 2030 payment determination. For each voluntary and subsequent mandatory reporting period, we would collect data on the THA/TKA PRO–PM in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy and Security Rules (45 CFR parts 160 and 164, subparts A, C, and E), and other applicable law.

(b) Review by Measure Applications Partnership (MAP)

We included the THA/TKA PRO–PM for the Hospital OQR in the publicly available “2022 Measures Under Consideration List” (MUC 2022-026).²⁷⁷ The MAP Coordinating Committee supported the measure, as referenced in the 2022–2023 Final Recommendations report to HHS and CMS.²⁷⁸

The MAP members noted that a similar version of this measure has been adopted for use in the Hospital IQR Program, however, there currently is no measure that assesses PROs among THA/TKA patients in HOPDs for the Hospital OQR Program. The MAP highlighted that the key strategy for the Hospital OQR Program is to ensure that procedures done in any type of facility, including HOPDs, have equivalent quality. As such, the MAP members agreed that measures of quality of procedures in hospital settings should extend to HOPDs, to the extent feasible and appropriate, so that consumers can compare quality of a specific procedure across different facility types.²⁷⁹

In addition, the MAP members stated that the goal of the PRO–PM is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patient health and reducing the burden of their disease. They agreed that this measure aligns with the goal of patient-centered approaches to health care quality improvement and addresses the high

²⁷⁷ Centers for Medicare & Medicaid Services. 2022 Measures Under Consideration List. Available at: <https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx>

²⁷⁸ MAP MUC Preliminary Recommendations 2022-2023. Available at <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>

²⁷⁹ Ibid.

priority areas of patient and family engagement and communication/care coordination for the Hospital OQR program.²⁸⁰

(c) Measure Endorsement

The CBE endorsed the hospital-level version of the THA/TKA PRO-PM (CBE #3559) in November 2020.²⁸¹ We note that the HOPD version of the THA/TKA PRO-PM would use the same specifications as the CBE-endorsed hospital-level THA/TKA PRO-PM that is currently implemented in the Hospital IQR program with modifications to capture procedures for the HOPDs. We intend to seek CBE endorsement for the HOPD version of the THA/TKA PRO-PM in a future endorsement cycle.

We have noted in previous rulemaking (75 FR 72064) the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from CBE endorsement, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment. We propose this measure without CBE endorsement based upon strong MAP and public support combined with the importance of the measure for Medicare beneficiaries. In addition, there are two existing, CBE-endorsed versions of this measure, one at the clinician-group level (CBE #3639) and one for the hospital level (CBE #3559). We expect that the measure will perform similarly in the HOPD setting, and we intend on submitting the measures for CBE endorsement following data collection during voluntary reporting.

We refer readers to section XIV.E.7.a of this proposed rule for a discussion on the proposed THA/TKA PRO-PM form, manner, and timing submission requirements.

We invite public comment on this proposal.

²⁸⁰ Ibid.

²⁸¹Centers for Medicaid & Medicare Services. Hospital-Level, Risk-Standardized Improvement Rate in Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA). Available at: <https://cmit.cms.gov/cmit/#/FamilyView?familyId=1618>

c. Proposed Adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient) Measure Beginning with the Voluntary CY 2025 Reporting Period followed by Mandatory Reporting Beginning with the CY 2026 Reporting Period/CY 2028 Payment Determination

(1) Background

The use of computed tomography (CT) scans has greatly improved the diagnosis and treatment of many conditions, and as such, over 80 million CT scans are performed each year in the US.²⁸² Most CT scans are performed as outpatient procedures.²⁸³ CT scans expose patients to low-dose ionizing radiation which is known to contribute to the development of cancer.²⁸⁴ The Biological Effects of Ionizing Radiation (BEIR) VII report by the United States National Academy of Sciences defined low-dose radiation as doses up to 100 millisieverts (mSv).²⁸⁵ A low dose CT scan of the chest delivers 1.5 mSv of radiation, while a regular-dose CT chest scan delivers 7 mSv of radiation.²⁸⁶ In comparison, a conventional chest x-ray delivers about 0.1 mSv of radiation.²⁸⁷

There is a large body of research that suggests that exposure to ionizing radiation within the same range that is routinely delivered by CT scans increases a person's risk of developing

²⁸² Harvard Health Publishing. (2021). Radiation Risk from Medical Imaging. Available at: <https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging>

²⁸³ Food and Drug Administration. Computed Tomography. Available at: <https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/computed-tomography-ct>

²⁸⁴ Harvard Health Publishing. (2021). Radiation Risk from Medical Imaging. Available at: <https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging>

²⁸⁵ Siegel JA, Greenspan BS, Maurer AH, et al. (2018). The BEIR VII Estimates of Low-Dose Radiation Health Risks Are Based on Faulty Assumptions and Data Analyses: A Call for Reassessment. *Journal of Nuclear Medicine*, 59 (7) 1017-1019. <https://doi.org/10.2967/jnumed.117.206219>

²⁸⁶ Ibid.

²⁸⁷ Environmental Protection Agency. Radiation Sources and Doses. Available at: <https://www.epa.gov/radiation/radiation-sources-and-doses>

cancer.^{288,289,290,291} One study found that patients who received CT scans, particularly women and adults aged 45 years or younger, had an elevated risk of developing thyroid cancer and leukemia.²⁹² Another study found that patients who received CT scans had a 0.7 percent higher risk of developing cancer in their lifetime compared to the general United States population.²⁹³ Cancer risk increased for patients who underwent multiple CT scans, ranging from 2.7 to 12 percent.²⁹⁴ While the likelihood of developing cancer from a CT scan is small on an individual level, it has been estimated that the percentage of cancers attributable to CT scans in the United States may be as high as two percent.²⁹⁵

CT image quality and radiation dose are related; as radiation dose increases, image quality increases until a diagnostic threshold is reached, at which point no further diagnostic benefit from image quality occurs.^{296,297} Conversely, too little radiation dose can produce inadequate image quality. Research suggests that current radiation doses utilized for CT scans may be lowered between 50 percent and 90 percent without impacting image diagnostic

²⁸⁸ Berrington de Gonzalez A, Daniels RD, Cardis E, et al. (2020). Epidemiological Studies of Low-Dose Ionizing Radiation and Cancer: Rationale and Framework for the Monograph and Overview of Eligible Studies. *J Natl Cancer Inst Monogr*, 2020(56), 97-113. <https://doi.org/10.1093/jncimonographs/lgaa009>

²⁸⁹ Cao CF, Ma KL, Shan H, et al. (2022). CT Scans and Cancer Risks: A Systematic Review and Dose-response Meta-analysis. *BMC Cancer*, 22, 1238. <https://doi.org/10.1186/s12885-022-10310-2>

²⁹⁰ Hauptmann M, Daniels R, Cardis E, et al. (2020). Epidemiological Studies of Low-Dose Ionizing Radiation and Cancer: Summary Bias Assessment and Meta-Analysis. *J Natl Cancer Inst Monogr*, 2020(56), 188-200. <https://doi.org/10.1093/jncimonographs/lgaa010>

²⁹¹ Shao YH, Tsai K, Kim S, Wu YJ, Demissie K. (2020). Exposure to Tomographic Scans and Cancer Risks. *JNCI Cancer Spectr*, 4(1). <https://doi.org/10.1093/jncics/pkz072>

²⁹² Ibid.

²⁹³ Harvard Health Publishing. (2021). Radiation Risk from Medical Imaging. Available at: <https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging>

²⁹⁴ Ibid.

²⁹⁵ Berrington de González A, Mahesh M, Kim KP, et al. (2009). Projected cancer risks from computed tomographic scans performed in the United States in 2007. *Archives of internal medicine*, 169(22), 2071–2077. <https://doi.org/10.1001/archinternmed.2009.440>

²⁹⁶ Goldman LW. (2007). Principles of CT: Radiation Dose and Image Quality. *Journal of Nuclear Medicine Technology*, 35(4), 213-225. <https://doi.org/10.2967/jnmt.106.037846>

²⁹⁷ Smith-Bindman R, Chu P, Wang Y, Chung R, et al. (2020). Comparison of the Effectiveness of Single-Component and Multicomponent Interventions for Reducing Radiation Doses in Patients Undergoing Computed Tomography: A Randomized Clinical Trial. *JAMA Intern Med*, 180(5), 666-675. <https://doi.org/10.1001/jamainternmed.2020.0064>

utility.^{298,299,300,301,302} Based on the evidence of harm from excessive radiation and evidence that radiation doses could be lowered in many patients' situation without deteriorating image diagnostic utility to the point of rendering exams unacceptable, we believe it is important to promote patient safety by ensuring that patients are exposed to the lowest possible level of radiation while preserving image quality.

(2) Overview of Measure

The Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient) electronic clinical quality measure (eCQM) (the Excessive Radiation eCQM), which was developed by the University of California San Francisco and is stewarded by Alara Imaging, Inc., provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses while preserving image quality. The measure calculates the percentage of eligible CT scans that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam.³⁰³ This measure provides a metric toward reducing unintentional harm to patients from CT scans. Setting a standard for diagnostic CT scans to prevent unnecessarily high radiation doses while preserving image quality would provide hospitals with a reliable method to assess harm

²⁹⁸ Greffier J, Hamard A, Pereira F, et al. (2020). Image quality and dose reduction opportunity of deep learning image reconstruction algorithm for CT: a phantom study. *Eur Radiol*, 30(7), 3951-3959. <https://doi.org/10.1007/s00330-020-06724-w>

²⁹⁹ Gottumukkala RV, Kalra MK, Tabari A, Otrakji A, Gee MS. (2019). Advanced CT Techniques for Decreasing Radiation Dose, Reducing Sedation Requirements, and Optimizing Image Quality in Children. *Radiographics*, 39(3), 709-726. <https://doi.org/10.1148/rg.2019180082>

³⁰⁰ Den Harder AM, Willeminck MJ, van Doormaal PJ, et al. (2018). Radiation dose reduction for CT assessment of urolithiasis using iterative reconstruction: A prospective intra-individual study. *Eur Radiol*, 28(1), 143-150. <https://doi.org/10.1007/s00330-017-4929-2>

³⁰¹ Rob S, Bryant T, Wilson I, Somani BK. (2017). Ultra-low-dose, low-dose, and standard-dose CT of the kidney, ureters, and bladder: is there a difference? Results from a systematic review of the literature. *Clin Radiol*, 72(1), 11-15. <https://doi.org/10.1016/j.crad.2016.10.005>

³⁰² Konda SR, Goch AM, Leucht P, et al. (2016). The use of ultra-low-dose CT scans for the evaluation of limb fractures: is the reduced effective dose using CT in orthopaedic injury (REDUCTION) protocol effective? *Bone Joint J*, 98-B(12), 1668-1673. <https://doi.org/10.1302/0301-620X.98B12.BJJ-2016-0336.R1>

³⁰³ Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>

reduction efforts and modify their improvement efforts. This measure also addresses high priority areas as stated in our Meaningful Measures Framework, including the transition to digital quality measures and the adoption of high-quality measures that improve patient outcomes and safety.³⁰⁴ Additionally, the Excessive Radiation eCQM supports the National Quality Strategy goal of promoting safety because it works to reduce preventable harm to patients.³⁰⁵ The measure was developed according to evidence and consensus-based clinical guidelines for optimizing CT radiation doses, including guidelines developed by the American College of Radiology, American College of Cardiology, Image Wisely 2020, and the American Association of Physicists in Medicine.^{306,307,308,309310}

Measure testing by the measure developer across a total of 16 inpatient and outpatient hospitals and a large system of outpatient radiology practices revealed that availability, accuracy, validity, and reproducibility were high for all of the measure's required data elements and the variables that were calculated by the translation software. The measure developer further assessed the reporting burden by administering surveys to each of the participating hospitals and outpatient groups. The measure developer found the burden to be small to moderate, comparable to the burden of measure reporting for other measures. Additionally, the measure developer noted that the burden of reporting the Excessive Radiation eCQM fell to information technology personnel rather than physicians.

³⁰⁴ Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy>

³⁰⁵ Centers for Medicare & Medicaid Services. CMS Quality Strategy. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>

³⁰⁶ American College of Radiology. (2015). Development and Revision Handbook. Available at: <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/DevelopmentHandbook.pdf>

³⁰⁷ Hirshfeld JW, Ferrari VA, Bengel FM, et al. (2018). 2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: *Best Practices for Safety and Effectiveness*. *Catheter Cardiovasc Interv*, 2018(92), E35–E97. <https://doi.org/10.1002/ccd.27659>

³⁰⁸ Image Wisely 2020. Available at: <https://www.imagewisely.org/Imaging-Modalities/Computed-Tomography/Diagnostic-Reference-Levels>

³⁰⁹ American Association of Physicists in Medicine. The Alliance For Quality Computed Tomography. Available at: <https://www.aapm.org/pubs/CTProtocols/>

Measure testing found that assessing radiation doses and providing audit feedback to radiologists resulted in significant reductions in dose levels. The testing sites also noted that the assessment of their doses as specified in the measure was helpful for identifying areas for quality improvement. According to the measure developer, over 40 letters were submitted in support of the measure, including several from radiologists and medical physicists who serve as leaders of the testing sites, that confirmed the measure was feasible and that data assembly would not pose a large burden.

The Excessive Radiation eCQM was submitted to the CBE for endorsement review in the Fall 2021 cycle (CBE #3663e) and was endorsed on August 2, 2022. The measure was also included in the 2022 MUC List.³¹¹ The MAP Hospital Workgroup reviewed the MUC List on December 13-14, 2022. The Workgroup noted that the Hospital OQR Program currently does not have any measures assessing the risk of radiation exposure from CT scans. The Workgroup also noted that the measure addresses the “Safety” Meaningful Measures 2.0 Healthcare Priority and would encourage shared decision-making between providers and patients.³¹² The MAP’s Final Report on February 1, 2023 supported the Excessive Radiation eCQM for rulemaking in the Hospital OQR Program.³¹³

(3) Data Sources

The Excessive Radiation eCQM uses hospitals’ electronic health record (EHR) data and radiology electronic clinical data systems, including the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS). Medical imaging information such as Radiation Dose Structured Reports and image pixel data are stored according to the universally adopted Digital Imaging and Communications in Medicine (DICOM) standard. Currently, eCQMs cannot access and process data elements in their original DICOM formats.

³¹¹ Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>

³¹² Ibid.

³¹³ Ibid.

Hospitals may choose to use any available software that performs the necessary functions to comply with measure requirements. One such example is the Alara Imaging software,³¹⁴ which fulfills these requirements by linking primary data elements, assessing CT scans for eligibility for inclusion in the measure, and generating three data elements mapped to clinical terminology for EHR consumption (CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and Calculated CT Global Noise) within the hospital's firewall.³¹⁵ While the Alara Imaging software and the necessary updates to the software are proprietary, these would be available to all reporting entities free of charge and accessible by creating a secure account through the measure steward's website. Alara Imaging Inc. would also provide free of charge necessary education materials including step-by-step instructions on creating an account and linking their EHR and PACS data to the software. Hospitals and their vendors would be able to use the data elements created by this software to calculate the eCQM and to submit results to the Hospital OQR Program via Quality Reporting Document Architecture (QRDA) Category I files as they do for all other eCQMs.

(4) Measure Specifications

The measure numerator is diagnostic CT scans that have a size-adjusted radiation dose greater than the threshold defined for the specific CT category. The threshold is determined by the body region being imaged and the reason for the exam, which affects the radiation dose and image quality required for that exam. The numerator also includes CT scans with a noise value greater than a threshold specific to the CT category.³¹⁶

³¹⁴ Alara Imaging. Available at: <https://www.alaracare.com/>

³¹⁵ Additional information on measure software security and processes is available at <https://www.alaracare.com/our-solutions>.

³¹⁶ Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>

The measure denominator is all diagnostic CT scans performed on patients ages 18 and older during the one-year measurement period which have an assigned CT category, a size-adjusted radiation dose value, and a global noise value.³¹⁷

The measure excludes CT scans that cannot be categorized by the area of the body being imaged or reason for imaging. These include scans that are simultaneous exams of multiple body regions outside of four commonly performed multiple region exams defined by the measure, or scans that cannot be classified based on diagnosis and procedure codes. Exams that cannot be classified are specified as LOINC code 96914-7, CT Dose and Image Quality Category, Full Body. The measure also has technical exclusions for CT scans missing information on the patient's age, Calculated CT Size-Adjusted Dose, or Calculated CT Global Noise. We refer readers to the eCQI Resource Center (https://ecqi.healthit.gov/ecqm/oqr/pre-rulemaking/2024/cms1206v1#quicktabs-tab-tabs_pre_rule_measure-0) for more details on the measure specifications.

(5) Data Submission and Reporting

We propose the adoption of the Excessive Radiation eCQM as a voluntary measure for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We would utilize the voluntary period to monitor the implementation and operationalization of the measure. We refer readers to section XIV.E.6.b of this proposed rule for a discussion of the Excessive Radiation eCQM reporting and data submission requirements. We also refer readers to section XIV.E.6 of this proposed rule for a discussion of our previously finalized eCQM reporting and submission policies.

We invite public comment on this proposal.

³¹⁷ Ibid.

4. Previously Finalized and Proposed Hospital OQR Program Measure Sets

a. Summary of Previously Finalized and Newly Proposed Hospital OQR Program Measure Set for the CY 2026 Payment Determination

We refer readers to the CY 2023 OPPTS/ASC final rule (87 FR 72100 through 72102) for a summary of the previously finalized Hospital OQR Program measure set for the CY 2025 payment determination. Table 66 summarizes the previously finalized and newly proposed Hospital OQR Program measures for the CY 2026 payment determination:

TABLE 66: Proposed Hospital OQR Program Measure Set for the CY 2026 Payment Determination

CBE #	Measure Name
0514	MRI Lumbar Spine for Low Back Pain†
None	Abdomen CT – Use of Contrast Material
0669	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	Median Time for Discharged ED Patients (Previously referred to as Median Time from ED Arrival to ED Departure for Discharged ED Patients)
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
0658	Colonoscopy Follow-Up Interval (Previously referred to as Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients)*
1536	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery)**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
3490	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	Hospital Visits after Hospital Outpatient Surgery
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) – About Facilities and Staff***
None	OAS CAHPS – Communication About Procedure***
None	OAS CAHPS – Preparation for Discharge and Recovery***
None	OAS CAHPS – Overall Rating of Facility***
None	OAS CAHPS – Recommendation of Facility***
3636	COVID-19 Vaccination Coverage Among Health Care Personnel*
None	Breast Cancer Screening Recall Rates
None	ST-Segment Elevation Myocardial Infraction (STEMI) electronic clinical quality measure (eCQM)****

†We note that CBE endorsement for this measure was removed.

* In this proposed rule, we propose a measure modification to Colonoscopy Follow-Up Interval beginning with the CY 2024 reporting period/CY 2026 payment determination.

** In the CY 2023 OPPTS/ASC final rule (87 FR 72097 through 72099), we finalized keeping data collection and submission voluntary for the Cataracts Visual Function measure for the CY 2025 reporting period and subsequent

years. In this proposed rule, we propose to standardize the surveys offered to patients pre- and post-surgery beginning with the CY 2024 reporting period.

*** In the CY 2022 OPPTS/ASC final rule (86 FR 63840), we finalized voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

**** In this proposed rule, we propose a measure modification to COVID-19 Vaccination Coverage Among HCP beginning with the CY 2024 reporting period/CY 2026 payment determination.

***** The STEMI eCQM was adopted in the CY 2022 OPPTS/ASC final rule (86 FR 63837 through 63840), beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

b. Summary of Previously Finalized and Newly Proposed Hospital OQR Program Measure Set for the CY 2027 Payment Determination and Subsequent Years

Table 67 summarizes the previously finalized and newly proposed Hospital OQR Program measures beginning with the CY 2027 payment determination and subsequent years:

TABLE 67: Proposed Hospital OQR Program Measure Set for the CY 2027 Payment Determination and Subsequent Years

CBE #	Measure Name
0514	MRI Lumbar Spine for Low Back Pain†
None	Abdomen CT – Use of Contrast Material
0669	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	Median Time for Discharged ED Patients (Previously referred to as Median Time from ED Arrival to ED Departure for Discharged ED Patients)
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	HOPD Procedure Volume (Previously referred to as Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures)*
0658	Colonoscopy Follow-Up Interval (Previously referred to as Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients)
1536	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery)**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
3490	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	Hospital Visits after Hospital Outpatient Surgery
None	OAS CAHPS – About Facilities and Staff
None	OAS CAHPS – Communication About Procedure
None	OAS CAHPS – Preparation for Discharge and Recovery
None	OAS CAHPS – Overall Rating of Facility
None	OAS CAHPS – Recommendation of Facility
3636	COVID–19 Vaccination Coverage Among Health Care Personnel
None	Breast Cancer Screening Recall Rates
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM
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)
3663e	Excessive Radiation eCQM (Previously referred to as Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults eCQM)*****

†We note that CBE endorsement for this measure was removed.

* In this proposed rule, we propose to re-adopt the HOPD Procedure Volume measure with modification beginning with the voluntary CY 2025 reporting period and mandatory beginning with the CY 2026 reporting period/CY 2028 payment determination.

** In the CY 2023 OPPTS/ASC final rule with comment period (87 FR 72097 through 72099), we finalized keeping data collection and submission voluntary for this measure for the CY 2025 reporting period and subsequent years.

***In this proposed rule, we propose to adopt the THA/TKA PRO-PM beginning with voluntary CYs 2025 and 2026 reporting periods and mandatory beginning with the CY 2027 reporting period/CY 2030 payment determination.

****In this proposed rule, we propose to adopt the Excessive Radiation eCQM beginning with the voluntary CY 2025 reporting period and mandatory beginning with the CY 2026 reporting period/CY 2028 payment determination.

5. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2019 OPPTS/ASC final rule (83 FR 59104 and 59105) and the CY 2022 OPPTS/ASC final rule (86 FR 63861) for our policies regarding maintenance of technical specifications for quality measures. We maintain technical specification manuals that can be found on the CMS website at: <https://qualitynet.cms.gov/outpatient/specifications-manuals>. Technical specifications for eCQMs used in the Hospital OQR Program are contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update), which are available, along with implementation guidance documents, on the eCQI Resource Center website at: <https://ecqi.healthit.gov/>.

We are not proposing any changes to these policies in this proposed rule.

6. Public Display of Quality Measures

We refer readers to the CY 2009, CY 2014, CY 2017, and CY 2021 OPPTS/ASC final rules (73 FR 68777 through 68779, 78 FR 75092, 81 FR 79791, and 85 FR 86193 through 86236 respectively) for our previously finalized policies regarding public display of quality measures.

We are not proposing any changes to these policies in this proposed rule.

a. Public Reporting Median Time for Discharged ED Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate

The Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure was adopted for reporting in the Hospital OQR Program beginning with the CY 2013 payment determination (75 FR 72086). The Median Time for Discharged ED Patients measure is a chart-abstracted measure that evaluates the time between the arrival to and departure from the ED, also known as

ED throughput time. The Median Time for Discharged ED Patients measure is calculated in stratified subsections for certain types of patients: Median Time for Discharged ED Patients-Reported Measure, which excludes psychiatric/mental health and transferred patients; Median Time for Discharged ED Patients-Psychiatric/Mental Health Patients, which includes information only for psychiatric/mental health patients; and Median Time for Discharged ED Patients-Transfer Patients, which includes information only for patients transferred from the ED; along with the Median Time for Discharged ED Patients-Overall Rate. The measure excludes patients who expired in the ED, left against medical advice, or whose discharge was not documented or unable to be determined.

In the CY 2011 OPPS/ASC final rule (75 FR 72086), we considered publicly displaying all strata; however, due to input from interested parties, we did not finalize public display of Median Time for Discharged ED Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate. Currently, measure data for the Median Time for Discharged ED Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate are not reported publicly on the Care Compare site. Measure data for the Median Time for Discharged ED Patients-Reported Measure is currently publicly displayed on the Care Compare site and in the corresponding downloadable data file for the Hospital OQR Program. We also collect and report Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients for public awareness of behavioral health gaps in the transfer of such patients, and per the CY 2018 OPPS/ASC final rule (82 FR 59437), we adopted a policy to publicly report these stratified behavioral health data beginning in July 2018 using data from patient encounters during the third quarter of 2017. We now believe displaying all strata will highlight and prioritize various issues in the health care system, specifically behavioral health and continuum of care.

We propose publicly reporting measure data for Median Time for Discharged ED Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate. Publicly reporting these measure stratifications can elucidate ED throughput performance gaps for

patients requiring higher levels of specialized care above what a facility is able to or provide. Data for these measure stratifications are not currently being reported publicly on the Care Compare site.

Beginning with the CY 2024, we propose to make data publicly available on our Care Compare website and in downloadable data files found at data.cms.gov for the following chart-abstracted measure strata: Median Time for Discharged ED Patients-Transfer Patients and the Median Time for Discharged ED Patients-Overall Rate which contains data for all patients.

We invite public comment on this proposal.

b. Overall Hospital Star Ratings

In the CY 2021 OP/ASC final rule (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Ratings). The Overall Star Ratings utilizes data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website. We refer readers to the CY 2021 OP/ASC final rule (85 FR 86193 through 86236) for our previously finalized policies regarding the Overall Star Ratings.

We are not proposing any changes to these policies in this proposed rule.

C. Hospital OQR Program Quality Measure Topics for Potential Future Consideration

1. Summary

We seek public comment on potential measurement topic areas for the Hospital OQR Program. This request for comment (RFC) seeks input on innovative measurement approaches and data sources for use in quality measurement to inform our work and, more specifically, the focus of measure development within the Hospital OQR Program. We identified three potential priority areas and we encourage the public to review and provide comment.

2. Background

We are seeking public comment to address: (1) quality measurement gaps in the HOPD setting, including the ED; (2) changes in outpatient care (such as shifts in volume, technology

use, and case complexity); (3) growth of concerns around workforce and patient safety; (4) the transition to digital quality measurement; and (5) interest in patient-reported outcomes.

Specifically, we seek comment on quality measurement topics for the Hospital OQR Program that include:

- Promoting Safety (Patient and Workforce);
- Behavioral Health; and
- Telehealth.

We seek input on the specific questions posed in this RFC.

3. Solicitation of Comments on Patient and Workforce Safety as a Measurement Topic Area in the Hospital OQR Program

Launched in April 2022, the CMS National Quality Strategy outlines CMS' aim to shape a resilient, high-value healthcare system through quality outcomes, safety, equity, and accessibility for all.³¹⁸ Improving safety through levers such as quality measurement is a critical objective of the National Quality Strategy. We acknowledge that promoting safety in order to achieve zero preventable harm requires developing measures that assess and hold healthcare systems accountable to keep individuals safe through preventative and treatment processes. Therefore, in this proposed rule, we are seeking public comment on patient and workforce safety measures. We are particularly interested in sepsis care for potential future inclusion in the Hospital OQR Program as a patient safety measure.

Sepsis is a life-threatening condition which can arise from simple infections (such as pneumonia or a urinary tract infection) and requires prompt recognition and early intervention, which can often occur in an ED.^{319,320} Although sepsis can affect anyone at any age, it is more

³¹⁸ Schreiber M, Richards AC, Moody-Williams J, et al. (2022). The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality. Available at: <https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality>

³¹⁹ McVeigh SE. (2020). Sepsis Management in the Emergency Department. *The Nursing clinics of North America*, 55(1), 71–79. <https://doi.org/10.1016/j.cnur.2019.10.009>

³²⁰ Seymour CW, Gesten F, Prescott HC, et al. (2017). Time to Treatment and Mortality during Mandated Emergency Care for Sepsis. *The New England journal of medicine*, 376(23), 2235–2244. <https://doi.org/10.1056/NEJMoa1703058>

common in infants, older adults, and patients with chronic health conditions such as diabetes and immunosuppressive disorders.³²¹ The Centers for Disease Control and Prevention (CDC) estimates annually that there are approximately 1.7 million adults diagnosed with sepsis with 270,000 resulting deaths.³²² Therefore, preventing, diagnosing, and treating sepsis effectively has been a focus of patient safety in recent years.^{323,324}

HOPDs may play a critical role in the initial assessment and evaluation of suspected sepsis patients through lab tests, diagnostic imaging, and collection of sepsis biomarkers.³²⁵ Timely and accurate sepsis diagnosis is essential to effective care. Research shows that performance of evidence-based time-sensitive therapies in EDs can lower the risk of organ dysfunction, reduce mortality, and mitigate the need for mechanical ventilation.^{326,327,328} In addition, using an interdisciplinary sepsis-response team to coordinate care in the ED shows potential in improving sepsis care management and enhancing patient outcomes.³²⁹ These findings highlight the role of HOPDs and EDs in the timely diagnosis and treatment of sepsis. Therefore, we believe the Hospital OQR Program may benefit from quality measures centered around sepsis care.

³²¹ National Institute of General Medical Sciences. (2021). Sepsis. Available at: <https://nigms.nih.gov/education/fact-sheets/Pages/sepsis.aspx>

³²² Centers for Disease Control and Prevention. (2022). What is Sepsis? Available at: <https://www.cdc.gov/sepsis/what-is-sepsis.html>

³²³ Rhee C, Dantes RB, Epstein L, & Klompas M. (2019). Using Objective Clinical Data to Track Progress on Preventing and Treating Sepsis: CDC's New 'Adult Sepsis Event' Surveillance Strategy. *BMJ Qual Saf*, 28(4), 305-309. <https://doi.org/10.1136/bmjqs-2018-008331>

³²⁴ Fay K, Sapiano MRP, Gokhale R, et al. (2020). Assessment of Health Care Exposures and Outcomes in Adult Patients with Sepsis and Septic Shock. *JAMA Netw Open*, 3(7), e206004. <https://doi.org/10.1001/jamanetworkopen.2020.6004>

³²⁵ Gauer R, Forbes D, & Boyer N. (2020). Sepsis: Diagnosis And Management. *American Family Physician*, 101(7), 409-418. <https://www.aafp.org/pubs/afp/issues/2020/0401/p409.html>

³²⁶ Arabi YM, Al-Dorzi HM, Alamry A, et al. (2017). The Impact of a Multifaceted Intervention Including Sepsis Electronic Alert System and Sepsis Response Team on the Outcomes of Patients with Sepsis and Septic Shock. *Annals of intensive care*, 7(1), 57. <https://doi.org/10.1186/s13613-017-0280-7>

³²⁷ Whiles BB, Deis AS, & Simpson SQ. (2017). Increased Time to Initial Antimicrobial Administration is Associated With Progression to Septic Shock in Severe Sepsis Patients. *Critical care medicine*, 45(4), 623-629. <https://doi.org/10.1097/CCM.0000000000002262>

³²⁸ Gavelli F, Castello LM, & Avanzi GC. (2021). Management of Sepsis and Septic Shock in the Emergency Department. *Internal and emergency medicine*. 16(6), 1649-1661. <https://doi.org/10.1007/s11739-021-02735-7>

³²⁹ Delawder JM, & Hulton L. (2020). An Interdisciplinary Code Sepsis Team to Improve Sepsis-Bundle Compliance: A Quality Improvement Project. *Journal of emergency nursing*, 46(1), 91-98. <https://doi.org/10.1016/j.jen.2019.07.001>

We also believe quality measures should align, to the extent possible, across CMS programs to minimize reporting burden. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50236 through 50241), we adopted the Severe Sepsis and Septic Shock: Management Bundle measure (CBE #0500³³⁰) (the Sepsis measure) into the Hospital Inpatient Quality Reporting (IQR) Program beginning with the FY 2015 reporting period/FY 2017 payment determination. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27027 through 27030), we proposed to adopt the Sepsis measure into the Hospital Value-Based Purchasing (HVBP) Program beginning with the FY 2026 program year. The Sepsis measure supports the efficient, effective, and timely delivery of high-quality sepsis care by providing a standard operating procedure for the early risk stratification and management of a patient with severe infection. When the care interventions in the measure are provided as a composite, health systems observe significant reductions in hospital length of stay, re-admission rates, and mortality.^{331,332}

We request comment on whether this measure would be appropriate and feasible for use in the Hospital OQR Program, as well as whether CMS should consider adopting an alternative measure that assesses the quality of sepsis care in the hospital outpatient setting.³³³

Additional safety measures may be needed to adequately monitor and maintain safety in the Hospital OQR Program, such as measurement of system-wide all-cause harm, in addition to the safety of observation care, procedures and services, medication errors, technology, and workforce. Patient and workforce safety are interconnected, as the safety of healthcare workers is critical to maintaining a safe and effective healthcare environment.³³⁴

³³⁰ In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

³³¹ Levy MM, Gesten FC, Phillips GS, et al. (2018). Mortality Changes Associated with Mandated Public Reporting for Sepsis: The Results of the New York State Initiative. *Am J Respir Crit Care Med*, 198(11), 1406-1412. <https://doi.org/10.1164/rccm.201712-2545OC>

³³² Bauer SR, Han X, Wang XF, et al. (2020). Association Between Compliance with the Sepsis Quality Measure (SEP-1) and Hospital Readmission. *Chest*, 158(2), 608-611. <https://doi.org/10.1016/j.chest.2020.02.042>

³³³ Centers for Medicare & Medicaid Services. (2023). Sepsis Bundle Project (SEP) National Hospital Inpatient Quality Measures. Available at: https://qualitynet.cms.gov/files/6391e95676962e0016ad9199?filename=2a-b_SEP-List_v5.14.pdf

³³⁴ McGaffigan P, Gerwig K, & Kingston MB. (2020). Workforce Safety Key to Patient Safety. *Healthcare Executive*. 35(6), 48-50. <https://www.ihl.org/resources/Pages/Publications/workforce-safety-key-to-patient-safety.aspx>

We are requesting input from interested parties on the following topics: (1) safety outcome priorities specific to settings, services, transitions and transfers, and access to care; (2) general cross-outpatient setting outcomes; (3) individual harms, including methodological approaches to patient identification and data collection, technological-derived harm, and use of electronic resources to mitigate potential for harm; and (4) workforce safety. Specifically, we are requesting comment on the following questions:

- What are interested parties' highest priority outcomes for ensuring safety in the outpatient setting, not limited to the following: overall priorities; priorities for specific settings (for example, EDs, HOPDs) and services (for example, observation care, emergent and non-emergent surgeries, procedures, and imaging); safety related to transitions between care settings; and safety around access to care (for example, a patient who lacks access to life-saving medications such as insulin, epinephrine, albuterol)?

- What outcomes should be measured across all settings within the Hospital OQR Program?

- Individual harms (such as wrong-site surgery) occur at low frequencies, presenting a challenge for the development of risk-adjusted quality measures that can be used to compare facilities. Existing measures in the Hospital OQR Program have used approaches such as the capture of utilization (for example, the Hospital Visits After Hospital Outpatient Surgery Measure (CBE #2687)) to indicate potential harm and longer measurement periods to improve measurement reliability.

- ++ Are there other methodological approaches or data that we could use to identify harm to patients receiving care in the outpatient setting?

- ++ What approaches could we use to capture harms associated with outpatient services (HOPD procedures, ED visits, outpatient clinic visits, outpatient imaging)?

- ++ How could electronic data sources or monitoring systems be leveraged to gather timely data on such errors?

- What aspects of workforce safety are important for us to consider for the Hospital OQR Program?

- As new technology becomes available and is used more widely (such as artificial intelligence (AI) for diagnoses, robotic surgery, and electronic health records (EHRs)), there is a potential for these technologies or their application to cause harm to patients. For example, AI algorithms trained on data that is under representative of certain racial, ethnic, or gender groups may misdiagnosis these same populations.³³⁵ At the same time, technology could also be leveraged to mitigate AI risks, improve safety, or facilitate quality measurement.

- ++ Which technologies are of the most concern in terms of potential for harm?

- ++ What measurable safety-related outcomes should CMS consider for the Hospital OQR Program?

- ++ What technologies could be leveraged to improve safety or facilitate its measurement?

4. Solicitation of Comments on Behavioral Health and Suicide Prevention in the Hospital OQR Program

Behavioral healthcare in the outpatient setting comprises a vast array of services for patients with a wide range of conditions. Behavioral health services are delivered in multiple settings by multiple types of providers, including but not limited to HOPDs, through partial observation, and in the ED.

Quality gaps in the area of hospital outpatient behavioral health include care coordination across settings, availability of services, and barriers to accessing services. In this RFC, we are seeking comment from interested parties on behavioral health topics based in part on work by the National Quality Forum (NQF), The National Committee for Quality Assurance (NCQA), and

³³⁵ Thomas, LB, Mastorides, SM, Viswanadhan, NA, et al. (2021). Artificial Intelligence: Review of Current and Future Applications in Medicine. *Federal practitioner : for the health care professionals of the VA, DoD, and PHS*, 38(11), 527–538. <https://doi.org/10.12788/fp.0174>

the CMS Behavioral Health Strategy.^{336,337,338} Behavioral health topics under consideration for measure development in the hospital outpatient setting include: availability and access, coordination of care, patient experience, patient-centered clinical care, prevention and treatment of chronic conditions, prevention of iatrogenic harm (that is, harm resulting from medical care), equity across all domains, and suicide prevention. We are particularly interested in measuring suicide screening in the hospital outpatient setting to improve early risk detection and facilitate appropriate behavioral health treatment.

Suicide is a serious but preventable public health threat and is one of the leading causes of death in the United States (US).³³⁹ In 2020, about 46,000 Americans died as a result of suicide and 12.2 million adults experienced suicidal ideation.³⁴⁰ Individuals with a recorded depressive disorder are about five times more likely to die by suicide after adjusting for sociodemographic factors and other mental health diagnoses than individuals without a recorded mental health condition.³⁴¹ Many factors contribute to suicide risk, including Major Depressive Disorder (MDD) diagnosis.^{342,343} MDD is a significant risk factor for suicide, indicating that patients with MDD are a critical population for intervention efforts.³⁴⁴

³³⁶ National Quality Forum. (2022). Opioid-Related Outcomes Among Individuals with Co-occurring Behavioral Health Conditions. Available at: [https://www.qualityforum.org/Projects/n-r/Opioids_and_Behavioral_Health_Committee/2022_Final_Report.aspx#onclick=%E2%80%9D_gaq.push\(\[%E2%80%98_trackEvent%E2%80%99,%E2%80%99Download%E2%80%99,%E2%80%99PDF%E2%80%99,this.href\]\);%E2%80%9DUsing Measurement to Promote Joint Accountability and Whole-Person Care](https://www.qualityforum.org/Projects/n-r/Opioids_and_Behavioral_Health_Committee/2022_Final_Report.aspx#onclick=%E2%80%9D_gaq.push([%E2%80%98_trackEvent%E2%80%99,%E2%80%99Download%E2%80%99,%E2%80%99PDF%E2%80%99,this.href]);%E2%80%9DUsing%20Measurement%20to%20Promote%20Joint%20Accountability%20and%20Whole-Person%20Care)

³³⁷ The National Committee for Quality Assurance. (2021). Behavioral Health Quality Framework: A Roadmap for Using Measurement to Promote Joint Accountability and Whole-Person Care. Available at: https://www.ncqa.org/wp-content/uploads/2021/07/20210701_Behavioral_Health_Quality_Framework_NCQA_White_Paper.pdf

³³⁸ Centers for Medicare and Medicaid Services. (2022). CMS Behavioral Health Strategy. Available at: <https://www.cms.gov/cms-behavioral-health-strategy>

³³⁹ Centers for Disease Control and Prevention. (2022). Facts About Suicide. Available at: <http://www.cdc.gov/suicide/facts/index.html>

³⁴⁰ Centers for Disease Control and Prevention. (2022). Suicide Prevention. Available at: <http://www.cdc.gov/suicide/index.html>

³⁴¹ Yeh HH, Westphal J, Hu Y, et al. (2019). Diagnosed Mental Health Conditions and Risk of Suicide Mortality. *Psychiatric services (Washington, D.C.)*, 70(9), 750–757. <https://doi.org/10.1176/appi.ps.201800346>

³⁴² Ibid

³⁴³ Cai H, Xie XM, Zhang Q, et al. (2021). Prevalence of Suicidality in Major Depressive Disorder: A Systematic Review and Meta-Analysis of Comparative Studies. *Frontiers in psychiatry*, 12, 690130. <https://doi.org/10.3389/fpsyt.2021.690130>

³⁴⁴ Moitra M, Santomauro D, Degenhardt L, et al. (2021). Estimating the Risk of Suicide Associated with Mental Disorders: A Systematic Review and Meta-regression Analysis. *Journal of psychiatric research*, 137, 242–249. <https://doi.org/10.1016/j.jpsychires.2021.02.053>

Research shows that in the weeks, months, and year prior to suicide, individuals significantly utilized healthcare services, providing an opportunity for assessment and prevention in the clinical setting.³⁴⁵ Nineteen percent of individuals who died by suicide with a recorded mental health diagnosis visited the ED within one year prior to their death while 7.5 percent visited the ED within one month.³⁴⁶ HOPDs may be an opportune setting for detecting suicide risk in persons with mental health diagnoses, such as MDD, and reducing the overall suicide rate. ED-initiated suicide prevention efforts can meaningfully reduce suicide attempts in individuals that are screened and receive evidence-based care.³⁴⁷

Under the Merit-based Incentive Payment System (MIPS), we adopted the Adult Major Depressive Disorder (MDD): Suicide Risk Assessment measure (CBE #0104). This measure aims to improve clinical assessment of suicide risk where a new or recurrent episode of MDD is identified and may be beneficial in the Hospital OQR Program. We request comment on this specific measure example, including whether interested parties believe this measure would be appropriate and feasible for use in the Hospital OQR Program, as well as other measures, such as a universal screening measure. More than half of those who die by suicide do not have a recorded mental health diagnosis.³⁴⁸ Universal suicide screening may improve identification of individuals who may not otherwise have been identified as at risk.³⁴⁹

Additional measures may be needed to adequately promote screening and treatment of behavioral health disorders in the outpatient setting. For example, measures geared towards prevention and treatment of substance use disorders. In 2021, 17.3 percent of adults over the age

³⁴⁵ Miller IW, Camargo CA, Arias SA, et al. (2017). Suicide Prevention in an Emergency Department Population: The ED-SAFE Study. *JAMA psychiatry*, 74(6), 563–570. <https://doi.org/10.1001/jamapsychiatry.2017.0678>

³⁴⁶ Ahmedani BK, Simon GE, Stewart C, et al. (2014). Health Care Contacts in the Year Before Suicide Death. *J Gen Intern Med*, 29, 870–877. <https://doi.org/10.1007/s11606-014-2767-3>

³⁴⁷ Miller IW, Camargo CA, Arias SA, et al. (2017). Suicide Prevention in an Emergency Department Population: The ED-SAFE Study. *JAMA psychiatry*, 74(6), 563–570. <https://doi.org/10.1001/jamapsychiatry.2017.0678>

³⁴⁸ Stone DM, Simon TR, Fowler KA, et al. (2018) Vital Signs: Trends in State Suicide Rates — United States, 1999–2016 and Circumstances Contributing to Suicide — 27 States, 2015. *MMWR*, 67, 617–624. <http://dx.doi.org/10.15585/mmwr.mm6722a1>

³⁴⁹ Boudreaux ED, Camargo CA, Arias SA, et al. (2016). Improving Suicide Risk Screening and Detection in the Emergency Department. *American Journal of Preventive Medicine*, 50(4), 445–453. <https://doi.org/10.1016/j.amepre.2015.09.029>

of 18 met the criteria for substance use disorder for drugs or alcohol.³⁵⁰ Outpatient screening of substance use disorders through tools such as SAMHSA’s Screening, Brief Intervention, and Referral to Treatment (SBIRT) may aid the early intervention and treatment for persons with substance use disorders and help identify those at risk of developing such disorders.^{351,352} We seek comment on whether screening for substance use disorders would be an appropriate measure topic for the Hospital OQR Program.

Furthermore, we seek broad input on behavioral health as a measurement topic area in the Hospital OQR Program based on, but not limited to, the following matters: (1) priorities for measuring outcomes of outpatient behavioral health services, particularly by setting within the HOPD; and (2) quality measure approaches to improve behavioral health access in outpatient settings. Specifically, we are requesting comment from interested parties on the following questions:

- Are there additional behavioral health topic areas that we should prioritize? Of the topics outlined in this RFC (availability and access, coordination of care, patient experience, patient-centered clinical care, prevention and treatment of chronic conditions, prevention of iatrogenic harm, equity across all domains, and suicide prevention), which are the highest priority? What are the most relevant quality gaps and outcomes related to behavioral health for hospital outpatient settings and services?

- Access is one of the biggest challenges around improving behavioral health outcomes. What measurement approaches could be used to drive improvements in access to services?

- Should CMS consider substance use disorder-related screening and counseling

³⁵⁰ Substance Abuse and Mental Health Services Administration. (2021).

Table 5.1B – Substance Use Disorder for Specific Substances in Past Year: Among People Aged 12 or Older; by Age Group, Percentages, 2021. Available at: <https://www.samhsa.gov/data/sites/default/files/reports/rpt39441/NSDUHDetailedTabs2021/NSDUHDetailedTabs2021/NSDUHDetailedTabsSect5pe2021.htm>

³⁵¹ Substance Abuse and Mental Health Services Administration. (2022). Screening, Brief Intervention, and Referral to Treatment (SBIRT). Available at: <https://www.samhsa.gov/sbirt>

³⁵² O'Connor EA, Perdue LA, Senger, CA, et al. (2018). Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA*, 320(18), 1910–1928. <https://doi.org/10.1001/jama.2018.12086>

measures in regards to behavioral health outcomes for the outpatient setting, and, if so, what specific quality measures should CMS include?

- Should CMS consider a measure related to universal suicide risk in the ED? Are there other interventions or measurement approaches targeted at suicide prevention that CMS should consider?

5. Solicitation of Comments on Telehealth as a Measurement Topic Area in the Hospital OQR Program

We define telehealth as the provision of healthcare services through two-way, real-time interactive telecommunications technology between patients and providers who are located at a distant site.³⁵³ Telemedicine has the potential to improve patient experience, outcomes, and access to healthcare.³⁵⁴ Telemedicine is also associated with cost-savings for both patients and healthcare systems.^{355,356} Telehealth utilization expanded greatly in the outpatient setting during the early months of the SARS-CoV-2 pandemic.³⁵⁷ The number of outpatient visits conducted via telehealth has since declined but remains higher than pre-pandemic levels.³⁵⁸

While telehealth provides a variety of benefits to patients and health systems, there is variability in telehealth's effectiveness across different outpatient services as some conditions may necessitate in-person physical examination or diagnostic testing.^{359,360} There are also known

³⁵³ Telehealth Services, 42 CFR 410.78 Available at: <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.78>

³⁵⁴ Corbett, JA, Opladen, JM, & Bisognano, JD. (2020). Telemedicine can revolutionize the treatment of chronic disease. *International Journal of Cardiology. Hypertension*, 7, 100051. <https://doi.org/10.1016/j.ijchy.2020.100051>

³⁵⁵ American Health Association. (2016). Telehealth: Helping Hospitals Deliver Cost-Effective Care. Available at: <https://www.aha.org/system/files/content/16/16telehealthissuebrief.pdf>

³⁵⁶ Patel KB, Turner K, Alishahi TA, et al. (2023). Estimated Indirect Cost Savings of Using Telehealth Among Nonelderly Patients With Cancer. *JAMA network open*, 6(1), e2250211. <https://doi.org/10.1001/jamanetworkopen.2022.50211>

³⁵⁷ Lo, J, Rae M, Amin, K, & Cox C. (2022). Outpatient telehealth use soared early in the COVID-19 pandemic but has since receded. *Peterson-KFF Health System Tracker*. Available at: <https://www.healthsystemtracker.org/brief/outpatient-telehealth-use-soared-early-in-the-covid-19-pandemic-but-has-since-receded/>

³⁵⁸ Ibid

³⁵⁹ Patel SY, Mehrotra A, Huskamp HA, et al. (2021). Variation in Telemedicine Use and Outpatient Care During The COVID-19 Pandemic in the United States. *Health affairs (Project Hope)*, 40(2), 349–358. <https://doi.org/10.1377/hlthaff.2020.01786>

³⁶⁰ Koonin LM, Hoots B, Tsang CA, et al. Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic — United States, January–March 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1595–1599. <http://dx.doi.org/10.15585/mmwr.mm6943a3>

disparities in the effectiveness of telehealth and its impact on outcomes as certain populations lack access to internet and digital devices, or lack familiarity with technology.^{361,362}

For the Hospital OQR Program, we are considering a measure focused on telehealth quality based on a framework developed by the CBE.³⁶³ This framework was chosen because it offers a comprehensive guide for developing telehealth measures under four domains: access, effectiveness, experience, and equity. We seek input from interested parties on the following topics: (1) inclusion and prioritization of areas of telehealth-related care, and in particular those priority topic areas discussed above; (2) addressing quality gaps in outpatient telehealth-related care, including across HOPD settings and services; (3) capturing utilization, and disparities resulting from utilization, of telehealth-related care for outpatient settings and services; and (4) understanding patient experience with outpatient telehealth services. Specifically, we are requesting comment from interested parties on the following questions:

- In reference to the telehealth-related topics outlined above, are there additional matters that we should prioritize for the Hospital OQR Program? Which subjects are of the highest priority?
- What do commenters believe are the most relevant clinical issues addressable through telehealth in outpatient settings, and gaps in care that telehealth can address?
- What are the highest priority concerns regarding disparities in access, use, or outcomes related to telehealth in the outpatient setting? Are there any settings or services that should be prioritized?
- Which existing outpatient quality measures should be stratified by telehealth as the mode of delivery?

³⁶¹ Ibid.

³⁶² Roberts ET, & Mehrotra A. (2020). Assessment of Disparities in Digital Access Among Medicare Beneficiaries and Implications for Telemedicine. *JAMA internal medicine*, 180(10), 1386–1389. <https://doi.org/10.1001/jamainternmed.2020.2666>

³⁶³ National Quality Forum. (2021). Rural Telehealth and Healthcare System Readiness Measurement Framework – Final Report. Available at: https://www.qualityforum.org/Publications/2021/11/Rural_Telehealth_and_Healthcare_System_Readiness_Measurement_Framework_-_Final_Report.aspx

- What are the most relevant patient-experience-related telehealth outcomes that should be measured?

D. Administrative Requirements

1. Proposal to Modify Requirements Regarding Hospital OQR Program Participation Status

We refer readers to § 419.46(b) for our current policies regarding participation in the Hospital OQR Program, including security official and system registration requirements. We propose to amend our participation regulation codified at § 419.46(b)(1) and (2) to replace references to “QualityNet” with “CMS-designated information system” or “CMS website,” and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

2. Proposal to Modify Requirements Regarding Hospital OQR Program Withdrawal

We refer readers to § 419.46(c) for our policies regarding requirements for withdrawal from the Hospital OQR Program. We propose to amend our withdrawal policy codified at § 419.46(c) to replace references to “QualityNet” with “CMS-designated information system” or “CMS website,” and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

Other than the proposal to amend § 419.46(c), we are not proposing any changes to these policies in this proposed rule.

E. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

Previously finalized quality measures and information collections discussed in this section were approved by the Office of Management and Budget (OMB) under control number 0938-1109 (expiration date February 28, 2025).³⁶⁴ An updated PRA package reflecting the

³⁶⁴ Office of Management and Budget. Office of Information and Regulatory Affairs. Available at: <https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0938-1109>

updated information collection requirements related to the proposals set forth in this section of the proposed rule will be submitted for approval under the same OMB control number.

1. Hospital OQR Program Annual Submission Deadlines

We refer readers to § 419.46(d) for our policies regarding clinical data submission deadlines. In the CY 2023 OPPI/ASC final rule (87 FR 72110 through 72112), we finalized alignment of the patient encounter quarters for chart-abstracted measures with the calendar year beginning with the CY 2024 reporting period/CY 2026 payment determination. To facilitate this process, we finalized transitioning to the new timeframe for the CY 2026 payment determination and subsequent years and use only three quarters of data for chart-abstracted measures in determining the CY 2025 payment determination as illustrated in the Tables 68, 69, and 70 below (87 FR 44734).

TABLE 68: CY 2024 Payment Determination* (Current state)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2022 (April 1 - June 30)	11/1/2022**
Q3 2022 (July 1 – September 30)	2/1/2023**
Q4 2022 (October 1 - December 31)	5/1/2023**
Q1 2023 (January 1 - March 31)	8/1/2023**

*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 nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 69: Finalized CY 2025 Payment Determination*(Future state—transition period)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2023 (April 1 - June 30)	11/1/2023**
Q3 2023 (July 1 – September 30)	2/1/2024**
Q4 2023 (October 1 - December 31)	5/1/2024**

* 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 nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 70: Finalized CY 2026 Payment Determination* (Future state)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q1 2024 (January 1 - March 31)	8/1/2024**
Q2 2024 (April 1 - June 30)	11/1/2024**
Q3 2024 (July 1 – September 30)	2/1/2025**

*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 nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

We propose to amend our submission deadline codified at § 419.46(d)(2) to replace references to “QualityNet” with “CMS-designated information system” or “CMS website,” and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

Other than the proposal to amend § 419.46(d)(2), we are not proposing any changes to these policies in this proposed rule.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data are Submitted Directly to CMS

We refer readers to the CY 2013 OPPI/ASC final rule (77 FR 68481 through 68484) and the CMS website, currently available at: <https://qualitynet.cms.gov>, for a discussion of the requirements for chart-abstracted measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2014 payment determination and subsequent years.

We are not proposing any changes to these policies in this proposed rule.

3. Claims-Based Measure Data Requirements

We refer readers to the CY 2019 OPPI/ASC final rule (83 FR 59106 through 59107), where we established a 3-year reporting period for the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure beginning with the CY 2020 payment determination. We refer readers to the CY 2022 OPPI/ASC final rule (86 FR 63863) where we finalized a 3-year reporting period for the Breast Cancer Screening Recall Rates measure.

We are not proposing any changes to these policies in this proposed rule.

4. Data Submission Requirements for the Outpatient and Ambulatory Surgery Consumer

Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measure

We refer readers to the CYs 2017, 2018, and 2022 OPPTS/ASC final rules (81 FR 79792 through 79794; 82 FR 59432 and 59433; and 86 FR 63863 through 63866, respectively) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measure. For more information about the modes of administration, we refer readers to the OAS CAHPS Survey website: <https://oascahps.org/>.

We are not proposing any changes to these policies in this proposed rule.

5. Data Submission Requirements for Measures Submitted via a Web-based Tool

a. Background

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 at available at <https://qualitynet.cms.gov>, for a discussion of the requirements for measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2017 payment determination and subsequent years. The information collections finalized in the aforementioned final rules were approved under OMB control number 0938-1109 (expiration date February 28, 2025).³⁶⁵ The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E, for more information.

We are not proposing any changes to these policies in this proposed rule.

b. Proposed HOPD Procedure Volume Measure Reporting and Data Submission Requirements

We propose to re-adopt the HOPD Procedure Volume measure with modification, beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We propose that hospitals submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 2025 reporting

³⁶⁵ Ibid.

period, the submission period to report the data to CMS through the HQR System would be January 1, 2026 to May 15, 2026, covering the performance period of January 1, 2025 to December 31, 2025. Following a 30-day preview period, CMS would publicly display data surrounding the top five most frequently performed procedures among HOPDs in each of the following eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.³⁶⁶ This data would be publicly displayed on the Care Compare website or another CMS website. We would assess and update the top five procedures in each category annually, as needed. We propose that hospitals would submit aggregate-level data through the CMS Web-based tool within the HQR System. We refer readers to the CY 2009, CY 2014, and CY 2017 OPPI/ASC final rules (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures. We previously codified our existing policies regarding data collection and submission under the Hospital OQR Program at § 419.46.

We invite public comment on this proposal.

c. Proposed Modification of Survey Instrument Use for the Cataracts Visual Function Measure Reporting and Data Submission Requirements

In section XIV.B.2.b of this proposed rule, we propose to modify the Cataracts Visual Function measure survey instrument use, beginning with the voluntary CY 2024 reporting period. The proposed modified measure would refine data collection by standardizing survey instruments that HOPDs can use, which would limit the allowable survey instruments to those listed below:

- The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25)
- The Visual Functioning Patient Questionnaire (VF-14)
- The Visual Functioning Index Patient Questionnaire (VF-8R)

³⁶⁶ Centers for Medicare & Medicaid Services. (2016). Hospital Outpatient Specifications Manuals version 9.1. Available at: <https://qualitynet.cms.gov/outpatient/specifications-manuals#tab9>

We also propose that hospitals submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the voluntary CY 2024 reporting period, the data submission period would be January 1, 2025 to May 15, 2025, covering the performance period of January 1, 2024 to December 31, 2024. Specifically, for data collection, we propose that hospitals submit aggregate-level data through the CMS Web-based tool within the HQR System. We previously codified our existing policies regarding data collection and submission under the Hospital OQR Program at § 419.46.

We invite public comment on this proposal.

d. Data Submission Requirements for Measures Submitted via the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Website

We refer readers to the CY 2014 OPPTS/ASC final rule (78 FR 75097 through 75100) for a discussion of the previously finalized requirements for measure data submitted via the CDC NHSN website. In addition, we refer readers to the CY 2022 OPPTS/ASC final rule (86 FR 63866), where we finalized the adoption of the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2022 reporting period/CY 2024 payment determination. In section XIV.B.2.a of this proposed rule, we discuss the proposed modification of the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2024 reporting period/CY 2026 payment determination. The requirements for measure data submitted via the CDC NHSN website would remain as previously finalized.

We are not proposing any changes to these policies in this proposed rule.

6. eCQM Reporting and Submission Requirements

a. Background

We refer readers to the CY 2014 OPPTS/ASC final rule (78 FR 75106 and 75107), the CY 2015 OPPTS/ASC final rule (79 FR 66956 through 66961), the CY 2016 OPPTS/ASC final rule (80 FR 70516 through 70518), the CY 2017 OPPTS/ASC final rule (81 FR 79785 through

79790), the CY 2018 OPPS/ASC final rule (82 FR 59435 through 59438), the CY 2022 OPPS/ASC final rule (86 FR 63867 through 63870), and the CY 2023 OPPS/ASC final rule (87 FR 72113 through 72114) for more details on previous discussion regarding future measure concepts related to eCQMs and electronic reporting of data for the Hospital OQR Program, including support for the introduction of eCQMs into the Program.

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63867 through 63868), where we finalized the adoption of the STEMI eCQM reporting and data submission requirements. For the CY 2024 reporting period/CY 2026 payment determination, hospitals must submit one self-selected quarter of data.

We are not proposing any changes to these policies in this proposed rule.

b. Proposed Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults eCQM Reporting and Data Submission Requirements

In section XIV.B.3.c of this proposed rule, we discuss the proposed adoption of the Excessive Radiation eCQM beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. In this proposed rule, we propose a progressive increase in the number of quarters for which hospitals report eCQM data. We propose that hospitals that submit Excessive Radiation eCQM data during the CY 2025 voluntary period may submit up to all four quarter(s) of data.

Beginning with the CY 2026 mandatory reporting period/CY 2028 payment determination, we propose that hospitals report two self-selected calendar quarters of data for the Excessive Radiation eCQM. Beginning with the CY 2027 reporting period/CY 2029 payment determination, we propose to require hospitals to report all four calendar quarters (one calendar year) of data for the Excessive Radiation eCQM. We believe that a phased implementation approach would allow facilities the ability to make the necessary adjustments for data submission over time and would produce more comprehensive and reliable quality measure data

for patients and providers. Furthermore, we believe that aligning the schedule with the STEMI measure will allow for a seamless transition from voluntary to mandatory reporting of all calendar quarters.

We also refer readers to Table 71 for a summary of the proposed quarterly data increase in eCQM reporting beginning with the CY 2025 reporting period.

TABLE 71: Proposed Progressive Increase in eCQM Reporting Beginning with the CY 2025 Reporting Period and for Subsequent Years

Calendar Year Period	Calendar Quarters of Reporting	Reporting Requirement
CY 2025 Reporting Period	Any quarter(s)	Voluntary
CY 2026 Reporting Period/CY 2028 Payment Determination	Two self-selected quarters	Mandatory
CY 2027 Reporting Period/CY 2029 Payment Determination	Four quarters (one calendar year)	Mandatory

We also propose to require Excessive Radiation eCQM data submission by May 15 in the year prior to the affected 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. For example, for the CY 2026 reporting period/CY 2028 payment determination, hospitals must report two self-selected quarters of data and would be required to submit eCQM data by May 15, 2027. This data submission deadline would follow our policies on submission deadlines for eCQM data defined in section XIV.E.6.e of this proposed rule.

We invite public comment on our proposals.

c. Electronic Clinical Quality Measure Certification Requirements for eCQM Reporting

(1) Use of the 2015 Edition Cures Update Certification Criteria

We refer readers to the CY 2022 OPPTS/ASC final rule (86 FR 63868 and 63869) for our policies regarding the requirement that hospitals participating in the Hospital OQR Program utilize certified technology updated consistent with the 2015 Edition Cures Update as finalized in the Office of the National Coordinator for Health Information Technology (ONC) 21st Century

Cures Act final rule (85 FR 25642 through 25961) beginning with the CY 2023 reporting period/CY 2025 payment determination.

We are not proposing any changes to these policies in this proposed rule.

d. File Format for eCQM Data, Zero Denominator Declarations, and Case Threshold Exemptions

(1) File Format for eCQM Data

We refer reader to the CY 2022 OPPS/ASC final rule (86 FR 42262) for our policies regarding the file format for eCQM data.

We are not proposing any changes to these policies in this proposed rule.

(2) Zero Denominator Declarations

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63869) for our policies regarding zero denominator declarations.

We are not proposing any changes to these policies in this proposed rule.

(3) Case Threshold Exemptions

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63869) for our policies regarding case threshold exemptions.

We are not proposing any changes to these policies in this proposed rule.

e. Submission Deadlines for eCQM Data

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63870) for our policies regarding submission deadlines for eCQM data.

We are not proposing any changes to these policies in this proposed rule.

7. Proposed Data Submission and Reporting Requirements for Patient-Reported Outcome-Based Performance Measures (PRO-PMs)

In section XIV.B.3.b of this proposed rule, we propose the adoption of the hospital-level THA/TKA PRO-PM into the Hospital OQR Program measure set. In this section of the

proposed rule, we propose the reporting and submission requirements for PRO-PM as a new type of measure to the Hospital OQR Program.

a. Submission of PRO-PM Data

(1) Data Submission Generally

In section XIV.B.3.b of this proposed rule, we propose adoption of the THA/TKA PRO-PM in the Hospital OQR Program beginning with voluntary CYs 2025 and 2026 reporting periods and mandatory reporting period beginning with the CY 2027/CY 2030 payment determination. We propose that hospitals and vendors use the HQR System for data submission for the THA/TKA PRO-PM, which would enable us to incorporate this new requirement into the infrastructure we have developed and use to collect other quality data. HOPDs may choose to: (1) send their data to CMS directly; or (2) utilize an external entity, such as through a vendor or registry, to submit data on behalf of the facility to CMS. We would provide hospitals with additional detailed information and instructions for submitting data using the HQR System through CMS' existing websites, through outreach, or both. Use of the HQR system leverages existing CMS infrastructure already utilized for other quality measures. The HQR System allows for data submission using multiple file formats (such as CSV, XML) and a manual data entry option, allowing facilities and vendors additional flexibility in data submission.

(2) Data Submission Reporting Requirements

(a) Voluntary Reporting Requirements for the Proposed THA/TKA PRO-PM

For hospitals participating in voluntary reporting for the THA/TKA PRO-PM as discussed in section XIV.B.3.b of this proposed rule, we propose that hospitals submit pre-operative PRO data, as well as matching post-operative PRO data, for at least 50 percent of their eligible elective primary THA/TKA procedures.

For the THA/TKA PRO-PM, we propose that the first voluntary reporting period for CY 2025 would include pre-operative PRO data collection from 90 to 0 days before the procedure (for eligible elective THA/TKA procedures performed from January 1, 2025, through

December 31, 2025) and post-operative PRO data collection from 300 to 425 days after the procedure. Therefore, during the first voluntary reporting period for CY 2025, hospitals would submit pre-operative data by May 15, 2026 and post-operative data by May 15, 2027, and we intend to provide hospitals with their results in confidential feedback reports in CY 2028. 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. After the initial submission of pre-operative data for the first voluntary period, hospitals would submit both pre-operative data for the second voluntary period and post-operative data for the first voluntary period by the same data submission deadline, but for the different voluntary reporting periods. For example, hospitals would need to submit: (1) post-operative data for the first voluntary reporting (for procedures performed between January 1, 2025, and December 31, 2025); and (2) pre-operative data for the second voluntary reporting (for procedures performed between January 1, 2026, and December 31, 2026) of the THA/TKA PRO-PM by May 15, 2027.

For the THA/TKA PRO-PM, we propose that the second voluntary reporting period for the CY 2026 reporting period would include pre-operative PRO data collection from 90 to 0 days before the procedure (for eligible elective THA/TKA procedures performed from January 1, 2026 through December 31, 2026) and post-operative PRO data collection from 300 to 425 days after the procedure. Hospitals would submit pre-operative data for the second voluntary reporting period by May 15, 2027 and post-operative data for the second voluntary reporting period by May 15, 2028. we intend to provide hospitals with their results in confidential feedback reports in CY 2029. HOPDs that voluntarily submit data for this measure would receive confidential feedback reports that detail submission results from the reporting period. Results of voluntary reporting would not be made publicly available. If feasible, we would calculate and provide each participating facility with their RSIR as part of the confidential

feedback reports. This would provide each facility with an indication of their performance relative to the other facilities that participate in the voluntary reporting period.

While we do not propose to publicly report the data we receive during the voluntary reporting periods for the THA/TKA PRO–PM facility-level RSIR, we propose to publicly report which facilities choose to participate in voluntary reporting and/or the percent of pre-operative data submitted by participating facilities for the first voluntary reporting period, and their percent of pre-operative and post-operative matched PRO data submitted for subsequent voluntary reporting periods. For example, if out of 100 eligible procedures a facility submits 45 pre-operative cases that match to post-operative cases, then we would report that the facility submitted 45 percent of matched pre-operative and post-operative PRO surveys during voluntary reporting.

We refer readers to Table 72 for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the voluntary reporting periods for THA/TKA PRO–PM.

TABLE 72: PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO–PM VOLUNTARY REPORTING

Reporting Cycle	THA/TKA Procedures Performed	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission	Preview/ Public Reporting
Voluntary Reporting CY 2025	January 1, 2025- December 31, 2025	October 3, 2024- December 31, 2025	May 15, 2026	October 28, 2025- February 28, 2027	May 15, 2027*	CY 2028
Voluntary Reporting CY 2026	January 1, 2026- December 31, 2026	October 3, 2025- December 31, 2026	May 15, 2027	October 28, 2026- February 28, 2028	May 15, 2028	CY 2029

*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.

**Public reporting of information on facility participation in the voluntary reporting periods would occur in CY 2028 for the CY 2025 reporting period and CY 2029 for the CY 2026 reporting period.

(b) Mandatory Reporting

Following the voluntary reporting periods, we propose that mandatory reporting of the THA/TKA PRO-PM would begin with reporting PRO data for eligible elective THA/TKA procedures from January 1, 2027 through December 31, 2027 (the CY 2027 performance period), impacting the CY 2030 payment determination. This initial mandatory reporting would include pre-operative PRO data collection from 90 days preceding the applicable performance period and from 300 to 425 days after the performance period. For example, pre-operative data from October 3, 2026 through December 31, 2027 (for eligible elective primary THA/TKA procedures from January 1, 2027 through December 31, 2027) and post-operative PRO data collection from October 28, 2027 to February 28, 2029. Pre-operative data submission would occur by May 15, 2028 and post-operative data submission would occur by May 15, 2029.

We intend to provide hospitals with their results in CY 2030 before publicly reporting results on the Compare tool hosted by HHS, currently available at <https://www.medicare.gov/care-compare>, or its successor website. We would provide confidential feedback reports during the voluntary period which would include the risk-standardized improvement rate (RSIR); as well as other results that support understanding of their performance prior to public reporting. For this first mandatory reporting period, hospitals that fail to meet the reporting requirements would receive a reduction of their Annual Payment Update (APU) in the CY 2030 payment determination. We propose that hospitals would be required to submit 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data as a minimum amount of data for mandatory reporting in the Hospital OQR Program.

We refer readers to Table 73 below. for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the first year of mandatory reporting.

TABLE 73: PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM FOR MANDATORY REPORTING

Reporting Cycle	THA/TKA Procedures Performed	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission	Preview and Public Reporting
Mandatory Reporting CY 2027	January 1, 2027- December 31, 2027	October 3, 2026- December 31, 2027	May 15, 2028	October 28, 2027- February 28, 2029	May 15, 2029	2030*

*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.

*Public reporting of information on facility results in the Mandatory Reporting periods would occur in CY 2030 for CY 2027 reporting period/CY2030 payment determination.

We invite comment on these proposals.

8. Population and Sampling Data Requirements for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule (76 FR 74482 through 74483) for our policies regarding population and sampling data requirements.

We are not proposing any changes to these policies in this proposed rule.

9. Review and Corrections Period for Measure Data Submitted to the Hospital OQR Program

a. Chart-Abstracted Measures

We refer readers to the CY 2015 OPPS/ASC final rule (79 FR 66964 and 67014) for our policies regarding a review and corrections period for chart-abstracted measures in the Hospital OQR Program.

We are not proposing any changes to these policies in this proposed rule.

b. Web-Based Measures

We refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86184) for our policies regarding a review and corrections period for web-based measures in the Hospital OQR Program.

We are not proposing any changes to these policies in this proposed rule.

c. Electronic Clinical Quality Measures (eCQMs)

We refer readers to the CY 2022 OPPTS/ASC final rule (86 FR 63870) for our policies regarding a review and corrections period for eCQMs in the Hospital OQR Program. We refer readers to the CMS website (currently available at:

<https://qualitynet.cms.gov/outpatient/measures/eCQM>) and the eCQI Resource Center (available at: <https://ecqi.healthit.gov/>) for more resources on eCQM reporting.

We are not proposing any changes to these policies in this proposed rule.

d. OAS CAHPS Measures

We refer readers to the CY 2022 OPPTS/ASC final rule (86 FR 63870) and the CY 2017 OPPTS/ASC final rule (81 FR 79793) for our policies regarding a review and corrections period for OAS CAHPS measures in the Hospital OQR Program.

We are not proposing any changes to these policies in this proposed rule.

10. Hospital OQR Program Validation Requirements

a. Background

We refer readers to the CY 2011 OPPTS/ASC final rule (75 FR 72105 through 72106), the CY 2013 OPPTS/ASC final rule (77 FR 68484 through 68487), the CY 2015 OPPTS/ASC final rule (79 FR 66964 through 66965), the CY 2016 OPPTS/ASC final rule (80 FR 70524), the CY 2018 OPPTS/ASC final rule (82 FR 59441 through 59443), the CY 2022 OPPTS/ASC final rule (86 FR 63870 through 63873), the CY 2023 OPPTS/ASC final rule (87 FR 72115 through 72116), and § 419.46(f) for our policies regarding validation.

We are not proposing any changes to these policies in this proposed rule.

b. Use of Electronic File Submissions for Chart-Abstracted Measure Medical Records Requests

We refer readers to the CY 2022 OPPTS/ASC final rule (86 FR 63870) for additional information on the use of electronic file submissions for chart-abstracted measure medical records requests.

We are not proposing any changes to these policies in this proposed rule.

c. Time Period for Chart-Abstracted Measure Data Validation

We refer readers to the chart-abstracted validation requirements and methods we adopted in the CY 2014 OPSS/ASC final rule (78 FR 75117 through 75118) and codified at § 419.46(f)(1) for the CY 2025 payment determination and subsequent years. We refer readers to § 419.46(f)(1) for our policies regarding the time period for chart-abstracted measure data validation.

We are not proposing any changes to these policies in this proposed rule.

d. Targeting Criteria

We refer readers to the CY 2012 OPSS/ASC final rule (76 FR 74485), where we finalized a validation selection process in which we select a random sample of 450 hospitals for validation purposes and select an additional 50 hospitals based on specific criteria; the CY 2013 OPSS/ASC final rule (77 FR 68485 and 68486), where we finalized that a hospital will be preliminarily selected for validation based on targeting criteria if it fails the validation requirement that applies to the previous year's payment determination, and for a discussion of finalized policies regarding our medical record validation procedure requirements; the CY 2018 OPSS/ASC final rule (82 FR 59441), where we clarified that an "outlier value" for purposes of the targeting criterion; the CY 2022 OPSS/ASC final rule (86 FR 63872), where we finalized the addition of two targeting criteria: (1) any hospital that has not been randomly selected for validation in any of the previous three years; or (2) any hospital that passed validation in the previous year and had a two-tailed confidence interval that included 75 percent; and the CY 2023 OPSS/ASC final rule (87 FR 72115 through 72116), where we finalized an additional targeting criteria: any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters. We refer readers to § 419.46(f)(3) for our policies regarding the validation selection process and targeting criteria.

We are not proposing any changes to these policies in this proposed rule.

e. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

We refer readers to § 419.46(f)(4) for our policies regarding the educational review process, including validation score review and correction, for chart-abstracted measures.

We are not proposing any changes to these policies in this proposed rule.

11. Extraordinary Circumstances Exception (ECE) Process

We refer readers to § 419.46(e) for our policies regarding the extraordinary circumstances exception (ECE) process under the Hospital OQR Program. We propose to amend our exception policy codified at § 419.46(e)(1) to replace references to “QualityNet” with “CMS-designated information system” or “CMS website.” and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

Other than the proposal to amend § 419.46(e)(1), we are not proposing any changes to these policies in this proposed rule.

12. Hospital OQR Program Reconsideration and Appeals Procedures

We refer readers to § 419.46(g) for our policies regarding reconsideration and appeals procedures. We propose to amend our submission deadline codified at § 419.46(g)(1) to replace references to “QualityNet” with “CMS-designated information system” or “CMS website,” and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

Other than the proposal to amend § 419.46(g)(1), we are not proposing any changes to these policies in this proposed rule.

F. Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2024 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”. 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. 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.

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, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final rule with comment period reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update and the reduced conversion factor uses the reduced OPD update. The baseline OPPS

conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor – 0.02)

Reporting Ratio = Reduced Conversion Factor / Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor – 0.02) / (1 + OPD update factor)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard

adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, the rural sole community hospital adjustment, and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G of the CY 2023 OPPS/ASC proposed rule (87 FR 44533 through 44534).

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2024

We proposed 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 2024 annual payment update factor. For this CY 2024 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of \$87.488, 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 \$85.782. 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 proposed 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 2024, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of \$87.488, 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 \$85.782.

XV. Ambulatory Surgical Center Quality Reporting (ASCQR) Program Requirements, Proposals, and Requests for Comment

A. Background

1. Overview

We seek to promote higher quality, more efficient, and equitable healthcare for Medicare beneficiaries. Consistent with these goals, we have implemented quality reporting programs for multiple care settings, including the Ambulatory Surgical Center Quality Reporting (ASCQR) Program for ambulatory surgical center care.

2. Statutory Authority for the ASCQR Program

Section 1833(i)(7)(A) 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 section 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 OPSS/ASC final rule (76 FR 74492 through 74494) for a detailed discussion of the statutory authority of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to the following final rules for detailed discussions of the regulatory history of the ASCQR Program:

- CY 2012 OPSS/ASC final rule (76 FR 74492 through 74517);
- FY 2013 IPSS/LTCH PPS final rule (77 FR 53637 through 53644);
- CY 2013 OPSS/ASC final rule (77 FR 68492 through 68500);
- CY 2014 OPSS/ASC final rule (78 FR 75122 through 75141);
- CY 2015 OPSS/ASC final rule (79 FR 66966 through 66987);
- CY 2016 OPSS/ASC final rule (80 FR 70526 through 70538);
- CY 2017 OPSS/ASC final rule (81 FR 79797 through 79826);
- CY 2018 OPSS/ASC final rule (82 FR 59445 through 59476);
- CY 2019 OPSS/ASC final rule (83 FR 59110 through 59139);
- CY 2020 OPSS/ASC final rule (84 FR 61420 through 61434);
- CY 2021 OPSS/ASC final rule (85 FR 86187 through 86193);
- CY 2022 OPSS/ASC final rule (86 FR 63875 through 63911); and
- CY 2023 OPSS/ASC final rule (87 FR 72117 through 72136)

We have codified certain requirements under the ASCQR Program at 42 CFR part 416, subpart H (§ 416.300 through § 416.330). We refer readers to section XV.E of this proposed rule for a detailed discussion of the payment reduction for ASCs that fail to meet program requirements.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68493 and 68494) for a detailed discussion of the priorities we consider for quality measure selection for the ASCQR Program.

We are not proposing any changes to these policies in this proposed rule.

2. Retention of Previously Adopted ASCQR Program Measures

We previously finalized and codified at § 416.320(a) our policy regarding retention of quality measures adopted for the ASCQR Program. Specifically, our regulation at § 416.320(a) provides that we will retain quality measures previously adopted for the ASCQR Program as part of its measure set unless we remove, suspend, or replace the measure.

We are not proposing any changes to this policy in this proposed rule.

3. Removal, Replacement, or Suspension of Quality Measures from the ASCQR Program Measure Set

a. Immediate Removal of Program Measures

We refer readers to § 416.320(b) for our policies regarding immediate removal of a measure for the ASCQR Program based on evidence that the continued use of the measure as specified raises patient safety concerns. We propose to amend our measure removal policy codified at § 416.320(b) to replace references to “QualityNet” with “CMS-designated information system” or “CMS website,” and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

b. Removal, Replacement, or Suspension of Program Measures

We previously finalized and codified at § 416.320(c) our policies regarding removal of quality measures adopted for the ASCQR Program. Specifically, our regulation at § 416.320(c) provides that, unless a measure raises specific safety concerns, we will use the regular rulemaking process, allowing public comment, to remove, suspend, or replace quality measures in the ASCQR Program. Our regulation at § 416.320(c)(2) further provides that we will weigh whether to remove measures based on eight factors, including whether a measure is “topped-out” (§ 416.320(c)(2)(i)), based on criteria set forth in our regulation at § 416.320(c)(3). However, as provided in our regulation at § 416.320(c)(4), we will assess the benefits of removing a measure on a case-by-case basis and will not remove a measure solely on the basis of it meeting any of specific factor or criterion.

We are not proposing any changes to these policies in this proposed rule.

4. Modifications to Previously Adopted Measures

In this proposed rule, we propose to modify three previously adopted measures beginning with the CY 2024 reporting period/CY 2026 payment determination: (1) COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure; (2) Cataracts: Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery measure survey instrument use; and (3) Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure.

a. Proposed Modification of the COVID–19 Vaccination Coverage Among HealthCare Personnel (HCP) Measure Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

(1) Background

On January 31, 2020, the Secretary of the Department of Health and Human Services (HHS) declared a public health emergency (PHE) for the United States in response to the global

outbreak of SARS–COV–2, a then novel coronavirus that causes a disease named “coronavirus disease 2019” (COVID–19).³⁶⁷ Subsequently, the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure was adopted across multiple quality reporting programs, including the ASCQR Program (86 FR 63875 through 63833).³⁶⁸ COVID–19 has continued to spread domestically and around the world with more than 102.7 million cases and 1.1 million deaths in the United States alone as of February 13, 2023.³⁶⁹ The Secretary renewed the PHE on April 21, 2020 and then every three months thereafter, with the final renewal on February 9, 2023.³⁷⁰ The PHE ended on May 11, 2023; however, the public health response to COVID–19 remains a public health priority including vaccination efforts.³⁷¹

As stated in the CY 2022 OPPS/ASC final rule (86 FR 63876) and in our “Revised Guidance for Staff Vaccination Requirements,” vaccination is a critical part of the nation’s strategy to effectively counter the spread of COVID–19.^{372,373,374} We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care

³⁶⁷ U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

³⁶⁸ The Hospital Inpatient Quality Reporting Program (86 FR 45374 through 45382), the Hospital OQR Program (86 FR 63824 through 63833), the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the PPS-Exempt Cancer Hospital Quality Reporting Program (86 FR 45428 through 45434), the Long-Term Care Hospital Quality Reporting Program (86 FR 45438 through 45446), the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244 through 67248), and the Inpatient Rehabilitation Facility Quality Reporting Program (86 FR 42385 through 42396).

³⁶⁹ Centers for Disease Control and Prevention. COVID Data Tracker. Accessed February 13, 2023. Available at: <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

³⁷⁰ U.S. Dept. of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. (2023). Renewal of Determination that a Public Health Emergency Exists. Available at: <https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx>.

³⁷¹ U.S. Dept. of Health and Human Services. Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html>.

³⁷² Centers for Medicare & Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/revised-guidance-staff-vaccination-requirements>.

³⁷³ Centers for Disease Control and Prevention. (September 24, 2021). Morbidity and Mortality Weekly Report (MMWR). Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID–19 Hospitalizations Among Adults Without Immunocompromising Conditions – United States, March–August 2021. Available at: https://cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w.

³⁷⁴ Centers for Medicare & Medicaid Services. (2022). Revised Guidance for Staff Vaccination Requirements. Available at: <https://www.cms.gov/files/document/qs0-23-02-all.pdf>.

settings, including the ASC setting, to protect health care workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities. Studies indicate higher levels of population-level vaccine effectiveness in preventing COVID-19 infection among HCP and other frontline workers in multiple industries, with vaccines having a 90 percent effectiveness in preventing symptomatic and asymptomatic infection from December 2020 through August 2021.³⁷⁵ Since the Food and Drug Administration (FDA) issued emergency use authorizations (EUAs) for selected initial and primary vaccines for adults, vaccines have been highly effective in real-world conditions at preventing COVID-19 in HCP with up to 96 percent efficacy for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID-19.^{376,377,378,379} Overall, data demonstrate that COVID-19 vaccines are effective and prevent severe disease, hospitalization, and death from the COVID-19 infection.³⁸⁰

When we adopted the COVID-19 Vaccination Coverage Among HCP measure in the CY 2022 OPPTS/ASC final rule (86 FR 63875 through 63883), we acknowledged that the measure did not address booster shots for COVID-19 vaccination (86 FR 63881), although the FDA authorized, and the Centers for Disease Control and Prevention (CDC) recommended, additional doses and booster doses of the COVID-19 vaccine for certain individuals, particularly those who are immunocompromised due to age or condition or who are living or working in

³⁷⁵ Centers for Disease Control and Prevention. (August 27, 2021). Morbidity and Mortality Weekly Report (MMWR). Effectiveness of COVID-19 Vaccines in Preventing SARS-COV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance – Eight U.S. Locations, December 2020-August 2021. Available at: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm>.

³⁷⁶ Pilishivi T, Gierke R, Fleming-Dutra KE, et al. (2022). Effectiveness of mRNA Covid-19 Vaccine among U.S. Health Care Personnel. *New England Journal of Medicine*, 385(25), e90. <https://doi.org/10.1056/NEJMoa2106599>

³⁷⁷ Centers for Disease Control and Prevention. (2021). Morbidity and Mortality Weekly Report (MMWR). Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status – 13 U.S.

Jurisdictions, April 4-July 17, 2021. Available at: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm>.

³⁷⁸ Centers for Medicare & Medicaid Services. (2022). Revised Guidance for Staff Vaccination Requirements QSO-23-02-ALL. Available at: <https://www.cms.gov/files/document/qs0-23-02-all.pdf>.

³⁷⁹ Food and Drug Administration. (2020). FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine. Available at: <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>.

³⁸⁰ McGarry BE et al. (January 2022). Nursing Home Staff Vaccination and Covid-19 Outcomes. *New England Journal of Medicine*. 2022 Jan 27;386(4):397-398. Available online at: <https://pubmed.ncbi.nlm.nih.gov/34879189/>.

high-risk settings, such as HCP (86 FR 63881). However, we also stated that we believed the numerator of the measure was sufficiently broad to include potential future boosters as part of a “complete vaccination course” (86 FR 63881).

Since then, new variants of SARS–COV–2 have emerged around the world and within the United States. Specifically, the Omicron variant (and its related subvariants) is listed as a variant of concern by the CDC because it spreads more easily than earlier variants.³⁸¹ Vaccine manufacturers have responded to the Omicron variant by developing bivalent COVID–19 vaccines, which include a component of the original virus strain to provide broad protection against COVID–19 and a component of the Omicron variant to provide better protection against COVID–19 caused by the Omicron variant.³⁸² Booster doses of the bivalent COVID–19 vaccine have proven effective at increasing immune response to SARS–COV–2 variants, including Omicron, particularly in individuals who are more than six months removed from receipt of their primary series.³⁸³ These booster doses are associated with a greater reduction in infections among HCP and their patients relative to those who only received primary series vaccination, with a rate of breakthrough infections among HCP who received only the two-dose regimen of 21.4 percent compared to a rate of 0.7 percent among boosted HCP.^{384,385} Data from the existing COVID–19 Vaccination Coverage Among HCP measure demonstrate clinically significant variation in booster dose vaccination rates across ASCs.

³⁸¹ Centers for Disease Control and Prevention. (August 2021). Variants of the Virus. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html>.

³⁸² Food and Drug Administration. (November 2022). COVID–19 Bivalent Vaccine Boosters. Available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccines>.

³⁸³ Chalkias, S et al. (October 2022). A Bivalent Omicron-Containing Booster Vaccine against Covid–19. *N Engl J Med* 2022; 387:1279-1291. Available online at: <https://www.nejm.org/doi/full/10.1056/NEJMoa2208343>.

³⁸⁴ Prasad N et al. (May 2022). Effectiveness of a COVID–19 Additional Primary or Booster Vaccine Dose in Preventing SARS-CoV-2 Infection Among Nursing Home Residents During Widespread Circulation of the Omicron Variant - United States, February 14-March 27, 2022. *Morbidity and Mortality Weekly Report (MMWR)*. 2022 May 6;71(18):633-637. Available online at: <https://pubmed.ncbi.nlm.nih.gov/35511708/>.

³⁸⁵ Oster Y et al. (May 2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. *Clin Microbiol Infect*. 2022 May;28(5):735.e1-735.e3. Available online at: <https://pubmed.ncbi.nlm.nih.gov/35143997/>.

We believe that vaccination remains the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death. Given the availability of vaccine efficacy data, EUAs issued by the FDA for bivalent boosters, the continued presence of SARS–COV–2 in the United States, and variance among rates of booster dose vaccination, we believe it is important to modify the COVID–19 Vaccination Coverage Among HCP measure for HCP to receive primary series and booster vaccine doses in a timely manner per the CDC’s recommendation that bivalent COVID-19 vaccine booster doses might improve protection against SARS-CoV-2 Omicron sublineages.³⁸⁶

We propose to modify the COVID–19 Vaccination Coverage Among HCP measure to utilize the term “up to date” in the HCP vaccination definition. We also propose to update the numerator to specify the timeframes within which an HCP is considered up to date with CDC recommended COVID–19 vaccines, including booster doses, beginning with the CY 2024 reporting period/CY 2026 payment determination for the ASCQR Program.

We note that as we stated in the CY 2022 OPPS/ASC final rule (86 FR 63877), the COVID–19 Vaccination Coverage Among HCP measure is a process measure that assesses HCP vaccination coverage rates and not an outcome measure for which ASCs are held responsible for a particular outcome. We propose to adopt the same modification to versions of the measure that we have adopted for other quality reporting programs.³⁸⁷

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in various settings. ASCs report the required data for this measure via the CDC’s National Healthcare Safety

³⁸⁶ Centers for Medicare and Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Center for Clinical Standards and Quality/Quality, Safety & Oversight Group. Available at: <https://www.cms.gov/files/document/qs0-23-02-all.pdf>.

³⁸⁷ The Hospital Inpatient Quality Reporting Program, the Long-Term Care Hospital Quality Reporting Program and the PPS-Exempt Cancer Hospital Quality Reporting Program (88 FR 27074) as well as the Inpatient Psychiatric Facility Quality Reporting Program (88 FR 21290), the Skilled Nursing Facility Quality Reporting Program (88 FR 21332), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244), and the Inpatient Rehabilitation Facility Quality Reporting Program (88 FR 20985).

Network (NHSN). We refer readers to the CY 2022 OPPTS/ASC-final rule (86 FR 63877 through 63878) for more information on the initial review of the measure by the Measure Applications Partnership (MAP).³⁸⁸

We included an updated version of the measure on the Measures Under Consideration (MUC) list for the 2022-2023 pre-rulemaking cycle for consideration by the MAP. In December 2022, during the MAP's Hospital Workgroup discussion, the workgroup stated that the revision of the current measure captures up to date vaccination information in accordance with the CDC's updated recommendations for additional and booster doses since the measure's initial development. Additionally, the Hospital Workgroup appreciated that the revised measure's target population is broader and simplified from seven categories of HCP to four.³⁸⁹ During the MAP's Health Equity Advisory Group review, the group highlighted the importance of COVID-19 vaccination measures and questioned whether the proposed revised version of the measure excludes individuals with contraindications to FDA authorized or approved COVID-19 vaccines, and if the measure would be stratified by demographic factors. The measure developer confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator, but stated that the measure would not be stratified since the data are submitted at an aggregate rather than an individual level. The MAP Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually.³⁹⁰ We note that when reviewed by the MAP, reporting for contract personnel providing care or services not specifically included in the measure denominator was fully optional, whereas this reporting is now required to complete NHSN data entry, but is not included in the measure calculation. The developer also noted that the model used for this measure is based on the Influenza Vaccination

³⁸⁸ Interested parties convened by the consensus-based entity will provide input and recommendations on the Measures under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to <https://p4qm.org/PRMR-MSR> for more information.

³⁸⁹ Pre-rulemaking MUC lists and map reports. The Measures Management System. (n.d.). Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

³⁹⁰ Ibid.

Coverage Among HCP measure (CBE #0431).³⁹¹ We refer readers to sections XXIV.B and XXVI (Collection of Information) of this proposed rule for additional detail on the burden and impact of this proposal.

The proposed revised measure received conditional support for rulemaking from the MAP pending (1) testing indicating the measure is reliable and valid, and (2) endorsement by the consensus-based entity (CBE). The MAP noted that the previous version of the measure received endorsement from the CBE (CBE #3636)³⁹² and that the measure steward (CDC) intends to submit the updated measure for endorsement.³⁹³

(a) Measure Specifications

This measure is calculated quarterly by averaging the ASC's most recently submitted and self-selected one week of data. The measure includes at least 1 week of data collection a month for each of the three months in a quarter. The denominator is calculated as the aggregated number of HCP eligible to work in the ASC for at least one day during the week of data collection, excluding denominator-eligible individuals with contraindications as defined by the CDC for all 3 months in a quarter.³⁹⁴ Facilities report vaccination information for the following four, separate categories of HCP to NHSN:

- Employees: This includes all persons who receive a direct paycheck from the reporting facility (i.e., on the facility's payroll), regardless of clinical responsibility or patient contact.
- Licensed independent practitioners (LIPs): This includes only physicians (MD, DO), advanced practice nurses, and physician assistants who are affiliated with the reporting facility, but are not directly employed by it (i.e., they do not receive a paycheck from the reporting

³⁹¹ In previous years, we referred to the consensus-based entity (CBE) by corporate name. We have updated this language to refer to the CBE more generally.

³⁹² Centers for Medicare and Medicaid Services Measures Inventory Tool. (n.d.). Available at: <https://cmit.cms.gov/cmit/#/MeasureView?variantId=11670§ionNumber=1>.

³⁹³ The measure steward owns and maintains a measure while a measure developer develops, implements, and maintains a measure. In this case, the CDC serves as both the measure steward and measure developer. For more information on measure development, we refer readers to: Centers for Medicare and Medicaid Services (2023). Roles in Measure Development. Available at: <https://mmshub.cms.gov/about-quality/new-to-measures/roles>.

³⁹⁴ Centers for Disease Control and Prevention. (2022). Contraindications and precautions. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications>.

facility), regardless of clinical responsibility or patient contact. Post-residency fellows are also included in this category if they are not on the facility's payroll.

- Adult students/trainees and volunteers: This includes medical, nursing, or other health professional students, interns, medical residents, or volunteers aged 18 or older who are affiliated with the facility but are not directly employed by it (i.e., they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact.

- Other contract personnel: Contract personnel are defined as persons providing care, treatment, or services at the facility through a contract who do not fall into any of the previously discussed denominator categories.³⁹⁵ This also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract. We note that the other contract personnel category is required for data submission to NHSN, but is not included as part of the proposed COVID-19 Vaccination Coverage Among HCP measure.³⁹⁶

We are not proposing to modify the denominator exclusions. The numerator is calculated as the cumulative number of HCP in the denominator population who are considered up to date with CDC recommended COVID-19 vaccines. The term “up to date” is defined as meeting the CDC's set of criteria on the first day of the applicable reporting quarter. The current definition of “up to date” for COVID-19 vaccination can be found at:

<https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf>.

We refer readers to XV.D.1.c.(2) of this proposed rule for more details on the proposed modifications to this measure's specifications.

We propose that public reporting of the modified version of the COVID-19 Vaccination Coverage Among HCP for the ASCQR Program would begin with the Fall 2024 Care Compare refresh, or as soon as technically feasible.

³⁹⁵ For more details on the reporting of other contract personnel, we refer readers to the NHSN COVID-19 Vaccination Protocol, Weekly COVID-19 Vaccination Module for Healthcare Personnel available at: <https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf>.

³⁹⁶ Ibid.

(b) CBE Endorsement

The current version of the measure in ASCQR received CBE endorsement (CBE #3636) on July 26, 2022.³⁹⁷ The measure steward (CDC) intends to pursue CBE endorsement for the modified version of this measure.

(3) Data Submission and Reporting

We refer readers to the CY 2022 OPPTS/ASC final rule (86 FR 63879 through 63883) for information on data submission and reporting of this measure. While we are not proposing any changes to the data submission or reporting process, we propose that reporting of the updated, modified version of this measure would begin with the CY 2024 reporting period for the ASCQR Program. Under the data submission and reporting process, ASCs would collect the numerator and denominator for the COVID–19 Vaccination Coverage Among HCP measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personnel Safety (HPS) Component before the quarterly deadline to meet ASCQR Program requirements. If an ASC submits more than one week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, the third week data would be used. Each quarter, the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each ASC, which would be calculated by taking the average of the data from the three weekly rates submitted by the ASC for that quarter. CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC (86 FR 63878).

We refer readers to section XIV.B.2.a of this proposed rule for the same proposal for the Hospital OQR Program.

We invite public comment on this proposal.

³⁹⁷ Centers for Medicare & Medicaid Services. Measure Specifications for Hospital Workgroup for the 2022 MUC List. Available at: <https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf>.

b. Proposed Modification of the Survey Instrument Used for the Cataracts: Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery Measure Beginning with the Voluntary CY 2024 Reporting Period

(1) Background

In the CY 2014 OPPTS/ASC final rule (78 FR 75129), we finalized the adoption of the Cataracts: Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery (Cataracts Visual Function) measure beginning with the CY 2014 reporting period/CY 2016 payment determination. This measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function within 90 days following the cataract surgery via the administration of pre-operative and post-operative survey instruments (78 FR 75129). A “survey instrument” is an assessment tool that has been appropriately validated for the population for which it being used.³⁹⁸ For purposes of this proposed modification to the Cataracts Visual Function measure, the survey instruments we considered and are proposing to assess the visual function of a patient pre- and post-operatively to determine whether the patient’s visual function changed within 90 days of cataract surgery. Currently, examples of survey instruments assessing visual function include, but are not limited to, the National Eye Institute Visual Function Questionnaire (NEI-VFQ), the Visual Function (VF-14), the modified (VF-8R), the Activities of Daily Vision Scale (ADVS), the Catquest, and the modified Catquest-9. While the measure has been available for voluntary reporting in the ASCQR Program since the CY 2015 reporting period, a number of ASCs have reported data consistently using the survey instrument of their choice (87 FR 72119). We refer readers to the Cataracts Visual Function measure’s Measure Information Form (MIF) and the ASCQR Program Specifications Manual for additional detail, which is available at:

<https://qualitynet.cms.gov/asc/specifications-manuals>.

³⁹⁸ Ambulatory Surgical Center Specification Manual. (n.d.). Qualitynet. Retrieved March 21, 2023, from <https://qualitynet.cms.gov/asc/specifications-manuals>.

In the CY 2015 OPPTS/ASC final rule (79 FR 66984), we expressed concerns that clinicians' use of varying survey instruments would lead to inconsistent measure results. However, a study conducted a comparison among the 16 survey instruments currently accepted for use by ASCs in collecting data for this measure and found them to be scientifically validated, detected clinically important changes, and provided comparable results.³⁹⁹ While all 16 survey instruments in this study demonstrate usefulness for detecting clinically important change in cataract patients, some survey instrument's detection sensitivity scores higher than others.⁴⁰⁰

Several commenters responding to the CY 2022 OPPTS/ASC proposed rule (86 FR 63846) requested additional guidance from CMS regarding measure specifications and survey instruments for this Cataracts Visual Function measure in the Hospital OQR Program. We have considered this comment on this measure, and we agree that survey instruments for the assessment of visual function pre- and post-cataract surgery should be clarified in order to standardize acceptable survey instruments while minimizing collecting and reporting burden and to improve measure reliability. We propose to clarify which specific survey instruments may be used for the assessment of visual function pre- and post- cataract surgery for the Cataracts Visual Function measure in both the Hospital OQR Program and the ASCQR Program, to ensure alignment of this measure's specifications across our quality reporting programs. Thus, for the ASCQR Program, we propose to limit the survey instruments that an ASC may use to assess changes in a patient's visual function for purposes of the Cataracts Visual Function measure to those listed below:

- The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25)
- The Visual Functioning Patient Questionnaire (VF-14)
- The Visual Functioning Index Patient Questionnaire (VF-8R)

³⁹⁹ McAlinden C, Gothwal VK, Khadka J, et al. (2011). A head-to-head comparison of 16 cataract surgery outcome questionnaires. *Ophthalmology*.118(12):2374–81. <https://doi.org/10.1016/j.ophtha.2011.06.008>.

⁴⁰⁰ Ibid.

(2) Considerations for the Standardization of Survey Instruments Assessing Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery

We took into consideration several factors when identifying which specific survey instruments would be acceptable for ASCs to use when collecting data for the Cataracts Visual Function measure, such as comprehensiveness, validity, reliability, length, and burden. We believe that these three proposed survey instruments will allow ASCs to select the length of the survey instrument to be administered while ensuring adequate validity and reliability.^{401,402,403} All three of these proposed survey instruments are based upon the 51-item National Eye Institute Visual Function Questionnaire (NEI VFQ-51) survey instrument, which was the first survey instrument originally developed for assessing a patient's visual function before and after cataract surgery. Each of the three proposed survey instruments have progressively fewer numbers of questions than the NEI VFQ-51: 25 questions for the NEI VFQ-25, 14 questions for the VF-14, and 8 questions for the VF-8R. Even with fewer questions, all three of the proposed survey instruments have been validated as providing results comparable to the NEI VFQ-51. In addition, all three of the proposed survey instruments are readily available for ASCs to access and use.

We propose to allow ASCs to use the NEI VFQ-25 for administering and calculating this Cataracts Visual Function measure due to its comprehensiveness, its adequate validity and reliability, as well as its potential to reduce language barriers for patients. The NEI VFQ-25 is a shorter version of the NEI VFQ-51, being comprised of 25 items across 12 vision-specific domains (general health, general vision, ocular pain, near activities, distance activities, social

⁴⁰¹ Sivaprasad, S., Tschosik, E., Kapre, A., Varma, R., Bressler, N. M., Kimel, M., Dolan, C., & Silverman, D. (2018). Reliability and construct validity of the NEI VFQ-25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. *American Journal of Ophthalmology*, 190, 1–8. <https://doi.org/10.1016/j.ajo.2018.03.006>.

⁴⁰² Hecht, I., Kanclerz, P., & Tuuminen, R. (2022). Secondary outcomes of Lens and cataract surgery: More than just “best-corrected visual acuity.” *Progress in Retinal and Eye Research*, 101150. <https://doi.org/10.1016/j.preteyeres.2022.101150>.

⁴⁰³ Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Retrieved March 13, 2023, from https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303.

functioning, mental health, role difficulties, dependency, driving, color vision, and peripheral vision).⁴⁰⁴

The NEI VFQ-25, similar to the VF-14 and VF-8R, has adequate reliability and validity.

⁴⁰⁵ The NEI VFQ-25 composite, near activities, and distance activities subscales demonstrated good internal consistency reliability, test-retest reliability, convergent validity, and known-groups validity.⁴⁰⁶ Furthermore, the NEI VFQ-25's high internal consistency, indicates that items of the NEI VFQ-25 are highly related to each other and to the scale as a whole.⁴⁰⁷

In addition, the survey instrument is publicly available on the RAND website at no cost and has been translated to many languages, which is a valuable benefit for patients with limited English proficiency. The NEI VFQ-25 was chosen over other survey instruments to reduce potential language barriers, as, for example, the currently available Activities of Daily Vision Scale (ADVS) is dependent on English language skills.⁴⁰⁸ More information on the NEI VFQ-25 can be found at: https://www.rand.org/health-care/surveys_tools/vfq.html.

While the NEI VFQ-25 was shortened significantly from the original NEI VFQ-51, it has been criticized for its still lengthy test-time. However, our proposal to include this survey instrument in this measure's specifications allows for a more detailed assessment of cataract surgery outcomes as it was designed to include questions which are most important for persons who have chronic eye diseases.⁴⁰⁹ Further, if an ASC finds the NEI VFQ-25 particularly burdensome to administer, the ASC may choose from the other two survey instruments we

⁴⁰⁴ U.S. Department of Health and Human Services. (n.d.). *Visual function questionnaire 25*. National Eye Institute. Retrieved March 13, 2023, from <https://www.nei.nih.gov/learn-about-eye-health/outreach-campaigns-and-resources/outreach-materials/visual-function-questionnaire-25>.

⁴⁰⁵ Sivaprasad, S., Tschosik, E., Kapre, A., Varma, R., Bressler, N. M., Kimel, M., Dolan, C., & Silverman, D. (2018). Reliability and construct validity of the NEI VFQ-25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. *American Journal of Ophthalmology*, 190, 1–8. <https://doi.org/10.1016/j.ajo.2018.03.006>.

⁴⁰⁶ Ibid.

⁴⁰⁷ Ibid.

⁴⁰⁸ Mangione CM, Phillips RS, Seddon JM, et al. Development of the 'Activities of Daily Vision Scale'. A measure of visual functional status. *Med Care*. 1992;30(12):1111-1126. <https://doi.org/10.1097/00005650-199212000-00004>.

⁴⁰⁹ Hecht, I., Kanclerz, P., & Tuuminen, R. (2022). Secondary outcomes of Lens and cataract surgery: More than just “best-corrected visual acuity.” *Progress in Retinal and Eye Research*, 101150. <https://doi.org/10.1016/j.preteyeres.2022.101150>.

propose for inclusion in this measure’s specifications for ASCs to use for this measure, as both of these have even fewer survey questions to administer.

We also propose to allow ASCs to use the 14-item VF-14 and the 8-item VF-8R for administering and calculating this Cataracts Visual Function measure. Each can be administered in a shorter timeframe than the NEI VFQ-25 with high precision.^{410,411} Thus, the succinct formats of the VF-14 and VF-8R may ease ASCs’ burden in administering the survey instruments, and potentially increase the rate of patient responses for this measure, as compared with other survey instrument options we considered. Therefore, we propose including the VF-14 and VF-8R for this measure’s data collection specifications because we believe these survey instruments achieve results comparable with the longer NEI VFQ-25 and NEI VFQ-51 survey instruments with substantially fewer questions to administer.

Furthermore, we propose inclusion of the VF-14 because currently it is the most commonly used survey instrument and we believe it would be beneficial to allow the majority of physicians who have already been using the VF-14 to continue to have the option to do so.⁴¹² The VF-14 is comprised of 14 items relating to daily living activities and function, such as reading, writing, seeing steps, stairs or curbs, and operating a motor vehicle.⁴¹³ Studies using this survey instrument generally report significant and clinically important improvement following cataract surgery.⁴¹⁴ The VF-14 additionally has achieved adequate reliability and validity, proving it to be a dependable survey instrument for cataract outcomes.^{415,416}

⁴¹⁰ Ibid.

⁴¹¹ Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Retrieved March 13, 2023, from https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303.

⁴¹² Hecht, I., Kanclerz, P., & Tuuminen, R. (2022). Secondary outcomes of Lens and cataract surgery: More than just “best-corrected visual acuity.” *Progress in Retinal and Eye Research*, 101150. <https://doi.org/10.1016/j.preteyeres.2022.101150>.

⁴¹³ Ibid.

⁴¹⁴ Ibid.

⁴¹⁵ Ibid.

⁴¹⁶ Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Retrieved March 13, 2023, from https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303.

We propose the VF-8R, as it is the most concise of the three survey instruments, while still achieving adequate validity and reliability.⁴¹⁷ The VF-8R consists of questions related to reading, fine handwork, writing, playing board games, and watching television.⁴¹⁸ Given its conciseness compared to the majority of currently available survey instruments and its adequate psychometric properties, we believe that the VF-8R would be beneficial for measuring cataract surgery outcomes without prompting further patient survey fatigue.⁴¹⁹

For these reasons, we believe that the NEI VFQ-25, VF-14, and VF-8R are the most appropriate survey instruments for ASCs to use to assess a patient's visual function pre- and post-cataract surgery for purposes of calculating and submitting data for the Cataracts Visual Function measure in the ASCQR Program.

To standardize survey instrument administration for the Cataracts Visual Function measure, we propose to limit the survey instruments that can be used to administer this measure, beginning with the voluntary CY 2024 reporting period, to these three survey instruments: (1) NEI VFQ-25; (2) VF-14; and (3) VF-8R. We believe the use of these three survey instruments to report data on the Cataracts Visual Function measure would allow for a more standardized approach to data collection. Having a limited number of allowable survey instruments would also address several commenters' request for additional guidance on survey instruments as well as improve measure reliability.

(3) Considerations for Data Collection Modes for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Beginning with the Voluntary CY 2024 Reporting Period

As summarized in the CY 2023 OPPTS/ASC final rule (87 FR 72118 through 72120), many commenters expressed concern about the high administrative burden of reporting the

⁴¹⁷ Ibid.

⁴¹⁸ Pre-Cataract Surgery – Visual Functioning Index (VF-8R) patient. (n.d.). <https://eyecaresite.com/wp-content/uploads/2020/02/Visual-Functioning-Index-Pre-Cat-SX.pdf>.

⁴¹⁹ Ibid.

Cataracts Visual Function measure, as the measure uniquely requires coordination among clinicians of different specialties (that is, opticians and ophthalmologists). In an effort to decrease administrative burden surrounding in-office time constraints, we reiterate that, while we recommend the patient’s physician or optometrist administer, collect, and report the survey results to the ASC, the survey instruments required for this measure can be administered by the ASC itself via phone, by the patient via regular or electronic mail, or during clinician follow-up.

Scientific literature supports the conclusion that self-administered survey instruments produce statistically reliable results.^{420,421} Furthermore, scientific literature indicates that regular mail and electronic mail surveys respectively, are preferred by varying subgroups of patients. The inclusion of both options ensures that patients will be able to respond to survey instruments in their preferred format.^{422,423} These findings support the inclusion of varying survey instrument-collection methods for patient and provider convenience.

We invite public comment on this proposal.

c. Proposed Modification of Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Denominator Change to Align with Current Clinical Guidelines Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

⁴²⁰ Bhandari, N. R., Kathe, N., Hayes, C., & Payakachat, N. (2018). Reliability and validity of SF-12V2 among adults with self-reported cancer. *Research in Social and Administrative Pharmacy, 14*(11), 1080–1084. <https://doi.org/10.1016/j.sapharm.2018.01.007>.

⁴²¹ Stolwijk, C., van Tubergen, A., Ramiro, S., Essers, I., Blaauw, M., van der Heijde, D., Landewe, R., van den Bosch, F., Dougados, M., & Boonen, A. (2014). Aspects of validity of the self-administered comorbidity questionnaire in patients with ankylosing spondylitis. *Rheumatology, 53*(6), 1054–1064. <https://doi.org/10.1093/rheumatology/ket354>.

⁴²² Kelfve, S., Kivi, M., Johansson, B., & Lindwall, M. (2020). Going web or staying paper? the use of web-surveys among older people. <https://doi.org/10.21203/rs.3.rs-21136/v4>.

⁴²³ Meyer, V. M., Benjamens, S., Moumni, M. E., Lange, J. F., & Pol, R. A. (2020). Global overview of response rates in patient and health care professional surveys in surgery. *Annals of Surgery, 275*(1). <https://doi.org/10.1097/sla.0000000000004078>.

(1) Background

In 2019, colorectal cancer (CRC) accounted for the 4th highest rate of new cancer cases and 4th highest rate of cancer deaths in the United States.⁴²⁴ The American Cancer Society (ACS) estimates that in 2023, 153,020 individuals will be newly diagnosed with CRC and 52,550 individuals will die from CRC in the United States.⁴²⁵ The CDC advises, “[c]olorectal cancer almost always develops from precancerous polyps (abnormal growths) in the colon or rectum. Screening tests can find precancerous polyps, so that they can be removed before they turn into cancer. Screening tests can also find colorectal cancer early, when treatment works best. Regular screening, beginning at age 45, is the key to preventing colorectal cancer and finding it early.”⁴²⁶

In May 2021, the United States Preventive Services Task Force (USPSTF) issued a revised Final Recommendation Statement on CRC Screening.⁴²⁷ This replaced the prior USPSTF 2016 Final Recommendation Statement and included a number of updated policy recommendations based on new evidence and understandings of CRC and CRC screening. The USPSTF recommended that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of the previous recommendation of age 50.⁴²⁸ In addition, multiple professional organizations, including the ACS, American Society of Colon and Rectal Surgeons, and the U.S. Multi-Society Task Force on Colorectal Cancer (which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy), recommend that people

⁴²⁴ Centers for Disease Control. (2022). Colorectal Cancer Statistics. Available at: <https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/>.

⁴²⁵ American Cancer Society. (2023). Cancer Facts & Figures 2023. Available at: <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2023-cancer-facts-figures.html>.

⁴²⁶ Centers for Disease Control. (2022). What Should I Know About Screening?. Available at: https://www.cdc.gov/cancer/colorectal/basic_info/screening/index.htm.

⁴²⁷ US Preventive Services Task Force. (2021). Screening for Colorectal Cancer. *JAMA*, 325(19), 1965-1977. <https://doi.org/10.1001/jama.2021.6238>.

⁴²⁸ Ibid.

of average risk of CRC start regular screening at age 45.^{429,430,431} Based on the recent changes in clinical guidelines to begin CRC screening at age 45 instead of age 50, we propose to modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the “Colonoscopy Follow-Up Interval”) measure to follow these clinical guideline changes.

(2) Overview of Measure

We refer readers to the CMS Measures Inventory Tool and the ASCQR Specification Manual for more information on the Colonoscopy Follow-Up Interval measure, including background on the measure and a complete summary of measure specifications.^{432,433} Currently, the Colonoscopy Follow-Up Interval measure assesses the “percentage of patients aged 50 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.”⁴³⁴ We propose to amend the measure’s denominator language by replacing the phrase “aged 50 years” with the phrase “aged 45 years.” The measure denominator would be modified to “all patients aged 45 years to 75 years receiving screening colonoscopy without biopsy or polypectomy” from “all patients aged 50 years to 75 years receiving screening colonoscopy without biopsy or polypectomy.”⁴³⁵ We are not proposing any changes to the

⁴²⁹ Wolf A, Fontham ETH, Church TR, et al. (2018). Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA. Cancer J. Clin.*, 2018(68), 250-281. <https://doi.org/10.3322/caac.21457>.

⁴³⁰ American Society of Colon & Rectal Surgeons. Colorectal Cancer Screening and Surveillance Recommendations of U.S. Multisociety Task Force. Available at: <https://fascrs.org/healthcare-providers/education/clinical-practice-guidelines/colorectal-cancer-screening-and-surveillance-recom>.

⁴³¹ Patel SG, May FP, Anderson JC, Burke CA, et al. (2022). Updates on Age to Start and Stop Colorectal Cancer Screening: Recommendations From the U.S. Multi-Society Task Force on Colorectal Cancer. *The American Journal of Gastroenterology*, 117(1), 57-69. <https://doi.org/10.14309/ajg.0000000000001548>.

⁴³² Centers for Medicare & Medicaid Services. (2023). Measures Inventory Tool. Available at: <https://cmit.cms.gov/cmit/#/MeasureView?variantId=793§ionNumber=1>.

⁴³³ Qualitynet Home. (n.d.). Retrieved March 21, 2023, from <https://qualitynet.cms.gov/asc/specifications-manuals#tab6>.

⁴³⁴ Centers for Medicare & Medicaid Services. (2023). Measures Inventory Tool. Available at: <https://cmit.cms.gov/cmit/#/MeasureView?variantId=793§ionNumber=1>.

⁴³⁵ Ibid.

measure numerator, other measure specifications, exclusions, or data collection for the Colonoscopy Follow-Up Interval measure.

In the CY 2023 Physician Fee Schedule final rule (87 FR 69760 through 69767), we adopted the modified Colonoscopy Follow-Up Interval measure, which we propose here for the ASCQR Program, for the Merit-based Incentive Payment System (MIPS). We have considered the importance of aligning the minimum age requirement for CRC screening across quality reporting programs and clinical guidelines, and as a result, we propose to modify the Colonoscopy Follow-Up Interval measure denominator to “all patients aged 45 to 75 years” for the ASCQR Program. We propose the modification of the Colonoscopy Follow-Up Interval measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

We invite public comment on this proposal.

5. Proposed Adoption of New Measures for the ASCQR Program Measure Set

Section 1833(i)(7)(B) of the Act states that, except as the Secretary may otherwise provide, the provisions of section 1833(t)(17)(B) through (E) of the Act apply with respect to ASC services in a similar manner to the manner in which they apply to hospitals for the Hospital OQR Program. Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus-based entities. We have noted in previous rulemaking (76 FR 74494) the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from CBE endorsement, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

Section 1890A of the Act requires that we establish and follow a pre-rulemaking process for selecting quality and efficiency measures for our programs, including taking into consideration input from multi-stakeholder groups. As part of this pre-rulemaking process, the

CBE, with which we contract under section 1890 of the Act, convened these groups under the Measure Applications Partnership (MAP). The MAP is a public-private partnership created for the primary purpose of providing input to HHS on the selection of measures as required by section 1890(b)(7)(B) of the Act, including measures for the ASCQR Program. We followed this pre-rulemaking process for both of the measures we propose for adoption for the ASCQR Program under this section of the proposed rule, as further detailed below.

In this proposed rule, we propose to: (1) re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical Procedures measure, with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (2) adopt the 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), with voluntary reporting beginning with the CYs 2025 and 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination. In this section of the proposed rule, we provide additional information on these measure adoption proposals for the ASCQR Program.

a. Proposed Re-adoption with Modification of the ASC Facility Volume Data on Selected ASC Surgical Procedures Measure Beginning with the Voluntary CY 2025 Reporting Period Followed By Mandatory Reporting Beginning with the CY 2026 Reporting Period/CY 2028 Payment Determination

(1) Background

Hospital care has been gradually shifting from inpatient to outpatient settings.⁴³⁶ Further, research indicates that volume of services performed in ASCs will continue to grow, with some

⁴³⁶ Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3. Available at: https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf.

estimates projecting a 25 percent increase in patients between 2019 and 2029.⁴³⁷ In addition, as further discussed herein, larger facility surgical procedure volume may be associated with better outcomes due to having characteristics that improve care, such as efficient team work and increased surgical experience.⁴³⁸ In light of these trends in facility volume and more recent studies finding that volume is an indicator of quality, it is now especially important to track volume within ASCs, as it could provide valuable insight into the quality of ASCs' services for CMS and patients.

Although measuring the volume of procedures and other services has a long history as a quality metric, quality measurement efforts had moved away from collecting and analyzing data on volume because some considered volume simply a proxy for quality compared to directly measuring outcomes.⁴³⁹ However, experts on quality and safety have recently suggested that, while volume may not alone indicate better outcomes, it is still an important component of quality.^{440,441,442} Specifically, larger facility surgical procedure volume may be associated with better outcomes due to having characteristics that improve care.⁴⁴³ For example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications.⁴⁴⁴ This association between volume and patient outcomes may be attributable to greater experience or surgical skill, greater comfort

⁴³⁷ SG2 impact of Change Forecast predicts enormous disruption in health care provider landscape by 2029. Sg2. (2021). Retrieved March 28, 2023, from <https://www.sg2.com/media-center/press-releases/sg2-impact-forecast-predicts-disruption-health-care-provider-landscape-2029/>.

⁴³⁸ Jha AK. (2015) Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015. <https://jamanetwork.com/channels/health-forum/fullarticle/2760155>.

⁴³⁹ Ibid.

⁴⁴⁰ Ibid.

⁴⁴¹ Shang, M., Mori, M., Gan, G., Deng, Y., Brooks, C., Weininger, G., Sallam, A., Vallabhajosyula, P., & Geirsson, A. (2022). Widening volume and persistent outcome disparity in Valve Operations: New York Statewide Analysis, 2005-2016. *The Journal of Thoracic and Cardiovascular Surgery*, *164*(6). <https://doi.org/10.1016/j.jtcvs.2020.11.098>.

⁴⁴² Iwatsuki, M., Yamamoto, H., Miyata, H., Kakeji, Y., Yoshida, K., Konno, H., Seto, Y., & Baba, H. (2018). Effect of hospital and surgeon volume on postoperative outcomes after distal gastrectomy for gastric cancer based on data from 145,523 Japanese patients collected from a nationwide web-based data entry system. *Gastric Cancer*, *22*(1), 190–201. <https://doi.org/10.1007/s10120-018-0883-1>.

⁴⁴³ Jha AK. (2015) Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015. <https://jamanetwork.com/channels/health-forum/fullarticle/2760155>

⁴⁴⁴ Ibid.

with and, hence, likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure.

The ASCQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but it did so previously. We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74507 through 74509) where we adopted the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC Procedure Volume) measure beginning with the CY 2015 payment determination. This structural measure of facility capacity collected surgical procedure volume data on seven categories of procedures frequently performed in the ASC setting: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, Respiratory, and Genitourinary.⁴⁴⁵ We adopted the ASC Procedure Volume measure based on evidence that the volume of surgical procedures, particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased mortality (76 FR 74507).^{446,447} We further stated our belief that publicly reporting volume data would provide patients with beneficial information to use when selecting a care provider (76 FR 74507).

In the CY 2018 OPPS/ASC final rule (82 FR 59449 through 59450), we stated our belief at that time that other measures in the ASCQR Program on specific procedure types, such as the Unplanned Anterior Vitrectomy measure, could provide patients with more valuable ASC quality of care information than the ASC Procedure Volume measure. Thus, we removed the ASC Procedure Volume measure beginning with the CY 2019 payment determination based on the availability of other measures that are “more strongly associated with desired patient outcomes for the particular topic” (currently Factor 6 in our regulation at § 416.320(c)(vi)) (82 FR 59449).

⁴⁴⁵ ASC Specifications Manual version 5.1. Available at: <https://qualitynet.cms.gov/asc/specifications-manuals#tab6>.

⁴⁴⁶ Saito, Y., Tateishi, K., Kanda, M., Shiko, Y., Kawasaki, Y., Kobayashi, Y., & Inoue, T. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association*, 11(6). <https://doi.org/10.1161/jaha.121.023805>.

⁴⁴⁷ Vemulapalli, S., Carroll, J., & Mack, M. et al. (2019) Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. <https://doi.org/10.1056/NEJMs1901109>.

However, a commenter who opposed the removal of the ASC Procedure Volume measure at the time emphasized the measure data's usefulness for comparative research, outcomes research, immediate consumer value, and strategic planning (82 FR 59449). One commenter also expressed concern that non-availability of these data would interfere with the acceptance of ASC-based procedures, asserting that this measure helps to demonstrate the value of ASC-based procedures (82 FR 59449). These commenters further noted that the measure was not overly burdensome and, therefore, should not be removed (82 FR 59449). At the time, while we recognized the value of the measure and these concerns, we believed, overall, that the administrative burden and maintenance costs associated with this measure outweighed the benefits of keeping the measure in the ASCQR Program (82 FR 59449 through 59450).

In the CY 2023 OPPI/ASC final rule (87 FR 72127 through 72130), we stated that we have been considering re-adopting the ASC Procedure Volume measure for two reasons. First, since the removal of the ASC Procedure Volume measure, scientific literature has concluded that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care.⁴⁴⁸ Further supporting this position that volume metrics are an indicator of quality, one study found an inverse volume–mortality relationship related to transfemoral transcatheter aortic-valve replacement (TAVR) procedures performed from 2015 through 2017.⁴⁴⁹ Second, as discussed above, the recent shift of more surgical procedures being performed in outpatient settings has placed greater importance on tracking the volume of outpatient procedures in different settings, including ASCs. We believe that patients and their caregivers may benefit from the public reporting of facility-level volume measure data because the volume data illuminate which procedures are performed across ASCs, provide the ability to track volume changes by facility

⁴⁴⁸ Ogola GO, Crandall ML, Richter KM, & Shafi S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*, 85(3), 560–565. <https://doi.org/10.1097/TA.0000000000001985>.

⁴⁴⁹ Vemulapalli S, Carroll J, Mack M, et al. (2019). Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. <https://doi.org/10.1056/NEJMSa1901109>.

and procedure category, and can serve as an indicator for patients of which facilities are experienced with certain outpatient procedures. The ASC Procedure Volume measure was the only measure in the ASCQR Program measure set that captured facility-level volume within ASCs for both Medicare beneficiaries and non-Medicare patients. As a result of this measure's removal in the CY 2018 OPPTS/ASC final rule, the ASCQR Program currently does not capture outpatient surgical procedure volume in ASCs.

In response to our request for comment in the CY 2023 OPPTS/ASC proposed rule (87 FR 44748 through 44750) regarding the potential inclusion of a volume measure in the ASCQR Program, a few commenters suggested that we can determine facility volumes for procedures performed using Medicare Fee-For-Service (FFS) claims (87 FR 72129 through 72130). However, we note that the ASC Procedure Volume measure included the submission of both Medicare and non-Medicare volume data; thus, relying solely on the use of Medicare FFS claims data to simplify reporting would limit a future volume measure to only the Medicare program payer, leading to an incomplete representation of ASCs' procedural volume.⁴⁵⁰

Additionally, in response to our request for comment in the CY 2023 OPPTS/ASC proposed rule (87 FR 44748 through 44750), a few commenters stated that they believe there is a lack of evidence proving the correlation between volume and quality (87 FR 72129 through 72130). However, many studies in recent years have shown that volume does serve as an indicator of quality of care.^{451,452} For example, studies published since the CY 2018 OPPTS/ASC final rule found that patients at high volume hospitals for a specific procedure had lower rates of surgical site infections, complications, and mortality compared to patients at

⁴⁵⁰ The specifications for the removed ASC Procedure Volume measure are available in the ASC Specifications Manual version 5.1 available at <https://qualitynet.cms.gov/asc/specifications-manuals#tab6>.

⁴⁵¹ Ogola, Gerald O. Ph.D., MPH; Crandall, Marie L. MD, MPH; Richter, Kathleen M. MS, MBA, MFA; & Shafi, Shahid MD, MPH. (2018) High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*: September 2018— Volume 85—Issue 3—p 560–565 <https://doi.org/10.1097/TA.0000000000001985>.

⁴⁵² Vemulapalli, S., Carroll, J., & Mack, M. et al. (2019) Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. <https://doi.org/10.1056/NEJMs1901109>.

low-volume hospitals.^{453,454} We reiterate our belief, grounded in this published scientific literature, that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and assist consumers in making informed decisions about where they receive care.^{455,456}

(2) Overview of Measure

(a) Data Collection, Submission, Reporting, and Measure Specifications

The proposed ASC Procedure Volume measure collects data regarding the aggregate count of selected surgical procedures. Most ASC procedures fall into one of eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.⁴⁵⁷ For this proposed measure, data surrounding the top five most frequently performed procedures among ASCs in each category will be collected and publicly displayed. The top five procedures in each category would be assessed and updated annually as needed to ensure data collection of most accurate and frequently performed procedures.⁴⁵⁸

We propose that ASCs would submit aggregate-level data through the CMS web-based tool (currently the Hospital Quality Reporting (HQR) system), consistent with what was required during the measure's initial adoption (76 FR 74508). Data received through the HQR system would then be publicly displayed on the data.cms.gov website or another CMS website. We

⁴⁵³ Mufarrih, S.H., Ghani, M.O.A., Martins, R.S. et al. (2019) Effect of hospital volume on outcomes of total hip arthroplasty: a systematic review and metaanalysis. *J Orthop Surg Res* 14, 468. <https://doi.org/10.1186/s13018-019-1531-0>.

⁴⁵⁴ Saito, Y., Tateishi, K., Kanda, M., Shiko, Y., Kawasaki, Y., Kobayashi, Y., & Inoue, T. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association*, 11(6). <https://doi.org/10.1161/jaha.121.023805>.

⁴⁵⁵ Ogola GO, Crandall ML, Richter KM, Shafi, S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*, 85(3), 560–565. <https://doi.org/10.1097/TA.0000000000001985>.

⁴⁵⁶ Vemulapalli S, Carroll J, Mack M, et al. (2019). Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. <https://doi.org/10.1056/NEJMsa1901109>.

⁴⁵⁷ ASC Specifications Manual version 1.0b. Available at: <https://qualitynet.cms.gov/asc/specifications-manuals#tab6>.

⁴⁵⁸ Data source: Clinical Data Warehouse; CMS ASC Part B claims for encounters January 1, 2022 - December 31, 2022.

refer readers to § 416.315 for our codified policies regarding public reporting of data under the ASCQR Program.

We propose to re-adopt the ASC Procedure Volume measure with modification, with voluntary reporting beginning with the CY 2025 reporting period followed by mandatory reporting beginning with CY 2026 reporting period/CY 2028 payment determination. At the time of this measure's initial adoption in the CY 2012 OPPS/ASC final rule (76 FR 74509), we finalized that ASCs would report all-patient volume data with respect to six categories: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary. The first modification of this previously adopted measure that we propose is that the ASC Procedure Volume measure data collection will cover eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin. Furthermore, in response to commenter concerns regarding potential difficulty detecting procedural volume differentiation among these broad based categories (76 FR 74508), the second modification to this measure that we propose is that instead of collecting and publicly displaying data surrounding these eight broad categories, we would more granularly collect and publicly display data reported for the top five most frequently performed procedures among ASCs within each category will be collected. We refer readers to the Center for Medicare and Medicaid Services Inventory Tool for more information on this measure: <https://cmit.cms.gov/cmit/#/>.

We also propose that ASCs submit these data to CMS during the time period of January 1 through May 15 in the year prior to the affected payment determination year. For example, for the CY 2028 payment determination, the data submission period would be January 1, 2027 to May 15, 2027, covering the performance period of January 1, 2026 to December 31, 2026. We refer readers to section XV.D.1.c of this proposed rule for a more detailed discussion of the requirements for data submitted via a CMS online web-based tool. We previously codified our existing policies regarding data collection and submission under the ASCQR Program at § 416.310.

(b) Review by the Measure Applications Partnership (MAP)

The MAP conditionally supported the ASC Procedure Volume measure for rulemaking, pending testing indicating that the measure is reliable and valid, and endorsement by a CBE.⁴⁵⁹ Additionally, the MAP noted that electronic reporting of procedure volumes based on code lists should not be overly burdensome to ASCs, and the public reporting of specific procedure volumes may be useful to patients.

The MAP members expressed differing views on the value of volume data to patients. Specifically, the MAP members representing patients stated the measure would be useful to patients as they decide where to seek care, as one data point along with others (for example, advice from providers). However, other MAP members expressed concern about the value of volume data for informing patient decisions without other context and encouraged the use of outcome measures instead.⁴⁶⁰

As discussed above, we reiterate that various studies have found that there is a well-established positive correlation between the volume of procedures performed at a facility and the clinical outcomes resulting from that procedure. For instance, a recent systematic review highlighted by the MAP found a significant volume-outcome relationship in the vast majority (87 percent) of the 403 studies analyzed.⁴⁶¹ The MAP noted a similar review focused on outpatient surgeries that similarly found a significant volume-outcome relationship across eight studies.⁴⁶²

The MAP stated that this measure addresses a national trend in which surgeries are moving from hospital inpatient settings to ASCs, and that public reporting of this measure could

⁴⁵⁹ Pre-rulemaking MUC lists and map reports. Pre-Rulemaking MUC Lists and MAP Reports | The Measures Management System. (n.d.). Retrieved March 13, 2023, from <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

⁴⁶⁰ Ibid.

⁴⁶¹ Levaillant, M., Marcilly, R., Levaillant, L., Michel, P., Hamel-Broza, J.-F., Vallet, B., & Lamer, A. (2021). Assessing the hospital volume-outcome relationship in surgery: A scoping review. *BMC Medical Research Methodology*, 21(1). <https://doi.org/10.1186/s12874-021-01396-6>.

⁴⁶² Stanak, M., & Strohmaier, C. (2020). Minimum volume standards in day surgery: A systematic review. *BMC Health Services Research*, 20(1). <https://doi.org/10.1186/s12913-020-05724-2>.

help CMS and the public better understand differences in the quality of care provided at facilities.⁴⁶³ The MAP reported that ASC Procedure Volume measure data from 2015 and 2016 demonstrates variation in performance in the number of procedures performed by facilities in the 25th and 75th percentiles across the condition categories.⁴⁶⁴ These findings support our belief, grounded in additional published scientific literature, that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care.^{465,466}

In addition, the MAP noted the concurrent submission of MUC (Measures Under Consideration) 2022-030: Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures for inclusion in the Hospital Outpatient Quality Reporting (OQR) Program.⁴⁶⁷ The MAP highlighted that the specifications of the volume measure proposed for the Hospital OQR Program are aligned with the volume measure we propose for the ASCQR Program and, therefore, would facilitate comparisons of equivalent procedure volumes across ASCs and hospital outpatient departments (HOPDs), one of the key goals of the Hospital OQR and ASCQR Programs.

(c) Measure Endorsement

As discussed in the previous subsection of the proposed rule, the MAP reviewed and conditionally supported the ASC Procedure Volume measure pending testing indicating the measure is reliable and valid, and endorsement by a national consensus-based entity as the measure was not submitted for endorsement. We have noted in previous rulemaking (76 FR

⁴⁶³ Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: <https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/>.

⁴⁶⁴ Pre-rulemaking MUC lists and map reports. The Measures Management System. (n.d.). Retrieved March 13, 2023, from <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

⁴⁶⁵ Ogola, Gerald O. Ph.D., MPH; Crandall, Marie L. MD, MPH; Richter, Kathleen M. MS, MBA, MFA; Shafi, & Shahid MD, MPH. (2018) High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*: September 2018— Volume 85—Issue 3—p 560–565. <https://doi.org/10.1097/TA.0000000000001985>.

⁴⁶⁶ Saito, Y., Tateishi, K., Kanda, M., Shiko, Y., Kawasaki, Y., Kobayashi, Y., & Inoue, T. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association*, 11(6). <https://doi.org/10.1161/jaha.121.023805>.

⁴⁶⁷ Pre-rulemaking MUC lists and map reports. The Measures Management System. (n.d.). Retrieved March 13, 2023, from <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

74494) the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from endorsement by a national consensus-based entity, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

We considered the MAP's recommendation and propose to adopt the measure because we did not find any other measures of procedure volume and this measure was previously used in the ASCQR Program, with supporters of its use. Given the support from the MAP and feedback from public comment, as well as the increasing shift from inpatient to outpatient surgical procedures and evidence that volume metrics can promote higher quality healthcare for patients, we propose the readoption of this measure, with two modifications, in the ASCQR Program pending endorsement from a national consensus-based entity.

We invite public comment on this proposal.

b. Proposed Adoption of the 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) Beginning with Voluntary CYs 2025 and 2026 Reporting Periods Followed By Mandatory Reporting Beginning with the CY 2027 Reporting Period/CY 2030 Payment Determination

(1) Background

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257), we adopted the THA/TKA PRO-PM in the Hospital Inpatient Quality Reporting (IQR) Program beginning with voluntary reporting periods in FY 2025 and FY 2026, followed by mandatory reporting for eligible elective procedures occurring July 1, 2024 through June 30, 2025 for the FY 2028 payment determination. In this proposed rule, we propose the adoption of the THA/TKA PRO-PM into the ASCQR Program using the same specifications as finalized for the hospital-level measure adopted into the Hospital IQR Program (87 FR 49246 through 49257) with modifications to include procedures performed in the ASC setting.

Approximately six million adults aged 65 or older suffer from osteoarthritis in the United States.⁴⁶⁸ In 2013, there were approximately 568,000 hospitalizations billed to Medicare for osteoarthritis.⁴⁶⁹ Hip and knee osteoarthritis is one of the leading causes of disability among non-institutionalized adults,^{470,471} and roughly 80 percent of patients with osteoarthritis have some limitation in mobility.^{472,473} Elective THA and TKA are most commonly performed for degenerative joint disease or osteoarthritis, which affects more than 30 million Americans.⁴⁷⁴ THA and TKA offer the potential for significant improvement in quality of life by decreasing pain and improving function in a majority of patients, without resulting in a high risk of complications or death.^{475,476,477} However, not all patients experience benefit from these procedures.⁴⁷⁸ Many patients note that their pre-operative expectations for functional

⁴⁶⁸ Arthritis Foundation. (2018). Arthritis By the Numbers Book of Trusted Facts and Figures. Accessed March 8, 2019. Available at: <https://www.arthritis.org/getmedia/e1256607-fa87-4593-aa8a-8db4f291072a/2019-abtn-final-march-2019.pdf>.

⁴⁶⁹ Torio CM, & Moore BJ. (2016). National inpatient hospital costs: the most expensive conditions by payer, 2013. HCUP statistical brief #204. Healthcare Cost and Utilization Project (HCUP) Statistical Briefs. Rockville, MD, Agency for Healthcare Research and Quality. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK368492/>.

⁴⁷⁰ Guccione AA, Felson DT, Anderson JJ, et al. (1994). The effects of specific medical conditions on the functional limitations of elders in the Framingham Study. *American journal of public health*, 84(3), 351–358. <https://www.doi.org/10.2105/AJPH.84.3.351>.

⁴⁷¹ Barbour KE, Helmick CG, Boring M, & Brady TJ. (2017). Vital Signs: Prevalence of Doctor-Diagnosed Arthritis and Arthritis-Attributable Activity Limitation - United States, 2013-2015. *MMWR Morbidity and mortality weekly report*, 66(9), 246–253. <https://www.doi.org/10.15585/mmwr.mm6609e1>.

⁴⁷² Michaud CM, McKenna MT, Begg S, et al. (2006). The burden of disease and injury in the United States 1996. *Population health metrics*, 4, 11. <https://doi.org/10.1186/1478-7954-4-11>.

⁴⁷³ Theis KA, Murphy LB, Baker NA, & Hootman JM. (2019). When you can't walk a mile: Walking limitation prevalence and associations among middle-aged and older US adults with Arthritis: A cross-sectional, population-based study. *ACR Open Rheumatol*, 1(6), 350-358. <https://www.doi.org/10.1002/acr2.11046>.

⁴⁷⁴ Centers for Disease Control and Prevention. Osteoarthritis (OA). Accessed March 8, 2019. Available at: <https://www.cdc.gov/arthritis/basics/osteoarthritis.htm>.

⁴⁷⁵ Rissanen P, Aro S, Slati P, et al. (1995). Health and quality of life before and after hip or knee arthroplasty. *The Journal of arthroplasty*, 10(2), 169–175. [https://www.doi.org/10.1016/s0883-5403\(05\)80123-8](https://www.doi.org/10.1016/s0883-5403(05)80123-8).

⁴⁷⁶ Ritter MA, Albohm MJ, Keating EM, et al. (1995). Comparative outcomes of total joint arthroplasty. *The Journal of arthroplasty*, 10(6), 737–741. [https://doi.org/10.1016/s0883-5403\(05\)80068-3](https://doi.org/10.1016/s0883-5403(05)80068-3).

⁴⁷⁷ Sayah SM, Karunaratne S, Beckenkamp PR, et al. (2021). Clinical Course of Pain and Function Following Total Knee Arthroplasty: A Systematic Review and Meta-Regression. *J Arthroplasty*, 36(12), 3993-4002.e37. <https://www.doi.org/10.1016/j.arth.2021.06.019>.

⁴⁷⁸ National Joint Registry. National Joint Registry for England and Wales 9th Annual Report 2012. Available at: <https://www.hqip.org.uk/wp-content/uploads/2018/02/national-joint-registry-9th-annual-report-2012.pdf>.

improvement have not been met.^{479,480,481,482} In addition, clinical practice variation has been well documented in the United States,^{483,484,485,486,487} readmission and complication rates vary across hospitals,^{488,489} and international experience documents wide hospital-level variation in patient-reported outcome measure results following THA and TKA.⁴⁹⁰

Due to the absence of recently conducted, large scale and uniformly collected patient-reported outcome (PRO) data available from patients undergoing elective primary THA/TKA, we established an incentivized, voluntary PRO data collection opportunity within the Comprehensive Care for Joint Replacement (CJR) model to support measure development.⁴⁹¹ Elective THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (such as pain, mobility, and quality of life) can be

⁴⁷⁹ Suda AJ, Seeger JB, Bitsch RG, et al. (2010). Are patients' expectations of hip and knee arthroplasty fulfilled? A prospective study of 130 patients. *Orthopedics*, 33(2), 76–80. <https://www.doi.org/10.3928/01477447-20100104-07>.

⁴⁸⁰ Ghomrawi HM, Franco Ferrando N, Mandl LA, et al. (2011). How Often are Patient and Surgeon Recovery Expectations for Total Joint Arthroplasty Aligned? Results of a Pilot Study. *HSS journal: The musculoskeletal journal of Hospital for Special Surgery*, 7(3), 229–234. <https://www.doi.org/10.1007/s11420-011-9203-6>.

⁴⁸¹ Harris IA, Harris AM, Naylor JM, et al. (2013). Discordance between patient and surgeon satisfaction after total joint arthroplasty. *The Journal of arthroplasty*, 28(5), 722–727. <https://www.doi.org/10.1016/j.arth.2012.07.044>.

⁴⁸² Jourdan C, Poiraudou S, Descamps S, et al. (2012). Comparison of patient and surgeon expectations of total hip arthroplasty. *PloS one*, 7(1), e30195. <https://www.doi.org/10.1371/journal.pone.0030195>.

⁴⁸³ Roos EM. (2003). Effectiveness and practice variation of rehabilitation after joint replacement. *Current opinion in rheumatology*, 15(2), 160–162. <https://doi.org/10.1097/00002281-200303000-00014>.

⁴⁸⁴ Anderson FA, Huang W, Friedman RJ, et al. (2012). Prevention of venous thromboembolism after hip or knee arthroplasty: findings from a 2008 survey of US orthopedic surgeons. *The Journal of arthroplasty*, 27(5), 659–666 e655. <https://doi.org/10.1016/j.arth.2011.09.001>.

⁴⁸⁵ American Academy of Orthopaedic Surgeons. (2011). Preventing Venous Thromboembolic Disease in Patients Undergoing Elective Hip and Knee Arthroplasty: Evidence-Based Guideline and Evidence Report. https://www.aaos.org/globalassets/quality-and-practice-resources/vte/vte_full_guideline_10.31.16.pdf.

⁴⁸⁶ Pincus D, et al. (2020). Association Between Surgical Approach and Major Surgical Complications in Patients Undergoing Total Hip Arthroplasty. *JAMA*, 323(11), 1070–1076. <https://doi.org/10.1001/jama.2020.0785>.

⁴⁸⁷ Siebens HC, Sharkey P, Aronow HU, et al. (2016). Variation in Rehabilitation Treatment Patterns for Hip Fracture Treated With Arthroplasty. *PM&R*, 8(3), 191–207. <https://doi.org/10.1016/j.pmrj.2015.07.005>.

⁴⁸⁸ Suter LG, Grady JN, Lin Z, et al. 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/OR Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). March 2013. Available at: <http://qualitynet.org/>.

⁴⁸⁹ Suter LG, Parzynski CS, Grady JN, et al. 2013 Measures Update and Specifications: Elective Primary Total Hip Arthroplasty (THA) AND/OR Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 2.0). March 2013. Available at: <http://qualitynet.org/>.

⁴⁹⁰ Rolfson O. (2010). Patient-reported Outcome Measures and Health-economic Aspects of Total Hip Arthroplasty: A study of the Swedish Hip Arthroplasty Register. Accessed July 20, 2013. Available at: https://gupea.ub.gu.se/bitstream/handle/2077/23722/gupea_2077_23722_1.pdf?sequence=1.

⁴⁹¹ Centers for Medicare & Medicaid Services. Comprehensive Care for Joint Replacement Model. Available at: <https://innovation.cms.gov/innovation-models/cjr>.

measured in a scientifically sound way,^{492,493} are influenced by a range of improvements in care,⁴⁹⁴ and demonstrate hospital-level variation even after patient case mix adjustment.^{495,496} Further, THA/TKA procedures are specifically intended to improve function and reduce pain, making PROs a meaningful outcome metric to assess.⁴⁹⁷

In the CY 2021 OPPI/ASC final rule (85 FR 86146), we announced that THA and TKA procedures were removed from the Inpatient Only Procedures (IPO) list and added to the ASC covered procedures list (CPL). As a result, the volume of THA and TKA procedures for Medicare beneficiaries aged 65 years and older have been increasing in outpatient settings, including ASCs.

We analyzed Part B Medicare FFS claims data for the number of ASC facility claims with THA/TKA procedures during CYs 2020, 2021, and 2022 (Table 74 below). Though we acknowledge that currently the total number of ASCs performing these procedures, and the number of procedures being performed in ASCs, is relatively low and there is wide variation in number of procedures performed in those ASCs, the number of procedures performed in the ASC setting has steadily grown.

TABLE 74: Distribution of Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) claims per ASC CY 2020-2021

CY	CPT	CPT Description	# ASCs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max

⁴⁹² Liebs TR, Herzberg W, Ruther W, et al. (2016). Quality-adjusted life years gained by hip and knee replacement surgery and its aftercare. *Archives of physical medicine and rehabilitation*, 97(5), 691–700. <https://doi.org/10.1016/j.apmr.2015.12.021>.

⁴⁹³ White D, & Master H. (2016). Patient Reported Measures of Physical Function in Knee Osteoarthritis. *Rheum Dis Clin North Am*, 42(2), 239–252. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4853650/>.

⁴⁹⁴ Kim K, Anoushiravani A, Chen K, et al. (2019). Perioperative Orthopedic Surgical Home: Optimizing Total Joint Arthroplasty Candidates and Preventing Readmission. *Journal of Arthroplasty*, 34(7), S91–S96. <https://doi.org/10.1016/j.arth.2019.01.020>.

⁴⁹⁵ Bozic KJ, Grosso LM, Lin Z, et al. (2014). Variation in hospital-level risk-standardized complication rates following elective primary total hip and knee arthroplasty. *The Journal of Bone and Joint Surgery*, 96(8), 640–647. <https://www.doi.org/10.2106/JBJS.L.01639>.

⁴⁹⁶ Makela KT, Peltola M, Sund R, et al. (2011). Regional and hospital variance in performance of total hip and knee replacements: A national population-based study. *Annals of medicine*, 43(sup1), S31–S38. <https://doi.org/10.3109/07853890.2011.586362>.

⁴⁹⁷ Liebs T, Herzberg W, Gluth J, et al. (2013). Using the patient’s perspective to develop function short forms specific to total hip and knee replacement based on WOMAC function items. *The Bone & Joint Journal*, 95(B), 239–243. <https://www.doi.org/10.1302/0301-620X.95B2.28383>.

2020	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	8	1	1.38	0.74	1	3
2020	27447	ARTHRP KNE CONDYLE&PLAT U MEDIAL&LAT COMPARTMENTS	568	8	19.20	32.87	1	296
2020	27130, 27447	All THA/TKA	569	8	19.18	32.90	1	296
2021	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	550	7	16.80	28.94	1	351
2021	27447	ARTHRP KNE CONDYLE&PLAT U MEDIAL&LAT COMPARTMENTS	749	12	28.20	46.57	1	509
2021	27130, 27447	All THA/TKA	782	16	38.83	69.01	1	860
2022	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	646	10	21.45	33.80	1	354
2022	27447	ARTHRP KNE CONDYLE&PLAT U MEDIAL&LAT COMPARTMENTS	854	16	33.78	53.85	1	594
2022	27130, 27447	All THA/TKA	881	22	48.47	80.81	1	948

Data source: CMS analysis, Medicare Part B claims January 1, 2020 - December 31, 2022 with a CPT code of 27130 or 27447

In the CY 2022 OPPI/ASC proposed rule (86 FR 42251 through 42252), we requested comment on the potential future adoption of the THA/TKA PRO-PM into the ASCQR Program. We refer readers to the CY 2022 OPPI/ASC final rule (86 FR 63896 through 63898) for a complete summary of feedback from interested parties.

Many commenters supported inclusion of the THA/TKA PRO-PM to the ASCQR Program as procedures move from inpatient to outpatient settings. Commenters noted it was important to monitor quality outcomes and publicly report results. Additionally, commenters stated that the measure is aligned with patient values, being presented in a manner that is easy to understand.

Other commenters did not support expansion of the measure to the ASCQR Program, and expressed concern with data collection burden, patient survey fatigue, and reporting thresholds. While we recognize that patient-reported outcome (PRO) based performance measures require providers to integrate data collection into clinical workflows, this integration provides opportunity for PROs to inform clinical decision making and benefits patients by engaging them in discussions about potential outcomes. Furthermore, we do not expect this measure to contribute to survey fatigue as the PRO instruments used to calculate pre- and post-operative scores for this THA/TKA PRO-PM were carefully selected, with extensive interested party input, to be low burden for patients.^{498,499}

We propose to adopt the THA/TKA PRO-PM into the ASCQR Program beginning with two voluntary reporting periods, followed by mandatory reporting. The first voluntary reporting period would begin with the CY 2025 reporting period for eligible elective outpatient procedures between January 1, 2025 through December 31, 2025, and the second voluntary reporting period would begin with the CY 2026 reporting period for eligible outpatient procedures between January 1, 2026 through December 31, 2026. Mandatory reporting would begin with the CY 2027 reporting period/CY 2030 payment determination for eligible elective outpatient procedures occurring January 1, 2027 through December 31, 2027, impacting the CY 2030 payment determination and subsequent years. Because this proposed measure requires collection of data during the 3-month pre-operative period and the greater than 1-year post-operative period, there is a delay between when the elective THA/TKA procedures actually occur, when the results would be reported under the ASCQR Program, and when payment determinations occur. Therefore, we propose a 3-year gap between the reporting period and the payment determination year (for example, CY 2027 reporting period for the CY 2030 payment

⁴⁹⁸ *Pre-rulemaking MUC lists and map reports*. The Measures Management System. (n.d.). Retrieved March 13, 2023, from <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

⁴⁹⁹ Centers for Medicare and Medicaid Services Measures Inventory Tool. (n.d.). Retrieved March 28, 2023, from <https://cmit.cms.gov/cmit/#/MeasureView?variantId=11547§ionNumber=1>.

determination) for the ASCQR Program. We refer readers to section XV.B.5.b.(2)(a) of this proposed rule for more information on the reporting requirements.

(2) Overview of Measure

(a) Data Collection, Submission, Reporting and Measure Specifications

This measure reports the facility-level risk-standardized improvement rate (RSIR) in PROs following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older who were enrolled in Medicare FFS Part A and B for the 12 months prior to the date of the procedure and in Medicare FFS Part A and B during the procedure. The measure includes only elective primary outpatient THA/TKA procedures (patients with fractures and revisions are not included) performed at ASCs and does not include any inpatient procedures. The measure excludes patients with staged procedures (multiple elective primary THA or TKA procedures performed on the same patient during distinct encounters) that occur during the measurement period and excludes discontinued procedures (that is, procedures that were started but not completed).⁵⁰⁰

Substantial clinical improvement is measured by achieving a pre-defined improvement in score on one of the two validated joint-specific PRO instruments measuring hip or knee pain and functioning: (1) The Hip Dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) for completion by THA recipients; or (2) the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients. Improvement is measured from the pre-operative assessment (data collected 90 to 0 days before surgery) to the post-operative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk-adjusted to account for differences in patient case-mix. The

⁵⁰⁰ U.S. Department of Health and Human Services. (2021). Hospital Outpatient Prospective Payment System (OPPS): Use of Modifiers –52, -73, and –74 for Reduced or Discontinued Services. Available at: <https://www.hhs.gov/guidance/document/hospital-outpatient-prospective-payment-system-opps-use-modifiers-52-73-and-74-reduced-or>.

measure, as proposed, accounts for potential non-response bias in measure scores through inverse probability weighting based on likelihood of response.

We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257) for more information on the development of the hospital-level THA/TKA PRO-PM, including background on the measure and a complete summary of measure specifications, data sources, and measure calculation.

For additional details regarding the measure specifications, we also refer readers to the Hip and Knee Arthroplasty Patient-Reported Outcomes file, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology>.

(i) Data Sources

The THA/TKA PRO-PM uses four sources of data for the calculation of the measure: (1) PRO data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. As described in section XV.B.5.b.(1) of this proposed rule, the measure uses PRO data directly reported by the patient regarding their health, quality of life, or functional status associated with their health care or treatment. This patient reported-data are collected by facilities pre-operatively and post-operatively, and limited patient-level risk factor data are collected with PRO data and identified in claims as detailed in this section of the proposed rule.⁵⁰¹ The measure includes PRO data collected with the two joint-specific PRO instruments described in this section of the proposed rule—the HOOS, JR for completion by THA recipients and the KOOS, JR for completion by TKA recipients—from which scores are used to assess substantial clinical improvement. For risk-adjustment by pre-operative mental health score, ASCs would submit one of two additional PRO instruments, all the items in either the: (1) the Patient-Reported Outcomes Measurement Information System (PROMIS)-Global Mental Health

⁵⁰¹ Higgins JP, Thomas J, Chandler J, et al. (2019). *Cochrane handbook for systematic reviews of interventions*. John Wiley & Sons. <https://doi.org/10.1002/9781119536604>.

subscale; or (2) the Veterans RAND 12-Item Health Survey (VR-12) Mental Health subscale. The risk model also includes a one-question patient-reported assessment of health literacy—the Single Item Literacy Screener questionnaire.

Furthermore, the following data would be collected for identification of the measure cohort, for risk-adjustment purposes, and for the statistical approach to potential non-response bias. ASC facility claims data would be used to identify eligible elective primary outpatient THA/TKA procedures for the measure cohort to which submitted PRO data can be matched, and to identify additional variables for risk-adjustment and in the statistical approach to account for response bias, including patient demographics and clinical comorbidities up to 12 months prior to surgery. The Medicare Enrollment Database (EDB) identifies Medicare FFS enrollment and patient-identified race, and the Master Beneficiary Summary File allows for determination of Medicare and Medicaid dual eligibility enrollment status. Demographic information from the U.S. Census Bureau’s American Community Survey allows for derivation of the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index score. Race, dual eligibility, and AHRQ SES Index score are used in the statistical approach to account for potential non-response bias in the outcome calculation. We refer readers to section XV.B.5.b.(2)(iii) of this proposed rule for further details regarding the variables required for data collection and submission.

(ii) Measure Calculation

The ASC facility-level THA/TKA PRO-PM result is calculated by aggregating all patient-level results across the facility. This measure would be calculated and presented as a RSIR, producing a performance measure per facility which accounts for patient case-mix, addresses potential non-response bias, and represents a measure of quality of care following elective primary outpatient THA/TKA. Response rates for PRO data would be calculated as the percentage of elective primary ASC THA or TKA procedures for which complete and matched

pre-operative and post-operative PRO data have been submitted divided by the total number of eligible THA or TKA procedures performed at each facility.

(iii) Data Submission and Reporting

In response to feedback received from interested parties in the request for comments (RFCs) on this measure in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45408 through 45414) and the CY 2022 OPPI/ASC proposed rule (86 FR 42251 through 42252) and adoption of the measure in the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257), we propose to adopt the THA/TKA PRO-PM in the ASCQR Program utilizing flexible data submission approaches.

ASCs would submit the following variables collected pre-operatively between 90 and zero days prior to the THA/TKA procedure for each patient: Medicare provider number; Medicare health insurance claim (HIC) number/Medicare beneficiary identifier (MBI); date of birth; date of procedure; date of PRO data collection; procedure type; mode of collection; person completing the survey; facility admission date; patient-reported outcome measure version; PROMIS Global (mental health subscale items) or VR-12 (mental health subscale items); HOOS, JR (for THA patients); KOOS, JR (for TKA patients); Single-Item Health Literacy Screening (SILS2) questionnaire; BMI or weight (kg)/height (cm); chronic (≥ 90 day) narcotic use; total painful joint count (patient reported in non-operative lower extremity joint); and quantified spinal pain (patient-reported back pain, Oswestry index question^{502,503}).

ASCs would submit the following variables collected post-operatively between 300 and 425 days following the THA/TKA procedure for each patient: Medicare provider number; Medicare HIC number/MBI; date of birth; procedure date; date of PRO data collection; procedure type; mode of collection; person completing the survey; facility admission date; KOOS, JR (TKA patients); and HOOS, JR (THA patients). The data submission period for the

⁵⁰² Fairbank JC, & Pynsent PB. (2000). The Oswestry Disability Index. *Spine*. 25(22), 2940–52
https://journals.lww.com/spinejournal/Abstract/2000/11150/The_Oswestry_Disability_Index.17.aspx .

⁵⁰³ The Oswestry Disability Index is in the public domain and available for all hospitals to use.

THA/TKA PRO–PM would also serve as the review and correction period. Data would not be able to be corrected following the submission deadline.

We propose a phased implementation approach for adoption of this measure to the ASCQR Program, with voluntary reporting periods in CYs 2025 and CY 2026 followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination in the ASCQR Program. Voluntary reporting prior to mandatory reporting would allow time for facilities to incorporate the THA/TKA PRO–PM data collection into their clinical workflows and is responsive to interested parties’ comments as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45408 through 45414) and FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257). Given the numbers of ASCs, varied number of procedures being performed, and the extended follow-up periods, we considered extending the length of voluntary reporting.

Following the two voluntary reporting periods, we propose that mandatory reporting of the THA/TKA PRO–PM would begin with the CY 2027 reporting period/CY 2030 payment determination. For each voluntary and subsequent mandatory reporting period, we would collect data on the THA/TKA PRO–PM in accordance with Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy and Security Rules (45 CFR parts 160 and 164, subparts A, C, and E), and other applicable law.

(b) Review by Measure Applications Partnership (MAP)

We included the THA/TKA PRO–PM measure for the ASCQR Program in the publicly available “2022 Measures Under Consideration List.” (MUC2022– 026).⁵⁰⁴ The MAP Coordinating Committee supported the measure, as referenced in the MAP’s 2022–2023 Final Recommendations report to HHS and CMS.⁵⁰⁵

⁵⁰⁴ 2022 Measures Under Consideration List. Available at <https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx>

⁵⁰⁵ MAP MUC Preliminary Recommendations 2022-2023. Available at <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>

The MAP members noted that, while a similar version of this measure has been adopted for use in the Hospital IQR program, a measure that assesses PROs among THA/TKA patients in ASCs for the ASCQR Program does not currently exist. The MAP highlighted the key strategy for the ASCQR Program is to ensure that procedures done in any type of facility have equivalent quality. As such, the MAP members agree that quality measures regarding procedures in hospital settings should be incorporated into the ASCQR Program, to the extent feasible and appropriate, so that consumers can compare quality of a specific procedure across different facility types, including ASCs.⁵⁰⁶

In addition, the MAP members stated that the goal of the THA/TKA PRO-PM is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patient health and reducing the burden of their disease. They agreed that this measure aligns with the goal of patient-centered approaches to health care quality improvement and addresses the high priority areas of patient and family engagement, communication, and care coordination for the ASCQR Program.⁵⁰⁷

(c) Measure Endorsement

The CBE endorsed the hospital-level version of the THA/TKA PRO-PM (CBE #3559) in November 2020.⁵⁰⁸ We note that the ASCQR Program version of the THA/TKA PRO-PM currently uses the same specifications as the CBE endorsed hospital-level THA/TKA PRO-PM with modifications that allow for the capture of procedures performed in for the ASC setting. We intend to seek CBE endorsement for the ASCQR Program's version of the THA/TKA PRO-PM in a future endorsement cycle.

We have noted in previous rulemaking (76 FR 74494) the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from CBE

⁵⁰⁶ Ibid.

⁵⁰⁷ Ibid.

⁵⁰⁸ Centers for Medicaid & Medicare Services. Hospital-Level, Risk-Standardized Improvement Rate in Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA). Available at: <https://cmit.cms.gov/cmit/#/FamilyView?familyId=1618>.

endorsement, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment. We propose this measure without CBE-endorsement based upon strong MAP and public support combined with the importance of the measure for Medicare beneficiaries. In addition, there are two existing, CBE-endorsed versions of this measure, one at the clinician-group level (CBE #3639) and one for the hospital level (CBE #3559). We expect that the measure will perform similarly in the ASC setting, and we intend on submitting the measure for CBE endorsement following data collection during voluntary reporting.

We refer readers to section XV.D.1.d of this proposed rule for a discussion on the THA/TKA PRO-PM form, manner, and timing submission requirements.

We invite public comment on this proposal.

6. ASCQR Program Quality Measure Set

a. Summary of Previously Finalized and Newly Proposed ASCQR Program Quality Measure Set for the CY 2024 Reporting Period/CY 2026 Payment Determination

We refer readers to the CY 2023 OPPS/ASC final rule (87 FR 72120 through 72121) for the previously finalized ASCQR Program measure set for the CY 2024 reporting period/CY 2026 payment determination.

Table 75 below summarizes the previously finalized and newly proposed ASCQR Program measures for the CY 2024 reporting period/CY 2026 payment determination.

TABLE 75: Proposed ASCQR Program Measure Set for the CY 2024 Reporting Period/CY 2026 Payment Determination

ASC #	CBE #	Measure Name
ASC-1	0263†	Patient Burn
ASC-2	0266†	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients**
ASC-11	1536†	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome

ASC #	CBE #	Measure Name
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel**

† CBE endorsement was removed.

* In the CY 2023 OPSS/ASC final rule (87 FR 72118 through 72120), we finalized to keep data collection and submission voluntary for this measure for the CY 2025 reporting period and subsequent years. In this proposed rule, we propose to standardize the surveys offered to patients pre- and post-surgery beginning with the CY 2024 reporting period/CY 2026 payment determination.

** In this proposed rule, we propose measure modifications to the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients and COVID-19 Vaccination Coverage Among HCP measures that begin with the CY 2024 reporting period/CY 2026 payment determination.

b. Summary of Previously Finalized and Newly Proposed ASCQR Program Quality Measure

Set for the CY 2025 Reporting Period/CY 2027 Payment Determination and Subsequent Years

Table 76 summarizes the previously finalized and newly proposed ASCQR Program measures for the CY 2025 reporting period/CY 2027 payment determination.

TABLE 76: Proposed ASCQR Program Measure Set for the CY 2025 Reporting Period/CY 2027 Payment Determination

ASC #	CBE #	Measure Name
ASC-1	0263†	Patient Burn
ASC-2	0266†	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-7	None	ASC Procedure Volume (Previously referred to as ASC Facility Volume on Selected ASC Surgical Procedures)**
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	The Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) - About Facilities and Staff
ASC-15b	None	OAS CAHPS - Communication About Procedure
ASC-15c	None	OAS CAHPS - Preparation for Discharge and Recovery
ASC-15d	None	OAS CAHPS - Overall Rating of Facility
ASC-15e	None	OAS CAHPS - Recommendation of Facility
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel

ASC #	CBE #	Measure Name
ASC-21	3636	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)***

† CBE endorsement was removed.

* In the CY 2023 OPPS/ASC final rule (87 FR 72118 through 72120), we finalized to keep data collection and submission voluntary for this measure for the CY 2025 reporting period and subsequent years.

** In this proposed rule, we propose to readopt the ASC Procedure Volume measure as a voluntary measure beginning with the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

*** In this proposed rule, we propose to adopt 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) as a voluntary measure beginning with the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination.

7. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for previously adopted ASCQR Program measures. These specifications are updated as we modify the ASCQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the CMS website (currently at: <https://qualitynet.cms.gov/asc/specifications-manuals>).⁵⁰⁹ Our policy on maintenance of technical specifications for the ASCQR Program are codified in our regulations at § 416.325. We propose to amend our measure maintenance regulation at § 416.325(c) to replace references to “QualityNet” with “CMS-designated information system” or “CMS website,” and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

8. Public Reporting of ASCQR Program Data

We refer readers to the CYs 2012, 2016, 2017, and 2018 OPPS/ASC final rules (76 FR 74514 through 74515; 80 FR 70531 through 70533; 81 FR 79819 through 79820; and 82 FR 59455 through 59470, respectively) for detailed discussion of our policies regarding the public reporting of ASCQR Program data, which are codified in our regulations at § 416.315 (80 FR 70533).

We are not proposing any changes to these policies in this proposed rule.

⁵⁰⁹ Qualitynet Home. (n.d.). Retrieved March 21, 2023, from <https://qualitynet.cms.gov/asc/specifications-manuals>.

C. Administrative Requirements

1. Requirements Regarding Data Submission

We refer readers to § 416.310(c)(1)(i) for our current policies regarding submission of data via our online data submission tool, including security official and system registration requirements. We propose to amend our collection and submission regulation at § 416.310(c)(1)(i) to replace references to “QualityNet” with “CMS-designated information system” or “CMS website,” and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

2. Requirements Regarding Program Participation

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75133 through 75135) for a complete discussion of the participation status requirements beginning with the CY 2014 payment determination. In the CY 2016 OPPS/ASC final rule (80 FR 70533 through 70534), we codified these requirements regarding participation status for the ASCQR Program in our regulations at § 416.305. We propose to amend our withdrawal regulation at § 416.305(b)(1) to replace references to “QualityNet” with “CMS-designated information system” or “CMS website,” and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

Previously finalized quality measures and information collections discussed in this section were approved by the Office of Management and Budget (OMB) under control number 0938–1270 (expiration date August 31, 2025). An updated PRA package reflecting the updated information collection requirements related to the proposals set forth in this section of the proposed rule will be submitted for approval under the same OMB control number.

1. Data Collection and Submission

a. Background

We previously codified our existing policies regarding data collection and submission under the ASCQR Program in our regulations at § 416.310.

b. Requirements for Claims-Based Measures

(1) Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs beginning with the CY 2012 reporting period/CY 2014 payment determination. In the CY 2016 OPPS/ASC final rule (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program in our regulations at § 416.310(a)(1) and (2). We note that the previously finalized data processing and collection period requirements will apply to any future claims-based measures using QDCs adopted in the ASCQR Program.

We are not proposing any changes to these policies in this proposed rule.

(2) Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59472) (and the previous rulemakings cited therein), as well as our regulations at §§ 416.310(a)(3) and 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. We also refer readers to section XVI.D.1.b of the CY 2022 OPPS/ASC final rule (86 FR 63904 through 63905), where we finalized that our policies for minimum threshold, minimum case volume, and data completeness requirements apply to any future claims-based-measures using QDCs adopted in the ASCQR Program.

We are not proposing any changes to these policies in this proposed rule.

(3) Requirements Regarding Data Processing and Collection Periods for Non-QDC Based, Claims-Based Measure Data

We refer readers to the CY 2019 OPPS/ASC final rule (83 FR 59136 through 59138) for a complete summary of the data processing and collection requirements for the non-QDC based, claims-based measures. We codified the requirements regarding data processing and collection periods for non-QDC, claims-based measures for the ASCQR Program in our regulations at § 416.310(b). We note that these requirements for non-QDC based, claims-based measures apply to the following previously adopted measures:

- Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; and
- Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (CBE #3357).

We are not proposing any changes to these policies in this proposed rule.

c. Requirements for Data Submitted Via an Online Data Submission Tool

(1) Requirements for Data Submitted Via a CMS Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59473) (and the previous rulemakings cited therein) and our regulations at § 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the HQR System (formerly referred to as the QualityNet Secure Portal)⁵¹⁰ to host our CMS online data submission tool, available by securely logging in at: <https://hqr.cms.gov/hqrng/login>. We note that, in the CY 2018 OPPS/ASC final rule (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes at § 416.310(c)(1)(i).

- The following previously finalized measures require data to be submitted via a CMS online data submission tool beginning with the CY 2019 reporting period/CY 2021 payment

⁵¹⁰ The HQR System was previously referred to as the QualityNet Secure Portal.

determination: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients;

- Cataracts Visual Function measure (Previously referred to as Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery);

- Normothermia Outcome; and

- Unplanned Anterior Vitrectomy.

In the CY 2022 OPPI/ASC final rule (86 FR 63883 through 63885), we finalized our proposal to require and resume data collection beginning with the CY 2023 reporting period/CY 2025 payment determination for the following four measures:

- Patient Burn;

- Patient Fall;

- Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and

- All-Cause Hospital Transfer/Admission.

Measure data for these measures must be submitted via the HQR System.

Other than the proposal to amend § 416.310(c)(1)(i) and (d)(1) discussed in section XV.C.1 of this proposed rule, we are not proposing any changes to these policies in this proposed rule.

(a) Proposed Data Submission and Reporting Requirements for the ASC Procedure Volume Measure

In section XV.B.5.a of this proposed rule, we propose to re-adopt the ASC Procedure Volume measure (with modification), with voluntary reporting beginning with the CY 2025 reporting period followed by mandatory reporting beginning with CY 2026 reporting period/CY 2028 payment determination. We also propose that ASCs submit these data to CMS through the HQR System during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 2025 reporting period, 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 this proposed measure, we will collect and publicly display data surrounding the top five most frequently performed procedures among ASCs in each of the following eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.⁵¹¹ We will assess and update the top five procedures in each category annually as needed. We propose that ASCs would submit aggregate-level data through the CMS web-based tool (currently the HQR system). Data received through the HQR system website will then be publicly displayed on the data.cms.gov website, or other CMS website, following our 30-day preview period of submitted data.

We refer readers to our regulation at § 416.315 for our codified policies regarding public reporting of data under the ASCQR Program, as well as our existing policies regarding data collection and submission under the ASCQR Program in our regulations at § 416.310.

We invite public comment on this proposal.

(b) Proposed Data Submission and Reporting Requirements for the Cataracts Visual Function Measure

In section XV.B.4.b of this proposed rule, we propose to modify the Cataracts Visual Function measure by standardizing acceptable survey instruments, beginning with the CY 2024 reporting period, which would limit the allowable survey instruments to those listed below:

- The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25)
- The Visual Functioning Patient Questionnaire (VF-14)
- The Visual Functioning Index Patient Questionnaire (VF-8R)

We also propose that ASCs submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY

⁵¹¹Ambulatory Surgical Center Specifications Manuals . Available at <https://qualitynet.cms.gov/asc/specifications-manuals#tab6>.

2024 reporting period, the data submission period would be January 1, 2025 to May 15, 2025, covering the performance period of January 1, 2024 to December 31, 2024. Specifically, for data collection, we propose that ASCs submit aggregate-level data through the HQR System. We previously codified our existing policies regarding data collection and submission under the ASCQR Program in our regulations at § 416.310.

We invite public comment on this proposal.

(2) Requirements for Data Submitted Via a Non-CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPTS/ASC final rule (78 FR 75139 through 75140) and the CY 2015 OPPTS/ASC final rule (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS online data submission tool (specifically, the CDC's National Health Safety Network [NHSN]). We codified our existing policies regarding the data collection periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool in our regulations at § 416.310(c)(2). While we did not finalize any changes to those policies in the CY 2022 OPPTS/ASC final rule (86 FR 63875 through 63883), we did finalize policies specific to the COVID-19 Vaccination Coverage Among HCP measure, for which data will be submitted via the CDC NHSN. In section XV.B.4.a of this proposed rule, we discuss the proposed modification of the COVID-19 Vaccination Coverage Among HCP measure beginning with the CY 2024 reporting period/CY 2026 payment determination. The requirements for measure data submitted via the CDC NHSN website would remain as previously finalized.

We are not proposing any changes to these policies in this proposed rule.

d. Proposed Data Submission and Reporting Requirements for Patient-Reported Outcome-Based Performance Measures (PRO-PMs)

In section XV.B.5.b of this proposed rule, we propose to adopt the THA/TKA PRO-PM into the ASCQR Program measure set. We also propose the reporting and submission requirements for PRO-PM measures as a new type of measure to the ASCQR Program.

(1) Submission of PRO-PM Data

(a) Data Submission Generally

We believe that ASCs should have the choice of selecting from multiple submission approaches, in line with input received by the measure developer during measure development and comments as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414), which recommended that we provide multiple options for data submission mechanisms to ensure flexibility.

In section XV.B.5.b of this proposed rule, we propose that both ASCs and vendors use the HQR System for data submission for the THA/TKA PRO-PM, which would enable us to incorporate this new requirement into the infrastructure we have developed and use to collect other quality data. We would provide ASCs with additional detailed information and instructions for submitting data using the HQR System through CMS' existing websites, and through outreach, or both.

We invite public comment on these proposals.

(2) Data Submission Reporting Requirements

(a) Data Submission Requirements for Measures Submitted via a Web-based Tool

We refer readers to the QualityNet website available at: <https://qualitynet.cms.gov> for a discussion of the requirements for measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2017 payment determination and subsequent years. The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E, for more information regarding the HIPAA Privacy and Security Rules.

(b) Voluntary Reporting Requirements for the Proposed THA/TKA PRO-PM

For ASCs participating in voluntary reporting for the THA/TKA PRO-PM as discussed in section XV.B.5.b of this proposed rule, we propose that ASCs submit pre-operative PRO data, as

well as matching post-operative PRO data, for at least 45 percent of their eligible elective primary THA/TKA procedures.

For the THA/TKA PRO-PM, we propose that the first voluntary reporting period for the CY 2025 reporting period would include pre-operative PRO data collection from 90 to 0 days before the procedure (for eligible elective THA/TKA procedures performed from January 1, 2025 through December 31, 2025) and post-operative PRO data collection from 300 to 425 days after the procedure. Therefore, during this first voluntary reporting period for CY 2025, ASCs would submit pre-operative data by May 15, 2026 and post-operative data by May 15, 2027, and we intend to provide ASCs with their results in confidential feedback reports in CY 2028. 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. After the initial submission of pre-operative data for the first voluntary period, ASCs would submit both pre-operative and post-operative data by the same day, but for different time periods. For example, ASCs would need to submit: (1) post-operative data for the first voluntary reporting period (for procedures performed between January 1, 2025 and December 31, 2025); and (2) pre-operative data for the second voluntary reporting (for procedures performed between January 1, 2026 and December 31, 2026) of the THA/TKA PRO-PM by May 15, 2027.

For the THA/TKA PRO-PM, we propose that the second voluntary reporting period for the CY 2026 reporting period would include pre-operative PRO data collection from 90 to 0 days before the procedure (for eligible elective THA/TKA procedures performed from January 1, 2026, through December 31, 2026) and post-operative PRO data collection from 300 to 425 days after the procedure. ASCs would submit pre-operative data by May 15, 2027 and post-operative data by May 15, 2028, and we intend to provide ASCs with their results in confidential feedback reports in CY 2029. ASCs that voluntarily submit data for this measure would receive confidential feedback reports that detail submission results from the reporting period. Results of

voluntary reporting would not be made publicly available. If feasible, we would calculate and provide each participating ASC with their RSIR as part of the confidential feedback reports. This would provide each ASC with an indication of their performance relative to the other facilities that participate in the voluntary reporting period.

While we do not propose to publicly report the data we receive during the voluntary reporting periods for the THA/TKA PRO-PM facility-level RSIR, we propose to publicly report which ASCs choose to participate in voluntary reporting and/or the percent of pre-operative data submitted by participating ASCs for the first voluntary reporting period, and their percent of pre-operative and post-operative matched PRO data submitted for subsequent voluntary reporting periods. For example, if out of 100 eligible procedures a facility submits 45 pre-operative cases that match to post-operative cases, then we would report that facilities submitted 45 percent of matched pre-operative and post-operative PRO surveys during voluntary reporting.

We refer readers to Table 77 for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the voluntary reporting periods for THA/TKA PRO-PM.

TABLE 77: PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM VOLUNTARY REPORTING

Reporting Cycle	Performance Period	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission	Confidential Reporting
Voluntary Reporting CY 2025	January 1, 2025-December 31, 2025	October 3, 2024-December 31, 2025	May 15, 2026	October 28, 2025-March 1, 2027	May 15, 2027*	CY 2028**
Voluntary Reporting CY 2026	January 1, 2026-December 31, 2026	October 3, 2025-December 31, 2026	May 15, 2027*	October 28, 2026-February 29, 2028	May 15, 2028	CY 2029**

*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.

**Public reporting of information on facility participation in the voluntary reporting periods would occur in CY 2028 for the CYs 2025 and 2026 reporting periods.

(c) Mandatory Reporting

Following the two voluntary reporting periods, we propose that mandatory reporting of the THA/TKA PRO-PM would begin with reporting PRO data for eligible elective THA/TKA procedures from January 1, 2027 through December 31, 2027 (the CY 2027 performance period), impacting the CY 2030 payment determination. This initial mandatory reporting would include pre-operative PRO data collection from 90 days preceding the applicable performance period and from 300 to 425 days after the performance period. For example, pre-operative data from October 3, 2026 through December 31, 2027 (for eligible elective primary THA/TKA procedures from January 1, 2027 through December 31, 2027) and post-operative PRO data collection from October 28, 2027 to February 28, 2029. Pre-operative data submission would occur by May 15, 2028 and post-operative data submission in May 15, 2029.

We intend to provide ASCs with their results in CY 2030 before publicly reporting results on the Compare tool hosted by HHS, currently available at <https://www.medicare.gov/care-compare>, or its successor website. We would provide confidential feedback reports during the voluntary period which would include the RSIR as well as other results that support understanding of their performance prior to public reporting. For this first mandatory reporting period, facilities that fail to meet the reporting requirements would receive a reduction of their Annual Payment Update (APU) in the CY 2030 payment determination. We propose that ASCs would be required to submit 45 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data as a minimum amount of data for mandatory reporting in the ASCQR Program.

We refer readers to Table 78 for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the first mandatory reporting period.

TABLE 78: PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM FOR MANDATORY REPORTING

Reporting Cycle	Performance Period	Pre-Procedure	Pre-Procedure	Post-Procedure	Post-Procedure	Confidential Reporting
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		Data Collection (0 to 90 days before the procedure)	Data Submission Date	Data Collection (300 to 425 days after the procedure)	Data Submission	
Mandatory Reporting CY 2027	January 1, 2027- December 31, 2027	October 3, 2026- December 31, 2027	May 15, 2028	October 28, 2027- February 28, 2029	May 15, 2029	CY 2030*

*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. Public reporting of information on facility results in the mandatory reporting period would occur in CY 2030 for CY 2027 reporting period/CY2030 payment determination.

We invite comment on these proposals.

e. ASCQR Program Data Submission Deadlines

We refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86191) for a detailed discussion of our data submission deadlines policy, which we codified in our regulations at § 416.310(f).

We are not proposing any changes to this policy in this proposed rule.

f. Review and Corrections Period for Measure Data Submitted to the ASCQR Program

Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86191 through 86192) for a detailed discussion of our review and corrections period policy, which we codified in our regulations at § 416.310(c)(1)(iii).

We are not proposing any changes to this policy in this proposed rule.

g. ASCQR Program Reconsideration Procedures

We refer readers to the CY 2016 OPPS/ASC final rule (82 FR 59475) (and the previous rulemakings cited therein) and § 416.330 for the ASCQR Program's reconsideration policy.

We are not proposing any changes to this policy in this proposed rule.

h. Extraordinary Circumstances Exception (ECE) Process

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59474 through 59475) (and the previous rulemakings cited therein) and § 416.310(d) for the ASCQR Program's

extraordinary circumstance exceptions (ECE) request policy. We propose to amend our exception policy codified at § 416.310(d)(1) to replace references to “QualityNet” with “CMS-designated information system” or “CMS website”, and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

E. 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 2022, 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). 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 above 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”, “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 2023 OPPS/ASC final rules with comment period we did not make any other changes to these policies. We propose the continuation of these policies for the CY 2024 reporting period/CY 2026 payment determination.

XVI. Proposed Requirements for the Rural Emergency Hospital Quality Reporting

(REHQR) Program

A. Background

1. Overview

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 facilities in rural settings.

We refer readers to section XVI of the CY 2023 Hospital Outpatient Prospective Payment System (OPPS)/Medicare Ambulatory Surgical Center Payment System (ASC) final rule (87 FR 72136 through 72150) for an overview of the REHQR Program.

2. Statutory and Regulatory History of Quality Reporting for REHs

Congress established Rural Emergency Hospitals (REHs) as a new Medicare provider type in the Consolidated Appropriations Act (CAA), 2021. Section 125 of Division CC of the CAA added section 1861(kkk) to the Social Security Act (the Act). This section defines an REH as a facility that, in relevant part, was, as of December 27, 2020 (1) a critical access hospital (CAH); or (2)(i) a subsection (d) hospital with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area,⁵¹² or (ii) a subsection (d) hospital with not more than 50 beds that was treated as being in a rural area.^{513,514} Among other requirements, an REH must apply for enrollment in the Medicare program, provide emergency department (ED) services and observation care, and not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility).^{515,516} At the election of the REH, it can also provide certain services furnished on an outpatient basis.⁵¹⁷

3. Proposal to Codify the Statutory Authority of the REHQR Program

We propose to codify the statutory authority for the REHQR Program at 42 CFR 419.95 by adding paragraph (a) “Statutory Authority.” Section 1861(kkk)(7)(A) of the Act authorizes the Secretary to implement a quality reporting program requiring REHs to submit data on measures in accordance with the Secretary's requirements in section 1861(kkk)(7). Section 1861(kkk)(7)(B)(ii) requires REHs to submit quality measure data to the Secretary “in a form and manner, and at a time, specified by the Secretary.” The Act does not require the Secretary to provide incentives for submitting this data under the REHQR Program, nor does it require the Secretary to impose penalties for failing to comply with this requirement under the REHQR Program.

⁵¹² As defined in section 1886(d)(2)(D) of the Act.

⁵¹³ Pursuant to section 1886(d)(8)(E) of the Act.

⁵¹⁴ As set out under section 1861(kkk)(3) of the Act.

⁵¹⁵ 42 CFR part 485 subpart E (§§ 485.500 through 485.546).

⁵¹⁶ Qualification Requirements for REHs are set out under section 1861(kkk)(2) of the Act.

⁵¹⁷ See section 1861(kkk)(1)(A)(ii) of the Act.

We invite public comment on this proposal.

B. REHQR Program Quality Measures

1. Considerations in the Selection of REHQR Program Quality Measures

As we stated in the CY 2023 OPPTS/ASC final rule, we seek to adopt a concise set of important, impactful, reliable, accurate, and clinically relevant measures for REHs that would inform consumer decision-making regarding care and drive further quality improvement efforts in the REH setting (87 FR 72137). As we considered potential measures for the REHQR Program, we prioritized measures that had undergone previous consensus-based entity (CBE)⁵¹⁸ review for the hospital outpatient department setting that reflect important areas of service for REHs while adhering to the CMS National Quality Strategy goals,⁵¹⁹ Strategic Plan,⁵²⁰ Meaningful Measures 2.0 initiatives,⁵²¹ and the Department of Health and Human Services' (HHS) Strategic Plan.⁵²² When identifying potential measures for the REHQR Program, we focused on the considerations of service and patient volume, care accountability and quality, rurality and setting relevance, and health equity.

We note that under section 1861(kkk)(7)(C)(i) of the Act, unless the exception of subclause (ii) applies, a measure selected for the REHQR Program must have been endorsed by the entity with a contract under section 1890(a) of the Act, also known as the CBE. The CBE is a voluntary, consensus-based, standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The CBE was established to standardize healthcare quality measurement and

⁵¹⁸ In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

⁵¹⁹ CMS (2023). What is the CMS National Quality Strategy? Available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>. Last accessed April 13, 2023.

⁵²⁰ CMS (2023). CMS Strategic Plan. Available at: <https://www.cms.gov/cms-strategic-plan>. Last accessed March 10, 2023.

⁵²¹ CMS (2022), Meaningful Measures 2.0: Moving from Measures Reduction to Modernization. Available at <https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization>. Last accessed April 13, 2023.

⁵²² HHS (2022). Strategic Plan FY 2022 – 2026. Available at <https://www.hhs.gov/about/strategic-plan/2022-2026/index.html>. Last accessed March 10, 2023.

reporting through its consensus development processes. We have generally adopted CBE-endorsed measures in our reporting programs. However, section 1861(kkk)(7)(C)(ii) provides an exception to CBE-endorsement, which is 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. In general, we prefer to adopt measures that have been endorsed by the CBE identified by the Secretary; however, due to lack of an endorsed measure for a given setting, procedure, or other aspect of care, the requirement that measures reflect consensus among affected parties can be achieved in other ways, including input from the measure development process, through broad acceptance, use of the measure(s) in other programs, and through public comment.

We propose to adopt four measures in this proposed rule: (1) Abdomen Computed Tomography (CT) - Use of Contrast Material; (2) Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients; (3) Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy; and (4) Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery – for the REHQR Program measure set. The proposed measures are currently adopted measures in the Hospital Outpatient Quality Reporting (OQR) Program. We recognize REHs will be smaller hospitals that will likely have limited resources compared with larger hospitals in metropolitan areas.⁵²³ For the REHQR Program, we intend to seek balance between the costs associated with reporting data and the benefits of ensuring safety and quality of care through measurement and public reporting. Because REHs will consist of hospitals formerly operating as either CAHs or subsection (d) hospitals, we assessed whether these facilities have successfully reported the proposed measures within the

⁵²³ American Hospital Association, Rural Report. (February, 2019), 2019 Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-quality, *Affordable Care* 3. Available at <https://www.aha.org/system/files/2019-02/rural-report-2019.pdf>. Last accessed February 28, 2023.

context of the Hospital OQR Program with sufficient volume to meet CMS case number thresholds for data to be publicly reported. We note that CAHs report data voluntarily under the Hospital OQR Program. We considered reporting rates and measure performance for subsection (d) hospitals that are eligible to convert to REHs and also analyzed data for other subsection (d) hospitals that are not eligible for conversion to permit comparisons of these providers' ability to report these data in sufficient numbers to permit public reporting and to view comparative performance. Table 79 includes the results of this analysis.

TABLE 79: Number of Hospitals Publicly Reporting Measures Proposed for the REHQR Program

Abdomen Computed Tomography (CT) - Use of Contrast Material*					
Statistic	Critical Access Hospitals	Subsection (d) hospitals with ≤ 50 beds Rural Only	Subsection (d) hospitals with ≤ 50 beds Urban Only	Subsection (d) hospitals with 51 -100 beds	Subsection (d) hospitals with >100 beds
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	1,060 (77.9%)	151 (75.5%)	146 (48.7%)	500 (89.9%)	2,060 (93.8%)
Mean (CT studies)	6.3	7.5	7.4	6.4	6.0
10th Percentile	1.7	2.4	0.6	1.7	1.4
25th Percentile	2.9	4.2	2.2	3.2	3
Median	5	6.5	4.7	5.35	5.1
75th Percentile	7.8	10.1	8.1	8.15	7.9
90th Percentile	12.1	14	12.7	11.7	11

*Ratio of CT abdomen studies that are performed both with and without contrast of all CT abdomen studies performed. Lower scores indicate better performance.

Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients – Overall Rate*					
Statistic	Critical Access Hospitals	Subsection (d) hospitals with ≤ 50 beds Rural Only	Subsection (d) hospitals with ≤ 50 beds Urban Only	Subsection (d) hospitals with 51 -100 beds	Subsection (d) hospitals with >100 beds
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	1,126 (82.7%)	163 (81.5%)	173 (57.7%)	507 (91.2%)	2,081 (94.7%)
Mean (minutes)	125.9	130.0	142.5	156.7	193.6
10th Percentile	91	99	97	111	138
25th Percentile	106	109	113	130	160
Median	123	130	137	153	188
75th Percentile	142	148	169	179	219
90th Percentile	164	159	197	204	254

*Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients - Reported Measure, Excluding Psychiatric/Mental Health and Transfer Patients*					
Statistic	Critical Access Hospitals	Subsection (d) hospitals with ≤ 50 beds Rural Only	Subsection (d) hospitals with ≤ 50 beds Urban Only	Subsection (d) hospitals with 51 -100 beds	Subsection (d) hospitals with >100 beds
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	1,124 (82.6%)	163 (81.5%)	173 (57.7%)	507 (91.2%)	2,078 (94.6%)
Mean (minutes)	118.5	122.6	137.0	150.6	188.0
10th Percentile	86	94	92	106	133
25th Percentile	100	104	110	125	155
Median	116	122	132	148	183
75th Percentile	134	140	159	172	214
90th Percentile	153	153	191	199	248

*Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

Median Time from ED Arrival to ED Departure for Discharged ED Patients - Psychiatric/Mental Health Patients*					
Statistic	Critical Access Hospitals	Subsection (d) hospitals with ≤ 50 beds Rural Only	Subsection (d) hospitals with ≤ 50 beds Urban Only	Subsection (d) hospitals with 51 -100 beds	Subsection (d) hospitals with >100 beds
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	703 (51.7%)	128 (64.0%)	87 (29.0%)	419 (75.4%)	1,869 (85.1%)
Mean (minutes)	213.1	208.6	265.9	267.8	340.9
10th Percentile	118	119	120	142	174
25th Percentile	148	143.5	169	181	226
Median	190	187.5	230	232	294
75th Percentile	243	237	312	315	395
90th Percentile	333	330	444	406	552

*Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

Median Time from ED Arrival to ED Departure for Discharged ED Patients - Transfer Patients*					
Statistic	Critical Access Hospitals	Subsection (d) hospitals with ≤ 50 beds Rural Only	Subsection (d) hospitals with ≤ 50 beds Urban Only	Subsection (d) hospitals with 51 -100 beds	Subsection (d) hospitals with >100 beds
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total Eligible)	934 (68.6%)	145 (72.5%)	119 (39.7%)	384 (69.1%)	681 (31.0%)
Mean (minutes)	259.4	300.6	321.7	315.2	366.3
10th Percentile	162	186	201	210	236
25th Percentile	194	214	249	247	276
Median	242	256	300	299.5	341
75th Percentile	301	311	376	360.5	422
90th Percentile	385	387	486	439	519

*Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery* Excluding Eye Surgery and Routine Colonoscopy					
Statistic	Critical Access Hospitals	Subsection (d) hospitals with ≤ 50 beds Rural Only	Subsection (d) hospitals with ≤ 50 beds Urban Only	Subsection (d) hospitals with 51 -100 beds	Subsection (d) hospitals with >100 beds
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	182 (13.4%)	78 (39.0%)	184 (61.3%)	403 (72.5%)	1,939 (88.3%)
Mean (ratio of predicted to expected visits)	1.006	1.024	0.988	1.016	1.010
10th Percentile	0.9	0.9	0.8	0.9	0.8
25th Percentile	0.9	1	0.9	0.9	0.9
Median	1	1	1	1	1
75th Percentile	1	1.1	1.1	1.1	1.1
90th Percentile	1.1	1.2	1.2	1.2	1.2

*Ratio of “predicted” unplanned hospital visits to the number of “expected” unplanned hospital visits. Lower scores indicate better performance.

Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy Rate*					
Statistic	Critical Access Hospitals	Subsection (d) hospitals with ≤ 50 beds Rural Only	Subsection (d) hospitals with ≤ 50 beds Urban Only	Subsection (d) hospitals with 51 -100 beds	Subsection (d) hospitals with >100 beds
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	609 (44.7%)	131 (65.5%)	131 (43.7%)	465 (83.6%)	1,945 (88.5%)
Mean (visits)	14.3	14.4	14.3	14.3	14.2
10th Percentile	13.6	13.4	13.2	13	12.7
25th Percentile	13.8	13.8	13.7	13.6	13.4
Median	14.2	14.2	14.2	14.2	14.1
75th Percentile	14.6	15	14.8	14.9	14.9
90th Percentile	15.1	15.6	15.6	15.7	15.7

*Rate is the number of unplanned hospital visits after colonoscopy (per 1,000 colonoscopies). Lower scores indicate better performance.

Data sources: Program Resource System (PRS) accessed January 10, 2023, Care Compare data updated each January 2018-2023, and CMS Providers of Services File (PSF) - Hospital & Non-Hospital Facilities Q3 2022. Includes all data submitted for all CAHs and subsection (d) hospitals open as of December 27, 2020.

Hospitals are considered eligible to report in Care Compare if they have a Medicare accept date prior to the latest measure end date and are open as of the PRS accessed date. March 31, 2022 is the measure end date for Hospital OQR Program measures for public reporting in the January 2023 Care Compare refresh.

Hospitals are considered reporting Hospital OQR Program measures if they have a score published on Care Compare. Requirements for publication include that aggregated case numbers reported be greater than or equal to 10. The published data value must not be "Not Available".

Rural/urban location is identified by the CMS PSF - Hospital & Non-Hospital Facilities Q3 2022. Rural/urban location is based on Core Based Statistical Area (CBSA), which indicates whether the county is defined as urban or rural to limit the analysis to areas currently viewed as rural.

Hospital bed size is the number of total Medicare certified beds listed in PRS.

Based on our analysis of these data, current to the January 2023 refresh of Care Compare, we note that a relatively high percentage of the hospitals eligible to convert to REH status have

reported aggregated measure data in sufficient number for disclosure per CMS privacy policy⁵²⁴ for the measures we propose for the initial REHQR Program measure set. For example, in comparing solely the averages for the Abdomen Computed Tomography (CT) - Use of Contrast Material measure, a significant majority of CAHs (77.9 percent) and rural subsection (d) hospitals with 50 or fewer beds (75.5 percent) have data publicly reported. In addition, for the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure, rural subsection (d) hospitals with 50 or fewer beds were more often able to have data publicly reported than urban subsection (d) hospitals with 50 or fewer beds (65.5 percent versus 43.7 percent), which indicates that this measure could be useful for small rural hospitals that convert. For this latter measure, while the mean values are similar across categories of hospitals, the results show that there are outlier hospitals with higher levels of hospital events following outpatient surgery than expected, which provides potentially valuable information when discerning individual hospital performance.

While it is not possible to identify the exact group of hospitals that will choose to convert to REH status, our analysis indicates that the services targeted by the proposed measures are relevant for hospitals that may participate in the REHQR Program as these hospitals are currently providing the services assessed by the selected measures with case volumes sufficient to meet thresholds to allow public reporting of the collected data.⁵²⁵

⁵²⁴ CMS Policy for Privacy Act Implementation & Breach Notification, July 23, 2007, Document Number: CMS-CIO-POL-PRIV01-01, p 4. Statistical, aggregate or summarized information created as a result of analysis conducted using identifiable CMS data obtained under CMS-approved projects/studies may only be disclosed if the data are not individual-specific and the data are aggregated to a level where no data cells contain 10 or fewer individuals.

⁵²⁵ CMS does not report measures publicly unless measures are the result of an analysis of more than 10 cases. See CMS Policy for Privacy Act Implementation & Breach Notification, July 23, 2007, Document Number: CMS-CIO-POL-PRIV01-01, p 4.

2. Retention of Measures Previously Adopted into the REHQR Program

a. Background

For purposes of our quality reporting programs, we retain measures from previously adopted measure sets for subsequent years unless otherwise specified; for example, see the Hospital OQR (42 CFR 419.46(i)(1)) and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs (§ 416.320(a)). As this approach establishes regularity and predictability for participating providers and suppliers, we seek to align the REHQR Program with this policy.

b. Proposal to Adopt and Codify a Measure Retention Policy for the REHQR Program

We propose that once adopted into the REHQR Program measure set, such measures are retained for use until we propose removal, suspension, or replacement. We also propose to codify this policy at § 419.95 by adding paragraph (e) “Retention and Removal of Quality Measures Under the REHQR Program.” In proposed paragraph (e)(1), we propose that quality measures would be adopted into the REHQR Program measure set until such time that such measures are proposed for removal, suspension, or replacement, as set forth at proposed paragraphs (e)(2) and (e)(3) of the section.

We invite public comment on these proposals.

3. Removal of Quality Measures from the REHQR Program Measure Set

a. Proposal to Adopt and Codify an Immediate Removal Policy for Adopted REHQR Program Measures

When there is reason to believe that the continued collection of a measure as currently specified raises potential patient safety concerns, we believe it would be appropriate for us to take immediate action to remove the measure from the REHQR Program outside of rulemaking. Therefore, we propose to adopt an immediate measure removal policy that would allow us to promptly remove such a measure and notify REHs and the public of the decision to remove the measure through standard hospital communication channels, including, but not limited to, REHQR Program-specific listservs and REHQR Program guidance currently housed on the

QualityNet website. We also propose to confirm the removal of the measure in the next appropriate rulemaking, typically an OPPS rulemaking cycle. We note that the Hospital OQR Program previously finalized a similar policy (74 FR 60634 through 60635).

We propose to codify this policy at § 419.95 by adding paragraph (e)(2) “Immediate Measure Removal.” In proposed paragraph (e)(2), we propose that in cases where CMS believes that the continued use of a quality measure as specified raises patient safety concerns, CMS would immediately remove the measure from the REHQR Program, promptly notify REHs and the public of the removal of the measure and the reasons for its removal, and confirm the removal of the measure in the next appropriate rulemaking.

We invite public comment on these proposals.

b. Proposal to Adopt and Codify a Measure Removal Factors Policy

The Hospital OQR and ASCQR Programs use similar sets of factors for determining whether to remove measures. For more detail on the measure removal factors in those programs, we refer readers to §§ 419.46(i)(3)(i) and 416.320(c)(2), respectively. Generally, we prefer to use similar removal factors across the quality reporting programs for consistency and alignment. Therefore, to enhance alignment with those programs, we propose to adopt a similar set of removal factors for the REHQR Program.

Specifically, we propose to adopt the following eight factors to determine conditions for measure removal from the REHQR Program:

- Factor 1. Measure performance among REHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (“topped-out” measures).
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.

- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

In addition, for the proposed Measure Removal Factor 1, we propose that a measure for the REHQR Program would be deemed topped-out by determining: (1) when the difference between the 75th and 90th percentiles for an REH's measure is within two times the standard error of all measure data reported for all REHs, and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.1.

We propose to codify these policies at § 419.95 by adding paragraph (e)(3), "Measure Removal, Suspension, or Replacement Through the Rulemaking Process." In proposed paragraph (e)(3), we propose that unless a measure raises specific safety concerns as set forth in proposed paragraph (e)(2) of the section, we would use rulemaking to remove, suspend, or replace quality measures in the REHQR Program. We also propose to adopt the eight removal factors discussed above by codifying them at proposed paragraph (e)(3)(i), in alignment with other quality reporting programs (74 FR 60634 through 60635, 77 FR 68472, and 83 FR 59082). Additionally, we propose to adopt the criteria to determine topped-out measures discussed above at proposed paragraph (e)(3)(ii). Similar to the Hospital OQR Program (79 FR 66941 through 66942), we propose to assess the benefits of removing a measure from the REHQR Program on a

case-by-case basis at proposed paragraph (e)(3)(iii). An REHQR Program measure would not be removed solely based on meeting any specific factor.

We invite public comment on these proposals.

4. Modifications to Previously Adopted Measures

a. Background

It is important for measures adopted for the REHQR Program to remain up-to-date. We believe the way to achieve this is to have in place a sub-regulatory process to incorporate non-substantive updates to measure specifications to facilitate the incorporation of scientific advances and updates to measure specifications in a as timely manner as possible.

b. Proposal to Adopt and Codify a Sub-Regulatory Measure Modification Policy

We propose a policy under which we would use a sub-regulatory process to make non-substantive updates to measures adopted for the REHQR Program. Examples of non-substantive changes to measures might include updated diagnoses or procedure codes. With respect to what constitutes substantive versus non-substantive changes, we expect to make this determination on a case-by-case basis.

We propose that when there is an update to an REHQR Program measure that we believe does not substantially change the nature of the measure, we would use a sub-regulatory process to incorporate those updates to the measure specifications that we apply to the program.

Specifically, we will develop a specifications manual that will provide the complete and current technical specifications and abstraction information for quality measures used in the REHQR Program. We would revise the specifications manual to clearly identify any updates, and would provide sufficient lead time for REHs to implement the revisions where changes to the data collection systems would be necessary. We would also provide notification of the measure specification updates on a designated website, currently the QualityNet website,

<https://qualitynet.cms.gov/>. We note that this proposed policy for the REHQR Program aligns

with the policies under the Hospital OQR Program (73 FR 68766 through 68767) and ASCQR Program (§ 416.325) that allow measures to be refined through a sub-regulatory process.

We propose to codify this policy at § 419.95(d) “Technical Specifications and Measure Maintenance Under the REHQR Program.” In proposed paragraph (d)(2), we propose that REHQR Program specifications would be updated based on whether the change is considered substantive or non-substantive, as determined by CMS. In proposed paragraph (d)(2)(ii), we propose that if CMS determines that a change to a measure previously adopted in the REHQR Program is non-substantive, CMS would use a sub-regulatory process to revise the specifications manual as discussed above.

Changes that we determine to be substantive would be those in which the changes are so significant that the measure is no longer the same measure. In proposed paragraph (d)(2)(i), we propose that we would utilize rulemaking to adopt substantive updates to measures previously adopted under the REHQR Program. We believe that this proposal adequately balances the need to incorporate updates to the REHQR Program measures in the most expeditious manner possible to maintain relevancy, reliability, and accuracy of data collection while also preserving the public’s ability to comment on updates that significantly change a measure.

We invite public comment on these proposals.

c. Proposal to Develop and Maintain Technical Specifications for Quality Measures

We intend to maintain technical specifications for adopted REHQR Program measures. We note that many of the measures considered for the REHQR Program have been previously adopted by the Hospital OQR Program. To simplify and streamline participation in the REHQR Program, we propose to adopt a policy for maintaining the measure specifications of REHQR Program measures that aligns with the Hospital OQR Program’s policy (83 FR 59104 through 59105).

In this proposed rule, we propose that, whenever we modify the REHQR Program measures and measure sets, we would also update the specifications manual for the REHQR

Program. The manuals containing specifications for previously adopted measures can be found on the QualityNet website at: <https://qualitynet.cms.gov/outpatient/specifications-manuals>. At proposed paragraph (d)(1) of § 419.95, “Technical Specifications and Measure Maintenance Under the REHQR Program,” we propose to update the specifications manual for REHQR Program measures at least every 12 months beginning with CY 2024.

We invite public comment on this proposal.

5. Proposed New Measures for the REHQR Program Measure Set

In this proposed rule, we propose to adopt four measures into the REHQR Program measure set beginning CY 2024: (1) Abdomen Computed Tomography (CT) - Use of Contrast Material measure; (2) Median Time from ED Arrival to ED Departure for Discharged ED Patients measure; (3) Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure; and (4) Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure. Three of these measures would be calculated from Medicare Fee-For-Service (FFS) claims and enrollment information. The fourth is a chart-abstracted measure. Many hospitals that are eligible to convert to REH status would already have established resources and experience with submitting these four measures as part of the Hospital OQR Program as previously discussed.

a. Proposal to Adopt the Abdomen Computed Tomography (CT) - Use of Contrast Material Measure

(1) Background

A CT study performed with and without contrast increases the radiation dose to patients,⁵²⁶ exposing them to the potential harmful side effects of the contrast material itself⁵²⁷ and

⁵²⁶ Sahbaee, P, et. al (2017). The Effect of Contrast Material on Radiation Dose at CT: Part II. A Systematic Evaluation across 58 Patient Models. *Radiology*, 283(3), 749–757. <https://doi.org/10.1148/radiol.2017152852>.

⁵²⁷ An, J, et. al. (2019). Differences in Adverse Reactions Among Iodinated Contrast Media: Analysis of the KAERS Database. *The Journal of Allergy and Clinical Immunology: In Practice*, 7(7), 2205-2211. <https://www.sciencedirect.com/science/article/abs/pii/S2213219819302570>.

it is often unnecessary.⁵²⁸ In the past, reports showed deviations from clinically appropriate American College of Radiology contrast practices for abdominal/pelvic CTs nationally.⁵²⁹ A 2020 study using CMS Care Compare data determined that hospitals are now conducting fewer duplicate abdomen CTs (that is, less often performing CTs twice, once with and once without contrast). These improvements are more pronounced among hospitals that formerly conducted the most duplicate abdomen CTs. The reduction in duplicate abdomen CTs observed in the 2020 study may indicate that the Abdomen Computed Tomography (CT) - Use of Contrast Material measure (the Abdomen CT) measure has been effective in identifying performance gaps among some hospitals. Thus, collecting data on this measure may have been effective in reducing duplicate abdomen CTs and lowering related patient risks.⁵³⁰ However, the same 2020 study found that duplicate abdomen CTs continue to occur.

We believe that the Abdomen CT measure is relevant for REH quality reporting. Although analysis of Care Compare data indicate the practice of duplicate scans continues with some hospitals large and small in both rural and urban settings, rural hospitals during the study period accounted for nearly half of those cases.⁵³¹ We note that this measure is also part of the Hospital OQR Program's measure set (adopted in the CY 2009 OPPS/ASC final rule (73 FR 68766)).

⁵²⁸ Hwang, IK, Lee, YS, Kim, J, Lee, YJ, Park, JH, Hwang. (2015). Do we really need additional contrast-enhanced abdominal computed tomography for differential diagnosis in triage of middle-aged subjects with suspected biliary pain. *Medicine*, 94(7):e546. doi: 10.1097/MD.0000000000000546.

⁵²⁹ Broder JS, Hamedani AG, Liu SW, Emerman CL. (2013). Emergency department contrast practices for abdominal/pelvic computed tomography—a national survey and comparison with the American College of Radiology Appropriateness Criteria(®). *J Emerg Med*, 44(2): 423–433. Available at: <https://doi.org/10.1016/j.jemermed.2012.08.027>. Last accessed February 28, 2023.

⁵³⁰ Davis, M, McKiernan, C, Lama, S, Parzynski, C, Bruetman, C, & Venkatesh, A., (July, 2020). Trends in publicly reported quality measures of hospital imaging efficiency, 2011–2018. *American Journal of Roentology* 215: 153–158. Available at <https://www.ajronline.org/doi/pdf/10.2214/AJR.19.21993>. Last accessed April 3, 2023.

⁵³¹ Ibid.

(2) Measure Overview

This measure provides the percentage of CT abdomen and abdominopelvic studies performed with and without contrast out of all CT abdomen studies performed (those without contrast, those with contrast, and those with both).

Section 1890A(a)(2) of the Act outlines the pre-rulemaking process established under section 1890A of the Act, which requires the Secretary to make available to the public by December 1 of each year a list of quality and efficiency measures under consideration. The Abdomen CT measure was on the 2022 Measures Under Consideration (MUC) list,⁵³² and the Measure Applications Partnership (MAP) Hospital Workgroup provided conditional support for this measure to be included in rulemaking for the REHQR Program. The MAP provides an annual review of the MUC list, and presents CMS with its recommendations in its Final Recommendations.⁵³³ In its February 1, 2023 Final Recommendations, the MAP noted that the measure addresses a critical priority of patient safety in rural hospitals for the REHQR Program.⁵³⁴ In the Final Recommendations, the MAP noted that the Health Equity Advisory Group expressed the importance of the measure and its potential to advance health equity, and the Rural Health Advisory Group discussed the measure in detail and cited no concerns with regard to rural health. The MAP conditionally supported the measure for rulemaking, pending testing indicating the measure is reliable and valid, and having CBE endorsement.⁵³⁵

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

⁵³² Centers for Medicare & Medicaid Services (CMS). 2022 Measures Under Consideration Spreadsheet. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>. Last accessed March 13, 2023.

⁵³³ Interested parties convened by the consensus-based entity will provide input and recommendations on the Measures under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to <https://p4qm.org/PRMR-MSR> for more information.

⁵³⁴ Centers for Medicare & Medicaid Services (CMS). *2022-2023 MAP Final Recommendations*. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>. Last accessed April 13, 2023.

⁵³⁵ *Ibid.*

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. The Abdomen CT measure is not CBE endorsed and we were unable to identify any other CBE-endorsed measures on this topic; therefore, we believe the exception in section 1861(kkk)(7)(C)(ii) of the Act applies for this measure. Also, we believe the measure has received sufficient support from consensus organizations, given the conditional support for the measure by the MAP Hospital Workgroup,⁵³⁶ favorable comments received by the Health Equity Advisory Group,⁵³⁷ and lack of objection by the Rural Health Advisory Group.⁵³⁸

We propose to adopt the Abdomen CT measure into the REHQR Program measure set beginning with the CY 2024 reporting period. By addressing the critical priority area of patient safety in rural hospitals, collecting data on this measure seeks to ensure that CT abdomen imaging in rural communities adheres to evidence-based clinical guidelines. Inclusion of this measure aligns with the CMS National Quality Strategy goals of embedding quality into the care journey, as well as the goal of promoting safety,⁵³⁹ and is aligned with the priorities we identified for our Meaningful Measures 2.0 initiative, including using only high-value quality measures that impact key quality domains and aligning measures across our programs.⁵⁴⁰

(3) Data Sources

This measure addresses excessive radiation exposure from improper outpatient imaging procedures in Medicare beneficiaries. It would be calculated using Medicare FFS final action

⁵³⁶ CMS, 2022 Measures Under Consideration Spreadsheet.

⁵³⁷ CMS, 2022-2023 MAP Final Recommendations.

⁵³⁸ Ibid.

⁵³⁹ CMS (2023). What is the CMS National Quality Strategy? Available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>. Last accessed April 13, 2023.

⁵⁴⁰ CMS (2022), Meaningful Measures 2.0: Moving from Measures Reduction to Modernization. Available at <https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization>. Last accessed April 13, 2023.

claims and enrollment data for hospital services paid through the OPSS for abdomen CT studies performed in the REH setting. Data from the hospital outpatient file is used to determine beneficiary inclusion (for example, a CT abdomen study performed at an REH) and exclusion (that is, diagnoses of adrenal mass, hematuria, infections of the kidney, jaundice, liver lesion (mass or neoplasm), malignant neoplasm of bladder, malignant neoplasm of pancreas, diseases of urinary system, pancreatic disorders, non-traumatic aortic disease, and unspecified disorder of kidney or ureter).⁵⁴¹

(4) Measure Calculation

This measure calculates the percentage of CT abdomen and abdominopelvic studies that are performed with and without contrast out of all CT abdomen studies performed (those with contrast, those without contrast, and those with both). The measure would be calculated based on a 12-month window of claims data. From this patient cohort, the numerator contains patients who had a combined CT abdomen study (that is, a CT abdomen study without contrast followed by a CT abdomen study with contrast, documented using the CT Abdomen With and Without Contrast CPT code). For this measure, lower scores indicate less usage of CT scanning as scans with and without contrast are typically not medically necessary, which means a high-performing facility reports a value nearer to zero, whereas facilities that may be performing too many combined CT abdomen studies score closer to 100 percent.⁵⁴²

(5) Cohort

This measure would apply to Medicare beneficiaries enrolled in original, Medicare FFS who underwent an abdomen or abdominopelvic CT study with or without contrast performed at an REH. This measure does not include Medicare managed care beneficiaries, non-Medicare patients, or beneficiaries who were admitted to the hospital as inpatients. A beneficiary can be

⁵⁴¹ YNHHS/CORE and The Lewin Group, 2021. *Abdomen Computed Tomography (CT)—Use of Contrast Material (OP-10): 2021 Annual Reevaluation Report*. Available at: https://qualitynet.cms.gov/files/607ee75eaba8620022335d7e?filename=OP=10_2021_ReevalReport.pdf. Last accessed March 13, 2023.

⁵⁴² Ibid.

included in the measure's initial patient population multiple times because each abdomen or abdominopelvic CT (without contrast, with contrast, or both with and without contrast) performed at an REH during the data collection period is counted once in the measure's denominator.

This claims-based imaging measure is not risk-adjusted; instead, Medicare FFS beneficiaries who have a clinical diagnosis of one or more conditions for which imaging with and without contrast is considered appropriate are excluded from the measure.⁵⁴³ Thus, this measure does not include beneficiaries with the following conditions: adrenal mass, hematuria, infections of kidney, jaundice, liver lesion (mass or neoplasm), malignant neoplasm of bladder, malignant neoplasm of pancreas, diseases of urinary system, pancreatic disorders, non-traumatic aortic disease, and unspecified disorder of kidney or ureter.⁵⁴⁴

We invite public comment on this proposal.

b. Proposal to Adopt the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients Measure

(1) Background

Care provided in the ED will likely be a focus of REH services and we seek measures that assess the quality of care in this setting. Improving ED throughput times is important for alleviating overcrowding and reducing wait times.⁵⁴⁵ Crowding has led to a number of potentially avoidable problems in EDs, including ambulance diversion, prolonged patient waiting times, and potentially poor patient outcomes due to delays, such as in the administration of medication.⁵⁴⁶

⁵⁴³ American College of Radiology. ACR Appropriateness Criteria. Available at: <https://www.acr.org/Clinical-Resources/ACR-Appropriateness-Criteria>. Last accessed April 4, 2023.

⁵⁴⁴ Centers for Medicare & Medicaid Services Measures Inventory Tool (CMIT). Abdomen Computed Tomography (CT) - Use of Contrast Material. Available at <https://cmit.cms.gov/cmit/#/MeasureView?variantId=1842§ionNumber=1>. Last accessed April 3, 2023.

⁵⁴⁵ Smalley, CM, Simon, EL, Meldon, SW, et al. (2020). The impact of hospital boarding on the emergency department waiting room. *JACEP Open*, 1(5):1052-1059. doi: 10.1002/emp2.12100.

⁵⁴⁶ Kelen GD, Wolfe R, D-Onofrio G, Mills AM, Diercks D, Stern SA, Wadman MC, Sokolove PE. Emergency Department Crowding: The Canary in the Health Care System. *NEJM Catalyst*. 2021; 5(2). <https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0217>. Last accessed February 28, 2023.

The Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (the Median Time for Discharged ED Patients measure was adopted for reporting in the Hospital OQR Program beginning with the CY 2013 payment determination (75 FR 72086).

(2) Measure Overview

The Median Time for Discharged ED Patients measure is a chart-abstracted measure that evaluates the time between the arrival to and departure from the ED, also known as ED throughput time.

As described in the measure specifications and Measure Information Form (MIF),^{547,548} measure data are stratified for four separate calculations: (1) the Overall Rate is calculated as the overall rate; (2) the Reported Measure calculates data for all patients excluding psychiatric/mental health patients and transfer patients; (3) Psychiatric/Mental Health calculates data for psychiatric/mental health patients; and (4) Transfers calculates data for transfer patients.

Although section 1861(kkk)(7)(c)(i) of the Act requires that measures specified by the Secretary for use in CMS hospital quality programs 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. This measure is not CBE-endorsed. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this

⁵⁴⁷ A Measure Information Form provides detail on the rationale for a measure as well as the relevant numerator statements, denominator statements and measure calculations.

⁵⁴⁸ Hospital OQR Program ED Throughput Measures Information Form. Available at: https://qualitynet.cms.gov/files/638e75e376962e0016ad907d?filename=1d_ED_Throughput_set_v16.0a.pdf (p. 1-26). Last accessed February 28, 2023.

topic; therefore, we believe the exception in section 1861(kkk)(7)(C)(ii) of the Act applies for this measure.

The Median Time for Discharged ED Patients measure was included in the 2022 MUC list.⁵⁴⁹ In its February 1, 2023 Final Recommendations, the MAP stated their belief that changes in wait times may not directly influence mortality or patient outcomes and had concerns that transfer times may be delayed due to weather and transport safety issues that are out of a facility's control. The Rural Health Advisory Group expressed similar concerns regarding the impact on transport times of issues beyond a facility's control, such as weather, local facility transport modalities, and distance; but also noted that transfer time for trauma patients is especially important. The Health Equity Advisory Group, however, emphasized the importance of the measure and its potential to advance health equity. Ultimately, the MAP did not provide support for this measure for the REHQR Program.⁵⁵⁰

We recognize the concerns expressed in the MAP Final Recommendation. However, we believe that ED wait times have significant impact on patients. Prolonged waiting times are associated with worse patient experience in patients discharged from the emergency department.⁵⁵¹ Studies demonstrate that higher patient satisfaction is associated with patient outcomes, including decreased mortality⁵⁵² and lower readmission rates.⁵⁵³

⁵⁴⁹ Centers for Medicare & Medicaid Services. *2022 Measures Under Consideration Spreadsheet*. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>. Last accessed March 13, 2023.

⁵⁵⁰ Centers for Medicare & Medicaid Services. *2022-2023 MAP Final Recommendations*. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>. Last accessed March 13, 2023.

⁵⁵¹ Nyce, A, Gandhi, S, Freeze, B, Bosire, J, Ricca, T, Kupersmith, E, Mazzarelli, A, Rachoin, J-S. Association of Emergency Department Waiting Times With Patient Experience in Admitted and Discharged Patients. 2021. *J Pat Exp* 8:1-7. <https://doi.org/10.1177/23743735211011404>.

⁵⁵² Glickman SW, Boulding W, Manary M, Staelin R, Roe MT, Wolosin RJ. et al. Patient satisfaction and its relationship with clinical quality and inpatient mortality in acute myocardial infarction. *Circ Cardiovasc Qual Outcomes*. 2010; 3:188–95. Available at https://www.ahajournals.org/doi/10.1161/CIRCOUTCOMES.109.900597?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed.

⁵⁵³ Boulding W, Glickman SW, Manary MP, Schulman KA, Staelin R. Relationship between patient satisfaction with inpatient care and hospital readmission within 30 days. *Am J Manag Care*. 2011;17:41–8. Available at https://www.ajmc.com/view/ajmc_11jan_boulding_41to48.

We acknowledge that transfer times may be delayed due to weather and transport safety issues that are out of a facility's control. However, we believe that some factors such as building transfer relationships and process improvements can be addressed by hospitals to improve ED wait times. Further, this information could be useful to Medicare beneficiaries and other interested parties toward assessing care provided and the care environment of a hospital. By implementing this measure, we are supporting CMS National Quality Strategy goals, including embedding quality into the care journey (for example, by addressing quality throughout the patient experience); promoting safety (for example, by minimizing associated negative patient outcomes, such as delayed administration of medications); and increasing alignment (given that this measure is used in other quality programs).⁵⁵⁴ Alignment of measures across CMS federal programs is also an objective of the Meaningful Measures 2.0 initiative.⁵⁵⁵ This measure also promotes the Meaningful Measures goal of driving outcome improvement through public reporting, given that CMS predicts that data for this measure will be reported in sufficient numbers to permit public reporting (see Table 79 in section XVI.B.1 of this proposed rule).

Care Compare data current to January 2023 show that CAHs and subsection (d) hospitals with fewer than 50 beds reported sufficient data for this measure under the Hospital OQR Program to be publicly reported for all of these strata, indicating that hospitals eligible to convert to REH status would be able to report data for this measure to a level sufficient for public reporting. Our proposal to publicly report these data is further described in section XVI.B.8.c of this proposed rule. Thus, we propose to adopt this measure in the REHQR Program beginning with the CY 2024 reporting period.

⁵⁵⁴ CMS (2023). What is the CMS National Quality Strategy? Available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>. Last accessed April 13, 2023.

⁵⁵⁵ CMS (2022), Meaningful Measures 2.0: Moving from Measures Reduction to Modernization. Available at <https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization>. Last accessed April 13, 2023.

(3) Data Sources

The measure would be calculated using chart-abstracted data on a rolling quarterly basis, and would be publicly reported in aggregate for one calendar year. Sources of the relevant data may include claims forms, electronic health care data, electronic health records (EHRs), or paper records. Data elements necessary for the calculation of the measure include arrival time, discharge code, Evaluation and Management (E/M) code, ED departure date, ED departure time, ICD-10-CM principal diagnosis code, and outpatient encounter date.

(4) Measure Calculation

The measure calculates the median time (in minutes) from ED arrival to time of departure from the ED for patients discharged from the ED. Reducing the time patients remain in the ED can improve access to treatment and increase quality of care.^{556,557} Improvement is noted as a decrease in the median value. The included population is any ED patient who completes an ED discharge process. This process measure is not risk-adjusted or risk-stratified.⁵⁵⁸ However, the measure is stratified by certain subgroups of patients, as described in the next section.

(5) Cohort

The Median Time for Discharged ED Patients measure is calculated in stratified subsections for certain types of patients: (1) Median Time from ED Arrival to ED Departure for Discharged ED Patients – Reported Measure, which excludes psychiatric/mental health and transferred patients; (2) Median Time from ED Arrival to ED Departure for Discharged ED Patients – Psychiatric/Mental Health Patients, which includes information only for psychiatric/mental health patients; (3) Median Time from ED Arrival to ED Departure for Discharged ED Patients – Transfer Patients, which includes information only for patients

⁵⁵⁶ Smalley, CM, Simon, EL, Meldon, SW, et al. (2020). The impact of hospital boarding on the emergency department waiting room. *JACEP Open*,1(5):1052-1059. doi: 10.1002/emp2.12100.

⁵⁵⁷ Kelen GD, Wolfe R, D-Onofrio G, Mills AM, Diercks D, Stern SA, Wadman MC, Sokolove PE. Emergency Department Crowding: The Canary in the Health Care System. *NEJM Catalyst*. 2021; 5(2). <https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0217>

⁵⁵⁸ CMIT. Median time from ED Arrival to ED Departure for Discharged ED patients. Available at <https://cmit.cms.gov/cmit/#/MeasureView?variantId=695§ionNumber=1>. Last accessed April 4, 2023.

transferred from the ED; and (4) Median Time from ED Arrival to ED Departure for Discharged ED Patients – Overall Rate. The measure excludes patients who expired in the ED, left against medical advice, or whose discharge was not documented or unable to be determined.⁵⁵⁹

We invite public comment on this proposal.

c. Proposal to Adopt the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy Measure

(1) Background

Colonoscopies are one of the most frequently performed procedures in the outpatient setting in the United States,⁵⁶⁰ with more than 16 million procedures performed each year.⁵⁶¹

Colonoscopies are associated with a range of well-described and potentially preventable adverse events that can lead to hospital visits, repeat procedures, or surgical intervention for treatment, including colonic perforation, gastrointestinal (GI) bleeding, and abdominal pain.⁵⁶² While hospital visits are generally unexpected after an outpatient colonoscopy, the literature indicates that the majority of such visits occurring later than seven days post-procedure are more likely to be unrelated to the procedure.⁵⁶³ Such hospital visits occurring later than seven days post-procedure may be complicated by patient comorbidities and high risk factors.⁵⁶⁴

⁵⁵⁹ QualityNet. Hospital Outpatient Specifications Manuals. Available at:

<https://qualitynet.cms.gov/outpatient/specifications-manuals>. Last accessed April 5, 2023.

⁵⁶⁰ Definitive Healthcare. Top 10 Outpatient Procedures at Surgery Centers and Hospitals. Available at:

<https://www.definitivehc.com/blog/top-10-outpatient-procedures-at-asc-s-and-hospitals#:~:text=Definitive%20Healthcare%20data%20shows%20that,procedures%20at%20ASCs%20by%20volume>. Last accessed March 12, 2023.

⁵⁶¹ I Data Research. An Astounding 16.6 Million Colonoscopies are Performed Annually in The United States. (<https://idataresearch.com/an-astounding-19-million-colonoscopy-are-performed-annually-in-the-united-states/> [sic]). Accessed February 28, 2023.

⁵⁶² I. Ranasinghe, C.S. Parzynski, R. Searfoss, et al. Differences in colonoscopy quality among facilities: development of a post-colonoscopy risk-standardized rate of unplanned hospital visits.

Gastroenterology, 150 (2016), pp. 103-113 Available at: <https://www.gastrojournal.org/action/showPdf?pii=S0016-5085%2815%2901353-0>. Last accessed March 12, 2023.

⁵⁶³ L.B. Grossberg, A. Vodonos, K. Papamichael, et al. Predictors of post-colonoscopy emergency department use. *Gastrointest Endosc*, 87 (2018), pp. 517-525. Available at:

<https://www.sciencedirect.com/science/article/pii/S0016510717322010?viewFullText=true#sec4>. Last accessed March 12, 2023.

⁵⁶⁴ *Ibid.*

As noted in Table 79 with Hospital OQR Program data current to 2023, the average rate of reported unplanned hospital visits per 1,000 colonoscopies at CAHs and rural subsection (d) hospitals eligible for REH conversion are 14.3 (1.43 percent) and 14.4 (1.44 percent), respectively. These average rates are in line with those of small, urban subsection (d) hospitals, and larger, rural hospitals subsection (d) with 50 or more beds (that is, with categories of subsection (d) hospitals that are not eligible for REH conversion). Hospitals in these categories that are in the top 10th percentile in terms of numbers of cases (that is, unplanned hospital visits within 7 days of an outpatient colonoscopy) reported, however, do appear to perform differently. In this percentile, hospitals eligible for REH conversion do not perform as well as those that are not eligible for REH conversion. REH-eligible hospitals with these larger caseloads have a higher rate of unplanned hospital visits per 1,000 colonoscopies than non-REH eligible hospitals.

The Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy (the 7-Day Hospital Visit Rate After Outpatient Colonoscopy) measure was adopted for reporting in the Hospital OQR Program in 2015, first with a dry run (that is, confidential reports containing measure results were made available for hospitals to review, provide feedback, and become familiar with the measure methodology in advance of public reporting and impact on payment determinations), and then fully implemented beginning with the CY 2018 payment determination (79 FR 66948 through 66955).

(2) Measure Overview

The 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure was on the 2022 MUC list.⁵⁶⁵ In its February 1, 2023 Final Recommendations, the MAP considered and supported it for rulemaking for the REHQR Program given that a previous version of this measure specified for colonoscopies performed in ambulatory surgical centers (ASCs) and hospital outpatient departments (HOPDs) received endorsement from the CBE (CBE #2539) in

⁵⁶⁵ Centers for Medicare & Medicaid Services. *2022 Measures Under Consideration Spreadsheet*. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>. Last accessed March 13, 2023.

2014 and 2020, and that this measure is currently in use in the ASCQR and Hospital OQR Programs.⁵⁶⁶

As evidenced in Table 79, CAHs and small, rural subsection (d) hospitals—hospitals which are eligible to convert to REH status—performed a sufficient number of colonoscopies and had sufficient measure data for this measure to be publicly reported on the Care Compare site. Using data current to January 2023 for the Hospital OQR Program, out of those eligible to report data, 65.5 percent (131) of small, rural subsection (d) hospitals and 44.7 percent (609) of CAHs eligible to convert to REHs reported for this measure.

We believe this could be an important measure for those REHs that elect to provide outpatient services and for patients seeking information regarding complications following this procedure. Inclusion of this measure in the REHQR Program will also promote goals of the CMS National Quality Strategy, including embedding quality into the care journey; advancing health equity within and across settings; and increasing alignment of performance metrics, programs, policy, and payment across CMS.⁵⁶⁷ Inclusion will also advance goals of the Meaningful Measures 2.0 initiative, including by empowering consumers to make good health care choices by providing public transparency; and by leveraging quality measures to promote health equity and close gaps in care.⁵⁶⁸ Therefore, we propose to include the 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure in the REHQR Program beginning with the CY 2024 reporting period.

⁵⁶⁶ Centers for Medicare & Medicaid Services. *2022-2023 MAP Final Recommendations*. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>. Last accessed March 13, 2023.

⁵⁶⁷ CMS (2023). What is the CMS National Quality Strategy? Available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>. Last accessed April 13, 2023.

⁵⁶⁸ CMS (2022), Meaningful Measures 2.0: Moving from Measures Reduction to Modernization. Available at <https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization>. Last accessed April 13, 2023.

(3) Data Sources

This outcome measure is calculated using Medicare FFS claims and enrollment data, estimating a facility-level rate of risk-standardized, all-cause, unplanned hospital visits within 7 days of an outpatient colonoscopy among Medicare FFS patients aged 65 years and older.⁵⁶⁹ In alignment with the reporting period for this measure as used in the Hospital OQR Program, the initial reporting period is a three-year period beginning with patient encounters from January 1, 2024 through December 31, 2026 with annual updates on a rolling basis.⁵⁷⁰

(4) Measure Calculation

The measure defines the outcome as any (one or more) unplanned hospital visits within 7 days of an outpatient colonoscopy procedure.⁵⁷¹ For this measure, a hospital visit includes any ED visit, observation stay, or unplanned inpatient admission to any short-term, acute care facility.^{572,573} The measure score is the ratio of predicted hospital visits (numerator) over the expected hospital visits (denominator) multiplied by the national observed rate. The numerator is the number of predicted (meaning adjusted actual) hospital visits, which is the number of unplanned hospital visits the facility is predicted to have within 7 days of colonoscopy, and it accounts for the observed unplanned hospital visit rate, the number of colonoscopies performed at the facility, and the facility's case mix. The denominator is the number of expected hospital visits, which is the number of unplanned hospital visits the facility is expected to have based on the facility's case mix. It is the sum of all patients' expected probabilities of a hospital visit, given their risk factors and the risk of readmission at an average facility. The national observed

⁵⁶⁹ CMIT. Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Available at <https://cmit.cms.gov/cmit/#/MeasureView?variantId=1354§ionNumber=1>. Last accessed February 28, 2023.

⁵⁷⁰ CMS, Hospital Outpatient Specifications Manuals – Measure Information Form, 1.6 Outcome Measures, OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Available at https://qualitynet.cms.gov/files/638e788ffb845c00175c7aaf?filename=1u_OP32MIF_v16.0a.pdf. Last accessed February 28, 2023.

⁵⁷¹ 2022 Measure Updates and Specifications Report: Hospital Outpatient Quality Reporting Program. available at: <https://qualitynet.cms.gov/outpatient/measures/surgery/methodology>. Last accessed May 2, 2023.

⁵⁷² Ibid.

⁵⁷³ CMS, Frequently Asked Questions. Available at: <https://qualitynet.cms.gov/outpatient/measures/colonoscopy/resources>. Last accessed May 2, 2023.

rate is the national unadjusted number of patients who had a hospital visit post-colonoscopy among all patients who had a colonoscopy.⁵⁷⁴ Additional methodology details and information obtained from public comments for measure development are available at:

<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html> under “Hospital Outpatient Colonoscopy.”

We note that the measure calculation is comparable to the Hospital OQR Program version of the measure, as set out in the CY 2015 OPPTS/ASC final rule (79 FR 66948 through 66955).

(5) Cohort

The measure denominator includes Medicare patients with paid, final action claims for typical colonoscopies. The denominator excludes patients undergoing concomitant high-risk upper GI endoscopy because this is a more extensive procedure that places these patients at a higher risk for hospital visits than patients undergoing a typical colonoscopy, as well as patients with a history of inflammatory bowel disease (IBD) or diverticulitis in the year preceding the colonoscopy because we likely could not fully characterize and adjust for their pre-procedure risk of needing a post-procedure hospital visit or identify whether these admissions are planned or unplanned. The measure also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the month after the procedure to ensure all patients have complete data available for outcome assessment. For further discussion of the cohort for the 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, please see “2022 Measure Updates and Specifications Report: Hospital Outpatient Quality Reporting Program,” available at: <https://qualitynet.cms.gov/outpatient/measures/surgery/methodology>.

⁵⁷⁴ “Included colonoscopies” are outpatient colonoscopy procedures using Healthcare Common Procedure Coding System (HCPCS) codes G0121 and G0105, and Common Procedural Terminology (CPT) codes 45378, 45380, 45385, 45384, 45383, and 45381. This measure also uses a number of exclusion criteria. Additional methodology details and information obtained from public comments for measure development are available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html> under “Hospital Outpatient Colonoscopy.”

(6) Risk Adjustment

The statistical risk-adjustment model includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within seven days following colonoscopy. Additional methodology details and information for measure development are available at: <https://qualitynet.cms.gov/outpatient/measures/surgery/methodology>.

We invite public comment on this proposal.

d. Proposal to Adopt the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure

(1) Background

Most surgical procedures in the United States are performed in outpatient settings; there are approximately 23 million such procedures performed annually.⁵⁷⁵ Same-day surgery offers significant patient benefits as compared with inpatient surgery, including shorter waiting times, avoidance of hospitalizations, and rapid return home.⁵⁷⁶ Furthermore, as same-day surgery costs are significantly less than an equivalent inpatient surgery, there is a significant cost saving opportunity to the health system.⁵⁷⁷ With the ongoing shift towards outpatient surgery, assessing the quality of surgical care provided by hospitals has become increasingly important. Patients undergoing same-day surgery may require subsequent unplanned hospital visits for a broad range of reasons. While most outpatient surgery is safe, there are well-described and potentially preventable adverse events that occur after outpatient surgery, such as uncontrolled pain, urinary retention, infection, bleeding, and venous thromboembolism, which can result in unplanned hospital visits.⁵⁷⁸ Similarly, direct admissions after surgery that are primarily caused by nonclinical patient considerations (for example, lack of transport home upon discharge) or

⁵⁷⁵ Munnich, EL, & Richards, MR. (February, 2022). Long-run growth of ambulatory surgery centers 1990-2015 and Medicare payment policy. *Health Services Research*, 57(1), 66–71. <https://doi.org/10.1111/1475-6773.13707>.

⁵⁷⁶ Banner Health. Outpatient Experience & Benefits. Available at:

<https://www.bannerhealth.com/services/outpatient-surgery/experience-benefits>. Last accessed April 4, 2023.

⁵⁷⁷ Munnich, EL, & Parente, ST. (January, 2018). Returns to specialization: Evidence from the outpatient surgery market. *Journal of health economics*, 57, 147–167. <https://doi.org/10.1016/j.jhealeco.2017.11.004>.

⁵⁷⁸ Bongiovanni, T, Parzynski, C, Ranasinghe, I, Steinman, MA, & Ross, JS. (July 2021). Unplanned hospital visits after ambulatory surgical care. *PloS one*, 16(7), e0254039. <https://doi.org/10.1371/journal.pone.0254039>.

facility logistical issues (for example delayed start of surgery) are common causes of unplanned yet preventable hospital admissions following same-day surgery.⁵⁷⁹ Hospital utilization following same-day surgery is an important and accepted patient-centered outcome reported in the literature. As evidenced by one study, “national estimates of hospital visit rates following surgery vary from 0.5 to 9.0 percent based on the type of surgery, outcome measured (admissions alone or admissions and ED visits), and timeframe for measurement after surgery,”⁵⁸⁰ suggesting variation in surgical and discharge care quality. However, providers (hospitals and surgeons) are often unaware of their patients’ hospital visits after surgery because patients often present to the ED or to different hospitals.⁵⁸¹ This risk-standardized measure provides the opportunity for providers to improve the quality of care and to lower the rate of preventable adverse events that occur after outpatient surgery.

The Risk-Standardized Hospitalized Visits Within 7 Days After Hospital Outpatient Surgery (the 7-Day Hospital Visit Rate After Outpatient Surgery) measure was adopted for reporting in the Hospital OQR Program beginning with the CY 2020 payment determination (81 FR 79771).

(2) Measure Overview

The 7-Day Hospital Visit Rate After Outpatient Surgery measure would make unplanned patient hospital visits (ED visits, observation stays, or unplanned inpatient admissions) after surgery more visible to providers and patients through publicly reporting scores. It could also encourage providers to engage in quality improvement activities to reduce these visits by providing feedback to facilities and physicians. This measure meets the National Quality

⁵⁷⁹ Ibid.

⁵⁸⁰ Ibid.

⁵⁸¹ Williams, BR, Smith, LC, Only, AJ., Parikh, HR, Swiontkowski, MF, & Cunningham, BP. (September, 2021). Unplanned Emergency and Urgent Care Visits After Outpatient Orthopaedic Surgery. *Journal of the American Academy of Orthopaedic Surgeons. Global research & reviews*, 5(9), e21.00209. <https://doi.org/10.5435/JAAOSGlobal-D-21-00209>.

Strategy goals of embedding quality into the care journey and promoting safety.⁵⁸² We expect that the measure would promote improvement in patient care over time.

The 7-Day Hospital Visit Rate After Outpatient Surgery measure was on the 2022 MUC list.⁵⁸³ The Rural Health Advisory Group members did not have any rural health concerns about the measure. We believe that this proposed measure reflects consensus among the affected parties as public comment received during the MAP and measure development processes was in agreement with the MAP's conclusions on the measure. The CBE recommended the measure for rulemaking (CBE #2687).⁵⁸⁴

We believe it is important to reduce adverse patient outcomes associated with preparation for surgery, the procedure itself, and follow-up care. Therefore, we propose to include the 7-Day Hospital Visit Rate After Outpatient Surgery measure in the REHQR Program beginning with the CY 2024 reporting period.

(3) Data Sources

The proposed 7-Day Hospital Visit Rate After Outpatient Surgery measure would be 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. The exclusion of eye procedures is discussed below. The performance period for the measure is one year (that is, the measure calculation includes eligible outpatient same-day surgeries occurring within a 1-year

⁵⁸² CMS, What is the CMS National Quality Strategy? Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>.

⁵⁸³ Centers for Medicare & Medicaid Services. *2022 Measures Under Consideration Spreadsheet*. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>. Last accessed March 13, 2023.

⁵⁸⁴ Centers for Medicare & Medicaid Services. *MAP 2016 Considerations for Implementing Measures in Federal Programs - Hospitals*. Available at: https://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_Hospitals.aspx. Last accessed March 13, 2023.

timeframe),⁵⁸⁵ and would begin with the CY 2024 reporting period. We also considered increasing the data collection time period, to account for low volume, to 2 or 3 years.

(4) Measure Calculation

The measure outcome includes unplanned hospital visits within seven days after a surgery performed at an REH that are: (1) an inpatient admission at a separate hospital that can admit patients; or (2) an ED visit or observation stay at the REH or other hospital occurring after discharge. If more than one unplanned hospital visit occurs, only the first hospital visit within the outcome timeframe is counted in the outcome.

The facility-level measure score is a ratio of the predicted to expected number of post-surgical hospital visits among the hospital's patients. The numerator of the ratio is the number of hospital visits predicted for the hospital's patients accounting for its observed rate, the number of surgeries performed at the hospital, the case-mix, and the surgical procedure mix. The denominator of the ratio is the expected number of hospital visits given the hospital's case-mix and surgical procedure mix. A ratio of less than one indicates the hospital's patients have fewer post-surgical visits than expected compared to hospitals with similar surgical procedures and patients; and a ratio of greater than one indicates the hospital's patients were estimated as having more visits than expected.

To ensure the accuracy of the algorithm for attributing claims data and the comprehensive capture of hospital surgeries potentially affected by the CMS 3-day payment window policy,⁵⁸⁶ we identify physician claims for same-day surgeries in hospital settings from the Medicare Part B Standard Analytical Files (SAF) with inpatient admissions that occur within 3 days after these surgeries that lack a corresponding hospital facility claim. Under the 3-day payment window policy, all outpatient diagnostic services furnished to a Medicare beneficiary

⁵⁸⁵ QualityNet. 2022 Measure Updates and Specifications Report (2022), available at <https://qualitynet.cms.gov/outpatient/measure/surgery/methodology>. Last accessed February 28, 2023.

⁵⁸⁶ https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Three_Day_Payment_Window. Accessed May 4, 2023.

by a hospital (or an entity wholly owned or operated by the hospital), on the date of a beneficiary's admission or during the 3 days immediately preceding the date of a beneficiary's inpatient hospital admission, must be included on the Part A bill for the beneficiary's inpatient stay at the hospital. Hospitals must include the following information on the claim for a beneficiary's inpatient stay: (1) the diagnoses; (2) procedures; and (3) charges for all outpatient diagnostic services and admission-related outpatient nondiagnostic services that are furnished to the beneficiary during the 3-day payment window.⁵⁸⁷ A surgery identified as affected by this policy would be attributed to the appropriate hospital facility using the facility provider identification from the inpatient claim.⁵⁸⁸

(5) Cohort

The measure includes Medicare FFS patients aged 65 years and older undergoing same-day, outpatient surgery in REHs, excluding eye surgeries and colonoscopies, but including colonoscopy with biopsy.

“Same-day surgeries” are substantive surgeries and procedures listed on Medicare’s list of covered ASC procedures excluding eye surgeries and colonoscopies (except colonoscopy with biopsy).⁵⁸⁹ This list was developed for Medicare to identify surgeries that can be safely performed as same-day surgeries and do not typically require an overnight stay. Surgeries on the ASC list of covered procedures do not involve or require major or prolonged invasion of body cavities, extensive blood loss, major blood vessels, or care that is either emergent or life-threatening.

⁵⁸⁷ Three Day Payment Window Implementation of New Statutory Provision Pertaining to Medicare 3-Day (1-Day) Payment Window Policy - Outpatient Services Treated As Inpatient. Centers for Medicare and Medicaid Services (CMS). Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Three_Day_Payment_Window. Last accessed on March 28, 2023.

⁵⁸⁸ For additional methodology details, we refer readers to the documents posted at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology>, including “2016 Measure Updates and Specifications Report: Hospital Visits after Hospital Outpatient Surgery Measure (PDF)”. Last accessed March 21, 2023.

⁵⁸⁹ YNHHS/CORE (2016). 2016 Measure Updates and Specifications Report Hospital Outpatient Quality Reporting Program 2022. Available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology>. Last accessed March 21, 2023.

Although Medicare developed this list of surgeries for ASCs, we use it more broadly for this measure for two reasons. First, it aligns with our target cohort of surgeries that have low to moderate risk profile and are safe to be performed as same-day surgeries. By only including surgeries on this list in the measure, we effectively do not include surgeries performed at hospitals that typically require an overnight stay which are more complex, higher risk surgeries. Second, we use this list of surgeries because it is annually reviewed and updated by Medicare, and includes a transparent public comment submission and review process for addition or removal of procedures codes. To view the ASC covered procedures list for 2023, we refer readers to the CMS website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices>. On that page, readers may select “CMS-1772-FC” from the list of regulations. The ASC Addenda are contained in a zipped folder entitled “Addendum AA, BB, DD1, DD2, and EE.” Addendum AA includes the relevant list of covered surgeries.

For further discussion of the cohort for this measure, please see “2022 Measure Updates and Specifications Report: Hospital Outpatient Quality Reporting Program,” available at <https://qualitynet.cms.gov/outpatient/measure/surgery/methodology>.

The cohort for this measure excludes eye surgeries. Eye surgery is performed in high volume and is generally perceived as being “low risk.” However, studies have indicated non-insignificant levels of hospital visits following cataract surgery. One study reported 0.3 percent of patients as having an inpatient admission within 7 days following cataract surgery⁵⁹⁰ and another study showing a 1.77 percent of patients with ED visits within 30 days following cataract surgery.⁵⁹¹ The measure cohort also excludes procedures for patients who lack

⁵⁹⁰ Wang, SY, Blachley, TS, Andrews, CA, Avanian, JZ, Lee, PP, & Stein, JD. Feb 22, 2016). Hospitalization after Cataract Surgery in a Nationwide Managed-Care Population. *PLOS ONE* (11:2). <https://doi.org/10.1371/journal.pone.0149819>

⁵⁹¹ Sahil Aggarwal, Andrew Gross, Alex Snyder, Jay Rathinavelu, Terry Kim Leon Herndon. Younger Age and Longer Case Times Associated With Emergency Department Visits After Cataract Surgery Published: August 23, 2022DOI: <https://doi.org/10.1016/j.ajo.2022.08.017>

continuous enrollment in Medicare FFS Parts A and B in the seven days after the procedure to ensure all patients have complete data available for outcome assessment.

(6) Risk Adjustment

The statistical risk-adjustment model includes 25 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within 7 days following outpatient surgery.⁵⁹² The measure risk-adjusts for surgical procedure complexity using two variables. First, it adjusts for surgical procedure complexity using the Work Relative Value Units (RVUs).⁵⁹³ Work RVUs are assigned to each CPT procedure code and approximate procedure complexity by incorporating elements of physician time and effort. Second, it classifies each surgery into an anatomical body system group using the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification System (CCS),⁵⁹⁴ to account for organ-specific differences in risk and complications, which are not adequately captured by the Work RVU alone.

We invite public comment on this proposal.

6. Summary of Proposed REHQR Program Measure Set Beginning With the CY 2024

Reporting Period

Table 80 summarizes the proposed REHQR Program measure set beginning with the CY 2024 reporting period:

TABLE 80: Proposed REHQR Program Measure Set Beginning With the CY 2024 Reporting Period

CBE #	Measure Name
None	Abdomen Computed Tomography (CT) – Use of Contrast Material
None	Median Time from ED Arrival to ED Departure for Discharged ED Patients

⁵⁹² Information about the risk-adjustment model and measure methodology are located in the Measure Updates and Specifications Report available on QualityNet at:

<https://qualitynet.cms.gov/outpatient/measures/surgery/methodology>.

⁵⁹³ Coberly, S. (January 12, 2015). The Basics; Relative Value Units (RVUs). *National Health Policy Forum*.

Available at: https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1275&context=sphhs_centers_nhpf. Last accessed February 28, 2023.

⁵⁹⁴ HCUP Clinical Classifications Software for Services and Procedures. Healthcare Cost and Utilization Project (HCUP). 2008. Agency for Healthcare Research and Quality. Available at: https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcsproc.jsp. Last accessed February 28, 2023.

CBE #	Measure Name
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy*
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery

*Reporting period for this measure is a three-year period, beginning CYs 2024-2026.

7. REHQR Program Measures and Topics for Future Consideration

a. Request for Comment: Electronic Clinical Quality Measures (eCQMs) for Reporting Quality Data Under the REHQR Program

eCQMs are measures specified in a standard electronic format that use data electronically extracted from EHRs and/or health information technology systems to measure the quality of health care provided. Through electronic reporting, hospitals have leveraged EHRs to capture, calculate, and electronically submit quality data instead of manually chart-abstracting and submitting to CMS. Adoption of certain eCQMs into the REHQR Program could address high priority areas as stated in our Meaningful Measures Framework, including the transition to digital quality measures and the adoption of high-quality measures that improve patient outcomes and safety.⁵⁹⁵

We acknowledge that technological, monetary, and staffing barriers may present challenges to eCQM adoption and use at some REHs. Although some REH staff may have had experience reporting eCQMs in the Hospital IQR, Hospital OQR, or Medicare Promoting Interoperability (PI) Programs during the time period when their REHs were organized as CAHs or subsection (d) hospitals, we acknowledge that challenges will remain. We see evidence of these challenges when analyzing eCQM reporting under the Medicare PI Program for eligible hospitals and CAHs. Tables 81 and 82 compare urban and rural hospital eCQM reporting, as defined by census area, with respect to the Medicare PI Program for CY 2021. Most hospitals of all bed sizes successfully reported eCQMs, but eCQM submission compliance percentages for smaller hospitals and rural hospitals were slightly lower than for larger or urban hospitals.

⁵⁹⁵ CMS. Meaningful Measures Initiative. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy>. Last accessed April 3, 2023.

TABLE 81: Urban Hospitals that did or did not meet CY 2021 Reporting Period Promoting Interoperability eCQM Submission Requirements or were granted an Extraordinary Circumstances Exception (ECE)/Hardship Exception*

Hospital Type and Location	MET	Percent Met	NOT MET	Percent Not Met	ECE/Hardship	Percent with ECE/Hardship	Total
Rural and Urban Hospitals Eligible to submit eCQMs for CY 2021 Reporting Period	4,123	92.0%	286	6.4%	71	1.6%	4,480
Location							
Urban	3,088	95.1%	98	3.0%	60	1.8%	3,246
Bed Size Urban							
0-50	667	87.0%	81	10.6%	19	2.5%	767
51-100	408	96.5%	6	1.4%	9	2.1%	423
101+	2,013	97.9%	11	0.5%	32	1.6%	2,056
Provider Urban							
CAH	402	85.7%	67	14.3%	0	0.0%	469
IQR-Eligible	2,643	96.8%	26	1.0%	60	2.2%	2,729
Voluntary**	43	89.6%	5	10.4%	0	0.0%	48

*A CAH cannot request an extraordinary circumstances exception (ECE) if it is found to be noncompliant with the requirements of a quality reporting program, but they can request a Hardship Exception through the PI Program. Data source: Hospitals are identified from eCQM data submitted via Hospital Quality Reporting for FY 2023 and PRS accessed May 18, 2022. Hospitals are included if they were eligible to submit CY 2021 eCQM measures for FY 2023.

**Voluntary hospitals are those not required to participate in the Hospital IQR Program (located in Puerto Rico and other U.S. Territories and Maryland) as well as seven cancer centers or research hospitals that choose to report.

TABLE 82: Rural Hospitals that did or did not meet CY 2021 Reporting Period Promoting Interoperability eCQM Submission Requirements or were granted an Extraordinary Circumstances Exception (ECE)/Hardship Exception*

Hospital Type and Location	MET	Percent Met	NOT MET	Percent Not Met	ECE	Percent with ECE	Total
Rural and Urban Hospitals Eligible to submit eCQMs for CY 2021 Reporting Period	4,123	92.0%	286	6.4%	71	1.6%	4,480
Location							
Rural	1,035	83.9%	188	15.2%	11	0.9%	1,234
Bed Size Rural							
0-50	768	81.1%	170	18.0%	9	1.0%	947
51-100	122	93.1%	7	5.3%	2	1.5%	131
101+	145	92.9%	11	7.1%	0	0.0%	156
Provider Rural							
CAH	672	80.2%	166	19.8%	0	0.0%	838
IQR-Eligible	327	95.1%	6	1.7%	11	3.2%	344
Voluntary**	36	69.2%	16	30.8%	0	0.0%	52

*A CAH cannot request an extraordinary circumstances exception (ECE) if it is found to be noncompliant with the requirements of a quality reporting program, but they can request a Hardship Exception through the PI Program.

Data source: Hospitals are identified from eCQM data submitted via Hospital Quality Reporting for FY 2023 and PRS accessed May 18, 2022. Hospitals are included if they were eligible to submit CY 2021 eCQM measures for FY 2023.

**Voluntary hospitals are those not required to participate in the Hospital IQR Program (located in Puerto Rico and other U.S. Territories and Maryland) as well as seven cancer centers or research hospitals that choose to report.

We believe that certain eCQMs, if adopted into the REHQR Program, could provide insightful quality measure data for monitoring REHs and potentially lower provider burden. For example, the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults eCQM (the Excessive Radiation eCQM) could be adopted into the REHQR Program to improve patient outcomes and patient safety. This eCQM provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses while preserving image quality. The measure is expressed as a percentage of eligible CT scans that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam.⁵⁹⁶ This measure is not risk-adjusted. The purpose of this measure is to reduce unintentional harm to patients and provide REHs with a reliable method to assess harm reduction efforts and modify their improvement efforts. We propose adoption of the Excessive Radiation eCQM for the Hospital OQR Program. We refer readers to section XIV.B.3.c of this proposed rule for a discussion of the Hospital OQR Program proposal.

We also refer readers to section XIV of the CY 2022 OPSS/ASC proposed rule (86 FR 42232 through 42237) where we requested information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the Fast Healthcare Interoperability Resources (FHIR) standard. This will be taken into consideration in future years when deciding how and when to introduce eCQMs to the REHQR Program.

⁵⁹⁶ Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

We invite public comment on the use of eCQMs in the REHQR Program, any specific eCQM measures that we should consider for inclusion in the REHQR Program measure set, including the Excessive Radiation eCQM, and any considerations or criteria we should use in identifying eCQM measures to propose for future inclusion.

b. Request for Comment: Care Coordination Measures

As part of future rulemaking, we may consider adding measures to the REHQR Program measure set that are relevant to the coordination of care between REHs and other kinds of healthcare providers. REHs encounter challenges in coordinating care that are specific to rural settings. Geographically isolated areas typically have fewer healthcare settings and providers, and experience difficulties related to workforce shortages, transportation issues, and lack of information technology capabilities, such as the availability of broadband networks.⁵⁹⁷ Other challenges relate to shifting workforce availability (for example, issues related to the availability of traveling nurses or independent healthcare providers) and limited access to specialists, diagnostic equipment, and other resources.⁵⁹⁸ In particular, REHs are required to have in effect a transfer agreement with a level I or level II trauma center,⁵⁹⁹ such that patients that present at an REH with needs for longer-term inpatient care may receive that care. REHs must, therefore, address issues related to the coordination of care for transferred patients.

We have sought to identify measures relevant to care coordination in rural settings that are also important, impactful, reliable, accurate, and clinically relevant. In the CY 2023 OPPTS/ASC final rule, we provided responses to the comments received on our request for information on additional topics for quality measures appropriate for the REH setting (87 FR 72146 through 72149). Many of these comments addressed the provision of telehealth, an issue that impacts care coordination (87 FR 72146 through 72147). The CBE provided

⁵⁹⁷ Healthcare Access in Rural Communities. Rural Health Information Hub. Available at: <https://www.ruralhealthinfo.org/topics/healthcare-access>. Last accessed March 13, 2023.

⁵⁹⁸ Ibid.

⁵⁹⁹ Section 1861(kkk)(2)(C) of the Act.

additional information on this topic in 2021, when they identified a list of 324 measures relevant to the provision of telehealth.⁶⁰⁰ We believe that a number of these measures are directly related to the coordination of care, such as measures CBE #0006 Care Coordination, CBE #0097 Medication Reconciliation Post-Discharge, and CBE #0326 Advance Care Plan.⁶⁰¹ The current Medicare Beneficiary Quality Improvement Project (MBQIP) measures also include several “care transitions” measures that may be relevant to the coordination of care for REHs. Relevant MBQIP measures include Emergency Department Transfer Communication (on which we invited public comment in the CY 2022 OPPI/ASC proposed rule, at 86 FR 42285 through 42289), Discharge Planning, and Medication Reconciliation.⁶⁰²

We invite public comment on the use of care coordination measures including telehealth measures in the REHQR Program, any specific measures that we should consider for inclusion in the REHQR Program measure set regarding care coordination, and any considerations or criteria we should use in determining which if any coordination of care measures to propose for future inclusion.

c. Request for Comment: Tiered Approach Framework

We refer readers to section XVII of the CY 2022 OPPI/ASC proposed rule, where we included a request for information (RFI) on REHs (86 FR 42285 through 42289). We received more than 50 comments in response to the RFI, including one suggestion to implement a multi-tiered approach for quality measures and reporting requirements to incentivize REH reporting.

Within such a tiered framework, Tier 1 could encompass a set of measures that would be required for all REHs and would focus on measures applicable for the required ED and

⁶⁰⁰ Rural Telehealth and Healthcare System Readiness Measurement Framework Final Report (2021). Accessed March 28, 2023. Available at: https://www.qualityforum.org/Publications/2021/11/Rural_Telehealth_and_Healthcare_System_Readiness_Measurement_Framework_-_Final_Report.aspx.

⁶⁰¹ Ibid.

⁶⁰² Federal Office of Rural Health Policy (FORHP). MBQIP Measures (January 2023) - Current Medicare Beneficiary Quality Improvement Project (MBQIP) Measures. Available at: <https://www.ruralcenter.org/sites/default/files/2023-02/MBQIP-Measures.pdf>.

observation services at REHs. Tier 2 could apply only to REHs that choose to provide additional outpatient services; the measures in that set would be related to the optional services provided.

Measures being proposed in this proposed rule for adoption into the REHQR Program measure set are the: (1) Abdomen CT measure, (2) Median Time for Discharged ED Patients measure, (3) 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, and (4) 7-Day Hospital Visit Rate After Outpatient Surgery measure. Two of these proposed measures are related to services that REHs must provide to participate in the Medicare program. The other two proposed measures are related to services that could be furnished on an outpatient basis at the election of the REH.⁶⁰³ To fit into an example scenario of a tiered approach, Tier 1 could include the measures related to required services, which are the diagnostic, claims-based Abdomen CT measure, and the chart-abstracted Median Time for Discharged ED Patients measure. Tier 2 could consist of the measures related to services the REH may elect to provide, which are the claims-based 7-Day Hospital Visit Rate After Outpatient Colonoscopy and 7-Day Hospital Visit Rate After Outpatient Surgery measures.

The aforementioned tiered measures are only examples for the purposes of this request for comment to further discussion of this concept for the REHQR Program.

Such reporting could be phased-in; for example, as suggested by the commenter, all REHs could report the Tier 1 quality measures beginning at a designated time after their REH status began, and all REHs providing additional services would begin to submit Tier 2 data at a designated time after such services begin under the new REH status.

We invite public comment on the implementation of a tiered quality measure approach in the REHQR Program, considerations in designing the structure of a tiered framework, the number of measures in each tier, and considerations for designating measures for tiers of such a framework.

⁶⁰³ See section 1861(kkk)(1) of the Act.

8. Proposal to Display Quality Measure Data Publicly

a. Public Reporting of Quality Data Generally

Pursuant to the CAA, the Secretary shall establish procedures to make quality measure data submitted by REHs available to the public on a CMS website.⁶⁰⁴ Such procedures shall ensure that the REH has the opportunity to review, and submit corrections for, the data that is to be made public with respect to the REH prior to such data being made public.⁶⁰⁵ In this proposed rule, we propose to align our approach to the public display of measures with that of the Hospital OQR and ASCQR Programs. For detail on the public display of measures in the Hospital OQR and ASCQR Programs, we refer readers OPPS/ASC final rules of CY 2009 (73 FR 68777 through 67779), CY 2014 (78 FR 75092), and CY 2017 (81 FR 79791). We propose to make publicly reported data under the REHQR Program available to the public both on our Care Compare website and in downloadable data files located in the Provider Data Catalog (PDC), found at <http://data.cms.gov>. We intend to display these data publicly for any consumer or other member of the public beginning with measure data submitted relevant to services provided in CY 2024. To the extent possible, in order to publicly display these data, we will use the same information systems, business processes, and other infrastructure that we use to display data for the Hospital OQR and Hospital Inpatient Quality Reporting (IQR) Programs. This alignment of processes and policies will enhance alignment with other quality reporting programs and ease of understanding for REHs.

We also propose that participating REHs would be granted the opportunity to review their data before the information is published during a 30-day review and corrections period (the preview process). Similarly, to the Hospital OQR and Hospital IQR Programs, we would announce the timeframes for the preview period starting with the measure data submitted relevant to services provided in CY 2024 on a CMS website, such as QualityNet, or on

⁶⁰⁴ CAA, 2021, at section 125(a)(1)(B) of Division CC, adding section 1861(kkk)(7)(D) of the Act.

⁶⁰⁵ CAA, 2021, at section 125(a)(1)(B) of Division CC, adding section 1861(kkk)(7)(D) of the Act.

applicable listservs. We generally strive to display hospital quality measures data on the designated website as soon as possible after measure data have been submitted to CMS. However, if there are unresolved display issues or pending design considerations, we may make the data available on other, non-interactive, CMS websites. This preview process aligns with that of the Hospital OQR Program (81 FR 79791).

We propose to codify this policy at § 419.95 by adding paragraph (f) “Public Reporting of Data Under the REHQR Program.” In proposed paragraph (f), we propose that data that an REH submits for the REHQR Program would be made publicly available by a CMS Certification Number (CCN) on a CMS website in an easily understandable format after providing the REH an opportunity to review the data to be made public.

We invite public comment on this proposal.

b. Public Reporting of Proposed REHQR Program Claims-Based Measures

We propose to make measure scores for claims-based measures proposed for the REHQR Program measure set publicly available beginning with measure data submitted relevant to services provided in CY 2024. As discussed above in section XVI.B.5 of this proposed rule, we propose to adopt the following three claims-based measures into the REHQR Program measure set: (1) Abdomen CT measure, (2) 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, and (3) 7-Day Hospital Visit Rate After Outpatient Surgery measure.

Public reporting measure data for a claims-based measure would not begin until completion of a data collection period specific to that claims-based measure, provided sufficient case volumes are achieved.^{606,607} For example, for the 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, the data collection period is three years; public reporting would begin

⁶⁰⁶ CMS does not report measures publicly unless measures are the result of an analysis of more than 10 cases.

⁶⁰⁷ CMS Policy for Privacy Act Implementation & Breach Notification, July 23, 2007, Document Number: CMS-CIO-POL-PRIV01-01, p 4. Statistical, aggregate or summarized information created as a result of analysis conducted using identifiable CMS data obtained under CMS-approved projects/studies may only be disclosed if the data are not individual-specific and the data are aggregated to a level where no data cells contain 10 or fewer individuals.

after completion of an initial three-year data collection period, or CY 2027, provided the hospital had sufficient case volumes. We plan to provide additional detail on the timeline of publicly reporting this data in future rulemaking.

The display of these data would rely on the same business processes and resources that are currently in use for the Hospital OQR and Hospital IQR Programs. The data would be available to the public both on our Care Compare website and in downloadable data files located in the Provider Data Catalog (PDC), found at <http://data.cms.gov>. Data associated with these three claims-based measures would be updated annually.

We invite public comment on this proposal.

c. Public Reporting of the Proposed Median Time from ED Arrival to ED Departure for Discharged ED Patients Measure

In the Hospital OQR Program, only data for two out of the four strata of the Median Time for Discharged ED Patients measure are reported publicly. Measure data for the Median Time for Discharged ED Patients – Reported Rate is currently publicly displayed on the Care Compare site and in the downloadable data files located in the PDC, found at <https://data.cms.gov>, for the Hospital OQR Program. Additionally, measure data for the Median Time for Discharged ED Patients – Psychiatric/Mental Health Patients is publicly displayed in downloadable data files located in the PDC, in order to address a behavioral health gap in the publicly reported Hospital OQR Program measure set.⁶⁰⁸

While data for the Median Time for Discharged ED Patients – Transfer Patients measure stratification is not currently reported publicly for hospitals participating in the Hospital OQR Program, we believe publicly reporting measure data for this stratum for REHs is imperative to allow for the identification of REH ED throughput performance gaps for patients requiring higher levels of specialized care above what an REH is able to provide. Likewise, data for the

⁶⁰⁸ CMS adopted a policy to publicly report measure data for the Median Time for Discharged ED Patients – Psychiatric/Mental Health Patients in the CY 2018 OPPI/ASC final rule (82 FR 59437).

Median Time for Discharged Patients – Overall Rate measure stratification are not currently reported publicly for hospitals participating in the Hospital OQR Program. However, we believe publicly reporting measure data for this stratum for REHs participating in the REHQR Program is important to provide an account of all patients seen in the REH’s ED, beyond identifying specific performance in certain patient populations as reflected by the other strata calculated for this measure. We note that the Median Time for Discharged ED Patients measure is of particular importance for the REHQR Program because care provided in EDs will likely be a focus of REH services; as such, we seek to provide transparency in publicly reporting of all the strata calculated for this measure. For a more detailed discussion of our proposal to adopt the Median Time for Discharged ED Patients measure in the REHQR Program, please refer to section XVI.B.5.b of this proposed rule.

We propose to make publicly available data received from REHs to calculate the following measure strata for the Median Time for Discharged ED Patients measure: (1) Median Time for Discharged ED Patients – Overall Rate; (2) Median Time for Discharged ED Patients – Reported Measure; (3) Median Time for Discharged ED Patients – Psychiatric/Mental Health Patients; and (4) Median Time for Discharged ED Patients – Transfer Patients. We intend to display these data publicly beginning with the first quarter of measure data submitted relevant to services provided in CY 2024 in which case thresholds are met. We plan to provide additional detail on the timeline of publicly reporting this data in future rulemaking. As discussed above, display of these data would rely on the same business processes and resources that are currently in use for the Hospital OQR and Hospital IQR Programs.

We invite public comment on these proposals.

C. Administrative Requirements

1. Proposal to Codify Administrative Requirements

Section 1861(kkk)(7)(B)(i) of the Act provides that, with respect to each year beginning with 2023, or each year beginning on or after the date that is one year after one or more measures

are first specified under section 1861(kkk)(7)(C) of the Act, an REH shall submit data to the Secretary in accordance with section 1861(kkk)(7)(B)(ii). Clause (ii) states that, with respect to each such year, an REH shall submit to the Secretary data on quality measures in a form and manner, and at a time, specified by the Secretary for purposes of section 1861(kkk)(7)(B) of the Act.

We finalized foundational administrative requirements for REHs participating in the REHQR Program in the CY 2023 OPPTS/ASC final rule (87 FR 71752, and 72149 through 72150). In that rule, we require REHs must (1) register on a CMS website before beginning to report data; and (2) identify and register a security official as part of that registration process. We also require REHs to submit data on all quality measures to CMS. We propose to codify the participation requirements in the REHQR Program at § 419.95(b) “Participation in the REHQR Program.”

We note that we intend to propose additional administrative requirements as appropriate for the REHQR Program in subsequent rulemaking.

We invite public comment on these proposals.

D. Form, Manner, and Timing of Data Submitted for the REHQR Program

1. Proposal to Align and Codify Submission of REHQR Program Data

We refer readers to the CYs 2014, 2016, and 2018 OPPTS/ASC final rules (78 FR 75110 through 75111; 80 FR 70519 through 70520; and 82 FR 59439, respectively) where we finalized our policies for clinical data submission for the Hospital OQR Program. We codified these submission requirements at § 419.46(d). We propose to align the policies regarding submission of program data for the REHQR Program with those from the Hospital OQR Program.

We also propose to codify this policy at § 419.95 by adding paragraph (c) “Submission of REHQR Program Data.” In proposed paragraph (c)(1), we would require that REHs that participate in the REHQR Program must submit to CMS data on measures selected under section 1861(kkk)(7)(C) of the Act in a form and manner, and at a time specified by CMS. REHs

sharing the same CMS Certification Number (CCN) must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes. In proposed paragraph (c)(2), we propose that submission deadlines by measure and by data type be posted on a CMS website. 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-work day for Federal employees by statute or executive order would be extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or executive order.

We invite public comments on these proposals.

2. Proposed Requirements for Chart-Abstracted Measures Where Patient-Level Data are Submitted Directly to CMS Beginning With the CY 2024 Reporting Period

We propose to adopt one initial chart-abstracted measure for the CY 2024 reporting period and for subsequent years: Median Time for Discharged ED Patients. Measure data for this measure would be submitted via the HQR System (formerly referred to as the QualityNet Secure Portal). In developing this proposal, we also considered proposing that REHs submit data for this measure on an annual rather than quarterly basis to help reduce burden for REHs participating in the REHQR Program. However, we note that REHs would have been reporting this measure on a quarterly basis under the Hospital OQR Program and would thus be acclimated to this reporting frequency. Therefore, to enhance alignment with this program, we propose a similar data submission frequency on a quarterly basis. We refer readers to the CY 2015 OPPS/ASC and CY 2023 OPPS/ASC final rules for a discussion of our previously finalized policies regarding submissions deadlines for chart-abstracted measures for the Hospital OQR Program (79 FR 66964; 87 FR 72110 to 72112).

Beginning with the CY 2024 reporting period, the applicable patient encounter quarters for chart-abstracted data and their corresponding data submission deadlines are as follows in Table 83.

TABLE 83: CY 2024 Reporting Period and Subsequent Years*

Patient Encounter Quarter	Clinical Data Submission Deadline
Q1 2024 (January 1 – March 31)	08/01/2024
Q2 2024 (April 1 – June 30)	11/01/2024
Q3 2024 (July 1 – September 30)	02/01/2025
Q4 2024 (October 1 – December 31)	05/01/2025

*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 nonwork day for Federal employees by statute or executive order would be extended to the first day thereafter.

We propose to adopt these dates as deadlines for submitting chart-abstracted measure data for the REHQR Program.

We invite public comment on this proposal.

3. Proposed Claims-Based Measure Data Requirements Beginning With the CY 2024 Reporting Period

We propose to adopt three initial claims-based measures for the CY 2024 reporting period and for subsequent years: Abdomen CT; 7-Day Hospital Visit Rate After Outpatient Colonoscopy (CBE #2539); and 7-Day Hospital Visit Rate After Outpatient Surgery (CBE #2687). In calculating these and future claims-based measures, we propose to use Medicare claims data for services with encounter dates on or after January 1, 2024.

We invite public comment on this proposal.

4. Proposal to Adopt and Codify a Review and Corrections Period for Measure Data Submitted to the REHQR Program

In the event that an REH submits data for a measure, such as the chart-abstracted Median Time for Discharged ED Patients measure proposed for adoption in section XVI.B.5.b of this proposed rule, and later discovers or suspects the data provided were not accurate, it may need to submit corrected data. To address this need, we propose to adopt the same policies currently in place for the Hospital OQR Program. Under the Hospital OQR Program, hospitals submit chart-abstracted data to CMS on a quarterly basis. These data are typically due approximately four months after the quarter has ended. We refer readers to the CY 2015 OPPI/ASC final rule

for a discussion of our previously finalized policies regarding submissions deadlines for chart-abstracted measures for the Hospital OQR Program (79 FR 66964).

Hospitals are encouraged to submit data early in the submission schedule so that they can identify errors and resubmit data before submission deadlines. Hospitals can continue to review, correct, and change these data up until the close of each submission deadline. For example, under the Hospital OQR Program, we finalized a 4-month period as the review and corrections period for chart-abstracted data (79 FR 66964). During this review and corrections period, hospitals can enter, review, and correct data submitted directly to CMS. However, after the submission deadline, hospitals would not be allowed to change these data. Under the Hospital OQR Program, we generally provide rates to hospitals for the measures that have been submitted for chart-abstracted, patient-level data 24 to 48 hours following submission deadline.

We propose to adopt this same policy under which an REH may review and submit corrections to measure data, and that for chart-abstracted measure data, an REH may review and submit corrections to measure data submitted for a period of four months after the reporting quarter has ended. We also propose to codify this policy at § 419.95 by adding paragraph (c)(3) “Review and Corrections Period.” In proposed paragraph (c)(3), we propose that REHs would have a review and corrections period for all quality data submitted, which runs concurrently with the data submission period, when they would be able to enter, review, and correct data submitted prior to the submission deadline. In addition, we propose that after the submission deadline, these data cannot be changed.

We invite public comment on this proposal.

5. Extraordinary Circumstances Exceptions (ECE) Process

a. Proposal to Adopt an ECE Process for the REHQR Program

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their control. It is our goal not to penalize such entities for such circumstances and we do not

want to unduly increase their burden during these times. We propose an Extraordinary Circumstances Exceptions (ECE) process for REHs to request and for CMS to grant extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the REH. Under this proposed process, CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the REH, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. Because we do not anticipate that such systemic errors will happen often, we do not anticipate granting exceptions on this basis frequently.

We propose that CMS may grant an exception to one or more data submission deadlines and requirements upon request by an REH, pursuant to specific requirements for submission of such a request described below. In addition, we propose that CMS may grant exceptions at its own discretion, without an accompanying request from an affected REH, when CMS determines that an extraordinary circumstance has occurred.

For an REH to request consideration of an exception to the requirement to submit quality data or medical record documentation for one or more quarters, the REH would follow specific requirements for submission of an ECE request form available on a CMS website. We note that the following information must appear on the request form: the REH's CCN; the REH's name; the REH's CEO or other REH-designated personnel contact information, including name, email address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable); REH's reason for requesting an exception; evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and a date when the REH believes it would again be able to submit REHQR Program data and/or medical record documentation, and a justification for the proposed date.

The request form must be signed by the REH's designated contact, whether or not that individual is the CEO. A request form is required to be submitted within 90 days of the date that

the extraordinary circumstance occurred. Following receipt of such a request, CMS would provide an email acknowledgement using the contact information provided in the request notifying the designated contact that the REH's request has been received and following CMS' decision, CMS would notify the REH using the same contact information. In the case where CMS grants exceptions to REHs that have not requested them because we determine that an extraordinary circumstance has occurred in a region or locale, we would communicate this decision to REHs and vendors through routine communication channels, including but not limited to emails and notices on a CMS website.

We also propose to codify these policies at § 419.95 by adding paragraph (g), "Exception." In proposed paragraphs (g)(1) and (g)(2), we propose that we may grant, upon the request of the REH or at our discretion, an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the REH.

We invite public comment on this proposal.

XVII. Changes to Community Mental Health Center (CMHC) Conditions of Participation (CoPs)

A. Background and Statutory Authority

The Consolidated Appropriations Act (CAA) of 2023 (Pub. L. 117-328) was signed into law on December 29, 2022. Section 4124 of division FF of this legislation established coverage of intensive outpatient services (IOP) in community mental health centers (CMHC). Section 4124 of the CAA, 2023 extends Medicare coverage and payment of IOP services furnished by a CMHC beginning January 1, 2024, allowing coverage of both partial hospitalization services (PHP) and IOP services to be furnished by CMHCs at section 1832(a)(2)(J) of the Act.

Additionally, the CAA, 2023 revised section 1861(ff) of the Act to define IOP services while also amending the definition of PHP services. The statutory definitions provide distinctions between the two programs for Medicare purposes.

Section 1861 (ff)(3)(B)(iv) of the Act authorizes the Secretary to establish the requirements that a CMHC must meet to participate in the Medicare Program, and these CoPs are set forth in regulations at 42 CFR part 485, subpart J (42 CFR 485.900). On October 29, 2013, we published a final rule in the **Federal Register** titled “Medicare Program: Conditions of Participation (CoP) for Community Mental Health Centers” (78 FR 64604), hereinafter referred to as “2013 CoP CMHC final rule”, which established CoPs for CMHCs.

In order to implement division FF, section 4124 of the CAA, 2023, we propose to modify the requirements for the CMHC to include IOP services throughout the CoPs.

Under section 1861(ff)(3)(B)(iii) of the Act, a CMHC must provide at least 40 percent of its services to individuals who are not eligible for Medicare Part B. This requirement is reflected in the CoPs at § 485.918(b)(1)(v).⁶⁰⁹ Under this requirement, CMHCs must submit a self-attestation certification statement upon initial application to enroll in Medicare, and as a part of revalidation, including any off-cycle revalidation. Medicare enrollment will be denied or revoked in instances where the CMHC fails to provide the certification statement as required. In addition, Medicare enrollment will also be denied or revoked if the 40 percent requirement, as specified in section 1861(ff)(3)(B)(iii) of the Act and § 485.918(b)(1)(v), is not met. We solicit public comment on how the provision of IOP services may impact the populations CMHCs serve as well as the potential impact on meeting the 40 percent requirement.

We also propose to revise the personnel qualifications of Mental Health Counselors (MHCs) and add personnel qualifications of Marriage and Family Therapists (MFTs) to the CMHC CoPs. Division FF, section 4121 of the CAA, 2023, establishes a new Medicare benefit category for MHC services and MFT services furnished by and directly billed by MHCs and MFTs, respectively. At the time of publication of the 2013 CoP CMHC final rule (78 FR 64604), there were no specific personnel requirements (for purposes of the Medicare program) for Mental Health Counselors (MHCs). We believe it was necessary to recognize and

⁶⁰⁹ <https://www.reginfo.gov/public/do/PRAOMBHISTORY?ombControlNumber=0938-1245#>

outline specific personnel requirements for MHCs due to their integral role in providing mental health services to CMHC clients. We believe that MFTs are also essential mental health professionals who may furnish services in a CMHC, and propose adding MFTs to § 485.904 Condition of participation: Personnel qualifications. According to the American Association for Marriage and Family Therapy, a professional association for the MFT field, one of the settings an MFT may practice is in a CMHC.⁶¹⁰ The CAA 2023 does not require CMHCs to employ MFTs or MHCs; however, we believe the services provided by both MHCs and MFTs are integral to ensuring the health and safety of CMHC clients. We seek comment on the revised personnel qualifications for MHCs.

B. Provisions of the Proposed Rule

Section 4124 of the CAA, 2023 provides intensive outpatient services to be included as services provided by CMHCs under the Medicare Program. We propose the following revisions to the CMHC CoPs.

1. § 485.900 Basis and Scope

Currently, a CMHC may receive Medicare payment for partial hospitalization services if it meets the CMHC CoPs. Our regulations are intended to protect the health and safety of CMHC clients and support quality care. We propose to update the CoPs for CMHCs to reflect the statutory addition of IOP services provided by CMHCs to protect the health and safety of clients. Both PHP and IOP services are outpatient mental health services for adults and children who have an acute mental illness, including, but not limited to, conditions such as depression, schizophrenia, and substance use disorders. The Medicare Statute authorizes the PHP program for clients that need a higher level and intensity of care, a minimum of 20 hours per week (section 1861(ff)(1) of the Act). A Medicare beneficiary qualifies if they otherwise require inpatient psychiatric care in the absence of such services (section 1835(a)(2)(F) of the Act). The PHP program may assist in transitioning from these institutional settings to community-based

⁶¹⁰ https://www.aamft.org/Consumer_Updates/MFT.aspx

services. PHP and the addition of IOP services are important components in the continuum of mental health care and services. Both PHP and IOP are more intensive than office-based counseling but less intense than inpatient psychiatric care. Both PHP and IOP programs can serve beneficiaries as a step-up in care if additional support is needed or a step down in managing symptoms. The addition of IOP services in a CMHC would assist in ensuring the continuum of coverage of outpatient mental health services under the Medicare program. Medicare coverage of IOP services may help address barriers to access to mental health care, which may also address inequities in mental health care and services. In order to implement division FF, section 4124 of the CAA, 2023, we propose to modify the CMHC CoP at § 485.900(a)(1) through (a)(3). These modifications would allow CMHCs to receive payments for IOP services under Medicare Part B, establish requirements for the provision of IOP services in CMHCs, provide IOP services to clients, and include IOP services in the Medicare provider agreement.

2. § 485.904 Personnel Qualifications

Section § 485.904 of the CMHC CoP establishes staff qualifications, and paragraph (a) requires all professionals who furnish services directly, under an individual contract, or under arrangements with a CMHC to be legally authorized (licensed, certified, or registered) in accordance with applicable Federal, State and local laws, and be required to act only within the scope of their State licenses, certifications, or registrations. The staff qualifications set out at §485.904(b), *Standard: Personnel qualifications for certain disciplines*, are consistent with, or similar to, those set forth in CoPs for other provider types in the Medicare regulations. As part of the 2013 CMHC CoP final rule, we established personnel qualifications for MHCs at § 485.904(b)(5). Division FF, section 4124 of the CAA, 2023, established a new Medicare benefit category for MFTs and MHC services in section 1861(III) of the Act, including a definition for MFTs in section 1861(III)(2) of the Act and MHCs in section 1861(III)(4) of the Act. Section 1861(III)(4) of the CAA 2023 defines the term ‘mental health counselor’ to mean an

individual who: (1) possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under the State law of the State in which such individual furnishes the services described in paragraph (3); (2) is licensed or certified as a mental health counselor, clinical professional counselor, or professional counselor by the State in which the services are furnished; (3) after obtaining such a degree has performed at least 2 years of clinical supervised experience in mental health counseling; and (4) meets such other requirements as specified by the Secretary. Section 1861(III)(2) of the Act defines the term 'marriage and family therapist' to mean (1) possesses a master's or doctor's degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law of the State in which such individual furnishes the services described in paragraph (1); (2) is licensed or certified as a marriage and family therapist by the State in which such individual furnishes such services; (3) after obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy; and (4) meets such other requirements as specified by the Secretary.

To support the health and safety of CMHC clients and to promote consistency and clarity of CMHC personnel qualifications, we believe it is best to align the personnel qualifications for MFTs and MHCs with the requirements set out in the CAA, 2023. The statutory requirements for MHCs and MFTs are being codified in the CY 2024 Physician Fee Schedule proposed payment rule that is published elsewhere in the **Federal Register**. We propose to modify the MHC personnel requirement at § 485.904(b)(5) by cross-referencing the definition of an MHC at § 410.54 and adding a new requirement at § 485.904(b)(12), cross-referencing the definition of an MFT at § 410.53.

3. § 485.914 Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client

The requirements at § 485.914 establish requirements for admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client in accordance with sections

1835(a)(2)(F) and 1861(ff) of the Act. These CoPs identify general areas that would be included in a client assessment and the timeframes for completing the assessments to help the CMHC ensure it is identifying the needs in all areas in a timely fashion. At § 485.914(a)(1), we require that clients are assessed and admitted to receive partial hospitalization (PHP) services, and (2) the CMHC must also meet separate requirements as specified in § 485.918(f). The requirements at § 485.918(f) reference additional PHP requirements of 42 CFR part 410 (CMHC services and definition) and § 424.24(e) (the content of the certification and plan of treatment requirements). We propose to modify the current CoP at § 485.914(a)(2) to add IOP requirements and reference applicable requirements the CMHC must meet that are specific to IOP services at proposed § 485.918(g). This proposed standard for IOP is discussed later in section XVII.A.5 of this proposed rule.

Currently, § 485.914(d) requires that the CMHC update each client's comprehensive assessment through the CMHC interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), when changes in the client's status, responses to treatment, or goal achievement have occurred and in accordance with current standards of practice. Section 485.914(d)(2) requires that the assessment must be updated no less frequently than every 30 days for clients that receive PHP services. We note that this aligns with the changes made in section 4124(a) of the CAA, 2023 to the definition of "partial hospitalization services" in section 1861(ff)(1) of the Act, which requires that a physician determine (not less frequently than monthly) that a client has a need for such services. This update includes information on the client's progress toward desired outcomes, a reassessment of the client's response to care and therapies, and the client's goals. We believe that for some clients, more frequent reviews are necessary since clients with ongoing mental illness may be subject to frequent and/or rapid changes in status, needs, acuity, and circumstances, and the client's treatment goals may change, thereby affecting the type and frequency of services that should be furnished. The CMHC interdisciplinary treatment team uses assessment information to guide necessary reviews and/or

changes to the client's active treatment plan.⁶¹¹ Currently, § 485.914(d)(2) addresses how often a CMHC must update a PHP client's assessment, and we propose to add IOP requirements to this standard, using the same period (30 days).

4. § 485.916 Treatment Team, Person-centered Active Treatment Plan, and Coordination of Services

The review and update of the CMHC client's person-centered active treatment plan plays an integral role in outlining the care and services provided by the CMHC. The current requirements at § 485.916(d) indicate that the active treatment plan be updated with current information from the client's comprehensive assessment and information concerning the client's progress toward achieving outcomes and goals specified in the active treatment plan. The active treatment plan is reviewed at specified intervals but no less frequently than every 30 calendar days. Under this current requirement, the revised active treatment plan must include information from the client's initial evaluation and comprehensive assessments, the client's progress toward outcomes and goals specified in the active treatment plan, and changes in the client's goals. In addition, the CMHC is required to meet partial hospitalization program requirements specified under § 424.24(e).

We propose to modify language at § 485.916(d) to include IOP requirements and a specific reference to the proposed requirement at § 424.24(d). As the CMHC must meet partial hospitalization program requirements specified under § 424.24(e), they must meet IOP program requirements specified under § 424.24(d) if such services are included in the active treatment plan.

5. § 485.918 Organization, Governance, Administration of Services, Partial Hospitalization Services

The CoP at § 485.918 establishes requirements for CMHC organization, governance, administration of services, and partial hospitalization services. This standard includes

⁶¹¹ <https://www.reginfo.gov/public/do/PRAOMBHISTORY?ombControlNumber=0938-1245#>

administrative and governance structure standards and clarifies the governing body's expectations. Other requirements under this standard are professional management responsibility, staff training, and physical environment. The overall goal of this CoP is to ensure that the management structure is organized and accountable. The requirement at § 485.918(b), Standard: Provision of services, specifies a comprehensive list of services that a CMHC is required to furnish. This list of services that CMHCs provide corresponds directly to the Act's statutory requirements in section 1861(ff)(3).

We propose to modify the section heading at § 485.918 by adding “intensive outpatient services,” such that the new section heading will be “Organization, governance, administration of services, partial hospitalization services, and intensive outpatient services.”

In addition, we propose to add IOP to the requirement at § 485.918(b)(1)(iii) for the provision of services. These proposed changes would recognize IOP, along with day treatment and PHP, as services that can be provided by a CMHC, other than in an individual's home or an inpatient or residential setting or psychosocial rehabilitation services.

We propose to redesignate the current requirements at § 485.918(g) to paragraph (h) and add a new standard for IOP services at § 485.918(g). This new requirement would specify the additional requirements a CMHC providing IOP services must meet based on the proposed requirements at § 410.2, § 410.44, § 410.111, and § 424.24(d) of this chapter. See section VIII.B.2 and VIII.C.2 of this proposed rule for a discussion of these additional requirements.

We solicit public comments on each of our proposals. In addition, we request comments from CMHC stakeholders regarding the impact of the proposed IOP requirements on the requirement that CMHCs provide at least 40 percent of their items and services to individuals who are not eligible for benefits under title XVIII of the Act, as specified at § 485.918(b)(1)(v). Specifically, we seek comment on the following:

- Do you expect the total number of clients served in your CMHC to increase with the addition of IOP?

- Do you expect that your CMHC would admit new clients directly into the IOP program, and do you have a sense of their anticipated insurance status?
- Do you expect that any of your PHP clients would step down to the IOP program? If so, can you provide an estimated percentage of PHP clients who would step down to the IOP program?
- Do you expect any of your outpatient treatment clients, such as office-based therapy, to step up to the IOP program?
- Do you expect that offering IOP would impact your ability to meet the 40 percent requirement at § 485.918(b)(1)(v)? This requirement states that the CMHC provides at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Act.

XVIII. Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges

A. Introduction and Overview

1. Statutory Basis and Background

Section 1001 of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by section 10101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), amended Title XXVII of the Public Health Service Act (the PHS Act), in part, by adding a new section 2718(e). Section 2718 of the PHS Act, entitled “Bringing Down the Cost of Health Care Coverage,” requires each hospital operating within the United States (U.S.) for each year to establish and update, and make public a list of the hospital’s standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act (the Act). Section 2718(b)(3) of the PHS Act requires the Secretary of the Department of Health and Human Services (Secretary) to

promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties.

In a final rule dated November 2019 (84 FR 65524) (herein referred to as the CY 2020 HPT final rule), we adopted requirements for hospitals to make public their standard charges in two ways: (1) as a comprehensive machine-readable file (MRF);⁶¹² and (2) in a consumer-friendly format. We codified these requirements at new 45 CFR part 180. We also explained our belief that these two different methods of making hospital standard charges public are necessary to ensure that such data are available to consumers where and when they are needed, including through data aggregation methods (for example, via integration into price transparency tools, electronic health records (EHRs), and consumer apps), and direct availability to consumers searching for hospital-specific charge information. Additionally, we believe such data can be used specifically by employers, researchers, and policy officials, and similar members of the public to help bring more value to healthcare.

Subsequently, in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63941), we strengthened the hospital price transparency (HPT) enforcement scheme in order to improve compliance rates and made other updates to the requirements. Specifically, we (1) increased the penalty amount for noncompliance through the use of a scaling factor based on hospital bed count; (2) deemed state forensic hospitals that meet certain requirements to be in compliance with the requirements of 45 CFR part 180, and (3) prohibited certain conduct that we concluded were barriers to accessing the standard charge information, including, specifically, prohibiting hospitals from coding their MRF in a fashion that made it inaccessible to automated searches and direct downloads.

⁶¹² We have previously generally described the machine-readable file (MRF) as a single digital file that is in a machine-readable format (as defined at 45 CFR 180.20), and we propose in this proposed rule to codify that definition in our regulations.

In both of those final rules, we stated that our policies requiring public release of hospital standard charge information are a necessary and important first step in ensuring transparency in healthcare prices for consumers. We also recognize that the release of hospital standard charge information is not itself sufficient to achieve our ultimate price transparency goals. The regulations are, therefore, designed to begin to address some of the barriers that limit price transparency, with a goal of increasing competition among healthcare providers to bring down costs.

2. Summary of Proposals in this Proposed Rule

We propose to amend several of our HPT requirements in order to improve our monitoring and enforcement capabilities by improving access to, and the usability of, hospital standard charge information; reducing the compliance burden on hospitals by providing CMS templates and technical guidance for display of hospital standard charge information; aligning, where feasible, certain HPT requirements and processes with requirements and processes we have implemented in the Transparency in Coverage (TIC) initiative; and making other modifications to our monitoring and enforcement capabilities that will, among other things, increase its transparency to the public. Specifically, we propose to: (1) define several terms; (2) revise the standard charge information and data elements that hospitals must include in their MRFs, as well as require hospitals to use a template developed by CMS (hereafter referred to as a ‘CMS template’) for purposes of complying with § 180.50 of our regulations, in order to standardize the displayed MRF data; (3) improve the accessibility of the hospital MRF by requiring hospitals to include a .txt file in the root folder that includes a direct link to the MRF and a link in the footer on its website that links directly to the publicly available webpage that hosts the link to the MRF; and (4) improve our enforcement process by updating our methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, working with health system officials to address noncompliance issues in one or more

hospitals that are part of a health system, and publicizing more information about CMS enforcement activities related to individual hospital compliance. Additionally, we are seeking comment on additional considerations for improving compliance and aligning consumer-friendly policies and requirements with other federal price transparency initiatives.

B. Proposal to Modify the Requirements for Making Public Hospital Standard Charges at 45 CFR 180.50

In the CY 2020 HPT final rule, we finalized, at 45 CFR 180.50, specific requirements with which hospitals must comply for the purpose of making public a single comprehensive list of standard charges for the items and services they provide, including requirements that govern the format, data elements, location and accessibility of the list, as well as the frequency by which they must update the list.

In this section, for the reasons discussed below, we propose to substantially modify § 180.50(a) through (d) of our regulations, which govern some of the requirements for how hospitals must make public their standard charges for all items and services they provide. Specifically, we propose to (1) define several new terms; (2) require hospitals to affirm the accuracy and completeness of the standard charges displayed in the MRF; (3) require hospitals to display additional data elements in their list of standard charges; (4) require display of standard charge information using a CMS template; and (5) adopt new requirements to improve the automated accessibility of the machine-readable file.

1. Proposed Definitions

We propose to add the following definitions to § 180.20:

- “CMS template” means a CSV format or JSON schema that CMS makes available for purposes of compliance with the requirements of § 180.40(a).
- “Consumer-friendly expected allowed amount” means the average dollar amount

that the hospital estimates it will be paid by a third party payer for an item or service.

- “Encode” means to enter data items into the fields of the CMS template.
- “Machine-readable file” means a single digital file that is in a machine-readable format.

In light of these proposed definitions, we further propose several technical and conforming revisions to ensure consistency of the use of these terms across the regulation. Specifically, we propose to replace references to “the file” and “the digital file” in § 180.50(d)(4) through (5) with the proposed defined term “machine-readable file”. Revisions to references to the “file” in the introductory text of § 180.50(c) and at § 180.50(e) are addressed as a part of other proposed changes within this proposed rule.

2. Proposal to Require Hospitals to Affirm the Accuracy and Completeness of Their Standard Charge Information Displayed in the MRF

Since we implemented the HPT regulations, we have received questions from the public regarding the accuracy and completeness of the standard charge information displayed by hospitals. Similar questions have also arisen in the course of our enforcement activities. Section 2718(e) of the PHS Act requires hospitals to make public each standard charge the hospital has established; however, a hospital may not have established certain types of standard charges defined by the regulation. For example, under our current regulations, a hospital that has not established any discounted cash prices for any item or service would not have any discounted cash prices to display in its MRF. Depending on the type of MRF format chosen by the hospital, the file may contain ‘blanks’ without explanation. Although a hospital that chooses to leave the discounted cash price field blank under this scenario would be in compliance with our regulations, a user of the MRF could be unsure as to whether the hospital has not established such charges, or, instead, has not complied with the requirement to disclose them in the MRF. Although many hospitals include explanatory information on the webpage associated

with the MRF or within the MRF itself (for example, in a CSV format, inserting ‘N/A’ in blank cells or adding an explanatory note), they currently do so on a voluntary basis.

We believe that requiring the hospital to affirm the accuracy and completeness of its MRF would mitigate the potential for public confusion as to whether the MRF is accurate and complete because it clarifies to the public that blank cells left in some formats (such as CSV which can be opened in a human-readable format) are intentional. Such an affirmation would also streamline our enforcement efforts by removing the need to initiate a compliance action asking for the hospital to verify that their file is accurate and complete. We therefore propose to require that each hospital affirm directly in its MRF (using a CMS template, which we propose in more detail at XVIII.B.2 of this proposed rule) that it has included all applicable standard charge information in its MRF as of the date in the MRF. We believe that requiring the hospital to add this affirmation directly in its MRF would make it clear to the public that the affirmation relates directly to that MRF, and would mitigate the potential for confusion if we only required that the affirmation appear on a website that links to the hospital’s MRF, especially if that website also links to other hospital MRFs.

We therefore propose to add new paragraph (a)(3) at § 180.50 to require that, in its MRF, each hospital add a statement affirming that, to the best of its knowledge and belief, the hospital has included all applicable standard charge information in its MRF, in accordance with the requirements of § 180.50, and that the information displayed is true, accurate, and complete as of the date indicated in the file.

We seek comment on this proposal.

3. Proposal to Improve the Standardization of Hospital Machine-Readable File (MRF) Formats and Data Elements

In this section, we propose to revise several requirements at § 180.50(b) and (c). We also propose to adopt technical edits to other sections of the HPT regulations that are

related to the revisions for alignment, conformity, and clarity.

a. Background

In the CY 2020 HPT final rule, we expressed our concern that lack of uniformity in the way that hospitals display their standard charges leaves the public unable to meaningfully use, understand, and compare standard charge information across hospitals (84 FR 65556). We stated that we agreed with commenters that standardization in some form is important to ensure high utility for users of hospital standard charge information, and we finalized an initial set of rules for making public all standard charges in an MRF at § 180.50. Section 180.50(a)(1) of our regulations states that a hospital must establish, update, and make public a list of all standard charges for all items and services online in the form and manner specified in that section, and § 180.50(a)(2) states that each hospital location operating under a single hospital license (or approval) that has a different set of standard charges than the other location(s) operating under the same hospital license (or approval) must separately make public the standard charges applicable to that location. If a hospital location operating under a single hospital license or approval shares the same set of standard charges as another hospital location operating under the same license or approval, then both hospital locations may post the same MRF. In other words, in the interest of burden reduction, hospital locations may share a file so long as the standard charges information displayed in the file are applicable to the indicated locations.

Section 180.50(b) of our regulations describes the required data elements that must be included, as applicable, in the hospital's MRF, which are the following:

- Description of each item or service provided by the hospital.
- The corresponding gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding payer-specific negotiated charge that applies to each item or

service when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each payer-specific negotiated charge must be clearly associated with the name of the third party payer and plan.

- The corresponding de-identified minimum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding de-identified maximum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding discounted cash price that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the CPT code, HCPCS code, DRG, NDC, or other common payer identifier.

When we finalized this set of standardized data elements, we stated our belief that they would help ensure that the public could compare standard charges for similar or the same items and services provided by different hospitals. Commenters had provided many additional suggestions for how to standardize the standard charge information displayed by hospitals, but we declined at the time to be more prescriptive in our approach. Instead, we indicated that we might revisit the requirements in future rulemaking should we find it necessary to make improvements in the display and accessibility of hospital standard charge information.

At § 180.50(c), the regulation specifies that the required (but “as applicable”) data elements must be published in a single digital file that is in a machine-readable format. The term

“machine-readable format” is defined at § 180.20 to mean a digital representation of data or information in a file that can be imported or read into a computer system for further processing.

Since we first implemented the regulation in January 2021, feedback in reports developed and made public by interested parties, particularly from IT specialists, researchers, employers, and others, indicates that more standardization of the files (including a specified template and standardization of additional contextual data elements) may be necessary to improve the public’s use and understanding of, and ability to make comparisons among, hospital standard charge information.^{613,614,615,616,617} In particular, IT specialists have indicated that the current flexibilities and lack of encoding specifications hinder the machine-readability of the data in the files, presenting a barrier to the intended use of the data. Additionally, hospitals have asked us for more specificity on how they should publicly display their standard charge information, with an emphasis on how they should explain and display their payer-specific negotiated charges. Some hospitals have suggested that a template developed by CMS could be useful to improve hospital compliance and reduce hospital burden. Further, the flexibilities that the current regulation permit insofar as the format of hospital standard charges information, and the very limited set of data elements required to be displayed under § 180.50, have presented an enforcement challenge. For example, because hospitals are permitted to display their information using a wide variety of file formats and data encoding practices, we must manually, via time and resource-intensive processes, review the information in the files to assess whether the information is consistent with the data element requirements at § 180.50(b). Some hospitals rename data elements, include additional data elements, or exclude, without explanation, data elements that are not applicable,

⁶¹³ <https://www.healthsystemtracker.org/brief/ongoing-challenges-with-hospital-price-transparency/>

⁶¹⁴ <https://energycommerce.house.gov/events/improving-drug-pricing-transparency-and-lowering-prices-for-american-consumers>

⁶¹⁵ <https://familiesusa.org/wp-content/uploads/2023/04/Power-of-Price-Transparency-final-4.19.23.pdf>

⁶¹⁶ <https://blog.turquoise.health/hospital-compliance-assessments/>

⁶¹⁷

<https://static1.squarespace.com/static/60065b8fc8cd610112ab89a7/t/60de0380cc0972060d0354eb/1625162631437/PRA+OPPS+Recommendations+June+2021%5B3%5D.pdf>

which can make it difficult to assess whether the information contained in the file is accurate and complete. This, in turn, slows compliance reviews and often requires us to engage in one-on-one discussions with hospitals. We therefore came to believe that requiring more specificity in formatting and encoding the MRFs, as well as increasing the number of required corresponding data elements hospitals must provide, would not only create efficiencies for public users of the MRFs and our efforts to enforce the requirements, but also improve the meaningfulness of the hospital's standard charges.

As a result, in the CY 2022 OPPI/ASC proposed rule (86 FR 42321), we sought comment on improving standardization of the data disclosed by hospitals in the MRF. In response, many commenters urged CMS to create a standard template for hospitals to use for posting their MRF, noting that such standardization could ease operational burdens, improve the public's (including employers and researchers) ability to make price comparisons across hospitals, and better enable third party data aggregation services to develop user-friendly consumer tools for displaying this information. Some commenters recommended that CMS work with providers and vendors to better understand the benefits of a standard template. Some hospitals also urged CMS to be more prescriptive, requesting that CMS standardize the MRF format and contents and provide additional clarification on how hospitals should indicate that they have not established all five types of standard charges for a particular listed item or service.

We requested the HHS Health Federally Funded Research and Development Center (FFRDC)⁶¹⁸ to more fully explore the feasibility of these commenters' recommendations, and to identify technical specifications and categories of information (referred to as "data elements") that we could consider proposing in future rulemaking to improve the usability and meaningfulness of the standard charges display. The Health FFRDC convened a technical expert panel (TEP) and used the TEP members' advice to make informed recommendations to CMS in

⁶¹⁸ MITRE operates HHS' Health FFRDC, a federally funded research and development center. For more information, see: <https://www.mitre.org/our-impact/rd-centers/health-ffrdc>

the summer of 2022.⁶¹⁹ The TEP was comprised of both MRF developers, specifically, hospitals (representatives of large and small acute and specialty care hospitals), and primary users of MRF data, specifically, researchers and information technology innovators. The TEP members discussed the challenges and complexities of displaying, in a meaningful way, all hospital standard charges in an MRF. The TEP members noted that increasing standardization of the MRF and the required data elements may improve the public's ability to make price comparisons across hospitals. TEP members indicated their belief that public display of hospital standard charge information is an important step toward transparency in prices for hospital items and services, but cautioned that hospitals use different methods to establish standard charges for items and services, resulting in charge/item and charge/service combinations that are often unique to that hospital. Therefore, some direct comparisons of hospital standard charges may continue to be a challenge if such comparisons are made under the assumption that hospitals always use the same methods to establish their standard charges and that the same charge/item and charge/service combinations are consistent across hospitals. As such, attempting to use hospital standard charges in isolation, without additional contextual information, can result in erroneous conclusions and comparisons. The members went on to discuss the potential benefits to both hospitals and the public if CMS required hospitals to display standard charge information that better described or contextualized their standard charges, including standard charge information related to complex contracting arrangements between hospitals and third party payers. The TEP also weighed the benefits with the potential burden hospitals would incur to display those new data elements and encode data in a more specified way.

First, the TEP members discussed what general machine-readable format(s) would be best suited to display hospital standard charges. The TEP members indicated that use of non-proprietary formats would be ideal because they are widely and freely available to both the

⁶¹⁹ MITRE, Hospital Price Transparency Machine-Readable File Technical Expert Panel Report and MITRE Recommendations to the Centers for Medicare & Medicaid Services, November, 2022.
<https://mitre.box.com/v/MITRE-MRF-TEP>

developers (the hospitals) and users (for example, IT developers and researchers) of the MRFs. The TEP members then considered different types of non-proprietary formats. They first considered whether a single non-proprietary format, such as JSON, should be recommended because of its ability to represent hierarchical relationships better than tabular non-proprietary formats, such as CSV. Whereas JSON's use of a hierarchical format could be beneficial because it would eliminate the need to leave data fields, sometimes numerous, blank if the hospital has no applicable corresponding information. However, TEP members noted that existing hospital systems often produce files in CSV, and that smaller, less-resourced, hospitals often lack the in-house capacity to develop and manage a JSON file. The TEP members therefore suggested that hospitals have a choice of JSON and CSV formats. The TEP members also discussed the specific technical layout of a CSV file, including a:

- “tall” format, with separate payer and plan data elements that provide the benefit of static header naming with less opportunity for standardization error and that is similar to existing output files that many hospitals are using to build their MRFs; and
- “wide” format, with variable payer-specific negotiated charge data elements that incorporate the payer and plan name into a single column header; this may reduce the file size because many data elements would not need to be repeated as frequently.

Ultimately, MITRE, as informed by TEP members, recommended to CMS that CMS provide hospitals with an option to use one of three layouts representing two types of machine-readable formats for displaying their standard charge information in an MRFs: (1) JSON schema (plain format), (2) CSV (“tall” format), or (3) CSV (“wide” format). TEP members indicated that this choice would balance the need for greater standardization for automated machine use of the files, while providing a hospital some flexibility to select the least burdensome format and layout to incorporate into its current MRF development process.

The TEP also discussed the data elements, or categories of standard charge information, that they believed should be included in the MRF, with a goal of improving the public's

understanding and use of hospital standard charges. These discussions focused on the challenges of displaying payer-specific negotiated charges, given the variety of ways that hospitals establish this type of standard charge, and data elements that would be necessary to help the public understand them. TEP members discussed several types of commercial contracting methodologies commonly used by hospitals to establish their payer-specific negotiated charges, including: fee schedule, case rate, per diem, percentage of total billed (or gross) charges, and others. Ultimately, the TEP agreed on the following data elements to improve the meaningfulness and facilitate automated aggregation of hospital standard charges: (1) general information such as file version and date of most recent update of the file; (2) hospital-specific information (such as hospital name and location, license number, financial aid policy); (3) data elements corresponding to the types of standard charges defined by the HPT regulation (that is, the gross charge, payer-specific negotiated charges by payer and plan, discounted cash price, and minimum and maximum de-identified negotiated rates) and, for payer-specific negotiated charges, the type of contracting methodology and whether the payer-specific negotiated charge established by the hospital is being expressed as a dollar amount versus an algorithm or percentage; and (4) data elements that enhance understanding of the item or service to which the standard charge applies, such as a general description of the item/service, billing class (for example, whether the standard charge is billed as a facility or professional service), the hospital setting in which the item or service is provided (for example, in the inpatient or outpatient setting), drug-specific information such as the drug unit and type of measurement (such as number of milligrams), and information related to corresponding codes (such as common billing codes, revenue center codes, modifiers). TEP participants also suggested including an open field that a hospital could use, as needed, to provide additional contextual information should it believe the template's data elements are insufficient to ensure a user's understanding of a standard charge displayed in the file.

The TEP members discussed a number of other data elements,⁶²⁰ but concluded that the burden on hospitals to gather and display such information would outweigh their benefit to users, or that it would be infeasible to include such information in an MRF. As such, MITRE did not recommend that CMS adopt them.

MITRE presented its findings and recommendations to CMS in the fall of 2022. After considering them, we announced in November of 2022 the availability of several ‘sample formats,’ that may be found on the HPT website,⁶²¹ that hospitals could voluntarily use to make public their standard charge information in an MRF. At the same time, we developed and made available a supplemental data dictionary that provides technical instructions to hospitals on how to conform to the sample formats and encode standard charge information. The sample formats and data dictionary can be found on the HPT website: <https://www.cms.gov/hospital-price-transparency/resources>. We encourage commenters to review the sample templates and data dictionary to inform their comments on these proposals.

b. Proposals to Require Hospitals to Encode All Data Items for Additional Data Elements in Their MRF

(1) Proposal to Encode, as Applicable, All Data Items in the MRF

Currently, the introductory text at § 180.50(b) states that a hospital must include all of the data elements (as specified in the paragraph) in its list of standard charges, “as applicable”. We propose to revise the introductory text for clarity to indicate that each

⁶²⁰ Those data elements included: ‘Billing Code Version’ which would be the version of a code set used by providers and payers; ‘Unit of Measurement’ which would be used for items and services other than drugs; ‘Place of Service Code’ used by Medicare to indicate where in a hospital a service would be provided; ‘Insurance Plan ID’ such as a Health Insurance Oversight System (HIOS) identifier⁶²⁰ or employer identification number (EIN) of the payer; ‘Contract Expiration Date’ to indicate how long a contract would be in place; ‘Bundled Codes’ which would indicate all individualized items and services that comprised a payer-specific negotiated rate or discounted cash price; ‘Covered Services’ which would indicate all the codes for services covered under a capitation arrangement; and a ‘Payment Learning & Action Network’ field which would indicate whether the hospital’s commercial contract met criteria for different types of value-based arrangements as defined by the Learning & Action Network’s Alternative Payment Model Framework (<https://innovation.cms.gov/innovation-models/health-care-payment-learning-and-action-network>).

⁶²¹ <https://www.cms.gov/hospital-price-transparency/resources>

hospital must encode, as applicable, all standard charge information corresponding to each required data element in its MRF.

This proposed revision would differentiate the standard charge information, or data values, that must be encoded in the MRF from the “data elements,” or categories of data as the basis for the CMS template. The term “data element” is currently used at § 180.50(b) in both ways, which, at the time we implemented the regulations, seemed appropriate because of the wide latitude of flexibility we were giving hospitals to display their standard charges. However, now that we propose to require hospitals to display complete standard charge information for an expanded set of data elements and to be much more prescriptive in how such data is encoded, we believe that adopting more precise terminology will make the display requirements easier to understand.

We believe that this proposed revision is necessary in light of our other proposals to be more prescriptive in the form and manner in which hospitals display their standard charge information, and would clarify that the term “data element” refers to a required category of data items encoded in the MRF, and not the standard charge information itself.

Under our proposal, the term “as applicable” would no longer refer to data elements (which, if finalized as proposed, would all be required) and instead would qualify the standard charge information that the hospital encodes in the MRF. Hospitals would thus be required to encode its MRF with all applicable standard charge information that corresponds to each of the required data elements. We note that the phrase “as applicable” does not mean that encoding standard charge information that corresponds to a required data element is “optional.” Rather, if a hospital has established standard charge information for a required data element at proposed new § 180.50(b)(1) through (4), the hospital would be required to display that information accurately and completely, in its MRF.

(2) Proposal to Revise and Expand the Required Data Elements

At new § 180.50(b)(1) through (4), we propose to revise and expand the required data elements which describe the categories of information the hospital must encode in its MRF. We propose to include most of the data elements suggested by the TEP and recommended by MITRE in its report to CMS⁶²² and note that many of the proposed data elements are incorporated in the CMS ‘sample formats’ currently available for voluntary use by hospitals on CMS’s HPT website.⁶²³

We propose to require hospitals to encode all applicable standard charge information for an expanded set of data elements in its MRF, which we believe would improve the public’s ability to better understand and therefore more meaningfully use hospital standard charges. We believe that this expanded set of data elements will make hospital standard charges more understandable and comparable across hospitals. We decided to make these proposals after considering: the feedback discussed above; our experience with enforcing the current HPT requirements; the FFRDC recommendations as informed by their TEP; and our evolving understanding of how hospitals establish payer-specific negotiated charges with third party payers.

We agree with the feedback we have received from various interested parties, the recommendations of the FFRDC, and publicly available reports that the machine-readable data needs to be contextualized and more precisely encoded to improve the public’s ability to understand and use hospital standard charges. We believe that this could largely be accomplished by requiring hospitals to conform to a CMS template layout and encode all applicable standard charge information in a consistent form and manner specified by CMS.

⁶²² MITRE, Hospital Price Transparency Machine-Readable File Technical Expert Panel Report and MITRE Recommendations to the Centers for Medicare & Medicaid Services, November, 2022.

<https://mitre.box.com/v/MITRE-MRF-TEP>

⁶²³ <https://www.cms.gov/hospital-price-transparency/resources>

(a) Proposed general data elements

Proposed new § 180.50(b)(1) would require a hospital to encode standard charge information for each of the following “general” data elements:

- Hospital name(s), license number, and location name(s) and address(es) under the single hospital license to which the list of standard charges apply.

Under this proposal, a hospital would be required to include the location to which its list of standard charges applies within the MRF itself, instead of simply on its website, as is currently required at 45 CFR 180.50(d). We believe this change is necessary because we have found that a single public website may host the files of several hospitals and identify each hospital location in text on the webpage. Because the hospital location is currently not listed on the file itself, the hospital information sometimes becomes disassociated from the file as it is further processed, making it difficult for end users of the data to connect standard charge information to a particular hospital, hospital location, or address. This is a result we did not intend when we finalized the initial display requirements. We believe that requiring hospitals to encode standard charge information for these data elements directly in the MRF will permit the public, including end users creating various aggregation tools, to connect the standard charge information in the file to a particular hospital’s site of care as they seek to make the information more actionable. Additionally, the current requirement at § 180.50(a)(2) indicates that each hospital location operating under a single hospital license (or approval) that has a different set of standard charges than the other location(s) operating under the same hospital license (or approval) must separately make public the standard charges applicable to that location. However, there is no current requirement for a hospital to indicate under what license the hospital is operating, making enforcement of this requirement challenging. By including the license number of the hospital in the file, CMS would better be able to validate and ensure that hospitals are complying with the

requirements because CMS would be able to directly connect the hospital name, license and MRF.

- The file version and date of the most recent update to the standard charge information in the MRF. First, we propose that hospitals indicate in their MRF the file version that corresponds to the CMS template that the hospital is using to display the standard charge information. File version information is necessary to provide certainty to users of the file (including CMS for purposes of automating review of MRFs) that they have coded to the correct format for processing the data. Second, we note that hospitals are currently required at § 180.50(e) to update, at least once annually, the standard charge information in the MRF and to clearly indicate the date that the standard charge information was most recently updated. Hospitals also currently have the flexibility to indicate the updated date in the file itself or otherwise in a manner that is clearly associated with the file. That flexibility would be eliminated with this proposal because we would require the date of last update to be indicated in the file itself. We therefore propose to make a necessary corresponding revision to § 180.50(e) to remove the sentence ‘The hospital must clearly indicate the date that the standard charge data was most recently updated, either within the file itself or otherwise clearly associated with the file.’ Requiring a hospital to include the date of the last update in the file itself is necessary for a machine to be able to automatically validate that the standard charge information in the file has been updated by the hospital at least once annually, as is required under section 2718(e) of the PHS Act and 45 CFR 180.50(e). Moreover, by placing the date of most recent update within the MRF, file users would be assured that the file they are using is the most recently available. Nothing in this proposal would prohibit a hospital from continuing to also indicate the date of the last update on its website in addition to indicating the date of the last update within its MRF.

(b) Proposals for Data Elements Related to Types of Standard Charges

First, at proposed new § 180.50(b)(2), we would consolidate into a single data element the standard charges (that is, the gross charge, payer-specific negotiated charge, de-identified minimum and maximum negotiated charge, and discounted cash price) that are currently listed as required data elements at § 180.50(b)(2) through (6). We note that this revision would remove the phrase “that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting” from each of the individually referenced type of standard charge at § 180.50(b)(2) through (6). This concept, however, would be retained and incorporated (as addressed in more detail below) as a separate data element (“setting”) and used to contextualize hospital items and services at new § 180.50(b)(3).

Second, we would continue to require that the payer-specific negotiated charges be displayed by name of the third party payer and plan(s), each indicated as a separate data element (for example, “payer name” and “plan name”). However—and as a result of our acquiring a better understanding of hospital and commercial payer contracting, we propose that hospitals may indicate plan(s) as categories (such as “all PPO plans”) when the established payer-specific negotiated charges are applicable to each plan in the indicated category. We believe this modification is necessary because we have learned that many hospital contracts are designed to negotiate the same rates across a grouping of payer plans, and not always on a plan-by-plan basis. For example, some hospitals have contracts stipulating that the payer-specific negotiated charges they establish with third party payers are for “all plans” offered by the third party payer, without specifying plan names. Similarly, a hospital’s contract with a payer may set forth the payer-specific negotiated charges for “all PPO plans” or “all managed care plans” without listing specific plan names. As a result, hospitals would be required to indicate payer-specific negotiated charges that apply to “Payer A” for “all PPO plans”, for example, rather than having to research and insert repetitious standard charge information for each named PPO

plan offered by Payer A. We believe this modification is necessary to ensure hospitals are not penalized for displaying information that is consistent with their contracting practices. Moreover, this practice could improve accessibility of the MRF by avoiding repetition of standard charge information that would unnecessarily increase file size. Additionally, because we propose to require hospitals to encode standard charge information in an MRF that conforms to a CMS template layout, the use of such template would ensure that the payer-specific negotiated charges remain ‘clearly associated’ with the name of each payer and plan. Accordingly, we propose to remove the phrase “clearly associated” from the regulatory text as a separate and distinct requirement in relationship to the data elements. Finally, we are aware of interested parties’ recommendations that the payer and plan be indicated in the MRF using some uniform, nationally applicable set of abbreviations. To the extent that a uniform nationally applicable set of abbreviations is available, we seek comment on a publicly available data source(s) that we may consider as we develop the technical instructions.

Third, we propose to require that hospitals indicate the contracting method they used to establish the payer-specific negotiated charge. TEP members indicated that including the contracting method within the MRF would bring necessary context to the payer-specific negotiated charges established by the hospital. For example, a hospital may have established a payer-specific negotiated charge as a ‘base rate’ for a service package.⁶²⁴ Without knowing that, a file user might assume that the listed payer-specific negotiated charge included every charge applicable to the provision of the item or service when, in fact, a ‘base rate’ charge likely would include non-standard adjustments and other added charges. Additionally, including this data element would align with the data element in the TIC template. We seek comment on contracting types that we should consider as allowed values in the CMS template, should this data element be finalized.

⁶²⁴ For additional discussion, please see the CY 2020 HPT final rule, 84 FR 65534.

Fourth, we propose to require that hospitals indicate whether the payer-specific standard charge listed should be interpreted by the user as a dollar amount, percentage, or, if the standard charge is based on an algorithm, the algorithm that determines the dollar amount for the item or service. Specifying whether the number indicated as the standard charge should be interpreted as a dollar figure or percentage would ensure that the data is machine-readable and would minimize confusion about the value inserted into a particular standard charge column. Knowledge of the algorithm for a standard charge that can only be expressed as an algorithm is necessary for consumer-friendly tools to estimate in dollars an individual's payer-specific negotiated charge. Similar to the existing technical instructions for the sample templates, CMS will provide technical instructions for hospitals to display standard charges expressed in dollars, percentages, and algorithms in order to ensure consistency and machine-readability.

Fifth, we propose a consumer-friendly data element called the 'expected allowed amount' that we would require a hospital to display in situations where the payer-specific negotiated charge cannot be expressed as a dollar figure. As finalized in the CY 2020 HPT final rule, the definition of a standard charge is the 'regular rate' established by the hospital for items and services provided to a 'specific group of paying patients.' In other words, the standard charge displayed in the MRF represents the exact rate that applies to all individuals in the group, for example, all individuals covered by a particular payer and plan. This amount is generally considered to be analogous to the 'allowed amount' that is established in the contract the hospital has with the third party payer, and that appears on a patient's explanation of benefits. This is the maximum payment the plan will pay for a covered health care service, and may also be called "eligible expense," "payment allowance," or "negotiated rate."⁶²⁵ A portion of this allowed amount is reimbursed to the

⁶²⁵ <https://www.cms.gov/files/document/nosurpriseactfactsheet-health-insurance-terms-you-should-know508c.pdf>

hospital by the third party payer while the hospital bills the consumer for the remainder which is described as the ‘out-of-pocket’ amount. As we explained in the CY 2020 HPT final rule, knowledge of the rate the insurer has negotiated with the hospital on the consumer’s behalf is essential for helping consumers determine their out-of-pocket cost estimates in advance. However, while essential, the standard charge information is not sufficient because the individual must obtain additional information from his or her third party payer related to the circumstances of their particular insurance plan (for example, what portion of the payer-specific negotiated charges would be paid by the plan and other plan dependencies such as the patient’s co-insurance obligations or where the patient has not satisfied their deductible for the year).

Since implementation of the HPT regulation, hospitals have become more transparent about how they establish their payer-specific negotiated charges. Based on our experience in enforcing the requirements of the regulation, we have learned that most commercial contracting methods result in a hospital’s ability to identify and display as a dollar figure the payer-specific negotiated charges they have established with third party payers. For example, a negotiated rate is established as a dollar amount for an item or service or service package (that is, the ‘base rate’), or is established as a percent discount off the gross charge for each item or service provided, or as a percentage of the Medicare rate which can be translated and displayed by the hospital as a standard dollar amount.

At other times, however, hospitals and payers establish the payer-specific negotiated charge by agreeing to an algorithm that will determine the dollar value of the allowed amount on a case-by-case basis after a pre-defined service package has been provided. This means that the standard charge that applies to the group of patients in a particular payer’s plan can only prospectively be expressed as an algorithm, because the resulting allowed amount in dollars will be individualized on a case-by-case basis for a

pre-defined service package, and thus cannot be known in advance or displayed as a rate that applies to each member of the group.

For example: Patients X and Y are under the same payer's plan. They both go to a hospital for the same procedure which is identified by the payer after analyzing the claim as having the same DRG code. The gross charges (that is, the charges billed on the claim to the payer) for each itemized item and service provided by the hospital for Patient X's procedure total \$1500, while Patient Y's gross charges for each itemized item and service provided by the hospital total \$2000. The hospital and payer have negotiated a payer-specific negotiated charge that is calculated as an amount equal to 50 percent off the total gross (or billed) charges for the procedure identified by the DRG code. The resulting charge (in dollars) for Patient X would be \$750 while resulting charge (in dollars) for Patient Y would be \$1000. In this example, the payer-specific negotiated charge (as an algorithm) is the same for each patient in the payer's plan for the procedure, but it is possible that each patient covered under this payer's plan would have a different resulting charge, in dollars, for the same procedure. In other words, in this example, there is no single dollar amount that would be appropriate for the hospital to post in its MRF as the payer-specific negotiated charge. Instead, the only payer-specific negotiated charge that applies to the group is the algorithm used to calculate the individualized dollar amount (in this example, the algorithm would be "50 percent of the total gross charges" that are billed on the claim for the procedure).

The reality of commercial healthcare contracting practices highlights a tension that sometimes exists between a hospital's establishment of a 'standard charge' that applies to a group of paying patients and the desire for individuals within the group to know and understand the specific cost of their care in dollars for specific hospital items or services. Currently, this tension is largely mitigated by price estimator tools that typically display 'estimated' dollar amounts that are based on past claims and, when available, knowledge of the contracting

arrangements to predict, often with very high accuracy,⁶²⁶ the most likely or expected allowed amount that will apply to an individual. When combined with the individual's insurance information, the individual's out-of-pocket can be determined and displayed. Therefore, as an alternative to leaving a 'blank' or 'N/A' in the MRF when no standard dollar amount is available, we allow hospitals to make public the standard algorithm that applies to the group. The publication of the algorithm makes it possible for a user of the file (such as a price estimator tool developer) to use that algorithm in conjunction with educated assumptions about the items or services likely to be utilized by a given patient for a given procedure, along with their corresponding gross charges, to estimate an allowed amount in dollars for the individual. This amount can be further personalized by including insurance information (such as the copay, co-insurance, or deductible) to determine the individual's estimated out-of-pocket dollar amount.

While we continue to support efforts via other methods, such as price estimator tools, for providing consumer-friendly and personalized out-of-pocket information, we have heard from interested parties that, when a hospital has negotiated a standard charge that can only be expressed as an algorithm, some estimate displayed in dollars within the MRF may be useful, particularly for making comparisons across hospitals. For example, an estimate displayed in dollars would permit users to make price comparisons across hospitals when, with respect to the same procedure and payer/plan, one hospital has established a payer-specific negotiated charge as an algorithm and a second as a dollar amount. We therefore considered whether and what data element could be required in the MRF to provide additional needed context for a payer-specific negotiated charge that is expressed as an algorithm.

We propose that when a hospital has established a payer-specific negotiated charge that can only be expressed as a percentage or algorithm, it must display alongside that percentage or algorithm a consumer-friendly 'expected allowed amount' in dollars

⁶²⁶ Stults, et al. Assessment of Accuracy and Usability of a Fee Estimator for Ambulatory Care in an Integrated Health Care Delivery Network. *JAMA Network Open*. 2019;2(12):e1917445.

for that payer/plan for that particular item or service. The ‘expected allowed amount’ would be the amount, on average, that the hospital estimates it will be paid for the item or service based on the contract with the third party payer. It is our understanding that hospitals often have such information already calculated and available as part of their revenue cycle management systems to provide a back-end check on their reimbursement from the third party payer, so we do not expect that the inclusion of such data in the MRF would represent a large burden. The ‘consumer-friendly expected allowed amount’ is likely to represent reimbursement for an average patient, rather than an exact amount, since, for a payer-specific negotiated charge based on an algorithm, the amount in dollars is known with certainty only after the patient has been discharged. As such, it is an estimate of the average amount that the hospital expects to receive for the item or service for all group members but not the final exact amount in dollars that would be actually apply to each group member. Even so, we believe this information would provide context to the public that is necessary to compare payer-specific negotiated charges across hospitals and a valuable benchmark against which price estimator tools can use to develop and estimate an individual’s personalized out-of-pocket costs. We propose to add this consumer-friendly ‘expected allowed amount’ to the list of required data elements at § 180.50(b)(2).

(c) Proposals for Data Elements Related to Hospital Items and Services

At new § 180.50(b)(3), we propose that hospitals be required to provide standard charge information for additional data elements. These data would describe hospital items and services that correspond to the standard charges established by the hospital as follows:

- Recasting as a separate data element, but otherwise without change, the presently required description of the item or service and whether the standard charge is

for an item or service provided in connection with an inpatient admission or an outpatient department visit.

- If a standard charge has been established for a drug, we propose that the hospital would be required to indicate the drug unit and type of measurement as separate data elements. We have seen hospital MRFs in which the drug unit and type of measurement are either not specified or are included in the same field as the description of the item or service. In the first case, when the drug unit and type of measurement is not specified, the user of the file has no basis for understanding the standard charge that the hospital has established. In other words, the description is not sufficient for the user to understand what quantity of the item or service the user would receive at the indicated standard charge amount. In the second case, when the drug unit and type of measurement are included in the same field as the description of the drug, the information is not easily machine-readable because computers are unable to parse the description if expressed as a ‘string’ of characters that are unique and undefined. Under this proposal, if the hospital has established a standard charge for a drug, the hospital would be required to encode the file with a description of the drug, including the applicable drug unit and type of measurement as a separate and distinct data element from the description. For example, if a hospital establishes a gross charge of \$2 for an item or service it describes as ‘aspirin 81mg chewable tablet – each’, the hospital would be required to input data for each of the required separate data elements, which would look something like this in the MRF, based on the current technical specifications in the data dictionary that accompanies the currently available sample templates: gross charge: 2; description: aspirin 81mg chewable tablet; unit of measurement: 1; type of measurement: UN.⁶²⁷ This indicates to

⁶²⁷ Where “UN” in the sample format data dictionary (found here: <https://www.cms.gov/hospital-price-transparency/resources>) stands for “unit” which, in this example, comes in the form of a tablet.

the public that the standard charge established by the hospital for this item or service is \$2.00 for a single tablet of a drug described as ‘aspirin 81mg chewable tablet.’

We are aware that hospitals may at times establish standard charges for units of items and services other than drugs. While we would encourage hospitals to be transparent about such information in the MRF, we only propose to add data elements for the unit and type of measurement of drugs because the codes (such as HCPCS codes) for non-pharmaceutical items and services typically include instructions or additional descriptions that clarify the unit and type of measurement for the indicated item or service, but the codes (typically National Drug Codes (NDC)) used for pharmaceutical agents do not, and we do not believe it is necessary to burden the hospital with a requirement to publicly disclose information that is already available to the users of the file. Additionally, the TEP members discussed this issue and concluded that drugs are a unique class of items and service when it comes to a user’s ability to clearly understand how hospitals are representing their standard charges. TEP members speculated that such challenges may arise because hospitals establish and display their standard charges for drugs using different methodologies. For example, it is often unclear in the hospital’s MRF whether the payer-specific negotiated charge for a drug is based on the billing unit for the NDC associated with the drug or the billing unit associated with the drug’s HCPCS code.

Based on our own experience in reviewing MRFs, we agree with the TEP members that more prescriptive requirements are necessary when it comes to display of standard charges for drugs and believe that requiring the drug unit and type of measurement as separate data elements would facilitate machine-readability and ensure clarity for the users of these files. We also agree with the TEP members that this proposal may introduce a burden on some hospitals that are already including such information in the description but would have to separate it for display in the CMS

template. Because of this potential burden, we considered an alternative approach by which we would require the drug unit and type of measurement to be included in the description or encoded as separate data elements. This alternative would ensure availability of the data to users of the MRF, albeit in a way that would not be optimized for machine-readability. However, in this case we believe the burden on hospitals is outweighed by the need for improvements in data machine-readability, and therefore propose to require hospitals to report this information as separate data elements. We note that nothing would preclude the hospital from also including the information in its description of the drug. We seek comment on this proposal and the alternative we considered but are not proposing.

(d) Proposals for Data Elements Related to Item or Service Billing

At new § 180.50(b)(2)(iv), we propose to specify data elements related to item or service billing. We believe data elements related to item or service billing are necessary because the standard charges that a hospital establishes are often dependent on the way an item or service is billed. As such, including billing information may improve the public's understanding of the standard charge that has been established for the item or service. In specifying these data elements, we would retain, without modification, the current requirement that the MRF include any code used by the hospital for purposes of accounting or billing for the item or service (the example of such codes would be removed from the reg text as unnecessary). We propose to add a requirement that the hospital specify any relevant modifier(s) needed to describe the established standard charge, and the code type(s) (for example, whether the code is based on HCPCS, CPT, APC, DRG, NDC, revenue center, or other type of code). As discussed by the TEP members, there are instances where a hospital has established different standard charges for the same item or service description, depending on additional factors such as modifiers or revenue centers that are not included in the file. As such, TEP members

agreed that some distinction to ensure meaningfulness of the standard charge would be helpful to users of the file and impose minimal hospital burden. Based on our experience in reviewing MRFs, we have also seen such instances and believe that requirements to include applicable codes that include modifiers and revenue center codes would help make necessary distinctions when multiple standard charges have been established for the same items or services. Separating the code itself (for example, the numbers of the code) from the code type (for example, “HCPCS”) would directly improve machine-readability.

(e) Summary of Proposed Required Data Elements

In summary, we believe these proposed modifications to § 180.50(b) are necessary to improve hospitals’ ability to display their standard charges in a more specific, clear, and standardized way. We believe the proposals would increase the meaningfulness of the standard charge information and heighten the public’s ability to understand and more efficiently aggregate and use the data. Further, as described above, we believe these proposals would improve and streamline CMS’s ability to enforce the HPT requirements.

Table 84 summarizes and compares the existing sample format data elements with the proposed data elements.

TABLE 84: Data Elements Comparison Chart

Data Element	Included in Sample Template (Yes/No)?	Included in Proposal (Yes/No)?
File Date	Yes	Yes
File Version	Yes	Yes
Hospital Name	Yes	Yes
Hospital License	Yes	Yes
Hospital Location	Yes	Yes
Hospital Address	No	Yes
Hospital Financial Aid Policy	Yes	No
Gross Charges	Yes	Yes
Cash Discounted Price	Yes	Yes
Payer-Specific Negotiated Charges (by	Yes	Yes

Data Element	Included in Sample Template (Yes/No)?	Included in Proposal (Yes/No)?
payer and plan; indicated as a dollar amount, percentage, or algorithm; type of contracting method)		
Minimum and Maximum Deidentified Negotiated Charges	Yes	Yes
Consumer-Friendly Expected Allowed Amount	No	Yes
Item/Service Description	Yes	Yes
Billing/Accounting Codes, Modifiers, and Code Type	Yes	Yes
Billing Class	Yes	No
Setting (Inpatient or Outpatient)	Yes	Yes
Drug Unit and Type of Measurement	Yes	Yes

We seek comment on these proposed revisions to § 180.50(b). Specifically, we seek comment on whether we should consider additional data elements to ensure the public’s understanding and ability to meaningful use the standard charge information as displayed in hospital MRFs. In particular, we seek comment from hospitals related to display of payer-specific negotiated charges and solicit specific examples of complex contracting methodologies so that we can provide specific recommendations and technical instructions on display of standard charges resulting from such methodologies in the CMS template.

c. Proposals to Specify Formatting Requirements for Display of Standard Charge Information Using a CMS Template

In this section, we propose to require each hospital to conform to the CMS template layout, data specifications, data dictionary, and to meet any other specifications related to the encoding of the hospital’s standard charge information in its MRF. We are

making these proposals in order to improve automated aggregation of the standard charge information in the hospital's MRFs. Additionally, we believe these proposals will streamline our enforcement capabilities.

While most hospitals are ensuring that the data they display appears in a machine-readable format (such as JSON or CSV), as required under the current regulation, many are not taking as much care to display the data that encodes the file in a way that improves machine-readability that facilitates automated aggregation of standard charge information. Even when individual hospitals make an effort to optimize the machine-readability of the data they include in the MRF, the lack of standardization in the MRF format data encoding limits the ability of users to aggregate MRF data in an automated way. This is because the format of the data encoded in the MRF is unknown to the user and therefore cannot be coded by them for further processing. This lack of standardization in format presents a barrier to intended use of the MRFs as expressed in the CY 2020 HPT final rule – that is, for enhancing the public's ability to use the data in, for example, consumer price estimator tools and in EHRs at the point of care for value-based referrals, or to aggregate and use the data to increase competition.

As indicated throughout the CY 2020 HPT final rule, we believed the flexibility that we initially afforded to hospitals was necessary to ensure that “each hospital operating in the United States” could implement the law and regulatory requirements. Now that hospitals have experience in making their standard charges public in an MRF and we have a better understanding of how hospitals establish their standard charges, we believe our data formatting requirements can be made more prescriptive to enhance the public's ability to use the hospital standard charge information to its fullest potential. These evolutionary changes may serve to decrease hospital burden.

To accomplish this, we propose to revise the introductory text at § 180.50(c) to require that each hospital must conform to the CMS template layout, data specifications,

and data dictionary when making public the standard charge information required under paragraph (b).

Should these proposed rules be finalized, we propose to make at least one CMS template available to hospitals, and hospitals would be required to conform to its layout and comply with technical instructions (located in the template, corresponding data dictionary, and other technical guidance) to be published on a CMS website (such as the HPT website or CMS GitHub). A hospital's failure to display its standard charge information in the form and manner specified by CMS could lead to a compliance action. The CMS template and accompanying technical specifications would describe the form and manner in which the hospital must organize, arrange, and encode its standard charge information for the required data elements (if finalized, and as discussed in XVIII.B.3.b of this proposed rule) in its MRF.

For purposes of this requirement, we propose to make available a CMS template in CSV and JSON formats. Additionally, we propose to make available three different layouts. The three layouts would be similar to the three 'sample formats' that are currently available on the HPT website.⁶²⁸ The three sample layout are: (1) JSON schema (plain format), (2) CSV ("wide" format), and (3) CSV ("tall" format). Although we considered proposing to require hospitals to display their standard charge information using only the JSON format, we concluded that some flexibility remains necessary given the variability in hospital sophistication and technical expertise, and the fact that these two proposed non-proprietary formats (CSV and JSON) appear to be the most frequently used by hospitals for displaying standard charges. We seek comment on this issue, and on whether we should instead require use of a single format (such as JSON).

Technical guidance, to which the hospital must conform for purposes of encoding the standard charge information, would be made available through, for example, a data

⁶²⁸ <https://www.cms.gov/hospital-price-transparency/resources>

dictionary and within the CMS template. The data dictionary would be similar to the data dictionary that CMS has developed for the ‘sample templates,’⁶²⁹ but would be updated to include any new policies that we finalize in the CY 2024 OPPI/ASC PPS final rule. This technical instruction would ensure consistent implementation and machine-readability of hospital MRFs across all hospitals. For example, CMS would provide guidance on how to conform to the CMS template layout and encode the data items for the required data elements; that guidance would also consist of the set of rules for the header and attribute naming and rules for allowed values for encoding standard charge information, including the data type (for example, enum, numeric, alphanumeric), data format (for example, string, float), and, in some cases, specific (“enum”) valid values (for example, “inpatient” “outpatient” “both”). The data dictionary could also include a section on ‘how to use the data dictionary’ which would provide educational information about the encoding instructions for those with low technology expertise. We believe that providing such direction via separate technical instructions is reasonable because such direction does not rise to the meaningful substance that is subject to notice-and-comment rulemaking, and it would enable CMS to update such technical specifications to keep pace with and respond to technical developments and inquiries. Moreover, this proposal is consistent with data disclosure formatting requirements of other CMS programs such as the EHR Incentive Program (see 42 CFR 412.614).

Hospitals that do not conform to the CMS template layout, data specifications, and data dictionary would be determined to be noncompliant with 42 CFR 180.50(c) and could be subject to a compliance action. In addition to providing a data dictionary, to further aid hospitals, we are considering whether we should develop an MRF validator tool, similar to the validator tool provided by TIC on the CMS GitHub website.⁶³⁰ The

⁶²⁹ <https://www.cms.gov/hospital-price-transparency/resources>

⁶³⁰ <https://github.com/CMSgov/price-transparency-guide-validator>

validator tool could be used by hospitals as a check for compliance with the formatting requirements of § 180.50(c), thereby providing some additional technical instruction and assurance that the formatting requirements have been met prior to posting the MRF online. We seek comment on whether hospitals would find a validator tool helpful and, if so, what technical specifications such a validator ought to assess.

We continue to encourage hospitals to provide any additional information they deem necessary to further explain or contextualize their standard charges, and we would provide technical instructions and specifications for hospitals to do so. For example, the data dictionary could include one or more optional data elements for inserting additional explanatory notes (similar to the “additional generic notes” data element included in the sample formats data dictionary), and could also permit hospitals to add other optional data elements such as ‘average reimbursement amounts’ derived from past claims, LAN designations, quality information, or the hospital’s financial aid policy, or any other categories of information the hospital wishes to convey to the public related to hospital’s standard charges.

Consistent with our proposal that hospitals must use a CSV or JSON format, we propose to remove the examples of specific types of machine-readable formats from the definition of “machine-readable format” at § 180.20. Similarly, we propose a technical edit to the naming convention at § 180.50(d)(5) to remove “[json|xml|csv]” and in its place add “[json|csv].”

If the proposals related to these formatting requirements are finalized, CMS will provide additional technical instructions for how a hospital should indicate non-applicability, when necessary. As explained more fully in section XVIII.B.3.b of this proposed rule, we propose to apply the term ‘as applicable’ to the standard charge information that the hospital encodes in the MRF, and not to the data elements themselves. We continue to recognize that a hospital may have no applicable standard

charge information to encode in some fields within a CMS template (this is particularly true for CSV formats, which can be opened in a human-readable spreadsheet format that forces column/row cross relationships between data elements which are not always applicable). We therefore reiterate that absence of encoded information does not necessarily mean that the MRF is incomplete. To illustrate using a specific example, a hospital may have established a gross charge for operating room time described as ‘OR time, first 15 minutes’ but may not have established any payer-specific negotiated charges that correspond to the same item or service. If the hospital has chosen to use the CMS CSV “wide” template (which can also be opened and viewed as a human-readable spreadsheet), a person may see that the cell at the intersection of the column ‘gross charge’ and row of ‘OR time, first 15 minutes’ would be encoded with the applicable standard charge amount but the cell at the intersection of any payer and plan’s ‘payer-specific negotiated charge’ column(s) and the row of ‘OR time, first 15 minutes’ would be empty. In this example, the absence of encoded data would be a result of non-applicability, not non-compliance, because the hospital has not established a standard charge with the payers for a 15-minute increment of OR time.

We caution users of the files who choose to view MRFs in human-readable formats from concluding that a hospital is noncompliant solely based on blanks or the hospital’s use of “N/A” (or other indicator(s) specified by CMS in guidance). To help mitigate ongoing misunderstandings by users of hospital MRF data, CMS intends to continue to educate the public on the standard charge information displayed by hospitals and proper interpretation of the information they contain. Additionally, as discussed in this proposed rule, we propose that hospitals include an affirmation of accuracy and completeness within the CMS template (see proposal in section XVIII.B.2.b of this proposed rule), which we believe would provide some assurance to users of hospital MRFs that the data is accurate and complete to the best of the hospital’s knowledge and

belief. Such an affirmation may also mitigate the need for a hospital to insert any indicator of non-applicability into its MRF. We are therefore not proposing to require insertion of such an indicator, although such indicators would not be precluded should a hospital wish to add them, so long as the hospital adheres to the technical specifications to preserve the machine-readability of the file. However, we seek comment on this issue. We seek comment on whether an indicator of non-applicability is necessary, whether such an indicator should be required or just recommended, and how CMS can best educate the public on the nature of standard charge information display, and, in particular, the potential for non-applicability in certain MRF formats.

Finally, if finalized, we propose a 60-day enforcement grace period for adoption and conformation to the new CMS template layout and encoding of standard charge information of the newly proposed data elements. To be clear, this proposal would be with respect solely to enforcement actions based on the new (if finalized) CMS template display requirements at revised § 180.50(b) and (c); it would in no way affect already-initiated compliance actions or actions for noncompliance with other requirements under part 180 as they are currently being implement. Additionally, this proposal would not apply to other proposals in this proposed rule which would become effective and enforced on January 1, 2024 including proposals related to inclusion of an affirmation statement in the hospital's MRF (discussed in section XVIII.B.2), the accessibility requirements as proposed and discussed in section XVIII.B.4 of this proposed rule, and any other proposals related to enforcement revisions discussed in section XVIII.C of this proposed rule. The effect of this proposal is that CMS would not begin to enforce any finalized requirement for hospitals to use the CMS template until 2 months after the effective date of the CY 2024 OP/ASC PPS final rule with comment period. We understand that some hospitals may have already adopted the sample format that CMS made available in November 2022, however, we propose to implement an enforcement

grace period to accommodate hospitals that have adopted formats that vary significantly from the sample format. We seek comment on this proposal. In particular, we seek comment on whether and why an enforcement grace period should or should not be applied.

4. Proposal to Improve the Accessibility of Hospital MRFs

Currently, the HPT regulations at § 180.50(d) describe our requirements for the location and accessibility of the hospital's MRF. Specifically, the regulations require a hospital to select a publicly available website for purposes of making public its standard charges (§ 180.50(d)(1)) and displaying the standard charges information in a prominent manner and clearly identified with the hospital location with which the standard charge information is associated (§ 180.50(d)(2)). Additionally, at § 180.50(d)(3), the hospital must ensure that the standard charge information is easily accessible, without barriers, including, but not limited to, ensuring the information is accessible: free of charge; without having to establish a user account or password; without having to submit personal identifying information (PII); and to automated searches and direct file downloads through a link posted on a publicly available website. At § 180.50(d)(4), the digital file and the standard charge information contained within that file must be digitally searchable and, at § 180.50(d)(5), the file must use a naming convention specified by CMS.

As we explained in the CY 2020 HPT final rule, because of the flexibility we allowed to hospitals to choose the internet location, we recognized and expected that there would be some variability in how hospitals would choose to publicly display their MRF and how quickly the file could be found by the public. However, we indicated our belief that standardizing a file name or website location information could provide consumers with a standard pathway to find the information and would provide some uniformity, making it easier for potential software to review information on each website.

We expressed our belief that specific requirements for file naming conventions and locations for posting on websites could also facilitate the monitoring and enforcement of the requirements.

We believe our current policies are sufficient for purposes of manual searches but may not be sufficient for automated searches. As we noted in the CY 2022 OPPS/ASC proposed rule, in our experience, many publicly available web pages that hospitals select to host the MRF (or a link to the MRF) are discoverable using simple manual internet searches (using key words such as the hospital name plus ‘standard charges,’ ‘price,’ or ‘machine-readable file’) or, for example, by navigating to the hospital’s home page and clicking and searching through pages related to patient billing and financing. However, despite the requirement for the MRF and the standard charge information contained in that file to be digitally searchable and the required naming convention, various MRF users, including IT developers and technology innovators, continue to express concerns that they can’t efficiently, via automated techniques, aggregate the files. We believe these challenges should be addressed because we believe that ensuring that the MRFs and their data contents are easily accessible, including by members of the public who develop tools that improve the public’s overall understanding and ability to use the information in meaningful ways, aligns with the MRFs’ intended use. As we indicated in the CY 2020 HPT final rule, we believe that “[b]y ensuring accessibility to all hospital standard charge data for all items and services, these data will be available for use by the public in price transparency tools, to be integrated into EHRs for purposes of clinical decision-making and referrals, or to be used by researchers and policy officials to help bring more value to healthcare.”

As a result, we considered methods that would specifically improve the automated accessibility of MRFs. Thus, at proposed new § 180.50(d)(6), we propose to require that a

hospital ensure that the public website it chooses to host the MRF establishes and maintains automated access to the MRF in two specific ways.

First, we propose, at new § 180.50(d)(6)(i) that the hospital ensure the public website includes a .txt file in the root folder that includes a standardized set of fields including the hospital location name that corresponds to the MRF, the source page URL that hosts the MRF, a direct link to the MRF (the MRF URL), and hospital point of contact information. CMS would make available the technical specifications for implementing this file in technical instructions, and could also consider creating a simple .txt generator tool to assist non-technical hospital personnel in generating a .txt file as well as plain-language instructions for complying with the requirement to post a .txt file to the root folder of the public website.

In considering this proposed approach to automating access to hospital MRFs, we identified several benefits, including: a standardized text file at a consistent location (for example, the root folder of the website) would provide automated tools a direct link to the MRF as opposed to the current approach of having to locate the correct webpage within the website; technical experts suggest this is a relatively simple, low burden method that could be applied by maintainers of any public website that hosts the MRF; and information included in the .txt file could include information necessary to validate the contents of the file, for example, by including hospital point-of-contact information. We also considered potential drawbacks of this approach, including that any standardization of this nature is subject to errors in formatting which could negate the benefit to automated access and generate a compliance action. We believe the benefits outweigh the drawbacks for having a hospital ensure that the public website it chooses to host the MRF includes a .txt file in the root folder that includes a direct link to the MRF to establish and maintain automated access.

Second, we propose at new § 180.50(d)(6)(ii) that the hospital ensure the public website includes a link in the footer on its website, including but not limited to the homepage, that is labeled “Hospital Price Transparency” and links directly to the publicly available webpage that

hosts the link to the MRF. We propose this requirement because we believe the addition of standardized hyperlinks in the footer of hospital websites would aid in the automation of MRF data retrieval by creating a predictable navigation path to internal web pages that describe the HPT program and providing direct links to the MRF location. Once a human or web crawler arrives at the webpage on which the MRF is located, it would be able to identify the specific location of the file(s) containing the pricing data. We believe that by making this information more easily accessible to automated searches and data aggregation, it would help third parties develop tools that further assist the public in understanding this information and capturing it in a meaningful way for making informed health care decisions. Moreover, we believe this requirement would be simple for hospitals to understand and implement, due to the website footer being a common place for hospitals to link to other information. In addition, using a standardized label for the link in the footer may make the location of the MRFs more visible to individual consumers manually searching for such files.

We seek comment on this proposed approach to improving accessibility of MRFs to automated searches. We particularly seek comment on whether there: may be better or more efficient ways of improving access to MRFs or the direct links to the MRFs; are additional benefits or challenges that we should alternatively consider; might be any challenges for automation tools to find MRFs when they are hosted by a publicly available website other than a website hosted by the hospital, and ways that would make those automated searches more easily accessible; and, might be any challenges for hospitals to meet the proposed requirements when the publicly available website hosting the MRF is not under direct control of the hospital. We also seek comment on whether the proposals to require use of a footer and .txt file, if finalized, are complementary to, or duplicative of, the requirements at § 180.50(d)(4) and (5) which, respectively, require that the digital file and standard charge information contained in that file must be digitally searchable; and that the file must use the naming convention specified by CMS at § 180.50(d)(5). We also seek comment on whether there is a better or more efficient

standardized label for the link in the footer on the website, including but not limited to the homepage, that links directly to the publicly available website that hosts the link to the MRF.

C. Proposals to Improve and Enhance Enforcement

Section 2718(b)(3) of the PHS Act requires the Secretary to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties. Our current monitoring and enforcement scheme is codified in our regulations at 45 CFR 180 subpart C.

Section 180.70(a) states that CMS may monitor and assess hospital compliance with section 2718(e) of the PHS Act via methods including, but not limited to, evaluating complaints made by individuals or entities to CMS, reviewing individuals' or entities' analysis of noncompliance, and auditing hospitals' websites. Should CMS conclude that a hospital is noncompliant with one or more of the requirements to make public standard charges, CMS may take any of the following actions described at § 180.70(b), which generally, but not necessarily, will occur in the following order:

- Provide a written warning notice to the hospital of the specific violation(s).
- Request a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements.
- Impose a CMP on the hospital and publicize the penalty on a CMS website if the hospital fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan.

To better understand hospitals' HPT compliance and the impact of our implementation efforts, CMS conducted website assessments in 2021 and in 2022. CMS evaluated fourteen criteria for the MRF, and either eleven criteria for the shoppable services display or two criteria for the price estimator tool, depending upon which the hospital chose to offer. In the first 2 years of program implementation, our website assessments demonstrated a substantial increase in hospitals meeting website assessment

criteria, increasing from 27 percent to 70 percent between 2021 and 2022.⁶³¹ Of the remainder of that 30 percent that failed to meet the criteria, 3 percent fully failed to meet website assessment criteria and 27 percent partially met website assessment criteria. Although these website assessments were not formal compliance reviews (which often require additional information from the hospital to make a final determination of compliance), we believe this demonstrates that hospitals are making improvements to come into compliance and that the increase is largely attributable to the increase in compliance penalties that went into effect in CY 2022, and our significant education, monitoring, and enforcement activities. We remain committed to ensuring compliance with our requirements and taking enforcement actions in areas of noncompliance.

Recently, we announced updates to our enforcement process⁶³² that are intended to increase the rates of HPT compliance. In this section, we make proposals that would further improve the efficiency, timeliness, and transparency of the compliance process.

1. Proposals for Improving Assessment of Hospital Compliance

At § 180.70(a), we finalized a process for monitoring hospital compliance with section 2718(e) of the PHS Act by which we may use monitoring efforts including, but not limited to, evaluating complaints made by individuals or entities to the CMS', reviewing individuals' or entities' analysis of noncompliance, and auditing hospitals' websites. The regulation text at § 180.70(a)(2) indicates that such methods are also used to 'assess' hospital compliance; however, we have found these methods to be more appropriate for monitoring, and not as appropriate or sufficient for assessing hospital compliance.

For example, a review of an MRF (such as is performed in a typical website assessment) may reveal some obvious deficiencies which can trigger a compliance action.

⁶³¹ <https://www.healthaffairs.org/content/forefront/hospital-price-transparency-progress-and-commitment-achieving-its-potential>

⁶³² <https://www.cms.gov/newsroom/fact-sheets/hospital-price-transparency-enforcement-updates>

Similarly, a complaint made by the public may be helpful in identifying an allegedly noncompliant hospital. While we appreciate and continue to encourage submission of complaints, there are many nuances and complexities associated with the way hospitals establish standard charges that can lead to questions related to, in particular, the accuracy and completeness of the standard charges information that is included in a hospital's MRF. By way of example, if a hospital's MRF does not include any 'discounted cash prices,' it can be difficult to determine whether the hospital is noncompliant with the requirement to disclose established discounted cash prices or whether the hospital has simply not established such charges and therefore has nothing to make public. Often, a hospital will preempt questions by making statements on its website or in the file to indicate when there is no applicable standard charges data to share with the public. But when such a public statement is absent, we find that it may be necessary for us to contact the hospital through our enforcement process to assess or determine whether the hospital is complying with the requirements of the regulation. In short, we have found it is necessary to employ methods beyond a simple audit of a hospital's website to definitively assess hospital compliance. We believe this distinction between monitoring and assessment activities is necessary because while monitoring activities can be used (by anyone, including CMS) to evaluate alleged noncompliance, only a formal CMS assessment can determine a hospital's compliance with the HPT requirements. We expect that many of these issues would be resolved if the proposed improvements to standardizing display of hospital standard charges (as discussed in section XVIII.B.3 of this proposed rule) are finalized as proposed. However, there could still be times when CMS would need additional information from the hospital to assess compliance.

We therefore propose to amend § 180.70(a)(2) to propose additional activities that CMS may use to monitor and assess for compliance. Specifically, we propose:

- To revise § 180.70(a)(2)(iii) to indicate that CMS may conduct a comprehensive

compliance review of a hospital's standard charges information posted on a publicly available website. We believe this proposal is necessary to clarify the methods we may use to determine a hospital's compliance with HPT requirements.

- At new § 180.70(a)(2)(iv), requiring an authorized hospital official to submit to CMS a certification to the accuracy and completeness of the standard charges information posted in the MRF at any stage of the monitoring, assessment, or compliance phase. We also propose at new § 180.50(a)(3) that the hospital affirm within the MRF the accuracy and completeness of the standard charges information. However, we believe that this additional authority to require a formal certification by an authorized official is necessary to assist CMS in enforcement of the regulations when questions or complaints arise about the completeness or accuracy of the data. This certification authority is necessary because CMS may need a formal certification to resolve any specific questions related to the standard charges displayed and the items and services for which the hospital has established a standard charge, which might not be answered by the proposed affirmation statement in § 180.50(a)(3). For example, a formal certification may be necessary if a complainant alleges that specific standard charges displayed in the hospital's MRF are incomplete or inaccurate, or if certain items and services were provided by the hospital but are not displayed in the MRF with corresponding standard charges. Formal certification would provide assurance to CMS that the information within the MRF has been verified by the authorized official and is valid.

- At new § 180.70(a)(2)(v), requiring submission to CMS of additional documentation as may be necessary to assess hospital compliance. Such documentation may include contracting documentation to validate the standard charges the hospital displays, and verification of the hospital's licensure status or license number, in the event that information was not provided in the MRF. We believe that this proposal is necessary

to enable CMS to adequately evaluate the hospital's publicly posted information to be able to assess compliance.

Further, we propose two technical revisions. First, we propose a technical revision to the introductory text at § 180.70(a) so that it would read "Monitoring and Assessment." Second, we propose to amend § 180.90 by revising paragraph (b)(2)(ii)(C) to remove the phrase "resulting from monitoring activities" and adding in its place the phrase "resulting from monitoring and assessment activities."

2. Proposal to Require Hospital Acknowledgement of Receipt of Warning Notice

Since the HPT regulations first became effective in January 2021, through June 2023, we have issued approximately 906 warning notices to hospitals. Though we send the compliance actions by tracked mail, a few hospitals have reported they did not receive the compliance action notifications. This causes delays in resolution of the deficiencies and in some cases resulted in additional compliance actions (for example, a request for a CAP) from CMS. Requiring that a hospital respond to CMS upon receipt of the warning notice will confirm receipt to CMS and hopefully prompt hospital personnel to appropriately route the warning notice to ensure timely corrective action.

We make clear that hospitals' internal process challenges do not (and in enforcement proceedings will not) excuse a hospital's HPT noncompliance. But, knowledge of this concern caused CMS to consider modifications to the compliance process for purposes of streamlining compliance activities and avoiding unnecessary re-reviews when a hospital has taken no action in response to a warning notice. Additionally, receiving confirmation of receipt directly from individuals at the organization responsible for resolving the deficiencies would streamline our enforcement by providing an appropriate compliance contact earlier in the enforcement process. We therefore propose at § 180.70(b)(1) that CMS will require that a hospital submit an acknowledgement of receipt of the warning notice in the form and manner, and by the

deadline, specified in the notice of violation issued by CMS to the hospital. As part of the confirmation of receipt, we may request contact information from the hospital to streamline further communications.

3. Proposal for Actions to Address Noncompliance Within Hospital Systems

Section 2718(e) of the PHS Act and the HPT regulations apply to ‘each hospital’ operating in the U.S. As such, when CMS determines that a hospital is out of compliance with the regulations, CMS takes a compliance action against the individual hospital. Many hospitals, however, are part of a broader health system where common management officials have some degree of oversight and management over multiple hospitals. For example, some health systems have centralized administrative activities that establish standard charges for all the hospitals in the system, or that are responsible for ensuring compliance with Federal requirements. Under our current regulation, as explained in more detail in section XVIII.C.4 of this proposed rule, we have authority to disclose information about CMS compliance activity only when CMS issues a CMP, at which time CMS posts the CMP notice on its website. We believe that amending the regulation to provide CMS with express authority to notify health system officials of a compliance action that CMS has taken against one or more hospitals within their system, and working directly with them, where appropriate, to educate health system leadership and aid them in bringing all hospitals in the system into compliance, could aid in streamlining hospital compliance and our enforcement process.

Therefore, we propose to add new § 180.70(c) to state that, in the event CMS takes an action to address hospital noncompliance (as specified in paragraph (b)) and the hospital is determined by CMS to be part of a health system, CMS may notify the health system leadership of the action and may work with hospital system leadership to address similar deficiencies for hospitals across the health system. In determining whether a hospital is part of a health system and health system contact information, we anticipate

using data from sources including, but not limited to, internal CMS systems such as the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) or the Chronic Conditions Data Warehouse (CCW). For example, PECOS may be used to identify relationships among organizations including ownership or enrollment associations.⁶³³

We believe that notifying health system officials of a compliance action taken against one of the hospitals in the system and working with health system officials and (where different) the hospital's officials to help the hospital to come into compliance would have several benefits. First, it could serve to ensure full and consistent compliance across all hospitals in the health system. Second, we believe the ability to work directly with health system officials, in addition to working with the noncompliant hospital, could reduce the need for compliance actions against other health system hospitals because the health system could more quickly and efficiently implement system-wide changes. For example, in one case multiple hospitals designated the same hospital system official as the point of contact to work with CMS. This allowed the hospital official to effectively correct violations cited across multiple locations and resulted in system-wide changes.

We seek comment on this proposal, including on whether there are additional data sources that CMS could access for purposes of identifying health system affiliation and leadership contact information.

4. Proposal to Publicize Compliance Actions and Outcomes

In the CY 2020 HPT final rule, we sought comment related to publicizing complaints and posting results of CMS assessments of hospitals' HPT compliance, including on the most effective way for CMS to publicize information regarding hospitals that fail to comply. Some commenters recommended publicizing noncompliant hospitals,

⁶³³ Cohen GR, Jones DJ, Heeringa J, Barrett K, Furukawa MF, Miller D, Mutti A, Reschovsky JD, Machta R, Shortell SM, Frazee T, Rich E. Leveraging Diverse Data Sources to Identify and Describe U.S. Health Care Delivery Systems. EGEMS (Wash DC). 2017 Dec 15;5(3):9. doi: 10.5334/egems.200. PMID: 29881758; PMCID: PMC5983023.

while one commenter expressed the belief that publicizing noncompliance even after imposition of a CMP would amount to “public shaming,” which the commenter believed would not be of benefit. We considered these comments and ultimately finalized a policy at § 180.90(e)(1) that, should CMS issue a CMP to a hospital it determines is noncompliant, CMS would post the notice of imposition of the CMP on a CMS website.

In finalizing this policy, we explained that we believed that publicizing a hospital’s noncompliance prior to imposing a CMP (for example) could be an effective tool to raise public awareness of, for example, incomplete hospital data, and could encourage hospitals to promptly remedy its violation(s) to avoid being publicly identified as noncompliant. However, we declined at the time to finalize publicizing information beyond publicizing the notice of imposition of a CMP. We indicated that we would consider revisiting through future rulemaking the timing for, and approach by, which CMS publicizes its determination of a hospital’s noncompliance with the requirements to make public standard charges.

As of June 27, 2023, CMS had issued approximately 906 warning notices and 371 requests for CAPs since the initial regulation went into effect in January 2021. Approximately 301 hospitals were determined by CMS after a comprehensive compliance review to not require any compliance action and approximately 457 hospitals received a closure notice from CMS after having addressed deficiencies indicated in a prior warning notice or a request for a CAP following an initial comprehensive compliance review. We have imposed CMPs on four hospitals and publicized those CMP impositions on our website.⁶³⁴ Every other hospital that we have identified as being noncompliant has either corrected its deficiencies or is cooperating with CMS to work towards correcting its deficiencies.

⁶³⁴ <https://www.cms.gov/hospital-price-transparency/enforcement-actions>

CMS routinely receives inquiries from the public, including state hospital associations, related to its compliance activities, asking, among other things, whether CMS has reviewed certain hospitals in certain states or other geographic locations. Given this significant public interest, we considered whether publicizing more information about CMS compliance activities and hospital-specific actions would be useful. We reviewed other federal programs that make public compliance actions for various programs, such as HHS/HRSA's 340B Drug Pricing Program which publicly posts audit results that include the name of the entity and state, audit findings, sanction, and corrective action status,⁶³⁵ CMS' Part C and D results related to the Medicare Advantage and Prescription Drug Plan program audits⁶³⁶ and compliance actions,⁶³⁷ and the FDA which provides the public access to an online, searchable dashboard of compliance actions, including warning letters.⁶³⁸

We believe that such information could improve the public's understanding and transparency of CMS' enforcement process by allowing interested parties to view compliance actions and determinations made by CMS. Additionally, making public compliance information may reduce repetitive complaints to CMS about hospital compliance issues and provide a central source of information for inquirers, including the media and state officials, who have expressed interest in this issue. Additionally, making these enforcement actions transparent may increase the likelihood that hospitals will more quickly come into compliance due to public scrutiny.

As a result, we propose at § 180.70(d) that CMS may publicize on its website information related to CMS' assessment of a hospital's compliance, any compliance actions taken against a hospital, the status of such compliance action(s), and the outcome

⁶³⁵ <https://www.hrsa.gov/opa/program-integrity/fy-22-audit-results>

⁶³⁶ <https://www.cms.gov/medicare/compliance-and-audits/part-c-and-part-d-compliance-and-audits/programaudits>

⁶³⁷ <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDComplianceActions>

⁶³⁸ <https://datadashboard.fda.gov/ora/cd/complianceactions.htm>

of such compliance action(s). Additionally, we propose at § 180.70(d) that CMS may publicize on its website information related to notifications that CMS may send to health system leadership, if proposals discussed in section XVIII.C.3 of this proposed rule are finalized. Should CMS decide to publicize this information on its website, it would apply uniformly to all hospitals. We further note that, similar to other such assessments, the information we would make public would only be relevant as of the date indicated, and should not be taken to suggest any ongoing state of compliance or noncompliance.

D. Seeking Comment on Consumer-Friendly Displays and Alignment with Transparency in Coverage and No Surprises Act

As we concluded in the CY 2020 HPT final rule, transparency in pricing is necessary and can be effective to help bring down the cost of healthcare services, reduce price dispersion, and benefit consumers of healthcare services, including patients and employers. We discussed research suggesting that making consumer-friendly pricing information available to the public can reduce healthcare costs for consumers. We noted that despite the growing consumer demand and awareness of the need for healthcare pricing data, there continued to be a gap in easily accessible pricing information for consumers to use for healthcare shopping purposes. Specifically, there is inconsistent (and many times nonexistent) availability of provider charge information, among other limitations to understanding data made available or barriers to use of the data. We stated our belief that this information gap could, in part, be filled by the release of hospital standard charges as required by section 2718(e) of the PHS Act.

In response to comments, we acknowledged that there are additional barriers that must be overcome to allow consumers to identify appropriate sites of care for needed services, determine out-of-pocket costs in advance, and utilize indicators of quality of care to make value-based decisions. As we previously described in the CY 2020 HPT final rule, we stated our (continuing) belief that the HPT regulations requiring hospitals to

make public standard charges are a necessary and important first step in ensuring transparency in healthcare prices for consumers, but that the release of hospital standard charge information is not sufficient by itself to achieve our ultimate goals for price transparency. We noted that HHS was continuing to explore other authorities to advance the Administration's goal of enhancing consumers' ability to choose the healthcare that is best for them, to make fully informed decisions about their healthcare, and to access both useful price and quality information. We also agreed with commenters that "surprise billing" was an issue of great concern to consumers and of great interest to both federal and state lawmakers. We noted that the HPT policies would not resolve that issue entirely, although we expressed our belief that it was possible that disclosure of hospital standard charges could help mitigate some consumer surprise billing (86 FR 65530).

As a result of comments indicating that long lists of standard charges might be difficult for the average person to directly use and understand, we considered ways that the authorities under section 2718(e) of the PHS Act could be used to require or encourage hospitals to make public standard charges for frequently provided services in a form and manner that might be more directly accessible and consumer-friendly. Ultimately, we finalized requirements for hospitals to display a list of payer-specific negotiated charges for a specified set and number of "shoppable" services as well as requirements intended to ensure the charge information for "shoppable" services would be presented in a way that is consumer-friendly, including presenting the information as a service package. We were also persuaded by commenters' suggestions that hospitals offering online price estimator tools that meet certain requirements including providing real-time individualized out-of-pocket cost estimates adequately satisfy our aim that hospitals communicate their standard charges in a consumer-friendly manner, and therefore deemed these price estimator tools as meeting our requirements for making public standard charges for a limited set of shoppable services (84 FR 65579).

Since finalizing these policies, additional federal price transparency initiatives that rely on other authorities that more directly empower consumers with pricing information have been, or are in the process of being, implemented. Specifically, since publication of the CY 2020 HPT final rule in 2019, the Transparency in Coverage (TIC) rule (85 FR 72158, finalized in 2020)⁶³⁹ and the No Surprises Act (NSA) (enacted as part of the Consolidation Appropriations Act of 2021) have been promulgated or enacted. Under the TIC final rules, with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2023, most group health plans and issuers of group or individual health insurance coverage are required, among other requirements, to disclose personalized pricing information for covered items and service to their participants, beneficiaries, and enrollees through an online consumer tool, or in paper form, upon request. Cost estimates must be provided in real-time based on cost-sharing information that is accurate at the time of the request.⁶⁴⁰ This requirement is being phased in over 2 years. An initial list of 500 shoppable services as determined by the DOL, HHS, and the Treasury (collectively, the Departments) will be required to be available via the internet based self-service tool for plan years that begin on or after January 1, 2023. The remainder of all items and services will be required to be available via these self-service tools for plan years that begin on or after January 1, 2024.

The NSA, which contains many provisions to protect consumers from surprise medical bills and to improve price transparency, will help patients understand health care costs in advance of care and to minimize unforeseen—or surprise—medical bills.⁶⁴¹ Section 9819 of the Internal Revenue Code (Code), section 719 of the Employee Retirement Income Security Act (ERISA), and section 2799A-4 of the PHS Act, as added by section 114 of division BB of the CAA, 2021, require group health plans and issuers

⁶³⁹ <https://www.federalregister.gov/documents/2020/11/12/2020-24591/transparency-in-coverage>

⁶⁴⁰ <https://www.cms.gov/healthplan-price-transparency/plans-and-issuers>

⁶⁴¹ <https://www.cms.gov/nosurprises>

of group or individual health insurance coverage to offer price comparison guidance by telephone and make available on the plan’s or issuer’s website a “price comparison tool” that (to the extent practicable) allows an individual enrolled under such plan or coverage, with respect to such plan year, such geographic region, and participating providers with respect to such plan or coverage, to compare the amount of cost-sharing that the individual would be responsible for paying under such plan or coverage with respect to the furnishing of a specific item or service by any such provider. In guidance issued on August 20, 2021, the Departments indicated that because the price comparison methods required by the CAA are largely duplicative of the internet-based self-service tool component of the TIC final rules, the Departments intend to propose rulemaking and seek public comment regarding whether compliance with the internet-based self-service tool requirements of the TIC Final Rules satisfies the analogous requirements set forth in section 9819 of the Code, section 719 of the ERISA, and section 2799A-4 of the PHS Act.⁶⁴²

Under section 2799B-6 of the PHS Act, as added by section 112 of title I of Division BB of the CAA, 2021, health care providers, health care facilities, and providers of air ambulance services are required to provide a good faith estimate (GFE) of expected charges for items and services to individuals who are not enrolled in a group health plan or group or individual health insurance coverage, Federal health care program, or Federal Employees Health Benefits (FEHB) program health benefits plan (uninsured individuals) or not seeking to file a claim with their group health plan, health insurance coverage, or FEHB health benefits plan (self-pay individuals). This GFE for uninsured (or self-pay) individuals must be provided in writing, either on paper or electronically (and may also be provided orally, if an uninsured (or self-pay) individual requests a good faith estimate

⁶⁴² FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (August 20, 2021), available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf>.

in a method other than on paper or electronically), upon request or at the time of scheduling health care items and services.

On October 7, 2021, HHS issued regulations implementing section 2799B-6 of the PHS Act related to GFEs for uninsured (or self-pay) individuals at 45 CFR 149.610.⁶⁴³ Under 45 CFR 149.610(b)(A) through (C), information regarding the availability of GFEs for uninsured (or self-pay) individuals must be written in a clear and understandable manner, prominently displayed (and easily searchable from a public search engine) on the convening provider's or convening facility's website, in the office, and on-site where scheduling or questions about the cost of items or services occur; orally provided when scheduling an item or service or when questions about the cost of items or services occur; and made available in accessible formats, and in the language(s) spoken by individual(s) considering or scheduling items or services with the convening provider or convening facility. At 45 CFR 149.610(c)(1), the content requirements of the GFE are outlined. The Departments have provided a sample of the GFE form online that includes the required information.⁶⁴⁴

For individuals who are enrolled in a group health plan or group or individual health insurance coverage, section 2799B-6 of the PHS Act requires providers and facilities to submit a GFE of expected charges to the covered individual's plan or issuer.⁶⁴⁵ Section 9816(f) of the Code, section 716(f) of the ERISA, and section 2799A-1(f) of the PHS Act, as added by section 111 of title I of Division BB of the CAA, 2021, require plans and issuers, upon receiving the GFE, to send an advanced explanation of benefits (AEOB) in clear and understandable language to the covered individual, through

⁶⁴³ Requirements Related to Surprise Billing; Part II, 86 FR 55980, 55983 (October 7, 2021), available at <https://www.govinfo.gov/content/pkg/FR-2021-10-07/pdf/2021-21441.pdf>.

⁶⁴⁴ <https://www.cms.gov/files/document/good-faith-estimate-example.pdf>

⁶⁴⁵ The Department of Health and Human Services (HHS) interprets the requirements described in section 2799B-6 of the PHS Act apply to providers and facilities furnishing items or services to individuals covered by the Federal Employees Health Benefits (FEHB) Program in the same manner as for individuals enrolled in a group health plan or group or individual health insurance coverage.

mail or electronic means, as requested by the covered individual.⁶⁴⁶ The AEOB must include the following information: (1) the network status of the provider or facility; (2) the contracted rate for the item or service, or, if the provider or facility is not a participating provider or facility, a description of how the covered individual can obtain information on providers and facilities that are participating; (3) the GFE received from the provider or facility; (4) a GFE of the amount the plan or coverage is responsible for paying; (5) the amount of any cost sharing which the covered individual would be responsible for paying with respect to the GFE received from the provider or facility; (6) a GFE of the amount that the covered individual has incurred towards meeting the limit of the financial responsibility (including with respect to deductibles and out-of-pocket maximums) under the plan or coverage as of the date of the AEOB; and (7) disclaimers indicating whether coverage is subject to any medical management techniques (including concurrent review, prior authorization, and step-therapy or fail-first protocols). The AEOB must also indicate that the information provided is only an estimate based on the items and services reasonably expected to be furnished, at the time of scheduling (or requesting) the item or service, and is subject to change; and any other information or disclaimer the plan, issuer, or carrier determines is appropriate and that is consistent with information and disclaimers required under this section of the statute.

In September 2022, the Departments and the Office of Personnel Management (OPM) published a request for information to inform rulemaking on the provisions of the No Surprises Act related to the AEOB and GFE for covered individuals. (See 87 FR 56905.)⁶⁴⁷ The RFI requested information and recommendations on transferring data from providers and facilities to plans, issuers, and carriers; other policy approaches; and

⁶⁴⁶ Pursuant to 5 U.S.C. 8902(p), FEHB carriers must comply with AEOB requirements in the same manner as those provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage.

⁶⁴⁷ <https://www.govinfo.gov/content/pkg/FR-2022-09-16/pdf/2022-19798.pdf>

the economic impacts of implementing these requirements. The Departments and OPM are carefully considering the public comments on the RFI as they, along with industry stakeholders, continue work toward developing the technical standards and policy framework necessary to support successful implementation of the AEOB and GFE for covered individuals.

As these new consumer-friendly requirements are in the process of becoming fully realized, we are interested in hearing from the public how the HPT requirements, in accord with the contours of the statutory authority conferred by section 2718(e) of the PHS Act, can best support and complement the consumer-friendly requirements found in these other price transparency initiatives. We particularly seek comment on:

- How, if at all, and consistent with its underlying legal authority, could the HPT consumer-friendly requirements at § 180.60 be revised to align with other price transparency initiatives?

- How aware are consumers about healthcare pricing information available from hospitals? We solicit recommendations on raising consumer awareness.

- What elements of health pricing information do you think consumers find most valuable in advance of receiving care? How do consumers currently access this pricing information? What are consumers' preferences for accessing this price information?

- Given the new requirements and authorities through TIC final rules and the NSA, respectively, is there still benefit to requiring hospitals to display their standard charges in a “consumer-friendly” manner under the HPT regulations?

- Within the contours of the statutory authority conferred by section 2718(e) of the PHS Act, should information in the hospital consumer-friendly display (including the information displayed in online price estimator tools) be revised to enhance alignment with price information provided under the TIC final rules and NSA regulations? If so, which data should be revised and how?

- How effective are hospital price estimator tools in providing consumers with actionable and personalized information? What is the minimum amount of personalized information that a consumer must provide for a price estimator tool to produce a personalized out-of-pocket estimate?

- How are third parties using MRF data to develop consumer-friendly pricing tools? What additional information is added by third parties to make standard charges consumer-friendly?

- Should we consider additional consumer-friendly requirements for future rulemaking, and to the extent our authorities permit? For example, what types of pricing information might give consumers the ability to compare the cost of healthcare services across healthcare providers? Is there an industry standard set of healthcare services or service packages that healthcare providers could use as a benchmark when establishing prices for consumers?

XIX. Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor

As discussed in the FY 2024 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) proposed rule (88 FR 26752), the Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into a Medicare Severity Diagnosis Related Group (MS-DRG). If any of the MCE claim edits are triggered, the claim is returned to the provider to correct any issues related to the coded claims data and resubmit the claim for processing by the MAC.

After patient information is screened through the MCE and further development of the claim is conducted, the cases are classified into the appropriate MS-DRG by the Medicare

GROUPER software program. The GROUPER program was developed as a means of classifying each case into an MS-DRG. The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS and therefore, also utilizes the MCE to identify cases that require further review before assignment into a Medicare Severity Long-Term Care Diagnosis Related Group (MS-LTC-DRG) can be made.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48874), we made available the FY 2023 ICD-10 MCE Version 40 manual file. The manual contains the definitions of the Medicare code edits, including a description of each coding edit with the corresponding diagnosis and procedure code edit lists. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 40 (and ICD-10 MS-DRGs) are posted on the CMS website at: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/ms-drg-classifications-and-software>. The MCE manual is currently comprised of two chapters: *Chapter 1: Edit code lists* provides a listing of each edit, an explanation of each edit, and as applicable, the diagnosis and/or procedure codes for each edit, and *Chapter 2: Code list changes* summarizes the changes in the edit code lists (for example, additions and deletions) from the prior release of the MCE software.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26758) and prior rulemaking, as we continue to evaluate the purpose and function of the MCE with respect to ICD-10, we encourage public input for future discussion, including with respect to whether there are concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. We note that historically, CMS has typically addressed the addition or deletion of MCE edits in its annual IPPS rulemakings, as well as the addition or deletion of ICD-10 diagnosis and procedure codes for the applicable MCE edit code lists effective October 1, consistent with the October 1 updates to the ICD-10 code set. We also note that currently, any changes applicable to the MCE edit code list in connection with the April 1

updates to the ICD-10 code set are made available on the CMS web site at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software>.

As we have continued to evaluate the purpose and function of the MCE with respect to ICD-10, we recognize a need to further examine the operability of the MCE software program, including the current list of edits and the definitions of those edits. We have also considered the operation of the MCE as compared to the claims editing programs used for other Medicare payment systems, including how those edits are defined and applied, as well as how they are updated and maintained. For example, the Outpatient Prospective Payment System (OPPS) “Integrated” Outpatient Code Editor (I/OCE) is a software program that combines editing logic with an ambulatory payment classification (APC) assignment program. Similar to the IPPS MCE, the I/OCE edits the claims data to identify errors and ensure accuracy of submitted data. The I/OCE also serves additional claims editing functions as compared to the IPPS MCE. CMS makes updates to the I/OCE through quarterly releases with effective dates of January 1, April 1, July 1, and October 1 of each year. The updates reflect modifications to the program logic, such as additions and deletions of the ICD-10-CM diagnosis codes and Healthcare Common Procedure Coding System (HCPCS) codes, adding, removing or revising APCs, activating and deactivating edits, and other related actions. Changes and updates to the I/OCE are announced through quarterly I/OCE Change Requests (CRs) that are posted to the CMS website for MACs and public download at:

<https://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/OCEQtrReleaseSpecs>. The public may submit any questions or concerns related to the I/OCE through the CMS website at:

<https://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/ContactUs>.

Similar to the claims editing programs used for the OPSS and other Medicare payment systems, the claims edits under the MCE serve the operational function of identifying cases that require further review before classification into an MS-DRG. As previously discussed, if an edit

is triggered, the claim is returned to the provider to correct any issues related to the coded claims data and to resubmit the claim for processing. Accordingly, consistent with the process that is used for updates to the I/OCE and other Medicare claims editing systems, we propose to address any future revisions to the MCE, including any additions or deletions of claims edits, as well as the addition or deletion of ICD-10 diagnosis and procedure codes to the applicable MCE edit code lists, outside of the annual IPPS rulemakings. As described further in this section, we anticipate generally announcing any such changes or updates to the MCE as part of our instructions issued to the MACs in connection with the April 1 and October 1 ICD-10 code updates.

Under our current process, we announce updates to the MCE in connection with the April 1 and October 1 ICD-10 code updates, as applicable. For example, as discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26767), we issued Change Request (CR) 13034, Transmittal 11746, titled “April 2023 Update to the Medicare Severity – Diagnosis Related Group (MS-DRG) Grouper and Medicare Code Editor (MCE) Version 40.1 for the International Classification of Diseases, Tenth Revision (ICD-10) Diagnosis Codes for Collection of Health-Related Social Needs (HRSNs) and New ICD-10 Procedure Coding System (PCS) Codes”, on December 15, 2022 (available on the CMS website at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r11746cp>) regarding the release of an updated version of the ICD-10 MS-DRG GROUPER and Medicare Code Editor software, Version 40.1, effective with discharges on and after April 1, 2023, reflecting the new diagnosis and procedure codes. We noted in the CR that the updated software, along with the updated ICD-10 MS-DRG V40.1 Definitions Manual and the Definitions of Medicare Code Edits V40.1 manual is available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software>. We issued similar instructions with respect to the October 1, 2022 updates to the MCE and related materials, including the release of the updated Version 40 ICD-10 MS-DRG GROUPER and Medicare Code Editor software, effective with discharges on

and after October 1, 2022, available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software> .

Under our proposed approach, we would continue to issue instructions to the MACs in connection with any April 1 or October 1 updates to the IPPS MCE, including the effective date for the appropriate version of the MCE software program and the Definitions of Medicare Code Edits manual, and where these resources may be found on the CMS web site. We would be interested in feedback as to whether it would also be helpful to list the specific MCE updates in the CR, including any additions or deletions of diagnosis or procedure codes or any addition or deletion of particular MCE edits. As previously noted, Chapter 2 of the MCE manual currently identifies the changes in the edit code lists (for example, additions and deletions) from the prior release of the MCE software. Beginning with the FY 2025 rulemaking, we would no longer address the addition or deletion of MCE edits or the addition or deletion of ICD-10 diagnosis and procedure codes for the applicable MCE edit code lists in the annual IPPS rulemakings.

We note that under this revised approach, we would also continue to welcome input from the public on the current edits, including input from providers and other users on how the MCE may currently be utilized in their respective workflow processes, as well as feedback on users' experience with the MCE, to inform any future revisions to the MCE.

We invite public comments on our proposal to remove discussion of the MCE from the annual IPPS rulemakings, beginning with the FY 2025 rulemaking, and to generally address future changes or updates to the MCE through instruction to the MACs, as previously described.

XX. Proposed Technical Edits for REH Conditions of Participation and Critical Access Hospital (CAH) CoP Updates

On November 23, 2022, we published a final rule for the Rural Emergency Hospital health and safety standards (or the Conditions of Participation) titled, "REH Conditions of Participation (CoP) and Critical Access Hospital (CAH) CoP Updates (CMS-3419-F)", which was included in the "Medicare Program: Hospital Outpatient Prospective Payment and

Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID-19” final rule with comment period (87 FR 71748). In that rule, we finalized the designation and certification for Rural Emergency Hospitals of part 485, subpart E, at 42 CFR 485.506. In the section titled, Statutory Authority and Establishment of Rural Emergency Hospitals as a Medicare Provider Type, we noted the following:

“In order to become an REH, section 1861(kkk)(3) of the Act requires that the facility, on the date of enactment of the CAA, 2021 (December 27, 2020), was a CAH or a rural hospital with not more than 50 beds. For the purpose of REH designation, section 1861(kkk)(3)(B) defines rural hospital as a subsection (d) hospital (as defined in section 1886(d)(1)(B) with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D) of the Act)), or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act.”

We reiterated these requirements in the discussion of the Designation and Certification of REHs (§ 485.506) and finalized the regulatory text for the requirement at 42 CFR 485.506; however, we inadvertently cited the incorrect statutory references. We propose to correct these statutory citations from “1881(d)(2)(D)” to “1886(d)(2)(D)” and from “1881(d)(1)(B)” to “1886(d)(1)(B)” at § 485.506(b) and (c).

XXI. Rural Emergency Hospitals (REHs): Proposal Regarding Payment For Rural Emergency Hospitals (REHs)

A. Background on Rural Emergency Hospitals

The Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116-260), was signed into law on December 27, 2020. In this legislation, Congress established Rural Emergency Hospitals (REHs), a new rural Medicare provider type, to help maintain access to rural outpatient hospital

services and prevent rural hospital closures. These providers furnish emergency department and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. Hospitals are eligible to convert to REHs if they were CAHs or rural hospitals with not more than 50 beds participating in Medicare as of the date of enactment of the CAA. For more information on the statutory authority for and the regulations implementing this new Medicare provider type, please refer to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72160 through 72161).

B. REH Payment Methodology

Pursuant to section 1834(x)(1) of the Act and CMS's implementing regulations at 42 CFR §§ 419.91 and 419.92(a)(1), payment for REH services is defined in terms of the amount of payment "that would otherwise apply under section 1833(t)," for covered outpatient department (OPD) services, increased by 5 percent. As discussed in the CY 2023 OPPS/ASC final rule with comment period, CMS interprets "rural emergency hospital services," as defined by section 1861(kkk)(1) of the Act, to include the scope of covered OPD services as defined in 1833(t)(1)(B) of the Act (excluding 1833(t)(1)(B)(ii) of the Act) (87 FR 72162). In the CY 2023 OPPS/ASC final rule with comment period, CMS also finalized regulations at 42 CFR 419.92(c) which address payment for services furnished by an REH that fall outside the scope of the covered OPD services under section 1833(t)(1)(B) of the Act. In addition, pursuant to section 1834(x)(2) of the Act, CMS codified at 42 CFR 419.92(b) that REHs will be paid an additional monthly facility payment, which was calculated for CY 2023 pursuant to the methodology described in the CY 2023 OPPS/ASC final rule with comment period and will be updated in subsequent years by the hospital market basket percentage increase as described in section 1886(b)(3)(B)(iii) of the Act.

C. Background on the IHS Outpatient All-Inclusive Rate (AIR) for Tribal and IHS Hospitals

For many years, tribal and IHS hospitals have been paid for hospital outpatient services furnished to Medicare beneficiaries based upon an outpatient per visit rate (the All-Inclusive

Rate or “AIR”), which is published annually by the IHS in the **Federal Register**. For additional information about the annual all-inclusive rates that IHS sets for inpatient and outpatient medical care provided by IHS facilities, please refer to IHS’s CY 2023 Reimbursement Rate Notice which appeared in the **Federal Register** on February 27, 2023 (88 FR 12387).

In the CY 2002 OPPS final rule, CMS explicitly excluded IHS hospitals from the OPPS (66 FR at 59893) and codified that exclusion at § 419.20(b)(4), explaining that these facilities would continue to be paid under the separately established rate (the AIR) that is published annually in the **Federal Register**.

D. Proposal to Pay IHS and Tribal Hospitals that Convert to an REH Under the AIR

While some tribal and IHS hospitals have expressed interest in converting to an REH, they have expressed significant reservations about doing so due to having to transition from their existing payment methodology under the AIR to the REH payment methodology. As discussed above, in accordance with 42 CFR 419.20(b)(4) and CMS’s longstanding policy, tribal and IHS hospitals are excluded from payment under the OPPS and instead are paid for hospital outpatient services under the AIR. In contrast, payment for REH services is defined in section 1834(x)(1) of the Act and under § 419.92(a)(1) as “the amount of payment that would otherwise apply under section 1833(t) of the Act for the equivalent covered OPD service.” Because there is no amount that would otherwise apply under section 1833(t) of the Act for hospital outpatient services furnished by tribal and IHS hospitals (because these hospitals have always been excluded from the OPPS for payment for hospital outpatient services), such services, when furnished by IHS operated or tribally operated REHs (hereinafter referred to as “IHS-REHs”), do not fall within the scope of “REH services.” Under § 419.92(c), “a service furnished by an REH that does not meet the definition of an REH service under § 419.91 is paid for under the payment system applicable to the service, provided the requirements for payment under that system are met.” Consequently, we propose that IHS-REHs be paid for hospital outpatient services under the same rate (the applicable AIR that is established and published annually by the IHS) that would

otherwise apply if these services were performed by an IHS or tribal hospital, consistent with the requirements of § 419.92(c). Under this proposal, the AIR would serve as payment for services furnished by IHS-REHs as part of an outpatient hospital encounter in the same manner as the AIR currently applies to IHS operated hospitals. Accordingly, to the extent that IHS hospitals are currently compensated via the AIR, rather than other Medicare payment mechanisms, for services other than hospital outpatient services that are furnished as part of an outpatient hospital encounter, CMS is proposing that an IHS-REH would also be paid via the AIR when furnishing such services as part of an outpatient hospital encounter. Further, we note that existing beneficiary coinsurance policies applicable to such services under the AIR would remain unchanged by our proposal.

We propose that IHS-REHs would receive the REH monthly facility payment consistent with how this payment is made to REHs that are not tribally or IHS operated. CMS pays the monthly facility payment, pursuant to section 1834(x)(2) of the Act, as a separate payment to the REH that is not tied to specific services. Likewise, there is nothing in the statute and CMS's implementing regulations (42 CFR 419.92(b)) that would preclude REHs, including tribally or IHS operated REHs, from receiving this payment, even if they are paid under a separate payment framework for hospital outpatient services provided to beneficiaries (87 FR 72167 through 72181). Therefore, we propose that IHS-REHs would receive the monthly facility payment, consistent with § 419.92(b).

We also believe that for IHS-REHs it would be most efficient from a claims processing perspective for the IHS-REHs to process their claims separately from other REHs. Therefore, we propose to update the OPSS claims processing logic to include an IHS-REH specific payment flag, which an IHS-REH provider would utilize to indicate that the provider is an IHS-REH and should be paid the AIR.

Allowing tribal and IHS hospitals to continue receiving payment for hospital outpatient services through the AIR would remove several barriers to these hospitals converting to REHs.

This proposal would provide tribal or IHS hospitals that convert to REHs greater predictability by allowing these facilities to continue to be paid via a familiar payment mechanism (the AIR), that will enable payment at the same rate that these hospitals are currently paid for outpatient hospital encounters. This proposal would also reduce the administrative burden for tribal and IHS hospitals to convert to an REH since they would already be familiar with reporting services and receiving payment using the AIR and would not need to invest in new software and additional staff training to receive payment for individual REH services at the REH payment rate. The continued use of the AIR would also make it easier for tribal and IHS providers that convert to an REH, but later determine it was the wrong decision for their facility, to convert back to a CAH or an inpatient hospital. Finally, CMS anticipates that this proposal would enable an increased number of rural tribal and IHS hospitals to attain an REH designation in a manner that would allow them to maintain their outpatient services, which may have a positive impact on health equity for Native Americans and people adversely affected by persistent poverty or inequality by facilitating access to health care in rural tribal communities.

We propose to add a new paragraph (d) to § 419.92 to codify that, beginning in CY 2024, IHS and tribally operated REHs, as defined in a proposed new paragraph (e) in § 419.92 as discussed below, will be paid under the outpatient hospital AIR that is established and published annually by the IHS instead of being paid the rates for REH services described in § 419.92(a)(1).

We also propose to amend § 419.93(a)(2), relating to services furnished by an off-campus provider-based department of an REH, to add a reference to the proposed new provision at § 419.92(d) for purposes of payment for services furnished by off-campus provider-based departments of IHS and tribally operated REHs.

Finally, we propose to establish a definition for IHS or tribally operated REHs, to identify the REHs that will be eligible to receive payment under the proposed new policy in § 419.92(d). Accordingly, we propose to add paragraph (e) to § 419.92 to codify that for purposes of

§ 419.92, an IHS or tribally operated REH means an REH, as defined in § 485.502, that is operated by the IHS or by a tribe or tribal organization with funding authorized by Title I or III of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

E. Exclusion of REHs from the OPSS

Hospitals that are excluded from payment under the OPSS are specified under § 419.20(b) of the regulations. Because, as described above, REHs are paid outside of the OPSS, we intended to revise § 419.20(b) during the CY 2023 rulemaking cycle to exclude REHs from payment under the OPSS. However, this intended revision was inadvertently omitted. Consequently, we are now proposing to codify the exclusion of REHs from the OPSS by adding new paragraph (5) to § 419.20(b).

XXII. Request for Public Comments on Potential Payment under the IPPS and OPSS for Establishing and Maintaining Access to Essential Medicines

A. Overview

On January 26, 2021, President Biden issued Executive Order 14001, “A Sustainable Public Health Supply Chain” (86 FR 7219), which launched a whole-of-government effort to strengthen the resilience of medical supply chains, especially for pharmaceuticals and simple medical devices. This effort was bolstered subsequently by Executive Orders 14005, 14017, and 14081 (86 FR 7475, 11849, and 25711, respectively). In June 2021, as tasked in Executive Order 14017 on “America’s Supply Chains,” the Department of Health and Human Services released a review of pharmaceuticals and active pharmaceutical ingredients, analyzing risks in these supply chains and recommending solutions to increase their reliability.⁶⁴⁸ In July 2022, as tasked in Executive Order 14001, the Biden–Harris Administration also released the *National Strategy for a Resilient Public Health Supply Chain*, which laid out a roadmap to support reliable

⁶⁴⁸ Department of Health and Human Services, *Review of Pharmaceuticals and Active Pharmaceutical Ingredients* (pp. 207–250), June 2021: <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>.

access to products for public health in the future, including through prevention and mitigation of medical product shortages.⁶⁴⁹

Over the last few years, shortages for critical medical products have persisted and continued to increase.⁶⁵⁰ For pharmaceuticals, even before the COVID-19 pandemic, nearly two-thirds of hospitals reported more than 20 drug shortages at any one time – from antibiotics used to treat severe bacterial infections to crash cart drugs necessary to stabilize and resuscitate critically ill adults.⁶⁵¹ The frequency and severity of these supply disruptions has only been exacerbated over the last few years.

Recent data supports that hospitals are estimated to spend more than 8.6 million personnel hours and \$360 million per year to address drug shortages, which will likely further result in treatment delays and denials, changes in treatment regimens, medication errors,^{652, 653, 654} as well as higher rates of hospital-acquired infections and in-hospital mortality.^{655, 656} The additional time, labor, and resources required to navigate drug shortages also increase health care costs.⁶⁵⁷

Hospitals' procurement preferences directly influence upstream intermediary and manufacturer behavior and can be leveraged to help foster a more resilient supply chain for

⁶⁴⁹ Department of Health and Human Services, *National Strategy for a Resilient Public Health Supply Chain*, July 2021: <https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf>

⁶⁵⁰ Senate Committee on Homeland Security & Governmental Affairs, *Short Supply: The Health and National Security Risks of Drug Shortages*, March 2023: <https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf>

⁶⁵¹ Vizient, *Drug Shortages and Labor Costs: Measuring the Hidden Costs of Drug Shortages on U.S. Hospitals*, June 2019: <https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129>

⁶⁵² American Journal of Health System Pharmacology, *National Survey on the Effect of Oncology Drug Shortages on Cancer Care*, 2013: <https://pubmed.ncbi.nlm.nih.gov/23515514/>

⁶⁵³ JCO Oncology Practice, *National Survey on the Effect of Oncology Drug Shortages in Clinical Practice*, 2022: <https://pubmed.ncbi.nlm.nih.gov/35544740/>

⁶⁵⁴ Journal of the American Medical Association, *Association between U.S. Norepinephrine Shortage and Mortality Among Patients with Septic Shock*, 2017: <https://pubmed.ncbi.nlm.nih.gov/28322415/>

⁶⁵⁵ Clinical Infectious Diseases, *The Effect of a Piperacillin/Tazobactam Shortage on Antimicrobial Prescribing and Clostridium difficile Risk in 88 US Medical Centers*, 2017: <https://pubmed.ncbi.nlm.nih.gov/28444166/>

⁶⁵⁶ New England Journal of Medicine, *The Impact of Drug Shortages on Children with Cancer: The Example of Mechlorethamine*, 2012: <https://pubmed.ncbi.nlm.nih.gov/23268661/>

⁶⁵⁷ Department of Health and Human Services, *ASPE Report to Congress: Impact of Drug Shortages on Consumer Costs*, May 2023: <https://aspe.hhs.gov/reports/drug-shortages-impacts-consumer-costs>

lifesaving drugs and biologicals. With respect to shortages, supply chain resiliency includes having sufficient inventory that can be leveraged in the event of a supply disruption or demand increase – as opposed to “just-in-time” inventory-management efficiency that can leave supply chains vulnerable to shortage.^{658 659} This concept is especially true for essential medicines, which generally comprise of products that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms. A resilient supply can also include essential medicines from multiple manufacturers, including the availability of domestic pharmaceutical manufacturing capacity, to diversify the sourcing of essential medicines. We believe it is necessary to support practices that can curtail pharmaceutical shortages of essential medicines and promote resiliency in order to safeguard and improve the care hospitals are able to provide to beneficiaries.

We are seeking comment on, and may consider finalizing based on the review of comments received, as early as for cost reporting periods beginning on or after January 1, 2024, separate payment under the IPPS, for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. This separate payment would not be budget neutral. An adjustment under the OPSS could be considered for future years.

B. Establishing and Maintaining a Buffer Stock of Essential Medicines

The report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*, as developed by the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) prioritized 86 essential medicines (hereinafter referred to as, the “essential medicines”) identified as either critical for minimum patient care in acute settings or important for acute care or important for acute care of respiratory

⁶⁵⁸ Department of Health and Human Services, Review of Pharmaceuticals and Active Pharmaceutical Ingredients (pp. 207–250), June 2021: <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>.

⁶⁵⁹ Department of Health and Human Services, National Strategy for a Resilient Public Health Supply Chain, July 2021: <https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf>

illnesses/conditions, with no comparable alternative available.^{660 661} When hospitals have insufficient supply of these essential medicines, such as during a shortage, care for Medicare beneficiaries can be negatively impacted. To mitigate negative care outcomes in the event of insufficient supply, hospitals can adopt procurement strategies that foster a consistent, safe, stable, and resilient supply of these essential medicines. Such procurement strategies can include provisions to maintain or otherwise provide for extra stock of product (for example, either to maintain or to hold directly at the hospital, arrange contractually for a distributor to hold, or arrange contractually with a wholesaler for a manufacturer to hold), which can act as a buffer in the event of an unexpected increase in product use or disruption to supply. We expect that the resources required to establish and maintain access to a minimal “buffer stock” of essential medicines, such as a 3-month supply, will generally be greater than the resources required to establish and maintain access to these medicines through alternative means that are more susceptible to supply chain disruptions (for example, through so-called “just-in-time” inventory practices). Given these additional resource costs, we are considering separate payment under the IPPS for 2024, and the OPPS for future years, for the costs of establishing and maintaining access to a buffer stock of essential medicines.

For the IPPS for 2024 and subsequent years, the Secretary could potentially make this separate payment for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines under section 1886(d)(5)(I) of the Act, which authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate.

For the OPPS, for future years, the Secretary could potentially make this separate payment for the additional resource costs under section 1833(t)(2)(E) of the Act. Section 1833(t)(2)(E) of the Act provides that the Secretary shall establish, in a budget neutral manner,

⁶⁶⁰ https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf

⁶⁶¹ <https://aspr.hhs.gov/newsroom/Pages/Essential-Medicines-May22.aspx>

other adjustments (in addition to outlier and transitional pass-through payments and payments for non-opioid treatments for pain relief) necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.

Additionally, sustaining sources of domestically sourced medical supplies can also help support continued availability in the event of public health emergencies and other disruptions.⁶⁶²

⁶⁶³ This concept is consistent with our current policy for domestic National Institute for Occupational Safety and Health (NIOSH) approved surgical N95 respirators (87 FR 72037). Hospitals, as major purchasers and users in the U.S. of essential medicines, can support the existence of domestic sources by sourcing domestically made essential medicines. However, we expect that domestically manufactured essential medicines may be more expensive than those sourced from some other countries that may have lower manufacturing costs.⁶⁶⁴ Given these additional resource costs, we took into account in developing the potential payment outlined in the previous paragraph (for the costs of establishing and maintaining access to a buffer stock of essential medicines) the increased costs to establish and maintain access to a buffer stock of domestically manufactured essential medicines.

In addition to essential medicines, we may consider expanding a potential Medicare payment policy in future years to include critical medical devices once the FDA's Critical Medical Device List (CMDL) becomes available. In accordance with implementation of Executive Order 14001 on a Sustainable Public Health Supply Chain, the FDA is leading an effort to develop this list of recommended medical devices that are critical to have on hand, at all

⁶⁶² Department of Health and Human Services, *Review of Pharmaceuticals and Active Pharmaceutical Ingredients* (pp. 207–250), June 2021: <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>

⁶⁶³ Department of Health and Human Services, *National Strategy for a Resilient Public Health Supply Chain*, July 2021: <https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf>

⁶⁶⁴ Department of Health and Human Services, *Review of Pharmaceuticals and Active Pharmaceutical Ingredients* (pp. 207–250), June 2021: <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>

times for patients, healthcare workers, and the U.S. public because of their clinical need. The list is expected to be available by the end of 2023.

C. Potential Separate Payment Under IPPS and OPSS for Establishing and Maintaining Access to a Buffer Stock of Essential Medicines

Currently, payment for the resources required to establish and maintain access to medically reasonable and necessary drugs and biologicals is generally part of the IPPS or OPSS payment. As noted in section XXII.B, we expect that the resources required to establish and maintain access to a buffer stock of essential medicines will generally be greater than the resources required to establish and maintain access to these medicines without such a buffer stock. Additionally, the resources required to establish and maintain access to a buffer stock of domestically manufactured essential medicines may generally be greater than the resources required to establish and maintain access to a buffer stock of these medicines from non-domestic sources. Given the policy goals discussed in sections XXII.A and XXII.B of this proposed rule, we believe it may be appropriate to pay separately for the additional resource costs associated with establishing and maintaining access, including through contractual arrangement, to a buffer stock of essential medicines. These potential separate payments would be in addition to payment for the essential medicines themselves, whether that payment is bundled with other items or services or the essential medicines are separately paid, and would help account for the additional resource costs associated with establishing and maintaining access, including through contractual arrangements, to a buffer stock of these essential medicines.

It is challenging to quantify these additional resource costs precisely based on currently available information. As noted in section XXII.B, hospitals could establish and maintain access to a buffer stock in a variety of ways, including, but not limited to, through contractual arrangements with distributors and wholesalers. Given the current challenge in precisely quantifying these additional resource costs, CMS could initially base the IPPS payment on the IPPS shares of the additional reasonable costs of a hospital to establish and maintain

access to its buffer stock. The use of IPPS shares in this payment adjustment would be consistent with the use of these shares for the payment adjustment for domestic NIOSH approved surgical N95 respirators (87 FR 72037). These costs, which could include costs to hold essential medicines directly at the hospital, arrange contractually for a distributor to hold, or arrange contractually with a wholesaler for a manufacturer to hold, could be reported to CMS by a hospital in aggregate on its cost report. These costs would not include the costs of the essential medicine itself. This reported information, along with existing information already collected on the cost report, could be used to calculate a Medicare payment for the estimated cost, specific to each hospital, incurred to establish and maintain access to its buffer stock of these essential medicines. (As noted in section XXII.B, essential medicines refers to the 86 essential medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*.) In accordance with the principles of reasonable cost as set forth in section 1861(v)(1)(A) of the Act and in 42 CFR 413.1 and 413.9, Medicare could make a lump-sum payment for Medicare's share of these additional inpatient costs at cost report settlement.

These payments for the IPPS shares of establishing and maintaining access to a buffer stock of essential medicines could be provided biweekly as interim lump-sum payments to the hospital and would be reconciled at cost report settlement. A provider could make a request for these biweekly interim lump sum payments for an applicable cost reporting period, as provided under 42 CFR 413.64 (Payments to providers: Specific rules) and 42 CFR 412.116(c) (Special interim payments for certain costs). These payment amounts would be determined by the Medicare Administrative Contractor (MAC), consistent with existing policies and procedures. In general, interim payments are determined by estimating the reimbursable amount for the year using Medicare principles of cost reimbursement and dividing it into 26 equal biweekly payments. The estimated amount is based on the most current cost data available, which will be reviewed and, if necessary, adjusted at least twice during the reporting period. (See CMS Pub 15-1 2405.2 for additional information.) The MACs could determine the interim lump-sum

payments based on the data the hospital may provide that reflects the information that could be included on a supplemental cost reporting form. CMS will separately seek comment through the PRA process on a potential supplemental cost reporting form that could be used for this purpose. In future years, the MACs could determine the interim biweekly lump-sum payments utilizing information from the prior year's cost report, which may be adjusted based on the most current data available. This would be consistent with the current policies for medical education costs, and bad debts for uncollectible deductibles and coinsurance paid on interim biweekly basis as noted in CMS Pub 15-1 2405.2. It is also consistent with the payment adjustment for domestically sourced NIOSH approved surgical N95 respirators (87 FR 72037).

We are seeking comment on, and may consider finalizing based on the review of comments received, as early as for cost reporting periods beginning on or after January 1, 2024, separate payment under IPPS for the IPPS share of the reasonable costs of establishing and maintaining access to a 3-month buffer stock of one or more essential medicine(s). Essential medicines for the potential IPPS separate payment would be the 86 essential medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*. An adjustment under OPSS could be considered for future years. We seek comment on all aspects of this potential payment policy.

If CMS were to finalize based on the review of comments received, as early as for cost reporting periods beginning on or after January 1, 2024, separate payment under IPPS, we are considering amending our regulations at 42 CFR 412.1 by revising paragraph (a)(1)(iv) to read as follows: “(iv) Additional payments are made for outlier cases, bad debts, indirect medical education costs, for serving a disproportionate share of low-income patients, for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators, and for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines.”

We are also considering amending our regulations, and seek comment on these potential revisions, at 42 CFR 412.2 by adding paragraph (f)(11) to read as follows: “(11) A payment adjustment for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines as specified in § 412.113.”

We are also considering amending our regulations, and seek comment on these potential revisions, at § 412.113 by adding paragraph (g) to read as follows:

“(g) Additional resource costs of establishing and maintaining access to a buffer stock of essential medicines: (1) Essential medicines are the 86 medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* developed by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and published in May of 2022. A buffer stock of essential medicines for a hospital is a 3-month supply of one or more essential medicines; (2) The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines for a hospital are the additional resource costs incurred by the hospital to directly hold a buffer stock of essential medicines for its patients, or arrange contractually for such a buffer stock to be held for use by the hospital for its patients. The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines does not include the resource costs of the essential medicines themselves; (3) For cost reporting periods beginning on or after January 1, 2024, a payment adjustment to a hospital for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines is made as described in paragraph (g)(4) of this section; and (4) The payment adjustment is based on the reasonable cost incurred by the hospital for establishing and maintaining access to a buffer stock of essential medicines during the cost reporting period.”

D. Comment Solicitation on Additional Considerations

In addition to the potential payment policy as described in section XXII.C of this proposed rule, we also take particular interest, and seek comment on, the following. We note that

we may consider amending, and finalizing, the potential policy under XXII.C of this proposed rule based on a review of the comments received on the following questions:

- How effective would this potential payment policy be at improving the resiliency of the supply chain for essential medicines and the care delivery system? How could it be improved, either initially or through future rulemaking? Are there suggested alternative pathways for establishing similar separate payments?

- The potential payment policy specified under section XXII.C of this proposed rule would account for any increased resource costs for a hospital to establish and maintain access to a buffer stock of domestically manufactured essential medicines compared to non-domestically manufactured ones. Even though the costs of essential medicines themselves is not considered a resource cost of establishing and maintaining access to a buffer stock, it is possible that there are additional resource costs, perhaps contractual, to establishing and maintaining access to a buffer stock of more expensive domestically manufactured essential medicines compared to non-domestically manufactured ones. What type of additional hospital resource costs are involved in establishing and maintaining access to domestically manufactured essential medicines compared to non-domestically manufactured ones? Are there alternative approaches that might better recognize the increased resource costs for a hospital to establish and maintain access to a buffer stock of domestically manufactured essential medicines? How might any suggested alternatives be better at improving the resiliency of the supply chain for essential medicines and the care delivery system? What standard should be used to define domestic manufacturing for suggested alternatives? Specifically, would the international trade rule of “substantial transformation” be appropriate to define domestic manufacturing, if that product was substantially transformed in the U.S.? Would hospitals have sufficient access to that information when making procurement decisions or doing reporting to CMS?

- Are the 86 essential medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* the appropriate initial list of essential

medicines for this potential payment policy? How often should HHS consider updating the respective list used for establishing these potential additional payments? For example, HHS expects it may update the essential medicine list every two years. Should that be the frequency for purposes of administering these additional payments? Also, what additional criteria should be considered when determining whether the list should be updated?

- Should HHS consider expanding the list of essential medicines used in establishing these potential additional payments to include essential medicines used in the treatment of cancer?
- Is a 3-month supply the appropriate amount of supply for the buffer stock or should an alternative duration be used? We recognize that a 3-month supply may not be feasible in all circumstances, given various factors, including, but not limited to, the shelf life of certain essential medicines. What additional considerations, if any, are needed?
- In general, how much of a buffer stock of these essential medicines are hospitals currently maintaining across different hospital types and regions (whether directly, or contractually through distributors or other partners)? Are there unique circumstances for safety net hospitals that should be taken into consideration in any potential payment policy?
- What type of additional hospital resource costs are involved in establishing and maintaining access to a buffer stock of essential medicines? To what degree, and under what circumstances, might hospitals use contractual arrangements? What type of contractual arrangements might be used?
- What flexibilities should exist for implementing buffer stock practices?
- What immediate impacts on the supply of essential medicines could be expected upon implementation of this potential policy? What steps, if any, would need to be taken to mitigate risks of possible demand-driven shortages as a result of implementation of such a policy?
- While the availability of essential medicines is critical at all times, it is especially the case for emergencies. Should there be a separate payment adjustment to more acutely address

supply issues that emerge specific to the case of preparedness as a pandemic or other public health emergency emerges?

- How should such a policy be considered for essential medicines that are currently in shortage, and thus potentially not appropriate for arranging to have buffer stock? What steps, if any, would need to be taken if an eligible essential medicine enters shortage while such a policy is in place?

- Should critical medical devices be considered in future rulemaking for inclusion in a potential payment policy?

- ++ Which types of medical devices do hospitals currently maintain in a buffer stock?

- ++ Do single use devices (including consumables) or reusable devices pose a greater risk of supply chain impact leading to shortages?

- ++ Are hospitals more likely to have a buffer stock of devices that are single use (including consumables) or reusable?

- ++ What levels of buffer stock do hospitals currently keep on hand for devices they consider critical?

- ++ Is the quantity of buffer stock dependent on type of medical device (single use vs. reusable)?

- ++ Generally, how many days of buffer stock is typically carried by device type?

- ++ What other factors are considered when determining which types of medical devices to maintain in a buffer stock?

- + What are the prevailing buffer stock strategies employed across device types (e.g., just in time, consignment, single warehousing, warehouse to warehouse)?

XXIII. Files Available to the Public via the Internet

The Addenda to the OPPTS/ASC proposed rules and final rules with comment period are published and available via the Internet on the CMS website. In the CY 2019 OPPTS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPTS

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 2024 and subsequent years, we propose to retain these columns that are updated to reflect the drug codes for which pass-through payment is expiring in the applicable year.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72250) for CY 2023, we changed the format of the OPPS Addenda A, B, and C by adding a column titled “Drug Pass-Through Expiration during Calendar Year” to include devices, so that the column reads: “Drug and Device Pass-Through Expiration during Calendar Year” where we flagged, through the use of an asterisk, each drug and device for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2024 and subsequent years, we propose to retain these columns that are updated to reflect the devices for which pass-through payment is expiring in the applicable year.

In addition, we propose to delete the column titled “Copayment Capped at the Inpatient Deductible” and instead to add 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 propose to add another column for notes. We propose that the “Note” column would contain multiple messages including, but not limited to, inflation-adjusted copayment of a Part B

rebateable drug, the copayment for a code capped at the inpatient deductible, or 8 percent of the reference product add-on applied for a biosimilar.

To view the Addenda to this proposed rule pertaining to proposed CY 2024 payments under the OPSS, we refer readers to the CMS website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html); select

“CMS-1786-P” from the list of regulations. All OPSS Addenda to this proposed rule are contained in the zipped folder titled “2024 NPRM OPSS Addenda” in the related links section at the bottom of the page. To view the Addenda to the CY 2024 OPSS/ASC proposed rule

pertaining to CY 2024 payments under the ASC payment system, we refer readers to the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/ASCPayment/ASC-Regulations-and-Notices.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html); select “CMS-1786-P” from the list of regulations. The ASC Addenda to the CY 2024 OPSS/ASC proposed rule are contained in a zipped folder titled “2024 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):

A. ICRs Related to Proposed Intensive Outpatient Physician Certification Requirements

As discussed in section VIII.B.3 of this proposed rule, we propose to codify the content of certification and plan of treatment requirements for intensive outpatient services at § 424.24(d). Specifically, we propose to mirror the PHP content of certification and plan of care treatment requirements at § 424.24(e), with the following exceptions: require the content of certification to include documentation that the individual requires such services for a minimum of 9 hours per week (with no requirement for a need for inpatient psychiatric care if the IOP services were not provided).

The proposed ICRs at § 424.24(d) are subject to the Act. However, we believe the burden associated with these ICRs are exempt, as defined by 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities. We believe the record keeping requirements described in section VIII.B.3 of this proposed rule are a usual and customary part of physicians' activities in developing the plan of treatment for existing patients in intensive outpatient programs, and that the requirements are similar to existing ICRs under Medicare for partial hospitalization patients.

B. ICRs Related to the Hospital OQR Program

1. Background

The Hospital Outpatient Quality Reporting (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 2011 through CY 2023

OPPS/ASC final rules (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through 67015; 80 FR 70580 through 70582; 81 FR 79862 through 79863; 82 FR 59476 through 59479; 83 FR 59155 through 59156; 84 FR 61468 through 61469; 85 FR 86266 through 86267; 86 FR 63961 through 63968, and 87 FR 72250 through 72252, respectively) for detailed discussions of the previously finalized Hospital OQR Program ICRs. The ICRs associated with the Hospital OQR Program are currently approved under OMB control number 0938-1109, which expires on February 28, 2025. In the CY 2023 OPPS/ASC final rule, our burden estimates were based on an assumption that approximately 3,350 hospitals would report data to the Hospital OQR Program. For this proposed rule, based on data from the CY 2023 Hospital OQR Program payment determination, which supports this assumption, we will continue to estimate that 3,350 hospitals will report data to the Hospital OQR Program, unless otherwise noted. While the exact number of hospitals required to submit data annually may vary, we use this estimate to be consistent with previous rules and for ease of calculation across reporting periods.

In the CY 2018 OPPS/ASC final rule (82 FR 52617), we finalized a policy to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the Hospital OQR Program. We note that since the CY 2023 OPPS/ASC final rule, BLS removed this labor category and added a new labor category titled “Medical Records Specialists.” While the most recent data from the BLS reflects a median hourly wage of \$24.56 per hour for all medical records specialists, \$26.06 is the hourly mean wage for “general medical and surgical hospitals,”⁶⁶⁵ which is an industry within medical records specialists. We believe the industry of “general medical and surgical hospitals” is more specific to our settings for use in our calculations than other industries that fall under medical records specialists, such as “office of

⁶⁶⁵ U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on March 6, 2023. Available at: <https://www.bls.gov/oes/current/oes292072.htm>.

physicians” or “nursing care facilities.” We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52617). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($\$26.06 \times 2 = \52.12) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

In section XIV.B.2 of this proposed rule, we propose to modify three previously adopted measures: (1) the COVID–19 Vaccination Coverage Among Healthcare Personnel measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) the Cataracts: Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery measure survey instrument usage, beginning with the voluntary CY 2024 reporting period; and (3) the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination. We propose to adopt three new measures: (1) 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, beginning with the voluntary CYs 2025 and 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination; (2) the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient) electronic clinical quality measure (eCQM), beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) readoption of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures measure with modification, with voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028

payment determination. We are also proposing to remove the Left Without Being Seen measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

2. Information Collection Burden for the Proposal to Modify the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2022 OPPTS/ASC final rule, we finalized adoption of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure for the Hospital OQR Program (87 FR 71748 through 72310). In section XIV.B.2.a of this proposed rule, we propose to modify the COVID-19 Vaccination Coverage Among HCP measure to utilize the term “up to date” in the HCP vaccination definition and update the numerator to specify the timeframes within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses, beginning with the CY 2024 reporting period/CY 2026 payment determination for the Hospital OQR Program. We previously discussed information collection burden associated with this measure in the CY 2022 OPPTS/ASC final rule (86 FR 63962).

We do not believe that the use of the term “up to date” or the update to the numerator will impact information collection or reporting burden because the modification changes neither the amount of data being submitted to CMS nor the frequency of data submission. Additionally, because we are not proposing any updates to the form, manner, and timing of data submission for this measure, we do not anticipate any increase in burden associated with this proposal. The modified COVID–19 Vaccination Coverage Among HCP measure would continue to be calculated using data submitted to the CDC under a separate OMB control number (0920-1317; expiration date January 31, 2024). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (enacted on November 14, 1986) (NCVIA) (Pub. L. 99-660).

3. Information Collection Burden for the Proposal to Modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Survey Instrument Use Beginning with the CY 2024 Reporting Period

In the CY 2014 OPPI/ASC final rule (78 FR 75102 through 75104), we finalized the adoption of the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery beginning with the CY 2016 payment determination; this measure currently is voluntary. In section XIV.B.2.b of this proposed rule, we propose to limit the survey instruments that can be used to administer this measure to three assessment tools: NEI VFQ-25, VF-14, and VF-8R, beginning with the CY 2024 reporting period.

Because the three assessment tools being proposed are currently allowable for collecting data for this measure, we do not believe limiting use to these three surveys would result in a change in burden. As a result, we are not proposing any changes in burden per response associated with this proposal. Additionally, as currently stated in the Hospital OQR Program Specifications Manual, the maximum annual sample case size for chart abstraction for this measure is 63 cases for hospitals with an outpatient population size of between 0 and 900 and 96 cases for hospitals with an outpatient population size of greater than 900.⁶⁶⁶ We are not proposing an increase in the required sample size for chart abstraction; therefore we do not believe there is any increase in burden associated with this proposal.

4. Information Collection Burden for the Proposal to Modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2014 OPPI/ASC final rule, we finalized the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure (78 FR 75101 through 75102). In section XIV.B.2.c of this proposed rule, we propose to amend the measure denominator language by removing the phrase "aged 50 years" and adding in its place the phrase "aged 45 years."

⁶⁶⁶ https://qualitynet.cms.gov/files/63c8361058e56000179b310e?filename=OQR_v16.0a_SpecsManual_011723.pdf

As currently stated in the Hospital OQR Program Specifications Manual, the maximum annual sample case size for chart abstraction for this measure is 63 cases for hospitals with an outpatient population size of between 0 and 900 and 96 cases for hospitals with an outpatient population size of greater than 900. We are not proposing an increase in the required sample size for chart abstraction; therefore, we do not believe there is any increase in burden associated with this proposal.

5. Information Collection Burden for the Proposal to Adopt the 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 Beginning with Voluntary CYs 2025 and 2026 Reporting Periods Followed by Mandatory Reporting Beginning with the CY 2027 Reporting Period/CY 2030 Payment Determination

In section XIV.B.3.b of this proposed rule, we propose to adopt the THA/TKA PRO-PM beginning with voluntary CYs 2025 and 2026 reporting periods, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination. This measure was previously adopted for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule with an estimated burden of 7.25 minutes (0.120833 hours) per patient to complete both the pre-operative and post-operative surveys and 10 minutes (0.167 hours) per hospital per response to collect and submit the measure data via the Hospital Quality Reporting (HQR) system (87 FR 49386 through 49387). We believe the estimated burden for both patient surveys and data submission would be the same for the Hospital OQR Program.

The THA/TKA PRO-PM uses four sources of data for the calculation of the measure: (1) patient-reported outcome (PRO) data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. We estimate no additional burden associated with claims data, Medicare enrollment and beneficiary data, and U.S. Census Bureau survey data as these data are already collected via other mechanisms such as Medicare enrollment forms, CMS Form 1500, and U.S. Census Informational Questionnaires. While we

are not proposing to require how hospitals collect PRO data for this measure, hospitals collecting PRO data would have multiple options for when and how they would collect these data so they could best determine the mode and timing of collection that works best for their patient population.

The possible patient touchpoints for pre-operative PRO data collection include the doctor's office, pre-surgical steps such as education classes, or medical evaluations that can occur in an office or at the hospital. The modes of PRO data collection could include completion of the pre-operative surveys using electronic devices (such as an iPad or tablet), pen and paper, mail, telephone, or through a patient portal. Post-operative PRO data collection modes are similar to pre-operative modes. The possible patient touchpoints for post-operative data collection can occur before the follow-up appointment, at the doctor's office, or after the follow-up appointment. The potential modes of PRO data collection for post-operative data are the same as for pre-operative data. If the patient does not or cannot attend a follow-up appointment, the modes of collection could include completion of the post-operative survey using email, mail, telephone, or through a patient portal. Similar to other surveys, like the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey, we believe the use of multiple modes would maximize response rates as it allows for different patient preferences.

For the THA/TKA PRO-PM data, hospitals would be able to submit data during two voluntary periods. The first voluntary reporting period would begin in CY 2025 for eligible procedures occurring between January 1, 2025 through December 31, 2025, and the second voluntary reporting period would begin with CY 2026 for eligible procedures occurring between January 1, 2026 through December 31, 2026. Voluntary reporting would be followed by mandatory reporting for eligible elective procedures beginning with the CY 2027 reporting period (occurring January 1, 2027 through December 31, 2027), impacting the CY 2030 payment

determination. Hospitals would need to submit data twice (pre-operative data and post-operative data).

For the purposes of calculating burden, similar to assumptions used for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386 through 49387), we estimate that during the voluntary periods, 50 percent of hospitals that perform at least one THA/TKA procedure would submit data for 50 percent of THA/TKA patients. For purposes of calculating burden, we estimate that, during the mandatory period, hospitals would submit for 100 percent of patients. While we propose to require hospitals to submit, at minimum, 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data, we are conservative in our estimate for the mandatory period in case hospitals exceed this threshold.

To estimate the cost burden for patients completing the surveys for this proposed measure, we refer to the “Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,” as it identifies the approach for valuing time when individuals undertake activities on their own time.⁶⁶⁷ Therefore, we estimate that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of \$20.71/hour. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of \$998, divided by 40 hours to calculate an hourly pre-tax wage rate of \$24.95/hour. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of \$20.71/hour. 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.

⁶⁶⁷ <https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework>

For burden estimating purposes for this proposed measure, we assume that most hospitals would likely undertake PRO data collection through a screening tool incorporated into their electronic health record (EHR) or other patient intake process. We estimate that approximately 526,793 THA/TKA procedures occur in the outpatient setting each year, and that many patients could complete both the pre-operative and post-operative questionnaires. However, from our experience with using this measure in the Comprehensive Joint Replacement model, we are also aware that not all patients who complete the pre-operative questionnaire would complete the post-operative questionnaire. For CY 2025 and CY 2026 reporting periods, we assume 131,698 patients would complete the survey ($526,793 \text{ patients} \times 0.50 \times 0.50 \text{ of hospitals}$) for a total of 15,914 hours annually ($131,698 \text{ respondents} \times 0.120833 \text{ hours}$) at a cost of \$329,579 ($15,914 \text{ hours} \times \20.71) across all hospitals. Beginning with mandatory reporting in the CY 2027 reporting period, we estimate a total of 63,654 hours ($526,793 \text{ patients} \times 0.120833 \text{ hours}$) at a cost of \$1,318,274 ($63,654 \text{ hours} \times \20.71) across all hospitals.

Regarding hospitals' burden related to submitting data for this proposed measure, which would be reported via the HQR System, we estimate a burden of 10 minutes per response. Hospitals would submit data associated with pre-operative surveys by March 31 of the CY following the CY in which the eligible procedures took place and would submit data associated with post-operative surveys by March 31 of the CY following the CY in which pre-operative data was submitted. Therefore, for the initial voluntary reporting period for eligible procedures occurring in CY 2025, pre-operative survey data submission would occur in the first quarter of the CY 2026 reporting period and post-operative survey data submission would occur in the first quarter of the CY 2027 reporting period. For each reporting period, we estimate that each hospital would spend 20 minutes (0.33 hours) annually ($10 \text{ minutes} \times 2 \text{ surveys}$) to collect and submit the data. For the voluntary CY 2026 reporting period, we estimate a burden for all participating hospitals of 279.2 hours ($0.167 \text{ hours} \times 3,350 \text{ hospitals} \times 50 \text{ percent}$) at a cost of \$14,552 ($279.2 \text{ hours} \times \52.12). For the voluntary CY 2027 reporting period, we estimate a

burden for all participating hospitals of 558.3 hours ($0.33 \text{ hours} \times 3,350 \text{ hospitals} \times 50 \text{ percent}$) at a cost of \$29,099 ($558.3 \text{ hours} \times \52.12). For the mandatory CY 2028 reporting period, we estimate a burden for all participating hospitals of 837.5 hours [$(0.167 \text{ hours} \times 3,350 \text{ hospitals} \times 50 \text{ percent}) + (0.167 \text{ hours} \times 3,350 \text{ hospitals})$] at a cost of \$43,651 ($837.5 \text{ hours} \times \52.12). For the mandatory CY 2029 reporting period and subsequent years, we estimate a total of 1,116.7 hours ($0.33 \text{ hours} \times 3,350 \text{ hospitals}$) at a cost of \$58,202 ($1,116.7 \text{ hours} \times \52.12).

With respect to any costs/burdens unrelated to data submission, we refer readers to section XXVI.C.3.b “Regulatory Impact Analysis” of this proposed rule.

6. Information Collection Burden for the Proposal to Adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient) eCQM, Beginning with the Voluntary CY 2025 Reporting Period, followed by Mandatory Reporting Beginning with the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.3.c of this proposed rule, we propose to adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level – Outpatient) eCQM, beginning with the voluntary CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. For the CY 2025 voluntary reporting period, hospitals would be able to voluntarily report the measure for one or more quarters during the year. For subsequent years, as described in section XIV.E.6.b of this proposed rule, we propose to gradually increase the number of quarters of data hospitals would be required to report on the measure starting with two self-selected quarters for the CY 2026 reporting period/CY 2028 payment determination, and all four quarters for the CY 2027 reporting period/CY 2029 payment determination.

For the voluntary reporting period in CY 2025, we estimate 20 percent of hospitals would voluntarily report at least one quarter of data for the measure with 100 percent of hospitals reporting the measure as proposed to be required in subsequent years. Similar to the ST-

elevation myocardial infarction (STEMI) eCQM for which adoption was finalized in the CY 2022 OPPTS/ASC final rule for the Hospital OQR Program, we assume a Medical Records Specialist would require 10 minutes to submit the data required per quarter for each hospital (86 FR 63962 through 63963). For the CY 2025 voluntary reporting period, we estimate an annual burden for all participating hospitals of 111.7 hours (3,350 hospitals \times 20 percent \times 0.1667 hours \times 1 quarter) at a cost of \$5,822 (111.7 hours \times \$52.12). For the CY 2026 reporting period/CY 2028 payment determination, we estimate the annual burden for all participating hospitals to be 1,116.7 hours (3,350 hospitals \times .1667 hours \times 2 quarters) at a cost of \$58,202 (1,116.7 hours \times \$52.12). For the CY 2027 reporting period/CY 2029 payment determination, we estimate the annual burden for all participating hospitals to be 2,233.3 hours (3,350 hospitals \times .1667 hours \times 4 quarters) at a cost of \$116,400 (2,233.3 hours \times \$52.12).

7. Information Collection Burden for the Proposal to Re-adopt with Modification the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures Measure, Beginning with the Voluntary CY 2025 Reporting Period Followed by Mandatory Reporting Beginning with the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.3.a of this proposed rule, we propose to re-adopt with modification the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures measure, beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. This measure was previously finalized in the CY 2012 OPPTS/ASC final rule with the assumption that, because hospitals must determine their populations for data reporting purposes - and most hospitals are voluntarily reporting population and sampling data for Hospital OQR Program purposes - the only additional burden would be the reporting of the data using a web-based tool (now the HQR system) (76 FR 74552 through 74553). This assumption continues to be applicable; therefore, we estimate the burden to be consistent with both the CY 2012 OPPTS/ASC final rule when the measure was initially adopted (76 FR 74552) and with the CY 2018 OPPTS/ASC final rule when the measure

was previously removed (82 FR 52618). We estimate that each participating hospital would spend 10 minutes per year to collect and submit the data for this measure. For the voluntary CY 2025 reporting period, we assume 20 percent of hospitals will report data, resulting in an annual burden of 111.7 hours (3,350 hospitals x 20 percent x 0.167 hours) at a cost of \$5,822 (111.7 hours x \$52.12). For mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, we estimate an annual burden of 558.3 hours (3,350 hospitals x 0.167 hours) at a cost of \$29,099 (558.3 hours x \$52.12).

8. Information Collection Burden for the Proposal to Remove the Left Without Being Seen Measure Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

In section XIV.B.1.a of this proposed rule, we proposed to remove the Left Without Being Seen measure beginning with the CY 2024 reporting period/CY 2026 payment determination. Under OMB control number 0938-1109 (expiration date February 28, 2025), the currently approved burden for this measure is estimated to be 10 minutes (0.1667 hours) per hospital to report measure data via a web-based tool located on a CMS website.⁶⁶⁸ In addition, as stated under OMB control number 0938-1109, there is no additional burden for abstraction of chart data associated with this measure. Therefore, we estimate the decrease in burden associated with the removal of this measure to be 558.3 hours (0.1667 hours x 3,350 hospitals) at a cost of \$29,100 (558.3 hours x \$52.12/hour).

9. Summary of Information Collection Burden Estimates for the Hospital OQR Program

In summary, under OMB control number 0938-1109 (expiration date February 28, 2025), we estimate that the proposals in this proposed rule would result in an increase of 67,004 hours at a cost of \$1,492,875 for 3,350 OPSS hospitals across a 6-year period from the CY 2024 reporting period/CY 2026 payment determination through the CY 2029 reporting period/CY 2030 payment determination. The following Tables 85 through 90 summarize the total burden

⁶⁶⁸ CY 2023 Final Rule Hospital OQR Program “Supporting Statement-A”. Available at: <https://www.reginfo.gov/public/do/DownloadDocument?objectID=129107500>.

changes for each respective CY payment determination compared to our currently approved information collection burden estimates (the table for the CY 2030 payment determination reflects the cumulative burden changes). We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109.

TABLE 85: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD/CY 2026 PAYMENT DETERMINATION

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2026 Payment Determination								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Proposed annual burden (hours) across OPPS hospitals	Previously finalized annual burden (hours) across OPPS hospitals	Net difference in annual burden hours
Remove Left Without Being Seen measure	-10	1	3,350	1	0.167	0	558.3	-558.3
Total Change in Information Collection Burden Hours: -558.3								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-558.3) = -\$29,100								

TABLE 86: SUMMARY OF 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 2027 Payment Determination								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Proposed annual burden (hours) across OPPS hospitals	Previously finalized annual burden (hours) across OPPS hospitals	Net difference in annual burden hours
Remove Left Without Being Seen measure	-10	1	3,350	1	0.167	0	558.3	-558.3
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	1,675	78.6	9.5	15,914	N/A	+15,914

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Payment Determination								
Add Excessive Radiation eCQM	10	1	670	1	0.167	111.7	N/A	+111.7
Readopt with modification Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	10	1	670	1	0.167	111.7	N/A	+111.7
Total Change in Information Collection Burden Hours: +15,579								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+15,579) = \$312,123								

**TABLE 87: SUMMARY OF 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 2028 Payment Determinations								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of OPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Proposed annual burden (hours) across OPPS hospitals	Previously finalized annual burden (hours) across OPPS hospitals	Net difference in annual burden hours
Remove Left Without Being Seen measure	-10	1	3,350	1	0.167	0	558.3	-558.3
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	1,675	78.6	9.5	15,914	N/A	+15,914
Add THA/TKA PRO-PM (Data Submission)	10	1	1,675	1	0.167	279.2	N/A	+279.2
Add Excessive Radiation eCQM	10	2	3,350	1	0.33	1,116.7	N/A	+1,116.7
Readopt with modification Hospital	10	1	3,350	1	0.167	558.3	N/A	+558.3

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2028 Payment Determinations								
Outpatient Volume on Selected Outpatient Surgical Procedures								
Total Change in Information Collection Burden Hours: +17,310								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+17,310) = \$402,332								

**TABLE 88: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION
COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029
PAYMENT DETERMINATION**

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2029 Payment Determination								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of OPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Proposed annual burden (hours) across OPPS hospitals	Previously finalized annual burden (hours) across OPPS hospitals	Net difference in annual burden hours
Remove Left Without Being Seen measure	-10	1	3,350	1	0.167	0	558.3	-558.3
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	3,350	157.3	19	63,654	N/A	+63,654
Add THA/TKA PRO-PM (Data Submission)	10	2	1,675	1	0.33	558.3	N/A	+558.3
Add Excessive Radiation eCQM	10	4	3,350	1	0.67	2,233.3	N/A	+2,233.3
Readopt with modification Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	10	1	3,350	1	0.167	558.3	N/A	+558.3
Total Change in Information Collection Burden Hours: +66,446								

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2029 Payment Determination
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+66,446) = \$1,463,772

**TABLE 89: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION
COLLECTION BURDEN CHANGE FOR THE CY 2028 REPORTING PERIOD/CY 2030
PAYMENT DETERMINATION**

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2030 Payment Determination								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of OPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Proposed annual burden (hours) across OPPS hospitals	Previously finalized annual burden (hours) across OPPS hospitals	Net difference in annual burden hours
Remove Left Without Being Seen measure	-10	1	3,350	1	0.167	0	558.3	-558.3
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	3,350	157.3	19	63,654	N/A	+63,654
Add THA/TKA PRO-PM (Voluntary Data Submission)	10	1	1,675	1	0.167	279.2	N/A	+279.2
Add THA/TKA PRO-PM (Mandatory Data Submission)	10	1	3,350	1	0.167	558.3	N/A	+558.3
Add Excessive Radiation eCQM	10	4	3,350	1	0.67	2,233.3	N/A	+2,233.3
Readopt with modification Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	10	1	3,350	1	0.167	558.3	N/A	+558.3
Total Change in Information Collection Burden Hours: +66,725								

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2030 Payment Determination
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+66,725) = \$1,478,324

**TABLE 90: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION
COLLECTION BURDEN CHANGE FOR THE CY 2029 REPORTING PERIOD/CY 2030
PAYMENT DETERMINATION**

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2030 Payment Determination								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of OPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Proposed annual burden (hours) across OPPS hospitals	Previously finalized annual burden (hours) across OPPS hospitals	Net difference in annual burden hours
Remove Left Without Being Seen measure	-10	1	3,350	1	0.167	0	558.3	-558.3
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	3,350	157.3	19	63,654	N/A	+63,654
Add THA/TKA PRO-PM (Data Submission)	10	2	3,350	1	0.33	1,116.7	N/A	+1,116.7
Add Excessive Radiation eCQM	10	4	3,350	1	0.67	2,233.3	N/A	+2,233.3
Readopt with modification Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	10	1	3,350	1	0.167	558.3	N/A	+558.3
	Total Change in Information Collection Burden Hours: +67,004							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+67,004) = \$1,492,875							

C. ICRs Related to the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPTS/ASC final rule (76 FR 74554), the FY 2013 IPPTS/LTCH PPS final rule (77 FR 53672), and the CY 2013 through CY 2023 OPPTS/ASC final rules (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; 81 FR 79863 through 79865; 82 FR 59479 through 59481; 83 FR 59156 through 59157; 84 FR 61469; 85 FR 86267; 86 FR 63968 through 63971; and 87 FR 72252 through 72253 respectively) for detailed discussions of the ASCQR Program ICRs we have previously finalized. The ICRs associated with the ASCQR Program for the CY 2014 through CY 2027 payment determinations are currently approved under OMB control number 0938-1270, which expires on August 31, 2025.

While the most recent data from the BLS reflects a median hourly wage of \$24.56 per hour for medical records specialists generally, \$26.06 is the hourly mean wage for medical records specialists in “general medical and surgical hospitals,”⁶⁶⁹ which we believe is more specific to our settings for use in our calculations than a position that may be found in other settings, such as “office of physicians” or “nursing care facilities.” We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (81 FR 79863 through 79864). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($\$26.06 \times 2 = \52.12) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

⁶⁶⁹ U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on March 6, 2023. Available at: <https://www.bls.gov/oes/current/oes292072.htm>.

Based on an analysis of the CY 2023 payment determination data, we found that, of the 5,697 ambulatory surgical centers (ASCs) that met eligibility requirements for the ASCQR Program, 5,181 ASCs received the full annual payment update (APU) because they complied with all applicable data reporting requirements for the ASCQR Program. In addition, 687 ASCs that were not required to participate in reporting did so, as well as 195 Hospitals Without Walls returned to active ASC billing, for a total of 6,063 participating facilities participating in the ASCQR Program. As noted in section XV.C.1 “Regulatory Impact Analysis” of this proposed rule, for the CY 2023 payment determination, all 5,181 ASCs that met eligibility requirements for the ASCQR Program received the APU including all facilities who were required, but exempted; 4,175 of these ASCs were required to participate without the public health emergency (PHE) exception (not applicable for current APU). On this basis, we estimate that 5,057 ASCs (4,175 + 687 + 195) will submit data for the ASCQR Program for the CY 2026 payment determination unless otherwise noted.

In section XV.B.4 of this proposed rule, we propose to modify three previously adopted measures: (1) the COVID–19 Vaccination Coverage Among Healthcare Personnel measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) the Cataracts: Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery measure survey instrument usage, beginning with the voluntary CY 2024 reporting period; and (3) Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination. We also propose to re-adopt with modification the ASC Facility Volume on Selected ASC Surgical Procedures measure, beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. Lastly, we propose to adopt the 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, beginning with

the voluntary CYs 2025 and 2026 reporting periods, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination.

2. Information Collection Burden for the Proposal to Modify the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2022 OPPTS/ASC proposed rule, we finalized adoption of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure for the ASCQR Program (86 FR 63875 through 63883). In section XV.B.4.a of this proposed rule, we propose to modify the COVID-19 Vaccination Coverage Among HCP measure to utilize the term “up to date” in the HCP vaccination definition and update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses, beginning with the CY 2024 reporting period/CY 2026 payment determination for the ASCQR Program. We previously discussed information collection burden associated with this measure in the CY 2022 OPPTS/ASC final rule (86 FR 63969).

We do not believe that the use of the term “up to date” or the update to the numerator will impact information collection or reporting burden because the modification changes neither the amount of data being submitted to CMS nor the frequency of data submission. Additionally, because we are not proposing any updates to the form, manner, and timing of data submission for this measure, we do not anticipate any increase in burden associated with this proposal. Furthermore, the modified COVID–19 Vaccination Coverage Among HCP measure would continue to be calculated using data submitted to the CDC under a separate OMB control number (0920-1317; expiration date January 31, 2024). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (enacted on November 14, 1986) (NCVIA).⁶⁷⁰

⁶⁷⁰ Pub. L. 99-660.

3. Information Collection Burden for the Proposal to Modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Survey Instrument Use Beginning with the CY 2024 Reporting Period

In the CY 2014 OPPI/ASC final rule with comment period (78 FR 75126 through 75127), we finalized the adoption of the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure beginning with the CY 2016 payment determination. In section XV.B.4.b of this proposed rule, we propose to limit the survey instruments that can be used to administer this measure to three assessment tools: NEI VFQ-25, VF-14, and VF-8R, beginning with the CY 2024 reporting period.

Because the three assessment tools being proposed are currently allowable for administering this measure, we do not believe limiting use to these three surveys would result in a change in burden. As a result, we are not proposing any changes in burden per response associated with this proposal. Additionally, as currently stated in the ASCQR Program Specifications Manual, the maximum annual sample case size for chart abstraction for this measure is 63 cases for ASCs with an outpatient population size of between 0 and 900 and 96 cases for ASCs with an outpatient population size of greater than 900.⁶⁷¹ We are not proposing an increase in the required sample size for chart abstraction; therefore we do not believe there is any increase in burden associated with this proposal.

4. Information Collection Burden for the Proposal to Modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure, Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2014 OPPI/ASC final rule, we finalized the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure (78 FR 75127 through 75128). In section XV.B.4.c of this proposed rule, we propose to amend the

⁶⁷¹ https://qualitynet.cms.gov/files/62900933404aa300169072f1?filename=12.0_ASC_Full_Specs_Mnl.pdf

measure denominator language by removing the removing the phrase “aged 50 years” and adding in its place the phrase “aged 45 years.”

As currently stated in the ASCQR Program Specifications Manual, the maximum annual sample case size for chart abstraction for this measure is 63 cases for ASCs with an outpatient population size of between 0 and 900 and 96 cases for ASCs with an outpatient population size of greater than 900. We are not proposing an increase in the required sample size for chart abstraction; therefore, we do not believe there is any increase in burden associated with this proposal.

5. Information Collection Burden for the Proposal to Readopt with Modification the ASC Facility Volume on Selected ASC Surgical Procedures Measure with the Voluntary CY 2025 Reporting Period followed by Mandatory Reporting Beginning with the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XV.B.5.a of this proposed rule, we propose to re-adopt with modification the ASC Facility Volume on Selected ASC Surgical Procedures measure with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. This measure was previously finalized in the CY 2012 OPPTS/ASC final rule with a burden estimate of 10 minutes per response (76 FR 74554). This measure was subsequently removed from the ASCQR Program in the CY 2017 OPPTS/ASC final rule with the same estimate of 10 minutes per response (82 FR 59479). Because this measure was originally adopted with the same burden estimate as the similar measure for the Hospital OQR Program, we continue to believe the burden per response is the same as the measure for the Hospital OQR Program, which we estimate to be 10 minutes per year in section XXIII.B.7 of this proposed rule. As a result, we estimate that each participating ASC would spend 10 minutes per year to collect and submit the data for this measure. For the voluntary CY 2025 reporting period, we assume 20 percent of ASCs will report data, resulting in an annual burden of 168.5 hours (5,057 ASCs x 20 percent x 0.167 hours) at a cost of \$8,782

(168.5 hours x \$52.12). For mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, we estimate an annual burden of 843 hours (5,057 ASCs × 0.167 hours) at a cost of \$43,937 (843 hours × \$52.12).

6. Information Collection Burden for the Proposal to Adopt the 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, Beginning with the Voluntary CY 2025 and CY 2026 Reporting Periods Followed by Mandatory Reporting Beginning with the CY 2027 Reporting period/CY 2030 Payment Determination

In section XV.B.5.b of this proposed rule, we propose to adopt the THA/TKA PRO-PM, beginning with the voluntary CY 2025 and CY 2026 reporting periods, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination. This measure was previously adopted for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule with an estimated burden of 7.25 minutes (0.120833 hours) per patient to complete both the pre-operative and post-operative surveys and 10 minutes (0.167 hours) per hospital per response to collect and submit the measure data via the HQR system (87 FR 49386 through 49387). We believe the estimated burden for both patient surveys and data submission would be the same for the ASCQR Program.

The THA/TKA PRO-PM uses four sources of data for the calculation of the measure: (1) patient-reported outcome (PRO) data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. We estimate no additional burden associated with claims data, Medicare enrollment and beneficiary data, and U.S. Census Bureau survey data as these data are already collected via other mechanisms such as Medicare enrollment forms, CMS Form 1500, and U.S. Census Informational Questionnaires. While we are not proposing to require how ASCs collect PRO data for this measure, ASCs collecting PRO data would have multiple options for when and how they would collect these PRO data so they

could best determine the mode and timing of collection that works best for their patient population.

The possible patient touchpoints for pre-operative PRO data collection include the doctor's office, pre-surgical steps such as education classes, or medical evaluations that could occur in an office or at the ASC. The modes of PRO data collection could include completion of the pre-operative surveys using electronic devices (such as an iPad or tablet), pen and paper, mail, telephone, or through a patient portal. Post-operative PRO data collection modes are similar to pre-operative modes. The possible patient touchpoints for post-operative data collection could occur before the follow-up appointment, at the doctor's office, or after the follow-up appointment. The potential modes of PRO data collection for post-operative data are the same as for pre-operative data. If the patient does not or cannot attend a follow-up appointment, the modes of collection could include completion of the post-operative survey using email, mail, telephone, or through a patient portal.

Similar to other surveys like the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey, we believe the use of multiple modes would maximize response rates as it allows for different patient preferences. For the THA/TKA PRO-PM data, ASCs would be able to submit data during two voluntary periods. The first voluntary reporting period would begin in CY 2025 for eligible procedures occurring between January 1, 2025 through December 31, 2025, and the second voluntary reporting period would begin with CY 2026 for eligible procedures occurring between January 1, 2026 through December 31, 2026. Voluntary reporting would be followed by mandatory reporting for eligible elective procedures beginning with the CY 2027 reporting period (occurring between January 1, 2027 through December 31, 2027), impacting the CY 2030 payment determination.

Whether participating in the voluntary reporting period or during subsequent mandatory reporting, ASCs would need to submit data twice (pre-operative data and post-operative data). For the purposes of calculating burden, we applied similar assumptions used for the Hospital

IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386 through 49387).

Specifically, we estimate that, during the voluntary periods, 50 percent of ASCs that perform at least one THA/TKA procedure would submit data and would do so for 50 percent of THA/TKA patients. For purposes of calculating burden for the mandatory period, we estimate that ASCs would submit for 100 percent of patients. While we propose to require ASCs to submit, at minimum, 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data, we are conservative in our estimate for the mandatory period in case ASCs exceed this threshold.

To estimate the cost burden for patients completing the surveys for this proposed measure, we believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of \$20.71/hour. We base this estimate on the 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.⁶⁷² To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of \$998, divided by 40 hours to calculate an hourly pre-tax wage rate of \$24.95/hour. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of \$20.71/hour. 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.

To estimate the burden of information collection for patients completing surveys for this proposed measure, we assume that most ASCs would likely undertake PRO data collection through a screening tool incorporated into their electronic health record (EHR) or other patient intake process. We estimate that approximately 42,706 THA/TKA procedures occur in an ASC

⁶⁷² <https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework>

each year, and that many patients could complete both the pre-operative and post-operative questionnaires. However, from our experience with using this measure in the Comprehensive Joint Replacement model, we are also aware that not all patients who complete the pre-operative questionnaire would complete the post-operative questionnaire. For the voluntary CY 2025 and CY 2026 reporting periods, we assume 10,677 patients would complete the survey (42,706 patients \times 0.50 \times 0.50 of ASCs) for a total of 1,290 hours annually (10,677 respondents \times 0.120833 hours) at a cost of \$26,716 (1,290 hours \times \$20.71) across all ASCs. Beginning with mandatory reporting in the CY 2027 reporting period/CY 2030 payment determination, we estimate a total of 5,160 hours (42,706 patients \times 0.120833 hours) at a cost of \$106,864 (5,160 hours \times \$20.71) across all ASCs.

Regarding ASCs' burden related to submitting data for this proposed measure, which would be reported via the HQR System, we estimate a burden of 10 minutes per response. ASCs would submit data associated with pre-operative surveys by March 31 of the CY following the CY in which the eligible procedures took place and would submit data associated with post-operative surveys by March 31 of the CY following the CY in which pre-operative data was submitted. Therefore, for the first voluntary reporting period for eligible procedures occurring in CY 2025, pre-operative survey data submission would occur in the first quarter of the CY 2026 reporting period and post-operative survey data submission would occur in the first quarter of the CY 2027 reporting period. For each of the two voluntary reporting periods, we estimate that each ASC would spend 20 minutes (0.33 hours) annually (10 minutes \times 2 surveys) to collect and submit the data. For the voluntary CY 2026 reporting period, we estimate a burden for all participating ASCs of 422 hours (0.167 hours \times 2,529 ASCs) at a cost of \$21,995 (422 hours \times \$52.12). For the voluntary CY 2027 reporting period, we estimate a burden for all participating ASCs of 843 hours (0.33 hours \times 2,529 ASCs) at a cost of \$43,937 (843 hours \times \$52.12). For the mandatory CY 2028 reporting period, we estimate a burden for all participating ASCs of 1,264 hours [(0.167 hours \times 2,529 ASCs) + (0.167 hours \times 5,057 ASCs)] at a cost of \$65,880

(1,264 hours × \$52.12). For the CY 2029 reporting period and subsequent years, we estimate a total of 1,686 hours (0.33 hours × 5,057 ASCs) at a cost of \$87,874 (1,686 hours × \$52.12).

With respect to any costs or burdens unrelated to data submission, we refer readers to section XXVI.C.4.b “Regulatory Impact Analysis” of this proposed rule.

7. Summary of Information Collection Burden Estimates for the ASCQR Program

In summary, under OMB control number 0938–1270 (expiration date August 31, 2025), we estimate that the proposals in this proposed rule would result in an increase of 7,689 hours at a cost of \$238,675 for 5,057 ASCs across a 6-year period from the CY 2024 reporting period/CY 2026 payment determination through the CY 2029 reporting period/CY 2030 payment determination. The following Tables 91 through 95 summarize the total burden changes for each respective CY payment determination compared to our currently approved information collection burden estimates (the table for the CY 2030 payment determination reflects the cumulative burden changes). We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1270.⁶⁷³

TABLE 91: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION

Activity	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2027 Payment Determination							
	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
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	2,529	4.2	0.51	1,290	N/A	+1,290
Readopt with modificatio	10	1	1,011	1	0.167	169	N/A	+169

⁶⁷³ CY 2023 Final Rule ASCQR Program “Supporting Statement-A”. Available at: https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911-0938-015.

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2027 Payment Determination								
n ASC Facility Volume on Selected ASC Surgical Procedures								
Total Change in Information Collection Burden Hours: +1,459								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+1,459) = \$35,498								

TABLE 92: SUMMARY OF 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 2028 Payment Determinations								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of OPPS 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
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	2,529	4.2	0.51	1,290	N/A	+1,290
Add THA/TKA PRO-PM Measure (Data Submission)	10	2	2,529	1	0.167	422	N/A	+422
Readopt with modification ASC Facility Volume on Selected ASC Surgical Procedures	10	1	5,057	1	0.167	843	N/A	+843
Total Change in Information Collection Burden Hours: +2,555								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+2,555) = \$92,648								

TABLE 93: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2029 Payment Determination								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of OPPS 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
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	5,057	8.4	1.02	5,160	N/A	+5,160
Add THA/TKA PRO-PM Measure (Data Submission)	10	2	2,529	1	0.33	843	N/A	+843
Readopt with modification ASC Facility Volume on Selected ASC Surgical Procedures	10	1	5,057	1	0.167	843	N/A	+843
Total Change in Information Collection Burden Hours: +6,846								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+6,846) = \$194,738								

TABLE 94: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 REPORTING PERIOD/CY 2030 PAYMENT DETERMINATION

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2030 Payment Determination								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of OPPS 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

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2030 Payment Determination								
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	5,057	8.4	1.02	5,160	N/A	+5,160
Add THA/TKA PRO-PM Measure (Voluntary Data Submission)	10	1	2,529	1	0.167	422	N/A	+422
Add THA/TKA PRO-PM Measure (Mandatory Data Submission)	10	1	5,057	1	0.167	843	N/A	+843
Readopt with modificatio n ASC Facility Volume on Selected ASC Surgical Pr ocedures	10	1	5,057	1	0.167	843	N/A	+843
Total Change in Information Collection Burden Hours: +7,268								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+7,268) = \$216,681								

**TABLE 95: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION
BURDEN CHANGE FOR THE CY 2029 REPORTING PERIOD/CY 2030 PAYMENT
DETERMINATION**

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2030 Payment Determination								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of OPPS 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
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	5,057	8.4	1.02	5,160	N/A	+5,160

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2030 Payment Determination								
Add THA/TKA PRO-PM Measure (Data Submission)	10	2	5,057	1	0.33	1,686	N/A	+1,686
Readopt with modification ASC Facility Volume on Selected ASC Surgical Procedures	10	1	5,057	1	0.167	843	N/A	+843
Total Change in Information Collection Burden Hours: +7,689								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+7,689) = \$238,675								

D. ICRs Related to the REHQR Program

1. Background

In section XVI. of this proposed rule, we discuss the requirements for the REH Quality Reporting (REHQR) Program. In this proposed rule, we propose to adopt four new measures, beginning with the CY 2024 reporting period: (1) the Abdomen Computed Tomography (CT) Use of Contrast Material measure; (2) the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure; (3) the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure; and (4) the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure. As we are establishing the REHQR Program in this proposed rule, the ICRs associated with the REHQR Program will be submitted for OMB approval under a new OMB control number.

While the most recent data from the Bureau of Labor Statistics reflects a median hourly wage of \$24.56 per hour for all medical records specialists, \$26.06 is the hourly mean wage for medical records specialists in “general medical and surgical hospitals.”⁶⁷⁴ We believe specialists

⁶⁷⁴ U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on March 6, 2023. Available at: <https://www.bls.gov/oes/current/oes292072.htm>.

in “general medical and surgical hospitals” is more specific to our settings for use in our calculations than a position that may be found in other medical record specialist settings, such as “office of physicians” or “nursing care facilities.” We propose to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage similar to the policy previously finalized in the CY 2018 OPPS/ASC final rule for the Hospital OQR Program (82 FR 52617). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($\$26.06 \times 2 = \52.12) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

Based on our analysis of CAHs and subsection (d) hospitals currently participating in the Hospital OQR Program with 50 beds or less, we have estimated 746 hospitals which would be both eligible to transition to REH status and are located in a State where legislation has passed as of March 2023 enabling transition to occur. We will revise this estimate in future rules when updated data are available.

2. Information Collection Burden for the Proposal to Adopt Three Claims-Based Measures Beginning with the CY 2024 Reporting Period

In sections XVI.B.5.a, XVI.B.5.c, and XVI.B.5.d of this proposed rule, we propose to adopt the following claims-based measures beginning with the CY 2024 reporting period: (1) the Abdomen Computed Tomography (CT) Use of Contrast Material measure; (2) the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure; and (3) the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure. Because these measures are calculated using data that are already reported to the Medicare program for payment purposes, adopting these measures does not result in additional burden for REHs participating in the REHQR Program.

3. Information Collection Burden for the Proposal to Adopt the Median Time from ED Arrival to ED Departure for Discharged ED Patients Measure Beginning with the CY 2024 Reporting Period

In section XVI.B.5.b of this proposed rule, we propose to adopt the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure beginning with the CY 2024 reporting period. This chart-abstracted measure was previously adopted as part of the Hospital OQR Program in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72086). Similar to reporting of this measure to the Hospital OQR Program as currently approved under OMB control number 0938-1109 (expiration date February 28, 2025), we estimate that chart-abstracted measures where patient-level data are submitted directly to CMS would take 2.9 minutes, or 0.049 hours. Further, based on sample size requirements for the measure in the Hospital OQR Program, we assume that each REH would similarly abstract and submit data from 63 cases per quarter, for a total of 252 cases per year.⁶⁷⁵ We therefore estimate that it would take approximately 12.2 hours (0.049 hours x 252 cases) at a cost of approximately \$636 per hospital (12.2 hours x \$52.12/hour) to collect and report data for this measure. Therefore, for all participating REHs, we estimate an annual chart-abstraction burden of 9,101 hours (12.2 hours per REH x 746 REHs) at a cost of \$474,344 per measure (9,101 hours x \$52.12/hour).

4. Summary of Information Collection Burden Estimates for the REHQR Program

In summary, we estimate that the proposals in this proposed rule would result in an initial burden of 9,101 hours at a cost of \$474,344 for 746 REHs annually beginning with the CY 2024 reporting period, as reflected in Table 96. We will submit these information collection estimates to OMB for approval as part of a new information collection request.

With respect to any costs/burdens unrelated to data submission, we refer readers to section XXVI.C.5.a “Regulatory Impact Analysis” of this proposed rule.

⁶⁷⁵ https://qualitynet.cms.gov/files/63c8361058e56000179b310e?filename=OQR_v16.0a_SpecsManual_011723.pdf

TABLE 96: SUMMARY OF REHQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD

Activity	Annual Recordkeeping and Reporting Requirements for the CY 2024 Reporting Period							
	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
Adopt Median Time from ED Arrival to ED Departure for Discharged ED Patients Measure	2.9	1	746	252	12.2	9,101	0	+9,101
Total Change in Information Collection Burden Hours: +9,101								
Total Cost Estimate: Updated Hourly Wage (\$52.12) x Change in Burden Hours (9,101) = \$474,344								

E. ICRs Related to Conditions of Participation (CoPs): Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client (§ 485.914)

To implement Division FF, section 4124 of the CAA 2023, we propose to modify the regulation text at § 485.914(a)(2) to include a cross-reference to § 485.918(g), which are additional requirements CMHCs must meet when assessing and admitting clients into the IOP program. At present, § 485.914(a)(2) solely pertains to PHP services with reference to § 485.918(f), which provides distinct criteria for clients evaluated and accepted for PHP services. We believe the burdens associated with these requirements are usual and customary business practice under 5 CFR 1320.3(b)(2). As such, the burden associated with these requirements is exempt from PRA; therefore, we are not proposing to seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.914(a)(2).

We also propose to revise § 485.914(d)(2), which sets forth standards for updating a PHP client's comprehensive assessment no less frequently than every 30 days. We propose to add "and IOP services," which would require the PHP and IOP client's interdisciplinary treatment team to update the assessment no less frequently than every 30 days. We believe that the burden associated with these requirements is the time required to update the comprehensive assessment and that this documentation is usual and customary business practice under 5 CFR 1320.3(b)(2). Therefore, we do not propose seeking PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.914(d)(2).

F. ICRs Related to Conditions of Participation (CoPs): Treatment team, Person-centered Active Treatment Plan, and Coordination of Services (§ 485.916)

We propose to modify § 485.916(d), which sets forth requirements for reviewing the person-centered active treatment plan. Currently, the interdisciplinary team is required to review, revise, and document the active treatment plan as frequently as the client's condition requires, but no less frequently than every 30 calendar days. A revised active treatment plan must include information from the client's updated comprehensive assessment and must document the client's progress toward the outcomes specified in the active treatment plan. CMHCs must also meet PHP program requirements specified under § 424.24(e) if such services are included in the active treatment plan. As Division FF, section 4124 of the CAA 2023 included coverage of IOP services for CMHCs, we believe it is necessary to add IOP services to this requirement and reference the specific IOP program requirements being proposed in section VIII.C.2 at § 424.24(d) of this proposed rule. We propose to cross-reference additional requirements specified under § 424.24(d) if a client's active treatment plan includes IOP services. The 2013 CMHC CoP final rule (78 FR 64603) included a burden for § 485.916(d) and is collected under OMB control number 0938-1245. The proposed revision to this requirement does not affect the burden. Therefore, we do not propose seeking PRA approval for any information collection or

recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.916(d).

G. ICRs Related to Conditions of Participation (CoPs): Organization, Governance, Administration of Services, Partial Hospitalization Services (§ 485.918)

To implement Division FF, section 4124 of the CAA, 2023, which extended coverage of IOP services for CMHCs, we propose to revise the title of § 485.918 to include IOP services. The overall goal of this section is to ensure that the management structure is organized and accountable for the services furnished. We propose to add “and intensive outpatient services” to the end of the section heading.

The requirement at § 485.918(b) “Standard: Provision of services” specifies a comprehensive list of services that a CMHC must furnish. This list of services that CMHCs provide corresponds directly to the Statutory requirements in section 1861(ff)(3) of the Act. We propose to add “and intensive outpatient services” to § 485.918(b)(1)(iii), which states where specific services cannot be furnished, such as other than in an individual's home or an inpatient or residential setting, or psychosocial rehabilitation services. We believe that adding IOP services to § 485.918(b)(1)(iii) is a usual and customary business practice under 5 CFR 1320.3(b)(2). Therefore, we are not proposing to seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.918(b)(1)(iii).

We propose to add a new standard at § 485.918(g), “Standard: Intensive Outpatient Services”, which will require all IOP services to meet all applicable requirements of 42 CFR 410 and 424. We also believe adding the IOP services requirement in the new proposed § 485.918(g) is a usual and customary business practice under 5 CFR 1320.3(b)(2). Therefore, we do not propose seeking PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.918(g).

H. ICRs Related to Hospital Price Transparency

In a final rule dated November 2019 (84 FR 65524) (herein referred to as the CY 2020 HPT final rule), we adopted requirements for hospitals to make public their standard charges in two ways: (1) as a comprehensive machine-readable file (MRF); and (2) in a consumer-friendly format. We codified these requirements at new 45 CFR part 180.50 and 180.60, respectively.

The existing information collection requirement and the associated burden were finalized in the CY 2020 HPT final rule and are currently approved under OMB control number is 0938-1369, which expires on December 31, 2023. We originally estimated the number of hospitals to be 6,002. We finalized an initial one-time burden 150 hours and cost of \$11,898.60 per hospital, resulting in a total national burden of 900,300 hours (150 hours x 6,002 hospitals) and \$71,415,397 (\$11,898.60 x 6,002 hospitals) to build processes and make required system updates to make their standard charge data publicly available: 1) as a comprehensive machine-readable file and 2) in a consumer-friendly format. Additionally, we estimated an on-going annual burden of 46 hours per hospital with a cost of \$3,610.88 per hospital, resulting in a total national burden of 276,092 hours (46 hours x 6,002 hospitals) and total cost of \$21,672,502 (\$3,610.88 x 6,002 hospitals), to make required annual updates to the hospital's standard charge data information. For a detailed discussion of the cost estimates for the requirements related to hospitals making their standard charge data publicly available we refer readers to our discussion in the collection of information section in the CY 2020 HPT final rule (84 FR 65591 through 65596).

In section XVIII of this proposed rule, we propose to revise regulations at 45 CFR 180.50 related to making public hospital standard charges in an MRF. First, we propose to add data elements to be included in the hospital's MRF and to require hospitals to conform to a CMS template layout. Second, to enhance automated access to the MRF, we propose that hospitals include a .txt file in the root folder of the public website it selects to host its MRF in the form and manner specified by CMS that includes a standardized set of fields, and a link in the footer on its website that is labeled "Hospital Price Transparency" and links directly to the publicly available

webpage that hosts the link to the MRF. We believe these proposed revisions would result in an increased collection burden to hospitals, both in one-time cost and ongoing annual cost.

Additionally, we are increasing the number of hospitals we believe to be subject to these requirements from 6,002 to 7,098 which would increase the estimated national burden. In the CY 2020 HPT final rule (84 FR 65591), we estimated that 6,002 hospitals would be subject to the hospital price transparency requirements. To derive the estimated number, we relied on data from the American Hospital Association (AHA).⁶⁷⁶ For this collection of information estimate, we are using updated hospital numbers based on the publicly available dataset from the Homeland Infrastructure Foundation-Level Data (HIFLD)⁶⁷⁷ hospital dataset because the HIFLD dataset compiles a directory of hospital facilities based on data acquired directly from state hospital licensure information and federal sources, and validates this data annually. Thus, we believe the HIFLD dataset is more accurate than the AHA Directory. The source data was available in a variety of formats (pdfs, tables, webpages, etc.) which is reviewed and geocoded and then converted into a spatial database. To estimate the number of hospitals subject to these requirements, we leveraged the HIFLD hospital dataset to identify 8,013 total hospitals. We then subtracted out 379 hospitals HIFLD identified as “closed” as well as hospitals that are deemed under the regulation to have met requirements (see 45 CFR 180.30) which included 339 federally owned non-military and military hospitals, and 197 State, local, and district run forensic hospitals. We therefore estimate that this proposed rule applies to 7,098 hospitals operating within the United States under the definition of “hospital.” Finally, we estimate the hourly cost for each labor category used in this analysis by referencing Bureau of Labor Statistics report on Occupational Employment and Wages (May 2022)⁶⁷⁸ in Table 97 below.

⁶⁷⁶ American Hospital Association. Fast Facts on U.S. Hospitals, 2019. Available at: <https://www.aha.org/statistics/fast-facts-us-hospitals>. The AHA listed 6,210 total hospitals operating in the US. To arrive at 6,002 hospitals, we subtracted the 208 federally owned or operated hospitals.

⁶⁷⁷ Homeland Infrastructure Foundation-Level Data hospital dataset accessed on May 3, 2023, located at <https://hifld-geoplatform.opendata.arcgis.com/datasets/hospitals/data>

⁶⁷⁸ U.S. Bureau of Labor Statistics, May 2022 national Occupational Employment and Wage Estimates United States, Occupational Employment and Wage Statistics. Accessed at <https://www.bls.gov/oes/tables.htm>

TABLE 97: OCCUPATION TITLES AND WAGE RATES

Occupational Title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefit (\$/hr)	Adjusted hourly wage (\$/hr)
General and Operations Managers	BLS 11-1021	\$59.07	\$59.07	\$118.14
Business Operations Specialists	BLS 13-1000	\$40.04	\$40.04	\$80.08
Network and Computer Systems Administrators	BLS 15-1244	\$46.71	\$46.71	\$93.42

First, we believe that hospitals would incur a one-time cost to update their processes and systems to 1) identify and collect the standard charge information represented by the newly proposed data elements, and 2) to conform the standard charge information for both the existing and newly proposed data elements in the proposed CMS template layout. To implement these requirements, we estimate that it would take, on average, 1 hour (at a cost of \$118.14 per hour) for a General and Operations Manager (BLS 11-1021) to review and determine proposed compliance requirements. We estimate it will take a Business Operations Specialist (BLS 13-1000), on average, 10 hours (at a cost of \$80.08 per hour) to develop and update the necessary processes and procedures and develop the requirements to implement the proposed CMS template. Once the existing systems have been identified and requirements developed, we estimate that a network and computer system administrator (BLS 15-1244) would spend, on average, 20 hours (at a cost of \$93.42 per hour), to make updates to existing systems to conform to the proposed CMS template layout and post it to the internet, including developing and posting the proposed txt file in the root folder of the public webpage it selects to host its MRF in the form and manner specified by CMS that includes a standardized set of fields specified by this proposed rule. Therefore, we are finalizing the total annual burden estimate for the first year to be 31 hours (1 hours + 10 hours + 20 hours) per hospital with a cost of \$2,787.34 (\$118.14 + \$80.08+ \$1,868.40) per hospital. The one-time national burden is calculated to be \$19,784,539.32 dollars (\$2,787.34 per hospital x 7,098 hospitals). (See Table 98 below.)

**TABLE 98: SUMMARY OF INFORMATION OF COLLECTION BURDENS
FOR THE FIRST YEAR**

Regulation section	OMB control no.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting (\$)
§ 180.50	0938-1369	7,098	7,098	31	220,038	\$19,784,539.32

In addition to the one-time cost to implement the proposed CMS template, we are providing a revised estimate of our annual burden estimates. As noted, we originally estimated an on-going annual burden of 46 hours, per hospital, for 6,002 hospitals to make annual updates to display their standard charge data. Originally, we estimated it would take on average: a general or operations manager 2 hours, per hospital, to review and determine updates in compliance with requirements; a business operations specialist 32 hours, per hospital, to gather and compile required information and post it to the internet; and a network and computer system administrator 12 hours to maintain requirements specified in the CY 2020 HPT final rule (84 FR 65596).

We estimate it will still take a general or operations manager 2 hours, per hospital, to review and determine updates in compliance with requirements. However, we now estimate an increased ongoing amount of time for a business operations specialist, from 32 hours to 40 hours per hospital, to identify and gather required additional data elements on an annual basis. This increase acknowledges that some hospitals may not update their systems in the first year to maintain and abstract newly required data elements in an automated way to facilitate future annual updates to the MRF, thus we expect a subset of hospitals will continue to spend time annually to gather their standard charge information. We continue to believe that it will still take a computer system administrator 12 hours to maintain and post the MRF in a manner that conforms to the CMS template layout. Therefore, we estimate an annual national burden of 383,292 hours (54 hours x 7,098 hospitals) and an annual national cost of \$32,370,571 dollars (\$4,560.52 per respondent x 7,098 hospitals). This represents a \$10,698,069 (\$32,370,571 -

\$21,672,502) increase over our previous estimated national annual burden for subsequent years.

We summarize our updated annual burden estimates in the Table 99 below.

TABLE 99: SUMMARY OF INFORMATION OF COLLECTION BURDENS FOR SUBSEQUENT YEARS

Regulation section	OMB control no.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting (\$)
§ 180	0938-1369	7,098	7,098	54	383,292	\$32,370,571

The new information collection requirements, as well as the one-time cost estimates and updated annual burden estimates discussed in this section will be submitted for OMB review and approval for OMB control number is 0938-1369.

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 [INSERT DATE 60 DAYS AFTER THE DATE OF FILING IN THE **FEDERAL REGISTER**].

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 2024. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates

for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We propose to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2022, through and including December 31, 2022, and processed through June 30, 2023, and updated HCRIS cost report information, as discussed in section X.F of this proposed rule.

This proposed rule is also necessary to make updates to the ASC payment rates for CY 2024, 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 2024. 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 this CY 2024 OPPS/ASC proposed rule, we propose to extend the 5-year interim period to 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. Further discussion of this proposed policy can be found in section XIII.G.2.b of this proposed rule.

B. Overall Impact of Provisions of this Proposed Rule

We have examined the impacts of this proposed 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 health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled “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 effect 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 the \$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.

We estimate that the total increase in Federal Government expenditures under the OPSS for CY 2024, compared to CY 2023, due to the changes to the OPSS in this proposed rule, would be approximately \$1.92 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2024, we estimate that the OPSS expenditures, including beneficiary cost-sharing, for CY 2024 will be approximately \$88.6 billion, which is approximately \$6.0 billion higher than estimated OPSS expenditures in CY 2023. Table 100 of this proposed rule displays the distributional impact of the CY 2024 changes in OPSS payment to various groups of hospitals and for CMHCs.

We note that under our proposed CY 2024 policy, drugs and biologicals are generally proposed to be paid at ASP plus 6 percent, WAC plus 6 percent, or 95 percent of AWP, as applicable. The impacts on hospital rates as a result of this proposed policy are reflected in the discussion of the estimated effects of this proposed rule.

We estimate that the proposed update to the conversion factor and other budget neutrality adjustments would increase total OPSS payments by 2.8 percent in CY 2024. 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 2023 and CY 2024, 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 2.9 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 2024 compared to CY 2023, to be approximately \$220 million. Tables 101 and 102 of this proposed rule display the redistributive impact of the CY 2024 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPSS Changes in this Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2024 policy changes on various hospital groups. We post our hospital-specific estimated payments for CY 2024 on the CMS website with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. On the website, select “Regulations and Notices” from the left side of the page and then select “CMS-1786-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 100 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 100 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 100, 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 CY 2024, we propose to pay CMHCs for partial hospitalization services under APCs 5853 (Partial Hospitalization (three services per day) for CMHCs) and 5854 (Partial Hospitalization (four or more services per day) for CMHCs) and to pay hospitals for partial hospitalization services under APCs 5863 (Partial Hospitalization (three services per day) for hospital-based PHPs) and 5864 (Partial Hospitalization (four or more services per day) for hospital-based PHPs). In addition, we propose to establish payment for four Intensive Outpatient Program (IOP) APCs, two for each provider type, including an APC for three services per day and an APC for four or more services per day.

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 2024 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 proposed to be 0.2 percentage point for CY 2024 (which is also the productivity adjustment for FY 2024 in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27005)), resulting in the proposed CY 2024 OPD fee schedule increase factor of 2.8 percent. We are using the OPD fee schedule increase factor of 2.8 percent in the calculation of the proposed CY 2024 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the estimates in Table 100 of this proposed rule.

To illustrate the impact of the CY 2024 changes, our analysis begins with a baseline simulation model that uses the CY 2023 relative payment weights, the FY 2023 final IPPS wage indexes that include reclassifications, and the final CY 2023 conversion factor. Table 100 shows the estimated redistribution of the increase or decrease in payments for CY 2024 over CY 2023 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2023 and CY 2024 (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 2.8 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated impact taking into account all payments for CY 2024 relative to all payments for CY 2023, 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 propose to maintain the current adjustment percentage for CY 2024. 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 2024 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 2023 and CY 2024 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2024 would increase Medicare OPPS payments by an estimated 2.9 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 3.0 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 100 shows the total number of facilities (3,567), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2022 hospital outpatient and CMHC claims data to model CY 2023 and CY 2024 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 2023 or CY 2024 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive 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 (3,472), 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 27 CMHCs at the bottom of the impact table (Table 100) 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 will experience a 0.0 increase, with the impact ranging from a decrease of 0.4 percent to an increase of 0.5, depending on the number of beds. Rural hospitals will experience an estimated increase of 0.4 overall. Major teaching hospitals will experience an estimated decrease of 0.3 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 2024 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 2023 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 2024 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 are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2024, 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 2024 is 0.88, which is different from the 0.89 PCR target for the CY 2023 OPPS/ASC final rule with comment period (87 FR 71788). 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 0.89, not the 0.88 target payment-to-cost ratio we propose to apply 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 2024 scaled weights and a CY 2023 conversion factor that included a budget neutrality adjustment for the effect of the proposed changes to the wage indexes between CY 2023 and CY 2024.

Column 4: All Budget Neutrality Changes Combined with the Market Basket Update

Column 4 demonstrates the combined impact of all of the proposed changes previously described and the proposed update to the conversion factor of 2.8 percent. Overall, these changes would increase payments to urban hospitals by 2.8 percent and to rural hospitals by 4.7 percent. Rural sole community hospitals would receive an estimated increase of 4.9 percent while other rural hospitals would receive an estimated increase of 4.4 percent.

Column 5: All Changes for CY 2024

Column 5 depicts the full impact of the proposed CY 2024 policies on each hospital group by including the effect of all changes for CY 2024 and comparing them to all estimated payments in CY 2023. 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 this 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 adjustments to the CY 2024 OPPS payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2023 update (and assumed, for modeling purposes, to be the same number for CY 2023), we included 59 hospitals in our model because they had both CY 2022 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2024 would increase payments to all facilities by 2.9 percent for CY 2023. We modeled the independent effect of all changes in Column 5 using the final relative payment weights for CY 2023 and the proposed relative payment weights for CY 2024. We used the final conversion factor for CY 2023 of \$85.585 and the proposed CY 2024 conversion factor of \$84.788 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 2024 IPPS/LTCH PPS proposed rule (87 FR 49427) of 5.8 percent (1.05755) to increase charges on the CY 2022 claims, and we used the overall CCR in the April 2023 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2023. Using the CY 2022 claims and a 5.8 percent charge inflation factor, we currently estimate that outlier payments for CY 2023, using a multiple threshold of 1.75 and a fixed-dollar threshold of \$8,625, would be approximately 0.78 percent of total payments. The estimated current outlier payments of 0.78 percent are incorporated in the comparison in Column 5. We

used the same set of claims and a charge inflation factor of 11.8 percent (1.118412) and the CCRs in the April 2023 OPSF, with an adjustment of 0.977799 (88 FR 27221), to reflect relative changes in cost and charge inflation between CY 2022 and CY 2024, to model the proposed CY 2024 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed dollar threshold of \$6,875. The charge inflation and CCR inflation factors are discussed in detail in the FY 2024 IPPS/LTCH PPS final rule (88 FR 27219 through 27223).

Overall, we estimate that facilities would experience an increase of 2.9 percent under this proposed rule in CY 2024 relative to total spending in CY 2023. This projected increase (shown in Column 5) of Table 100 of this proposed rule reflects the proposed 2.8 percent OPD fee schedule increase factor, added by the difference in estimated outlier payments between CY 2023 (0.78 percent) and CY 2024 (1.0 percent), minus 0.10 percent for the change in the pass-through payment estimate between CY 2023 and CY 2024. We estimate that the combined effect of all changes for CY 2024 would increase payments to urban hospitals by 2.8 percent. Overall, we estimate that rural hospitals would experience a 4.4 percent increase as a result of the combined effects of all the changes for CY 2024.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes would include an increase of 2.4 percent for major teaching hospitals and an increase of 3.5 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 3.0 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 3.0 percent, proprietary hospitals would experience an increase of 3.4 percent, and governmental hospitals would experience an increase of 5.8 percent.

c. Estimated Effects of OPSS Changes on CMHCs

The last line of Table 100 demonstrates the isolated impact on CMHCs, which historically have only furnished partial hospitalization services under the OPSS. As discussed in

section VIII.D of this proposed rule, we propose for CY 2024 to pay CMHCs under APC 5853 (Partial Hospitalization (3 services per day) for CMHCs) for PHP days with three or fewer services, and APC 5854 (Partial Hospitalization (four or more services per day) for CMHCs) for days with four or more services. We modeled the impact of this APC policy assuming CMHCs will continue to provide the same PHP care as seen in the CY 2022 claims used for ratesetting in this proposed rule. We did not exclude days with one or two services from our modeling for CY 2024, because our proposed policy would pay the per diem rate for APC 5853 for such days beginning in CY 2024. As a result of the proposed PHP APC changes for CMHCs, we estimate that CMHCs would experience a 5.8 percent increase in CY 2024 payments relative to their CY 2023 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 2024 wage index values, which result in an estimated decrease of 1.0 percent to CMHCs. Column 4 shows that combining the OPD fee schedule increase factor, along with the proposed changes in APC policy for CY 2024 and the proposed FY 2024 wage index updates, would result in an estimated increase of 5.9 percent.

Lastly, we note that as discussed in section VIII of this proposed rule, we propose to establish payment for intensive outpatient services furnished by CMHCs under APCs 5851 (Intensive Outpatient (3 services per day) for CMHCs) and 5852 (Intensive Outpatient (4 or more services per day) for CMHCs). Payment estimates for APCs 5851 and 5852 are not reflected in Table 100 but are discussed in section XXI.C.1.i of this proposed rule.

TABLE 100: ESTIMATED IMPACT OF THE PROPOSED CY 2024 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 *	3,567	0.0	0.1	2.9	2.9
ALL HOSPITALS	3,472	0.1	0.2	3.0	3.0
(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS	2,761	0.0	0.0	2.8	2.8
LARGE URBAN (GT 1 MILL.)	1,430	0.0	-0.1	2.7	2.8
OTHER URBAN (LE 1 MILL.)	1,331	0.0	0.2	3.0	2.8
RURAL HOSPITALS	711	0.4	1.4	4.7	4.4
SOLE COMMUNITY	375	0.3	1.7	4.9	4.4
OTHER RURAL	336	0.6	0.9	4.4	4.3
BEDS (URBAN)					
0 - 99 BEDS	934	0.5	0.1	3.4	3.2
100-199 BEDS	778	0.5	-0.1	3.2	3.2
200-299 BEDS	421	0.2	0.1	3.1	3.0
300-499 BEDS	397	0.0	0.7	3.4	3.2
500 + BEDS	231	-0.4	-0.4	2.0	2.1
BEDS (RURAL)					
0 - 49 BEDS	342	0.8	1.2	4.9	4.6
50- 100 BEDS	213	0.5	2.1	5.5	5.1
101- 149 BEDS	81	0.4	1.2	4.4	3.7
150- 199 BEDS	42	0.2	1.4	4.5	4.0
200 + BEDS	33	0.0	0.8	3.6	3.7
REGION (URBAN)					
NEW ENGLAND	131	0.1	-2.4	0.5	0.6
MIDDLE ATLANTIC	306	-0.1	1.4	4.1	4.2
SOUTH ATLANTIC	458	0.0	-0.6	2.2	2.3
EAST NORTH CENT.	419	0.0	-0.8	2.0	2.1
EAST SOUTH CENT.	158	-0.3	-0.2	2.3	2.3
WEST NORTH CENT.	183	-0.2	0.3	2.9	1.7
WEST SOUTH CENT.	459	0.2	-0.5	2.5	2.6
MOUNTAIN	210	0.0	-1.7	1.1	0.9
PACIFIC	388	0.2	2.7	5.7	5.8
PUERTO RICO	49	0.2	-0.6	2.3	2.3
REGION (RURAL)					
NEW ENGLAND	19	0.2	-1.0	2.0	2.4
MIDDLE ATLANTIC	47	0.3	8.3	11.6	11.5
SOUTH ATLANTIC	106	0.5	0.5	3.9	3.8
EAST NORTH CENT.	112	0.4	0.7	3.9	3.9
EAST SOUTH CENT.	139	0.7	0.2	3.6	3.6

	(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
WEST NORTH CENT.	85	0.2	1.8	4.8	3.7
WEST SOUTH CENT.	133	1.0	0.3	4.2	4.1
MOUNTAIN	46	0.2	0.9	3.9	2.0
PACIFIC	24	0.2	3.9	7.0	7.0
TEACHING STATUS					
NON-TEACHING	2,186	0.4	0.4	3.6	3.5
MINOR	872	0.1	0.3	3.2	3.0
MAJOR	414	-0.3	-0.2	2.2	2.4
DSH PATIENT PERCENT					
0	7	-0.9	-0.7	1.1	3.4
GT 0 - 0.10	247	-0.1	-0.3	2.4	2.2
0.10 - 0.16	248	0.3	-0.1	3.0	3.0
0.16 - 0.23	568	0.3	0.0	3.1	3.0
0.23 - 0.35	1,135	0.0	0.1	2.9	2.7
GE 0.35	852	-0.2	0.6	3.3	3.4
DSH NOT AVAILABLE **	415	7.1	1.5	11.7	12.2
URBAN TEACHING/DSH					
TEACHING & DSH	1,142	-0.1	0.0	2.6	2.6
NO TEACHING/DSH	1,197	0.3	0.1	3.3	3.2
NO TEACHING/NO DSH	7	-0.9	-0.7	1.1	3.4
DSH NOT AVAILABLE2	415	7.1	1.5	11.7	12.2
TYPE OF OWNERSHIP					
VOLUNTARY	1,985	0.0	0.3	3.1	3.0
PROPRIETARY	1,047	0.7	-0.1	3.5	3.4
GOVERNMENT	440	-0.2	0.0	2.7	2.8
CMHCs	27	4.0	-1.0	5.9	5.8

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2024 OPPS policies and compares those to the CY 2023 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2024 hospital inpatient wage index. The proposed rural SCH adjustment would continue our current policy of 7.1 percent, so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 1.0005 because the proposed CY 2024 target payment-to-cost ratio is less than the CY 2023 PCR target.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.8 percent OPD fee schedule update factor (3.0 percent reduced by 0.2 percentage point 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 included the frontier adjustment to Column 3 in this table.

	(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
*These 3,567 providers include children's 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 OPSS 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 OPSS payments will rise and will decrease for services for which the OPSS payments will fall. For further discussion of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H of this proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be approximately 18.0 percent for all services paid under the OPSS in CY 2024. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2024 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 proposed rule. Hospitals,

CMHCs, and ASCs would be affected by the changes in this proposed rule. Additionally, as discussed in section VIII of this proposed rule, we propose to establish payment for IOP furnished by RHCs, FQHCs, and OTPs. These providers of IOP are not paid under the OPSS and are not included in the impact analysis shown in Table 100; however, the proposed payment amount for OPSS APC 5861 would affect payments to these providers. We discuss estimated effects of proposed IOP policies in section XXI.C.1.i of this proposed rule.

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 \$1.9 billion in program payments for OPSS services furnished in CY 2024. 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 \$115 million in CY 2024. Currently, there are approximately 10 million dual-eligible beneficiaries, which represent approximately 30 percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 30 percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 57 percent Federal payments and 43 percent State payments. Therefore, for the estimated \$115 million Medicaid increase, approximately \$65 million would be from the Federal Government and \$50 million will be from State governments.

g. Alternative OPSS Policies Considered

Alternatives to the OPSS changes we propose and the reasons for our selected alternatives are discussed throughout this proposed rule.

- Alternatives Considered for the Claims Data used in OPSS and ASC Ratesetting due to the PHE.

We refer readers to section X.F. of this proposed rule for a discussion of our proposed policy of returning to the standard update process of using updated cost report data for OPSS

ratesetting. In that section, we discuss our consideration of issues regarding data updates, and in particular the selection of cost report data used, which would include some cost report data including the timeframe of the PHE. We note that were we to continue using cost report data from prior to the PHE it would potentially not be reflective of more updated cost and charging patterns. In this proposed rule, as discussed in section X.F. of this proposed rule, we propose a policy of resuming our regular cost report update process for CY 2024 OPPS ratesetting.

We note that these policy considerations also have ASC implications since the relative weights for certain surgical procedures performed in the ASC setting are developed based on the OPPS relative weights and claims data.

h. Health Equity Comment Solicitation

Advancing health equity is the first pillar of the CMS 2022 Strategic Framework.⁶⁷⁹ To gain insight into how OPPS and ASC policies could affect health equity, we are considering adding elements to our impact analysis that would detail how OPPS and ASC policies impact particular beneficiary populations. Beneficiary populations that have been disadvantaged or underserved by the healthcare system may include patients with the following characteristics, among others: members of racial and ethnic minorities; members of federally recognized Tribes; people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; members of rural communities; and persons otherwise adversely affected by persistent poverty or inequality.

We are seeking comment from interested parties about how we might structure an impact analysis that addresses how OPPS and ASC changes may impact beneficiaries of different groups. We currently present OPPS impacts by provider type, rural versus urban area, geographic region, teaching status, and ownership type. We are interested in what health equity questions we can examine within these existing categories to better understand the health equity impact of our policies. We also welcome suggestions about adding new categories or measures

⁶⁷⁹ Available at: <https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf>

of health equity in our impact analyses, such as using the area deprivation index (ADI) as a proxy for disparities related to geographic variation. Additionally, we are seeking comment on ways to continue building an OPPS health equity framework that allows us to develop policies that enhance health equity under our existing statutory authority.

i. Effects of Proposed IOP policies on Hospitals, CMHCs, FQHCs, RHCs, and OTPs

As discussed in section VIII of this proposed rule, we propose to establish payment for intensive outpatient services furnished by hospitals, CMHCs, FQHCs, and RHCs under a new IOP benefit. We also propose to establish payment for intensive outpatient services provided by OTPs under the existing OTP benefit. Estimates of the payment impacts for IOP furnished by hospitals are included in Table 100 of this proposed rule, based on utilization in the CY 2022 claims for days that we believe would likely be billed as IOP beginning in CY 2024.

Specifically, we modeled non-PHP days furnished by hospitals with 3 and 4 or more services from Table 43 of this proposed rule and at least one service from the list of primary services shown in Table 44 of this proposed rule.

Because CMHCs are currently only permitted to bill for partial hospitalization services, we are unable to model payments for IOP APCs 5851 and 5852 based on utilization from CY 2022 claims. Therefore, the payment impacts for IOP furnished by CMHCs are not included in Table 100. However, we anticipate there would be an increase in utilization for CMHCs beginning in CY 2024. We simulated potential utilization for IOP APCs 5851 and 5852 based on estimates of the volume of such services that we expect would be provided beginning in CY 2024. We calculated the number of non-PHP 3-service and 4-service days in the hospital setting, and compared this to the number of PHP 3-service and 4-service days in the hospital setting. We applied the same ratio of non-PHP to PHP days to estimate anticipated IOP claims in the CMHC setting for CY 2024. We believe this is appropriate, because as discussed in section VIII.C of this proposed rule, we propose that IOP and PHP days would consist of the same services and use the same HCPCS codes. Therefore, for public awareness, we are

including projections about potential IOP utilization for CMHCs using claims with a comparable number and type of services, which we believe is the best available estimate of IOP utilization in the future. Based on this methodology, we estimate that CMHCs would provide approximately 35,511 IOP days with three services and approximately 22,558 IOP days with four or more services. These projections correspond to an estimated \$6,593,452 in additional payments to CMHCs for the provision of intensive outpatient services. This represents an increase of roughly 165 percent relative to current CMHC payments for partial hospitalization services. We solicit comment on our assumptions and the methodology used to derive this estimate.

In section VIII.F.4 of this proposed rule, we discuss the special payment rules for FQHCs and RHCs to furnish intensive outpatient services as mandated by sections 4124(c)(1) and (c)(2) of the CAA, 2023. For both FQHCs and RHCs, we propose to set the IOP payment rate as based on the per diem payment amount determined for APC 5861 (Intensive Outpatient (3 services per day) for hospital-based IOPs). However, for IOP services furnished in FQHCs, we propose that that payment amount is based on the lesser of a FQHC's actual charges or the rate determined for APC 5861. Additionally, we propose that grandfathered tribal FQHCs will continue to have their payment based on the outpatient per visit rate when furnishing IOP services. That is, payment is based on the lesser of a grandfathered tribal FQHC's actual charges or the outpatient per visit rate.

FQHCs and RHCs currently bill for mental health services. Beginning January 1, 2024 these settings will be able to bill for certain mental health services determined to be IOP services that they were not able to furnish previously, for example group therapy. We anticipate there would be utilization of IOP services for both RHCs and FQHCs in CY 2024; however, since this is a new program for both settings, we are unable to project what that utilization would be or the associated Medicare expenditures. FQHCs and RHCs typically furnish primary care services therefore we believe that it may take time for these settings to build the internal framework needed to initiate and foster an IOP. With regard to RHCs, we note the statutory provision

which defines the term “rural health clinic” in section 1861(aa)(2)(K)(iv) of the Act, states that a RHC is not a facility which is primarily for the care and treatment of mental diseases. We believe this provision could cause low utilization of IOP services until RHCs can determine what they can or cannot furnish. Therefore, we believe extending coverage for IOP services in FQHCs and RHCs is unlikely to have a significant impact on overall Medicare spending.

As discussed in section VIII.G of this proposed rule, for CY 2024 and subsequent years, we propose to establish a weekly add-on code for IOP services furnished by OTPs for the treatment of opioid use disorder (OUD) and to revise the definition of OUD treatment services to include IOP services. In accordance with our methodology for other add-on adjustments to the bundled payment for OUD treatment services, we propose to apply an annual update based on the Medicare Economic Index (MEI) described in § 414.30, and apply a geographic adjustment based on the Geographic Adjustment Factor (GAF) described in § 414.26. Under this proposal, we would permit OTPs to bill a new HCPCS code (GOTP1) for IOP services based on a minimum of at least nine IOP services furnished to eligible patients per week, which would result in a payment rate of \$719.67.

We estimate that these proposed policies to allow OTPs to bill for IOP services beginning in CY 2024 would result in a negligible cost increase. In our analysis, we evaluated mental health services furnished to beneficiaries receiving care at OTPs, including for levels of care and types of services that are not currently reflected in the OTP benefit. Approximately 557 OTPs offer IOP services nationwide according to the National Substance Use and Mental Health Services Survey in 2021⁶⁸⁰. However, our analysis of claims data from Medicare beneficiaries receiving care under the OTP benefit from CY 2020-2022 indicated a small number of beneficiaries actually receive intensive care services equivalent to 9 hours or more a week to

⁶⁸⁰ Substance Abuse and Mental Health Services Administration, National Substance Use and Mental Health Services Survey (N-SUMHSS), 2021: Annual Detailed Tables. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2023. Weblink: https://www.samhsa.gov/data/sites/default/files/reports/rpt39450/2021%20N-SUMHSS%20Annual%20Detailed%20Tables_508_Compliant_2_8_2023.pdf

meet the minimum threshold for IOP services. Specifically, 85 percent of Medicare beneficiaries received only medications for OUD with basic counseling and no other mental health care, and thus did not likely utilize a higher level of care required for IOP services. For the remaining 15 percent of Medicare beneficiaries, approximately 0.5-0.7 percent received a higher acuity of care likely to meet the minimum 9 hours or more of services under IOPs. The estimated total annual cost per Medicare beneficiary with an OUD receiving IOP services at an OTP would be approximately \$38,000, however, this estimate assumes that a beneficiary would require this level of care every week of the calendar year, which we do not believe would be likely. Therefore, extending coverage for IOP services in OTP settings is unlikely to have a significant impact on overall Medicare spending.

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 2024 ASC relative payment weights by scaling the proposed CY 2024 OPPS relative payment weights by the proposed CY 2024 ASC scalar of 0.8649. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 101 and 102.

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. 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 2024 payment determinations would be based

on the application of a 2.0 percentage point reduction to the annual update factor, which would be the hospital market basket update for CY 2024. We calculated the proposed CY 2024 ASC conversion factor by adjusting the CY 2023 ASC conversion factor by 1.0017 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2023 and CY 2024 and by applying the CY 2024 productivity-adjusted hospital market basket update factor of 2.8 percent (which is equal to the proposed inpatient hospital market basket percentage increase of 3.0 percent reduced by a productivity adjustment of 0.2 percentage point). The proposed CY 2024 ASC conversion factor is \$53.397 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 2024 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2022 and CY 2024 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2024 changes will 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 2024 payments on an individual ASC will 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 2024 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2022 claims data. Table 101 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2023 payments to estimated CY 2024 payments, and Table 102 shows a comparison of estimated CY 2023 payments to estimated CY 2024 payments for procedures that we estimate would receive the most Medicare payment in CY 2023.

In Table 101, 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 101.

- 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 2023 ASC Payments were calculated using CY 2022 ASC utilization data (the most recent full year of ASC utilization) and CY 2023 ASC payment rates. The surgical specialty groups are displayed in descending order based on estimated CY 2023 ASC payments.

- Column 3—Estimated CY 2024 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 2024 compared to CY 2023.

As shown in Table 101, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the final update to ASC payment rates for CY 2023 will result in a 6 percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 6 percent decrease in aggregate payment amounts for nervous system procedures, a 3 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 7 percent increase in aggregate payment amounts for digestive system procedures, a 4 percent increase in aggregate payment amounts for cardiovascular system procedures, and a 6 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 2.8 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 2.8 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 6 percent increase in aggregate eye and ocular adnexa procedure payments. The increase in payment rates for eye and ocular adnexa procedures is a result of increased OPSS relative weights as a result of the APC restructuring to the Intraocular APC family and is further increased by the 2.8 percent ASC rate update for these procedures. Conversely, we estimate a 6 percent decrease in nervous system procedures related to the American Medical Association's RVU Update Committee (RUC) estimated shift in utilization from an existing high-cost neurostimulator procedure (CPT code 64685) to a new, lower-cost neurostimulator procedure (CPT code 0X43T) for CY 2024. For estimated changes for selected procedures, we refer readers to Table 101 provided later in this section.

TABLE 101: ESTIMATED IMPACT OF THE PROPOSED CY 2024 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2023 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2023 ASC Payments (in Millions) (2)	Estimated CY 2024 Percent Change (3)
Total	\$6,309	3
Eye	\$1,880	6
Nervous System	\$1,274	-6
Musculoskeletal	\$1,188	3
Gastrointestinal	\$937	7
Cardiovascular	\$276	4
Genitourinary	\$225	6

Table 102 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2024. The table displays 30 of the procedures receiving the greatest estimated CY 2023 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2023 program payment.

- Column 1–CPT/HCPCS code.
- Column 2–Short Descriptor of the HCPCS code.
- Column 3–Estimated CY 2023 ASC Payments were calculated using CY 2022 ASC utilization (the most recent full year of ASC utilization) and the CY 2023 ASC payment rates. The estimated CY 2023 payments are expressed in millions of dollars.

- Column 4–Estimated CY 2024 Percent Change reflects the percent differences between the estimated ASC payment for CY 2023 and the estimated payment for CY 2024 based on the proposed update.

TABLE 102: ESTIMATED IMPACT OF THE PROPOSED CY 2024 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2023 ASC Payment (in millions) (3)	Estimated CY 2024 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	\$1,251	6

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2023 ASC Payment (in millions) (3)	Estimated CY 2024 Percent Change (4)
63685	Insrt/redo spine n generator	\$314	-37
27447	Total knee arthroplasty	\$263	1
45380	Colonoscopy and biopsy	\$244	6
45385	Colonoscopy w/lesion removal	\$213	6
63650	Implant neuroelectrodes	\$194	-10
43239	Egd biopsy single/multiple	\$158	7
27130	Total hip arthroplasty	\$130	1
66991	Xcapsl ctrc rmvl insj 1+	\$113	15
64590	Insrt/redo pn/gastr stimul	\$106	-15
64483	Njx aa&/strd tfrm epi l/s 1	\$100	4
66982	Xcapsl ctrc rmvl cplx wo ecp	\$94	6
J1097	Phenylep ketorolac opth soln	\$82	-1
64635	Destroy lumb/sac facet jnt	\$76	2
29827	Sho arthrs srg rt&tr cuf rpr	\$75	6
36902	Intro cath dialysis circuit	\$67	7
64493	Inj paravert f jnt l/s 1 lev	\$66	4
G0105	Colorectal scrn; hi risk ind	\$65	7
27279	Arthrodesis sacroiliac joint	\$63	-2
66821	After cataract laser surgery	\$61	7
64561	Implant neuroelectrodes	\$53	4
65820	Relieve inner eye pressure	\$45	3
C9740	Cysto impl 4 or more	\$45	3
62323	Njx interlaminar lmbtr/sac	\$41	4
G0121	Colon ca scrn not hi rsk ind	\$40	7
15823	Revision of upper eyelid	\$38	4
45378	Diagnostic colonoscopy	\$37	7
0275T	Perq lamot/lam lumbar	\$36	5
64721	Carpal tunnel surgery	\$36	2
J1096	Dexametha opth insert 0.1 mg	\$34	-2

c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2024 update to the ASC payment system will 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 2024. 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 almost always be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense-based amount payable under the PFS. For those additional procedures that we proposed to designate as office-based in CY 2024, 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/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-](https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4.html)

[4.html](https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4.html)), we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this proposed rule. The first accounting statement, Table 103, illustrates the classification of expenditures for the CY 2024 estimated hospital OPPS incurred benefit impacts associated with the final CY 2024 OPD fee schedule increase. The second accounting statement, Table 104, illustrates the classification of expenditures associated with the 2.8 percent CY 2024

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. Table 105 includes the annual estimated impact of hospital OQR and ASCQR programs.

TABLE 103: ACCOUNTING STATEMENT: CY 2024 ESTIMATED HOSPITAL OPPTS TRANSFERS FROM CY 2023 TO CY 2024 ASSOCIATED WITH THE CY 2024 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	\$1,920 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPTS

TABLE 104: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2023 TO CY 2024 AS A RESULT OF THE PROPOSED CY 2024 UPDATED TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	\$130 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	\$130 million

TABLE 105: ESTIMATED COSTS IN CY 2024

CATEGORY	Costs
Burden	\$-11,688,943 million*
Regulatory Familiarization	\$17.204 million**

*The annual estimate includes the impact of Hospital OQR and ASCQR Programs.

** Regulatory familiarization costs occur upfront only.

3. Effects of Changes in Requirements for the Hospital Outpatient Quality Reporting (OQR)

Program

a. Background

We refer readers to the CY 2023 OPPTS/ASC final rule (87 FR 72278 through 72279) for the previously estimated effects of changes to the Hospital OQR Program for the CY 2025 payment determination. Of the 3,097 hospitals that met eligibility requirements for the CY 2023 payment determination for the Hospital OQR Program, we determined that 77 hospitals did not meet the requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor.

b. Impact of CY 2024 OPPS/ASC Proposed Rule Policies

We do not anticipate that the proposed Hospital OQR Program policies would significantly impact the number of hospitals that will receive payment reductions. In this proposed rule, we propose to: (1) modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) modify the Cataracts: Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery measure beginning with the voluntary CY 2024 reporting period; (3) modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (4) adopt the 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), beginning with the voluntary CYs 2025 and 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination; (5) adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient) electronic clinical quality measure (eCQM), beginning with the CY 2025 voluntary reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (6) re-adopt with modification the Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures 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 (7) remove the Left Without Being Seen measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

We refer readers to section XXIV.B of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Hospital OQR Program where we state

that for purposes of burden estimation, 3,350 hospitals will be considered and Table 89 where we estimate a total information collection burden increase for 3,350 OPPS hospitals of 67,004 hours at a cost of \$1,492,875 annually associated with our proposed policies for the CYs 2024 reporting period/CY 2026 payment determination and subsequent years, compared to our currently approved information collection burden estimates.

In section XIV.B.2.a of this proposed rule, we propose to modify the COVID-19 Vaccination Coverage among HCP measure to utilize the term “up to date” in the HCP vaccination definition and update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses. Although we anticipate this modification may require some hospitals to update information technology (IT) systems or workflow related to maintaining accurate vaccination records for HCP, we assume most hospitals are currently recording all necessary information for HCP such that this modification would not require additional information to be collected. Therefore, the financial impact of any required updates would be minimal. Finally, we do not estimate any changes to the effects previously discussed in the CY 2022 OPPS/ASC final rule for the Hospital OQR Program (86 FR 63984).

In section XIV.B.2.b of this proposed rule, we propose to modify the Cataracts: Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery measure by limiting the survey instrument that can be used to administer this measure to three assessment tools: National Eye Institute Visual Function Questionnaire (NEI VFQ-25), Visual Function Index (VF-14), and VF-8R. These surveys were found to have fewer noted limitations, present the lowest administrative burden, and achieve adequate validity and reliability compared to other surveys. We understand some hospitals may be currently using one of the other surveys which would no longer be allowable for collecting data for this measure, however, we believe any costs associated with modifying clinical practices would be negligible as these surveys are all publicly

available at no additional cost and are comparable survey instruments in form and manner for data collection and measure calculation to other surveys used for this measure.

In section XIV.B.3.b of this proposed rule, we propose the adoption of the THA/TKA PRO-PM. We assume the effects on outpatient hospitals would be similar to the effects previously discussed in the FY 2023 IPPS/LTCH PPS final rule for the inpatient hospital setting under the Hospital Inpatient Quality Reporting (IQR) Program (87 FR 49492). For hospitals that would not already be collecting these data for the Hospital IQR Program, there would be some non-recurring costs associated with changes in workflow and IT systems to collect the data for the Hospital OQR Program. The extent of these costs is difficult to quantify as different hospitals may utilize different modes of data collection (such as paper-based, electronically patient-directed, or clinician-facilitated). While we assume the majority of hospitals would report data for this measure directly to CMS via the CMS-designated information system (currently, the Hospital Quality Reporting (HQR) system), we assume some hospitals may elect to submit measure data using a third-party vendor, for which there are associated costs. To determine an estimate of third-party vendor costs, we looked at the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure (OMB control number 0938-098; expiration date September 30, 2024), which used an estimate of approximately \$4,000 per hospital to account for these costs. This per hospital cost estimate originates from this Paperwork Reduction Act analysis performed for 2012, therefore, to account for inflation (assuming end of CY 2012 to January CY 2023), we adjust the price using the Bureau of Labor Statistics Consumer Price Index and estimate an updated cost of approximately \$5,212 ($\$4,000 \times 130.3$ percent).⁶⁸¹

In section XIV.B.3.c of this proposed rule, we propose the adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level –

⁶⁸¹ U.S. Bureau of Labor Statistics. Historical CPI-U data. Accessed on March 9, 2023. Available at: <https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202301.pdf>.

Outpatient) eCQM. Similar to the CY 2022 OP/ASC final rule (86 FR 63837 through 63840), we believe that costs associated with adoption of eCQMs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program requirements, such as maintaining measure specifications in hospitals' electronic health record (EHR) systems for the eCQMs used in the Hospital OQR Program (83 FR 41771).

Regarding the remaining proposals, we do not believe any of these proposals would result in any additional economic impact beyond those discussed in section XXIV "Collection of Information" of this proposed rule, if adopted.

4. Effects of Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

a. Background

In section XV of this proposed rule, we discuss our proposed policies affecting the ASCQR Program. For the CY 2023 payment determination, of the 5,697 Ambulatory Surgical Centers (ASCs) that met eligibility requirements, we determined that 516 ASCs did not meet the requirements to receive the full annual payment rate update under the ASC fee schedule.

b. Impact of CY 2024 OP/ASC Proposed Policies

In this proposed rule, we propose to: (1) modify the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure beginning with the voluntary CY 2024 reporting period; (3) modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (4) re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical Procedures 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 (5) adopt the 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), beginning with voluntary CYs 2025 and CY 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination.

We refer readers to section XXIV.C of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the ASCQR Program and Table 94 where we estimate a total information collection burden increase for 5,057 ACSs of 7,689 hours at a cost of \$238,675 annually associated with our proposed policies and updated burden estimates for the CY 2025 reporting period/CY 2027 payment determination and subsequent years, compared to our currently approved information collection burden estimates.

In section XV.B.4.a of this proposed rule, we propose to modify the COVID-19 Vaccination Coverage among HCP measure to utilize the term “up to date” in the HCP vaccination definition and update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses. Although we anticipate this modification may require some facilities to update information technology (IT) systems or workflow related to maintaining accurate vaccination records for HCP, we assume most facilities are currently recording all necessary information for HCP such that this modification would not require additional information to be collected and, therefore, the financial impact of any required updates would be minimal. Finally, we do not estimate any changes to the effects previously discussed in the CY 2022 OPPS/ASC final rule for the ASCQR Program (86 FR 63985).

In section XV.B.4.b of this proposed rule, we propose to modify the Cataracts: Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery measure

by limiting the survey instrument that can be used to administer this measure to three assessment tools: NEI VFQ-25, VF-14, and VF-8R. These surveys were found to have fewer noted limitations, present the lowest administrative burden, and achieve adequate validity and reliability compared to other surveys. We understand some ASCs may be currently using one of the other surveys which would no longer be allowable for collecting data for this measure, however, we believe any costs associated with modifying clinical practices would be negligible as these surveys are all publicly available at no additional cost and are comparable survey instruments in form and manner for data collection and measure calculation to other surveys used for this measure.

In section XV.B.5.b of this proposed rule, we propose the adoption of the THA/TKA PRO-PM. We assume the effects on ASCs would be similar to those previously finalized for the inpatient hospital setting under the Hospital IQR Program as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49492). For ASCs that are not currently collecting these data, there would be 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 (such as paper-based, electronically patient-directed, or clinician-facilitated). While we assume the majority of ASCs would report data for this measure directly to CMS via the CMS-designated information system (currently, the HQR System), we also assume some ASCs may elect to submit measure data via a third-party vendor, for which there are associated costs. To determine an estimate of third-party vendor costs, we looked at the HCAHPS measure (OMB control number 0938-0981; expiration date September 30, 2024), which used an estimate of approximately \$4,000 per hospital to account for these costs. This estimate originates from 2012, therefore, to account for inflation (assuming end of CY 2012 to January CY 2023), we adjust the price using the Bureau of Labor Statistics

Consumer Price Index and estimate an updated cost of approximately \$5,212 ($\$4,000 \times 130.3$ percent).⁶⁸²

Regarding the remaining proposals, we do not believe any of these proposals would result in any additional economic impact beyond those discussed in section XXIV “Collection of Information” of this proposed rule, if adopted.

5. Effects of Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

a. Background

In section XVI of this proposed rule, we discuss our proposed policies affecting the REHQR Program. We propose to adopt four new measures, beginning with the CY 2024 reporting period: (1) the Abdomen Computed Tomography (CT) - Use of Contrast Material measure; (2) the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure; (3) the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure; and (4) the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure.

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 burden for submitting data to the REHQR Program and Table 96 where we estimate a total information collection burden for 746 REHs of 9,101 hours at a cost of \$474,344 annually associated with our proposed policies for the CY 2024 reporting period and subsequent years. Regarding the remaining proposals, we do not believe any of these proposals would result in any additional economic impact beyond those discussed in section XXIV “Collection of Information” of this proposed rule, if adopted.

b. Impact of CY 2024 OPPTS/ASC Proposed REHQR Program Policies

⁶⁸² U.S. Bureau of Labor Statistics. Historical CPI-U data. Accessed on March 9, 2023. Available at: <https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202301.pdf>

For CY 2024, we have determined there are 1,716 CAHs and rural subsection (d) hospitals with 50 or fewer beds that are eligible to convert to become an REH in the nation. Based on the March 2023 numbers of REH-eligible hospitals currently in the Hospital OQR program and in states with REH licensure provisions, we estimate 746 hospitals which could convert to REH status, and we use this number of REHs for our impact analyses. We acknowledge that the number of conversions could be less than or significantly greater than this estimate.

As hospitals eligible to convert to REH status have been eligible to report quality measures under the Hospital OQR Program and most of these hospitals have been reporting, we do not believe any of our administrative proposals would result in additional impact on these hospitals.

6. Estimated Effects of Changes to the CMHC CoPs

a. Impacts Related to Conditions of participation: Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client (§ 485.914)

Under the Medicare Program, in accordance with section 4124 of division FF of the CAA. 2023, we propose conforming regulations text changes to establish coverage for Intensive Outpatient Services (IOP) in CMHC at § 485.914 “Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client”. At § 485.914(a), we require that for clients who are assessed and admitted to receive partial hospitalization services, the CMHC must also meet separate requirements specified in § 485.918(f). In § 418.918(d)(2), we propose to add IOP services to the update of the assessment no less frequently than every 30 days. We do not expect any increase in burden for this modification, nor do we expect the changes for this provision will cause any appreciable expense or anticipated savings. Therefore, we do not believe this standard would impose any additional regulatory burden.

b. Impacts Related to Conditions of participation: Treatment team, Person-centered Active Treatment Plan, and Coordination of Services (§ 485.916)

This standard requires the active treatment plan to be updated with current information from the client's comprehensive assessment and information concerning the client's progress toward achieving outcomes and goals specified in the active treatment plan. With the addition of IOP services to CMHCs, we believe it is necessary to add IOP into this requirement and to reference the specific IOP program requirements being proposed in section VIII.B.2 at § 424.24(d) of this proposed rule. We do not expect any increase in burden for this modification, nor do we expect the changes for this provision will cause any appreciable expense or anticipated savings. Therefore, we do not believe this standard would impose any additional regulatory burden.

7. Impacts Related to Conditions of participation: Organization, Governance, Administration of Services, Partial Hospitalization Services (§ 485.918)

The requirement at § 485.918(b) Standard: Provision of services, specifies a comprehensive list of services that a CMHC is required to furnish. This list of services that CMHCs provide corresponds directly to the Statutory requirements in (section 1861(ff)(3) of the Act). We propose to modify the title at § 485.918, by adding intensive outpatient services after partial hospitalization services. In addition, we propose to add IOP to the requirement at § 485.918(b)(1)(iii) for the provision of services. This proposed change will recognize IOP, along with day treatment and PHP, as services that can be provided by a CMHC, other than in an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.

Lastly, we propose to add a new standard for IOP services at § 485.918(g). This new requirement would specify the additional requirements a CMHC providing IOP services must meet under proposed requirements at § 410.2, § 410.44, § 410.111, and § 424.24(d) of this chapter. We believe that modifying the title of this CoP to include IOP services, as well as adding IOP services to § 485.918(b)(1)(iii) and the proposed new standard at § 485.918(g) will not increase the burden for this modification. In addition, we do not expect the changes to this

provision will cause any appreciable amount of expense or anticipated savings, and we do not believe this standard would impose any additional regulatory burden.

8. Effects of Proposals Relating to Hospital Price Transparency

a. Background

Since the hospital price transparency regulation's (at 45 CFR 180) effective date on January 1, 2021, hospitals have been required to make their standard charges available to the public. Various interested parties have reported success in using the data to realize savings. These interested parties come from various parts of the healthcare industry and range from individuals to large organizations. Individual consumers of healthcare have accessed the pricing data to shop for care and save money, and they have created tutorials to teach others how to use this information to achieve similar results.⁶⁸³ Employers have used the data to reconsider their employee healthcare plans and renegotiate hospital contracts.^{684,685,686} Innovators have identified and aggregated the data allowing consumers of healthcare to more easily make meaningful comparisons.⁶⁸⁷ Insurers have evaluated data, identified hospitals that are cost outliers, and successfully renegotiated their contracts.⁶⁸⁸ Researchers⁶⁸⁹ and industry experts⁶⁹⁰ continue to expose potential savings by publishing on variation in negotiated charges and discounted cash

⁶⁸³ R&R Insurance. How I Saved Over 1K. Available at: <https://rrins.wistia.com/medias/rkefb7g3aq>

⁶⁸⁴ Minemyer, P. New Playbook Aims to Help Employers, Plan Sponsors Negotiate Hospital Prices. Fierce Healthcare. September 8, 2022. Available at: <https://www.fiercehealthcare.com/payers/new-playbook-aims-help-employers-plan-sponsors-negotiate-hospital-prices>

⁶⁸⁵ Hansard, S. One County Combed Hospital Data to Slash Health Plan Costs 43 percent. Bloomberg. February 6, 2023. Available at: <https://news.bloomberglaw.com/health-law-and-business/employer-health-plan-eyes-43-savings-from-payment-data-audits>

⁶⁸⁶ Hansard, S. Employer, Hospital Tensions Rise Over Price Transparency. Bloomberg. August 2, 2022. Available at: <https://news.bloomberglaw.com/health-law-and-business/tensions-between-employers-hospitals-up-with-transparency-push>

⁶⁸⁷ Turquoise Health. Patients- Shop Healthcare Like You Shop Anything Else. Available at: <https://turquoise.health/patients>

⁶⁸⁸ Pierce, S. Why BlueCross Blue Shield Tennessee is Renegotiating Provider Network Contracts. The Tennessean. August 18, 2022. Available at: <https://www.tennessean.com/story/opinion/2022/08/18/bluecross-blue-shield-tennessee-health-insurance-contracts/1033329002/>

⁶⁸⁹ Mouslim, M., Henderson, M. How New Data on Hospital "Discounted Cash Prices" Might Lead to Patient Savings. Health Affairs. November 8, 2021. Available at: <https://www.healthaffairs.org/doi/10.1377/forefront.20211103.716124/full/>

⁶⁹⁰ Smith, C., et al. Hospital Price Transparency Data: Case Studies for How to Use It. Milliman. May 3, 2022. Available at: <https://us.milliman.com/en/insight/hospital-price-transparency-data-case-studies-for-how-to-use-it>

prices for the same items and services both within and across hospitals. Taken together, such actions can motivate hospitals to compete on prices. Furthermore, as interested parties continue to identify new sources of value in this pricing data, the full potential is likely beyond what we previously imagined.

As discussed in more detail in section XVIII of this proposed rule, we believe the revisions we are proposing a number of changes to the hospital price transparency regulations at 45 CFR 180 to accelerate automated aggregation of hospital standard charge information, improve the public's ability to meaningfully understand and use the data, and support and streamline CMS compliance efforts. We propose to: (1) define several new terms; (2) require hospitals to include standard charge information for an increased number of data elements within the MRF and to conform to a CMS template layout data encoding specifications; (3) require hospitals to include a txt file in the root folder that includes a direct link to the MRF and a link in the footer on its homepage that links directly to the publicly available webpage that hosts the link to the MRF; and (4) improve our enforcement process by updating our methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, working with health system officials to address noncompliance issues in one or more hospitals that are part of a health system, and publicizing more information about CMS enforcement activities related to individual hospital compliance. Additionally, we are seeking comment on additional considerations for improving compliance and aligning consumer-friendly policies and requirements with other federal price transparency initiatives.

b. Overall Estimated Burden on Hospitals Due to Hospital Price Transparency Requirements

The hospital price transparency proposed policies are estimated to increase burden on hospitals (as defined at 45 CFR 180.20), as detailed in section XXIV "Collection of Information", including a one-time cost and increased ongoing costs. However, we believe that the benefits to the public justify this proposed regulatory action.

To analyze the costs of this proposed requirement, we used a baseline that assumes the existing requirements (adopted in the CY 2020 HPT final rule and the CY 2022 OPPTS/ASC final rule and codified at 45 CFR 180) remain in place over the time horizon of this RIA. That is, the retrospective analysis and revised cost estimates for recurring administrative burden contained in section XXIV “Collection of Information” inform our baseline scenario of no further regulatory action.

As detailed in the Collection of Information section, we estimate a one-time cost for this proposed requirement of approximately \$2,787 per hospital, or \$19,784,539 ($\$2,787 \times 7,098$) for all hospitals combined. To estimate a lower bound of potential burden, we assume hospitals may be sorted into three subsets. First, we note that the proposed MRF templates have been available since November 2022 and a number of hospitals may be already voluntarily meeting these proposed requirements. As a result, a potentially large subset of these hospitals with robust information systems who are fully compliant may only need to review this regulation to ensure that these proposed requirements are being met, which represents our low estimate. A second group of hospitals may have less flexible information systems and limited ability to leverage their existing ad-hoc efforts to adapt to the new requirements; for these hospitals we assume the full collection and implementation cost estimated above. A third subset of hospitals are assumed to not currently be meeting the requirements of existing HPT regulations and would be effectively implementing HPT requirements for the first time. The marginal burden on these hospitals would be limited to the difference in burden under the proposed regulation compared to the existing requirements which the hospital has yet to comply with; we assume the marginal burden to only be 20 percent of the preceding group because these hospitals would have been required to comply with existing regulations regardless of the new proposals. For the low estimate we assume hospitals are distributed 40, 40, and 20 percent across the three subsets described above, respectively. Finally, to account for uncertainty inherent in these types of estimates of administrative costs, we also provide a high estimate which reflects administrative

burden 50 percent greater than the primary estimate also detailed in section XXIV “Collection of Information” of this proposed rule. These cost range estimates are displayed in Table 106.

TABLE 106: COST RANGE ESTIMATES FOR FIRST YEAR

	Hospitals	Mean Cost / Hospital	Total Cost Burden
Primary Estimate	7,098	\$2,787	\$19,784,539
High Estimate	7,098	\$4,181	\$29,676,809
Low Estimate	7,098	\$1,274	\$9,040,620

In the CY 2020 HPT final rule, we estimated an on-going annual burden of 46 hours per hospital with a cost of \$3,610.88 per hospital, resulting in a total national burden of 276,092 hours and total cost of \$21,672,502. We anticipate the proposals in this proposed rule would increase hospital annual burden by 8 hours per year, as discussed in greater detail in section XXIV “Collection of Information” of this proposed rule. This would result in an increase the total national annual burden to 383,292 hours (54 hours x 7,098 hospitals) and an annual national cost of \$32,370,571 dollars (\$4,560.52 per respondent x 7,098 hospitals). This represents a \$10,698,069 (\$32,370,571 - \$21,672,502) increase over our previous estimated national annual burden for subsequent years.

c. Benefits of Proposals

Although we cannot quantify the benefits of including additional data elements and encoding such data in a CMS template layout, as proposed in this rule, we believe the proposed standardization requirements would help streamline the development and consumption of the MRF data, making it more actionable for consumers, employers, third party tool developers, and researchers.

(1) Benefits to Hospitals

We believe that requiring the proposed CMS template would assist hospitals with implementing the hospital price transparency regulation and would improve compliance rates,

thereby supporting the overarching goal of increasing healthcare pricing competition and lowering costs. As discussed in section XXIV “Collection of Information” of this proposed rule, hospitals have sought clarification on how to display their standard charges, particularly payer-specific negotiated charges established by the hospital, and they have indicated that having access to a CMS-developed template could be useful for improving hospital compliance with the HPT regulation.⁶⁹¹ As we noted in section XXIV “Collection of Information” of this proposed rule, in response to the CY 2022 OPPTS/ASC final rule request for information, hospitals urged CMS to be more prescriptive, requesting that CMS standardize the MRF format and contents. Additionally, researchers and experts suggest that a clear standard format would better support hospital compliance with the regulation.^{692,693,694,695} This sentiment was echoed in a Congressional hearing, when witnesses favored a standard template for MRF data, as a means, to support more hospitals complying with the regulation.⁶⁹⁶

(2) Benefits to Other Interested Parties

As discussed in the CY 2020 HPT final rule (84 FR 65538), we believe public access to hospital standard charge information can be useful to the public, including patients who need to obtain items and services from a hospital, consumers of healthcare who wish to view hospital prices prior to selecting a hospital, clinicians who use the data at the point of care when making

⁶⁹¹ American Hospital Association. AHA Statement on Lowering Unaffordable Costs: Examining Transparency and Competition in Health Care. March 28, 2023 <https://www.aha.org/testimony/2023-03-28-aha-statement-lowering-unaffordable-costs-examining-transparency-and-competition-health-care>

⁶⁹² The State of Hospital Pricing Transparency in Texas. Texas 2036. Available at: <http://pricetransparency.texas2036.org/>

⁶⁹³ Fourth Semi-Annual Hospital Price Transparency Report. Patient Rights Advocate. February 14, 2023. Available at: <https://www.patientrightsadvocate.org/february-semi-annual-compliance-report-2023>

⁶⁹⁴ Severn, Chris. Price Transparency Hospital Data: Why Am I Seeing Different Assessments of Hospital Compliance? Turquoise Health. October 18, 2022. Available at: <https://blog.turquoise.health/hospital-compliance-assessments/>

⁶⁹⁵ Andrews, M. A Progress Check on Hospital Price Transparency. KFF News. March 29, 2023. Available at: https://kffhealthnews.org/news/article/hospital-price-transparency-federal-rule-checkup-2023/?utm_campaign=KHN%3A%20Daily%20Health%20Policy%20Report&utm_medium=email&_hsmi=252217703&_hsenc=p2ANqtz-9H9illkRczNZhnmE0zhKuwc1oytcDvawv29aM7Fq7gAXWHc_9mjsY3PZkLrJX2vjIDADMQaZ0Yh01jC-NkJqQqflpFlg&utm_content=252217703&utm_source=hs_email

⁶⁹⁶ “Lowering Unaffordable Costs: Examining Transparency and Competition in Health Care.” Congressional House Committee on Energy and Commerce, Subcommittee on Health. March 28, 2023. Available at: <https://energycommerce.house.gov/events/health-subcommittee-hearing-lowering-unaffordable-costs-examining-transparency-and-competition-in-health-care>

referrals, employers searching for lower cost options for healthcare coverage, and other users of the data who may develop consumer-friendly price transparency tools or perform analyses to drive value-based policy-development. Since the establishment of the HPT regulation, innovators have made price information accessible to researchers, academics, employers, and the public. Numerous peer-reviewed academic studies have used the MRF data to conduct price analyses.^{697,698,699,700} Additionally, journalists and news outlets are now commonly conducting their own price analyses and research with HPT data obtained either directly from the hospital MRF or vendor price estimator tools. For example, some have compared prices of common medical procedures like childbirth, or hip and knee replacements among hospitals within specific regions.^{701,702} Across these publications, authors routinely state that some price comparisons may not be fully accurate due to lack of specificity and standardization of the available hospital MRF data.

Early feedback from interested parties, particularly from IT specialists, researchers, employers, and others who seek to use the standard charge information that hospitals are now required to make public, has indicated that increased standardization may be necessary to improve the public's understanding of the standard charges established by hospitals and the public's ability to make comparisons of standard charges from one hospital to the next. The proposed data elements and CMS templates would not only support hospitals in complying with

⁶⁹⁷ Gul, Z., et al. Large Variations in the Prices of Urologic Procedures at Academic Medical Centers 1 Year After Implementation of the Price Transparency Final Rule. *JAMA*. January 5, 2023. Available at:

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800088>

⁶⁹⁸ Rochlin, D., et al. Commercial Price Variation for Breast Reconstruction in the Era of Price Transparency. *JAMA*. December 14, 2022. Available here: <https://jamanetwork.com/journals/jamasurgery/article-abstract/2799698>

⁶⁹⁹ Jiang, X., et al. Price Variability for Common Radiology Services Within U.S. Hospitals. *Radiology*. October 18, 2022. Available at: <https://pubs.rsna.org/doi/10.1148/radiol.221815>

⁷⁰⁰ Mullens, C., et al. Evaluation of Prices for Surgical Procedures Within and Outside Hospital Networks in the US. *JAMA*. February 13, 2023. Available at:

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2801354?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=021323

⁷⁰¹ Maddox, W. How Much Do Insurance Plans Pay for Childbirth in North Texas? *D Magazine*. April 11, 2023. Available at: <https://www.dmagazine.com/healthcare-business/2023/04/how-much-do-insurance-plans-pay-for-childbirth-in-north-texas/>

⁷⁰² Analysis: Inconsistencies Within Hospital Price Transparency Data Make Costs Comparisons Difficult. *KFF*. February 10, 2023. Available at: <https://www.kff.org/health-costs/press-release/analysis-inconsistencies-within-hospital-price-transparency-data-make-cost-comparisons-difficult/>

the rule but also improve the quality and usefulness of MRF data available to consumers of the data, including researchers, innovators, employers, and payers. Studies suggest that standardization would improve the accuracy of price comparisons, the quality and usefulness of MRF data, and perhaps reduce wide variations in hospital prices.^{703,704} In a previous rule, we cited literature regarding consumer engagement with existing price transparency interventions demonstrating that disclosing price information positively impacts consumers of healthcare by allowing them to compare prices for common procedures and shift their demand towards lower-priced options (84 FR 65600). Similarly, studies have indicated that, as these MRF analyses are becoming more widespread, consumers are able to make better use of the pricing information. Standardization would likely remove many of the existing barriers to allow innovators to create more useful data products for consumers of healthcare and reduce some of the uncertainty that currently exists about how hospitals establish standard charges for the items and services they provide.⁷⁰⁵

d. Consideration of Increased Burden to Hospitals Due to Hospital Price Transparency Proposals

(1) Proposals Related to MRF Standardization and Accessibility of Hospital MRFs

Many hospitals have expressed concern over two major hurdles in implementing the HPT rule requirements: administrative burden⁷⁰⁶ and cost,^{707,708} and we acknowledge that the proposals for increasing the data elements and requiring use of a CMS template would impose an

⁷⁰³ Lo, J, et al. Ongoing Challenges with Hospital Price Transparency. Peterson-KFF Health System Tracker. February 10, 2023. Available here: <https://www.healthsystemtracker.org/brief/ongoing-challenges-with-hospital-price-transparency/#Select%20data%20for%20University%20of%20Chicago%20Hospitals>

⁷⁰⁴ Hospital Price Transparency: Understanding and Using the Data. National Consumer Law Center. January 25, 2023. Available at: <https://www.nclc.org/event/hospital-pricing-transparency-understanding-and-using-the-data/>

⁷⁰⁵ Severn, Chris. Price Transparency Impact Report Q3 2022. Turquoise Health. October 19, 2022. Available at: https://s3.us-west-1.amazonaws.com/assets.turquoise.health/impact_reports/TQ_Price-Transparency-Impact-Report_2022_Q3.pdf

⁷⁰⁶ Kacik, A. Hospital Price Transparency: Fines or Full Compliance? Modern Healthcare. January 24, 2023. Available at: <https://www.modernhealthcare.com/finance/hospital-price-transparency-compliance-cms-deaconess-sanford>

⁷⁰⁷ Jiang, J., et al. Price Transparency in Hospitals-Current Research and Future Directions. JAMA. January 5, 2023. Available at: <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800088>

⁷⁰⁸ Meghjani, T. Lawmakers Question Why Hospital Pricing Isn't Living Up to Transparency Goals. Bloomberg. March 28, 2023. Available at: <https://www.bloomberg.com/news/articles/2023-03-28/what-s-the-best-way-to-compare-hospital-costs-us-hearing-seeks-transparency?leadSource=verify%20wall#xj4y7vzkg>

additional one-time burden on hospitals. However, for the reasons discussed in this proposed rule, we believe that transparency is necessary to improve healthcare value, and that the proposals related to MRF standardization would assist hospitals in implementing the HPT regulations and assist numerous interested parties by creating clearer, more accurate data for purposes of price comparison and data analysis that can then be used to drive down healthcare costs. We believe these benefits justify the additional burden to hospitals. We continue to believe that improved hospital compliance with the required disclosure of this pricing information would allow providers, hospitals, insurers, employers, and patients to begin to engage each other and better utilize market forces to address the high cost of healthcare in a more widespread fashion. In addition, we continue to believe, as we noted in the CY 2020 HPT final rule (84 FR 65528), that there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare and lower healthcare costs.

In our CY 2020 HPT final rule, we finalized requirements for MRF accessibility. We prioritized accessibility because we want to be sure hospital standard charge information can be available for use by the public for creating price transparency tools, to be integrated into EHRs for purposes of clinical decision making and referrals, or to be used by researchers and policy officials to help bring more value to healthcare (45 FR 65555). Despite the requirement for the MRF and the standard charge information contained in that file to be digitally searchable and the required naming convention, users of the MRF information, such as IT developers and innovators, continue to express concerns related to challenges in efficiently aggregating the files in an automated way. Some innovators and researchers noted the difficulty in locating hospital MRFs because they are posted on obscure website locations or with links redirecting to vendor websites.^{709,710} We believe that ensuring the MRFs and the data contents are easily accessible to

⁷⁰⁹ Zuradzki, P. How to Parse Hospital Price Transparency Files. Turquoise Health. October 3, 2022. Available at: <https://blog.turquoise.health/how-to-parse-hospital-price-transparency-files/>

⁷¹⁰ Fourth Semi-Annual Hospital Price Transparency Report. Patient Rights Advocate. February 14, 2023. Available at: <https://www.patientrightsadvocate.org/february-semi-annual-compliance-report-2023>

automation aligns with the intended use of the MRFs and their content. Therefore, to increase access to the MRFs, we propose to require hospitals to post a .txt file to the root folder of the public website. To reduce burden on hospitals, CMS would provide both plain language instruction and develop a .txt generator to support this proposed requirement.

As we noted in the preamble, there would be several benefits to requiring a hospital to post a .txt file to the root folder of the public website. This proposed requirement would allow for automated tools to directly link to the MRF, as opposed to the manual location of the correct webpage within the website and may make the location of the MRFs more visible to individual consumers who are manually searching for such files. We believe that the benefit of automating the identification of the MRF location would outweigh the minimal burden to maintainers of the public webpage that hosts the MRF.

(2) Improvements in CMS Enforcement of Hospital Price Transparency

In the CY 2020 HPT final rule (84 FR 65525), we finalized actions to address hospital noncompliance by requiring hospitals determined by CMS to be in material violation of the HPT regulations to submit a corrective action plan (CAP) and to comply with the requirements of the CAP. For hospitals that fail to respond to or comply with the CAP, CMS may impose CMPs and publicize these penalties on a CMS website. However, there are many nuances and complexities associated with the way hospitals establish standard charges that can lead to questions related to the accuracy and completeness of the standard charges information that is included in a hospital's MRF. As mentioned before, we have found it is necessary to employ methods beyond a simple audit of a hospital's website to definitively assess hospital compliance. Although we expect that the deployment of a standardized MRF template would mitigate many of these questions, we may need additional clarification from the hospital to assess or determine accuracy and completeness of the data. As mentioned above, CMS proposes additional methods to assess compliance which include receiving confirmation of receipt of warning notices directly from individuals at the organization responsible for resolving the deficiencies.

While requiring that hospitals acknowledge receipt of warning notices may require additional effort for hospitals who have received notification of a deficiency, we believe it will streamline our enforcement by providing an appropriate compliance contact earlier in the enforcement process, so that we may provide any necessary technical assistance earlier in the compliance process. We also believe this proposed requirement would provide benefits to others, including consumers, researchers, and innovators, by supporting the public release of standard charge data in a timely and accurate manner.

We do not believe that our compliance activities represent a burden to hospitals and therefore have not included any costs in this burden related to them.

e. Limitations of our Analysis

It would be difficult for us to conduct a detailed quantitative analysis given the lack of studies at the national level on the regulatory impact of making price transparency information publicly available. Additionally, implementation of the requirements is relatively new, so the impacts may not yet be realized. Finally, several other price transparency initiatives have been implemented, or are in the process of being implemented, that may make a definitive analysis challenging. Since we cannot produce a detailed quantitative analysis, we have developed a qualitative discussion for this regulatory impact analysis, drawing from examples of experiences of the use of public price transparency data that has been released publicly. We have taken an approach that assesses potential directional impact of these proposed requirements (that is, increasing versus decreasing health care costs, increasing, or decreasing likelihood of certain market behaviors) rather than attempting more specific estimates due to the lack of empirical data. We believe there are many benefits with this regulation, particularly to speed the ability of users of the machine-readable files to identify, ingest, analyze and draw more meaningful comparisons of the hospital standard charge data and ultimately for consumers who will be able to benefit from cost savings through employer-payer negotiations, or through direct access to

hospital cost comparison data developed by innovators and researchers, allowing the ability to shop for the best value.

f. Alternatives Considered

This proposal is designed to begin to address some of the barriers identified that limit price transparency, with a goal of increasing competition among healthcare providers to bring down costs. Specifically, this proposed rule aims to make hospital standard charges more readily available to the public by improving machine-readability of the data and improving automated access to the MRFs. We considered a number of alternative approaches including reducing or increasing the number of proposed data elements, or limiting the CMS template to a single format (for example, JSON).

The proposal to increase data elements that are necessary to provide context to hospital standard charges represents nearly the entire cost in our burden estimate. Thus, reducing the number of proposed data elements would reduce hospital burden and the cost associated with gathering the data necessary to display which increasing the number of proposed data elements would increase hospital burden and the cost associated with gathering data for display. The proposed number of data elements is based on CMS contractor recommendations which took into consideration technical expert input (including input from hospital experts). These technical experts indicated that the data elements currently included in the sample formats found on the CMS website were necessary for providing context to hospital standard charges. They also indicated that the data elements we included in the sample formats strike a balance between burden on the hospital and benefit to the public.

The alternative proposal considered to limit hospital choice of format for the MRF to JSON would be expected to increase hospital burden for hospitals that lack technical expertise.

Ultimately, however, we determined that the alternatives would either limit the usefulness of hospital standard charge information or increase burden for hospitals without any additional benefit to for users of MRF standard charge information.

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 which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$123.06 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 \$984.48 (8 hours x \$123.06). Therefore, we estimate that the total cost of reviewing this regulation is \$1,574,184 (\$984.48 x 1,599).

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 will be reached by the requirements 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 will increase payments to small rural hospitals by approximately 5 percent; therefore, it should have a negligible impact on approximately 555 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 2023, that threshold is approximately \$177 million. This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than \$177 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 will 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 100 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.8 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 propose in this proposed rule will affect all classes of hospitals paid under the OPPS as well as both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2024. Table 100 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 2.9 percent increase in payments for all services paid under the OPPS in CY 2024, 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 OPPS would experience more significant gains or losses in OPPS payments in CY 2024.

The updates we are making to the ASC payment system for CY 2024 will affect each of the approximately 6,000 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will depend on its mix of patients, the proportion of the ASCs 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 101 demonstrates the estimated distributional impact among ASC surgical specialties of the productivity-adjusted hospital market basket update factor of 2.8 percent for CY 2024.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 26, 2023.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

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 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, and Reporting and recordkeeping requirements.

45 CFR Part 180

Hospitals, 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 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

2. Section 405.2400 is amended by adding paragraph (d) to read as follows:

§ 405.2400 Basis.

* * * * *

(d) Section 1834(y) - Payment for certain services furnished by rural health clinics.

3. Section 405.2401(b) is amended by adding the definition of “Intensive outpatient services” in alphabetical order to read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

Intensive outpatient services means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual’s home or in an inpatient or residential setting and that furnishes the services as described in § 410.44 of this chapter.

* * * * *

4. Section 405.2410 is amended by adding paragraph (c) to read as follows:

§ 405.2410 Application of Part B deductible and coinsurance.

* * * * *

(c) *Application of deductible and coinsurance for RHCs and FQHCs paid on the basis of the special payment rule described under § 405.2462(j) of this section.* (1) For RHCs, a coinsurance amount that does not exceed 20 percent of the payment determined under

§ 405.2462(j)(1) of this part; or

(2) For FQHCs, a coinsurance amount that does not exceed 20 percent of the payment determined under § 405.2462(j)(2).

5. Section 405.2411 is amended by adding paragraph (a)(7) to read as follows:

§ 405.2411 Scope of benefits.

(a) * * *

(7) Intensive outpatient services when provided in accordance with section 1861(ff)(4) of the Act and § 410.44 of this chapter.

* * * * *

6. Amend § 405.2446 by adding paragraph (b)(10) to read as follows:

§ 405.2446 Scope of services.

* * * * *

(b) * * *

(10) Intensive outpatient services when provided in accordance with section 1861(ff)(4) of the Act and § 410.44 of this chapter.

* * * * *

7. Section 405.2462 is amended by adding paragraph (j) to read as follows:

§ 405.2462 Payment for RHC and FQHC services.

* * * * *

(j) An RHC is paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter. There are no adjustments to this rate.

(1) If the deductible has been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the payment amount determined under paragraph (j)(1) of this section.

(2) If the deductible has not been fully met by the beneficiary prior to the RHC service,

Medicare pays eighty (80) percent of the difference between the remaining deductible and the payment amount determined under paragraph (j)(1) of this section; or

(3) If the deductible has not been fully met by the beneficiary prior to the RHC service, no payment is made to the RHC if the deductible is equal to or exceeds the payment amount determined under paragraph (j)(1) of this section.

(4) FQHCs are paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter, there are no adjustments to this rate. Except as noted in paragraph (f) of this section.

(i) Medicare pays eighty (80) percent of the lesser of the FQHC's actual charge or the payment rate determined under paragraph (j)(2) of this section; or

(ii) Medicare pays eighty (80) percent of the lesser of a grandfathered tribal FQHC's actual charge or the amount described under paragraphs (f)(2) and (f)(3) of this section.

(iii) No deductible is applicable to FQHC services.

8. Section 405.2463 is amended by revising paragraphs (c)(1)(ii) and (iii), and (c)(4)(ii) to read as follows:

§ 405.2463 What constitutes a visit.

* * * * *

(c) * * *

(1) * * *

(ii) Has a medical visit and a mental health visit or intensive outpatient services on the same day: or

(iii) Has an initial preventive physical exam visit and a separate medical, mental health, or intensive outpatient services visit on the same day.

* * * * *

(4) * * *

(ii) Has a medical visit and a mental health visit or intensive outpatient services on the

same day.

9. Section 405.2464 is amended by adding paragraph (f) to read as follows:

§ 405.2464 Payment rate.

* * * * *

(f) Payment for intensive outpatient services. Payment to RHCs and FQHCs is at the rate determined under § 405.2462(j).

10. Section 405.2468 is amended by adding paragraph (g) to read as follows:

§ 405.2468 Allowable costs.

* * * * *

(g) *Intensive outpatient services.* (1) For RHCs, costs associated with intensive outpatient services are not used to determine the amount of payment for RHC services under the methodology for all-inclusive rates under section 1833(a)(3) of the Act as described in § 405.2464(a).

(2) For FQHCs, costs associated with intensive outpatient services are not used to determine the amount of payment for FQHC services under the prospective payment system under section 1834(o)(2)(B) of the Act as described in § 405.2464(b).

11. Section 405.2469 is amended by revising paragraphs (a)(1) and (a)(2), and adding paragraphs (a)(3) and (b)(4) to read as follows:

§ 405.2469 FQHC supplemental payments.

(a) * * *

(1) The PPS rate if the FQHC is authorized to bill under the PPS;

(2) The Medicare outpatient per visit rate as set annually by the Indian Health Service for grandfathered tribal FQHCs; or

(3) The payment rate as determined in § 405.2462(j).

(b) * * *

(4) Payments received by the FQHC from the MA plan as determined on a per visit basis and the payment rate as determined in § 405.2462(j), less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

12. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd

13. Section 410.2 is amended by—

- a. In the definition r “Community mental health center (CMHC)”, revise paragraph (3);
- b. Adding the definition “Intensive outpatient services” in alphabetical order; and
- c. Revising the definition for “Participating”.

The revisions and addition read as follows:

§ 410.2 Definitions.

* * * * *

Community mental health center (CMHC) means an entity that –

* * *

(3) Provides day treatment or other partial hospitalization services or intensive outpatient services, or psychosocial rehabilitation services;

* * * * *

Intensive outpatient services mean a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in § 410.44.

Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization.

* * * * *

Participating refers to a hospital, CAH, SNF, HHA, CORF, or hospice that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or public health

agency that has a provider agreement to participate in Medicare but only for purposes of providing outpatient physical therapy, occupational therapy, or speech pathology services; or a CMHC that has in effect a similar agreement but only for purposes of providing partial hospitalization services and intensive outpatient services, and nonparticipating refers to a hospital, CAH, SNF, HHA, CORF, hospice, clinic, rehabilitation agency, public health agency, or CMHC that does not have in effect a provider agreement to participate in Medicare.

* * * * *

14. Section 410.3 is amended by revising paragraph (a)(2) to read as follows:

§ 410.3 Scope of benefits.

(a) * * *

(2) Services furnished by ambulatory surgical centers (ASCs), home health agencies (HHAs), comprehensive outpatient rehabilitation facilities (CORFs), and partial hospitalization services and intensive outpatient services provided by community mental health centers (CMHCs).

* * * * *

15. Section 410.10 is amended by revising paragraph (c) to read as follows:

§ 410.10 Medical and other health services: Included services.

* * * * *

(c) Services and supplies, including partial hospitalization services and intensive outpatient services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.

* * * * *

16. Section 410.27 is amended by revising paragraphs (a)(1)(iv)(B)(I), (a)(2), and (e) introductory text to read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

* * * * *

(a) * * *

(1) * * *

(iv) * * *

(B) * * *

(1) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished as specified in §§ 410.47 and 410.49, respectively. Through December 31, 2024, 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

* * * * *

(2) In the case of partial hospitalization services or intensive outpatient services, also meet the conditions of paragraph (e) of this section.

* * * * *

(e) Medicare Part B pays for partial hospitalization services and intensive outpatient services if they are –

* * * * *

17. Section 410.44 is added to read as follows:

§ 410.44 Intensive outpatient services: Conditions and exclusions.

(a) Intensive outpatient services are services that –

(1) Are reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(2) Are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization;

(3) Are furnished in accordance with a physician certification and plan of care as specified under § 424.24(d) of this chapter; and

(4) Include any of the following:

(i) Individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State law.

(ii) Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484 of this chapter.

(iii) Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients.

(iv) Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29.

(v) Individualized activity therapies that are not primarily recreational or diversionary.

(vi) Family counseling, the primary purpose of which is treatment of the individual's condition.

(vii) Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.

(viii) Diagnostic services.

(b) The following services are separately covered and not paid as intensive outpatient

services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(5) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

(c) Intensive outpatient programs are intended for patients who -

(1) Require a minimum of 9 hours per week of therapeutic services as evidenced in their plan of care;

(2) Are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment;

(3) Do not require 24-hour care;

(4) Have an adequate support system while not actively engaged in the program;

(5) Have a mental health diagnosis;

(6) Are not judged to be dangerous to self or others; and

(7) Have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program.

18. Section 410.67 is amended by--

a. In paragraph (b), amend the definition of “*Opioid use disorder treatment service*” by adding paragraph (ix);

b. Adding paragraph (c)(5);

d. Revising paragraph (d)(3);

e. Adding (d)(4)(i)(F); and

f. Revising paragraphs (d)(4)(ii) and (iii).

The revisions and additions read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

(ix) OTP intensive outpatient services, which means one or more services specified in § 410.44(a)(4) when furnished by an OTP as part of a distinct and organized intensive ambulatory treatment program for the treatment of Opioid Use Disorder and that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. OTP intensive outpatient services are reasonable and necessary for the diagnosis or active treatment of the individual's condition; are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and are furnished in accordance with a physician certification and plan of care, in which a physician must certify that the individual has a need for a minimum of nine hours of services per week and requires a higher level of care intensity compared to other non-intensive outpatient OTP services. OTP intensive outpatient services do not include FDA-approved opioid agonist or antagonist medications for the treatment of OUD, opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, or toxicology testing.

* * * * *

(c) * * *

(5) OTPs that provide OTP intensive outpatient services must meet the requirements set forth in § 424.24(d)(1) through (3) of this chapter related to content of certification, plan of treatment, and recertification for the purposes of furnishing OTP intensive outpatient services, except that the recertification required under § 424.24(d)(3)(ii) of this chapter may occur any time during an episode of care in which the 30th day from the start of IOP services falls.

* * * * *

(d) * * *

(3) At least one OUD treatment service described in paragraphs (i) through (v) of the definition of Opioid use disorder treatment service in paragraph (b) of this section must be furnished to bill for the bundled payment for an episode of care.

(4) * * *

(i) * * *

(F) For OTP intensive outpatient services, an adjustment will be made when at least nine OTP intensive outpatient services described in paragraph (b)(ix) of this section are furnished in a week. This adjustment will be based on the per diem payment rate for intensive outpatient services at hospital-based programs defined at 410.44(c) and multiplied by a factor of three for a weekly payment adjustment, excluding an amount equivalent to the amount included in the OTP weekly bundled payment for individual and group therapy.

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and OTP intensive outpatient services, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26 of this subchapter. For purposes of this adjustment, OUD treatment services that are furnished via an OTP mobile unit will be treated as if they were furnished at the physical location of the OTP registered with the Drug Enforcement Administration (DEA) and certified by SAMHSA.

(iii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments and OTP intensive outpatient services, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be updated annually using the Medicare Economic Index described in § 405.504(d) of this subchapter.

* * * * *

19. Revise the heading to Subpart E to read as follows:

Subpart E – Community Mental Health Centers (CMHCs) Providing Partial Hospitalization Services and Intensive Outpatient Services

20. Section 410.111 is added to read as follows:

§ 410.111 Requirements for coverage of intensive outpatient services in CMHCs.

Medicare part B covers intensive outpatient services furnished by or under arrangements made by a CMHC if they are provided by a CMHC as defined in § 410.2 that has in effect a provider agreement under part 489 of this chapter and if the services are--

(a) Prescribed by a physician and furnished under the general supervision of a physician;

(b) Subject to certification by a physician in accordance with § 424.24(d)(1) of this subchapter; and

(c) Furnished under a plan of treatment that meets the requirements of § 424.24(d)(2) of this subchapter.

21. Section 410.150 is amended by revising paragraph (b)(13) to read as follows:

§ 410.150 To whom payment is made.

* * * * *

(b) * * *

(13) To a community mental health center (CMHC) on the individual's behalf, for partial hospitalization services or intensive outpatient services furnished by the CMHC (or by others under arrangements made with them by the CMHC).

* * * * *

22. Section 410.155 is amended by revising paragraph (b)(2)(iii) to read as follows:

§ 410.155 Outpatient mental health treatment limitation.

* * * * *

(b) * * *

(2) * * *

(iii) Partial hospitalization services or intensive outpatient services not directly provided by a physician.

* * * * *

23. Section 410.173 is added to read as follows:

§ 410.173 Payment for intensive outpatient services in CMHCs: Conditions.

Medicare Part B pays for intensive outpatient services furnished in a CMHC on behalf of an individual only if the following conditions are met:

(a) The CMHC files a written request for payment on the CMS form 1450 and in the manner prescribed by CMS; and

(b) The services are furnished in accordance with the requirements described in § 410.111.

PART 416—AMBULATORY SURGICAL SERVICES

24. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

25. Section 416.171 is amended by revising paragraphs (a)(2)(iii), (iv), (vi), and (vii), and (a)(2)(viii)(B) and (C) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) * * *

(iii) For CY 2019 through CY 2025, the update is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(iv) For CY 2026 and subsequent years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

* * * * *

(vi) For CY 2019 through CY 2025, the hospital inpatient market basket update

determined under paragraph (a)(2)(iii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vii) For CY 2026 and subsequent years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(iv) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(viii) * * *

(B) For CY 2019 through CY 2025, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section, after application of any reduction under paragraph (a)(2)(vi) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(C) For CY 2026 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(iv) of this section, after application of any reduction under paragraph (a)(2)(vii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

* * * * *

26. Section 416.172 is amended by revising paragraph (d) to read as follows:

§ 416.172 Adjustments to national payment rates.

* * * * *

(d) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in §§ 410.152(a) and (i)(2) of this subchapter and in 42 CFR 489.30(b)(6).

* * * * *

27. Section 416.305 is amended by revising paragraph (b)(1) to read as follows:

§ 416.305 Participation and withdrawal requirements under the ASCQR Program.

* * * * *

(b) * * *

(1) An ASC may withdraw from the ASCQR Program by submitting to CMS a withdrawal of participation form that can be found in the secure portion of the CMS-designated information system.

28. Section 416.310 is amended by revising paragraphs (c)(1)(i) and (d)(1) to read as follows:

§ 416.310 Data collection and submission requirements under the ASQR Program.

* * * * *

(c) * * *

(1) * * *

(i) CMS-designated information system account for web-based measures. ASCs, and any agents submitting data on an ASC's behalf, must maintain an account for the CMS-designated information system in order to submit quality measure data to the CMS-designated information system for all web-based measures submitted via a CMS online data submission tool. A security official is necessary to set up such an account for the CMS-designated information system for the purpose of submitting this information.

* * * * *

(d) * * *

(1) *Upon request of the ASC.* Specific requirements for submission of a request for an exception are available on the CMS website.

* * * * *

29. 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 removal.* In cases where CMS believes that the continued use of a measure as specified raises patient safety concerns, CMS will immediately remove a quality measure from the ASCQR Program and will promptly notify ASCs and the public of the removal of the measure and the reasons for its removal through the ASCQR Program ListServ and the ASCQR Program CMS website. CMS will confirm the removal of the measure for patient safety concerns in the next ASCQR Program rulemaking.

* * * * *

30. Section 416.325 is amended by revising paragraph (c) to read as follows:

§ 416.325 Measure maintenance under the ASCQR Program.

* * * * *

(c) *Non-substantive changes.* If CMS determines that a change to a measure previously adopted in the ASCQR Program is non-substantive, CMS will use a sub-regulatory process to revise the ASCQR Program Specifications Manual so that it clearly identifies the changes to that measure and provide links to where additional information on the changes can be found. When a measure undergoes sub-regulatory maintenance, CMS will provide notification of the measure specification update on the CMS website and in the ASCQR Program Specifications Manual, and will provide sufficient lead time for ASCs to implement the revisions where changes to the data collection systems would be necessary.

PART 419—PROSPECTIVE PAYMENT SYSTEMS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

31. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh

32. Section 419.20 is amended by adding paragraph (b)(5) to read as follows:

§ 419.20 Hospitals subject to the hospital outpatient prospective payment system.

* * * * *

(b) * * *

(5) A rural emergency hospital (REH).

33. Section 419.21 is amended by revising paragraph (c) for read as follows:

§ 419.21 Hospital services subject to the outpatient prospective payment system.

* * * * *

(c) Partial hospitalization services and intensive outpatient services furnished by community mental health centers (CMHCs).

* * * * *

34. Section 419.41 is amended by adding paragraphs (d), (e), (f), and (g) to read as follows:

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

* * * * *

(d) Notwithstanding the foregoing, for a drug or biological for which payment is not packaged into a payment for a covered OPD service (or group of services) and is not a rebatable drug (as defined in section 1847A(i)(2)(A)), to calculate the program payment and copayment amounts CMS does the following:

(1) Determines the payment rate for the drug or biological for the quarter established under the methodology described by section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14) of section 1833(t) of the Act.

(2) Subtracts from the amount determined under paragraph (d)(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 (d)(1) of this section (less any applicable deductible under paragraph (d)(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 (d)(3) of this section from the

amount determined under paragraph (d)(1) of this section (less any applicable deductible determined under paragraph (d)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (d)(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.

(e) In the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), except if such drug does not have a copayment amount as a result of application of section 1833(t)(8)(E) of the Act, for which payment is not packaged into payment for a covered OPD service (or group of services) furnished on or after April 1, 2023, and the payment for such drug under the OPDS is the same as the amount for a calendar quarter under section 1847A(i)(3)(A)(ii)(I) of the Act, in lieu of the calculation of the copayment amount and the Medicare program payment amount otherwise applicable under paragraph (d) of this section (other than application of the limitation described in paragraph (c)(4)(i) of this section), the copayment and Medicare program payment amounts determined under §§ 410.152(m) and 489.30(b)(6) of this chapter shall apply.

(f) In the case of a qualifying biosimilar biological product (as defined in § 414.902 of this subchapter) that is furnished during the applicable five-year period (as defined in § 414.902 of this subchapter) for such product, the payment amount for such product with respect to such period is the amount determined in § 414.904(j)(2) of this subchapter.

(g) For dates of service on or after July 1, 2024, the payment amount for a biosimilar biological product (as defined in § 414.902 of this subchapter) during the initial period is the amount determined in § 414.904(e)(4)(ii) of this subchapter.

35. Section 419.46 is amended by revising the section heading and paragraphs (b), (c), (d)(2), (e)(1), (g)(1), and (i)(2) to read as follows:

§ 419.46 Requirements Under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(b) *Participation in the Hospital OQR Program.* To participate in the Hospital OQR Program, a hospital as defined in section 1886(d)(1)(B) of the Act and is paid under the OPPTS must—

- (1) Register on the CMS-designated information system before beginning to report data;
- (2) Identify and register a CMS-designated information system security official as part of the registration process under paragraph (b)(1) of this section; and
- (3) Submit at least one data element.

(c) *Withdrawal from the Hospital OQR Program.* A participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the CMS-designated information system. The hospital may withdraw any time up to and including August 31 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under paragraph (i) of this section, and is required to renew participation as specified in paragraph (b) of this section in order to participate in any future year of the Hospital OQR Program.

(d) * * *

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on the CMS website. 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-work day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a non-work day for Federal employees by statute or Executive order.

* * * * *

(e) * * *

(1) *Upon request by the hospital.* Specific requirements for submission of a request for

an exception are available on the CMS website.

* * * * *

(g) ***

(1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program in paragraph (b) of this section for a particular calendar year. Except as provided in paragraph (e) of this section, a hospital must submit a reconsideration request to CMS via the CMS-designated information system, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day as defined in paragraph (d)(2) of this section, of the affected payment year as determined using the date the request was mailed or submitted to CMS.

* * * * *

(i) * * *

(2) *Immediate measure removal.* For cases in which CMS believes that the continued use of a measure as specified raises patient safety concerns, CMS will immediately remove a quality measure from the Hospital OQR Program and will promptly notify hospitals and the public of the removal of the measure and the reasons for its removal through the Hospital OQR Program ListServ and the CMS website.

* * * * *

36. Section 419.92 is amended by adding paragraphs (d) and (e) to read as follows:

§ 419.92 Payment to rural emergency hospitals.

* * * * *

(d) *Payment for IHS or tribally operated REHs.* An Indian Health Service (IHS) or tribally operated REH, as defined in paragraph (e) of this section will be paid under the outpatient hospital All-Inclusive Rate that is established and published annually by the Indian Health Service rather than the rates for REH services described in paragraph (a)(1) of this section.

(e) *IHS or tribally operated REHs.* An Indian Health Service (IHS) or tribally operated REH is an REH, as defined in § 485.502 of this chapter, that is operated by the IHS or by a tribe or tribal organization with funding authorized by Title I or III of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

37. Section 419.93 is amended by revising paragraph (a)(2) to read as follows:

§ 419.93 Payment for an off-campus provider-based department of a rural emergency hospital.

(a) * * *

(2) Services that do not meet the definition of REH services under § 419.91 that are furnished by an off-campus provider-based department of an REH are paid as described under § 419.92(c) or, if applicable, § 419.92(d).

* * * * *

38. Section 419.95 is added to read as follows:

§ 419.95 Requirements under the Rural Emergency Hospital Quality Reporting (REHQR) Program.

(a) *Statutory authority.* Section 1861(kkk) (7) of the Social Security Act authorizes the Secretary to implement a quality reporting program requiring Rural Emergency Hospitals (REHs) to submit data on measures in accordance with the Secretary's requirements in this part.

(b) *Participation in the REHQR Program.* To participate in the REHQR Program, an REH as defined in section 1861(kkk) (2) of the Act must –

- (1) Register on a CMS website before beginning to report data;
- (2) Identify and register a security official as part of the registration process under paragraph (b)(1) of this section; and
- (3) Submit data on all quality measures to CMS as specified under paragraph (d) of this section.

(c) *Submission of REHQR Program data—(1) General rule.* REHs that participate in

the REHQR Program must submit to CMS data on measures selected under section 1861(kkk)(7)(C) of the Act in a form and manner, and at a time specified by CMS. REHs sharing the same CMS Certification Number (CCN) must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on a CMS website. 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-work day for Federal employees by statute or executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a non-work day for Federal employees by statute or executive order.

(3) *Review and corrections period.* For all quality data submitted, REHs will have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, REHs can enter, review, and correct data submitted. However, after the submission deadline, these data cannot be changed.

(d) *Technical specifications and measure maintenance under the REHQR Program.*

(1) CMS will update the specifications manual for measures in the REHQR Program at least every 12 months.

(2) CMS follows different procedures to update the measure specifications of a measure previously adopted under the REHQR Program based on whether the change is substantive or non-substantive. CMS will determine what constitutes a substantive versus a non-substantive change to a measure's specifications.

(i) *Substantive changes.* CMS will use rulemaking to adopt substantive updates to measures in the REHQR Program.

(ii) *Non-substantive changes.* If CMS determines that a change to a measure previously

adopted in the REHQR Program is non-substantive, CMS will use a sub-regulatory process to revise the specifications manual for the REHQR Program so that it clearly identifies the change to that measure and provide links to where additional information on the change can be found. When a measure undergoes sub-regulatory maintenance, CMS will provide notification of the measure specification update on a designated website and in the specifications manual, and will provide sufficient lead time for REHs to implement the revisions where changes to the data collection systems would be necessary.

(e) Retention and removal of quality measures under the REHQR Program.

(1) General rule for the retention of quality measures. Quality measures adopted for the REHQR Program measure set are retained for use, except when they are removed, suspended, or replaced as set forth in paragraphs (e)(2) and (e)(3) of this section.

(2) Immediate measure removal. In cases where CMS believes that the continued use of a quality measure as specified raises patient safety concerns, CMS will immediately remove the measure from the REHQR Program and will promptly notify REHs and the public of the removal of the measure and the reasons for its removal. CMS will confirm the removal of the measure in the next appropriate rulemaking.

(3) Measure removal, suspension, or replacement through the rulemaking process.

Unless a measure raises specific safety concerns as set forth in paragraph (e)(2) of this section, CMS will use rulemaking to remove, suspend, or replace quality measures in the REHQR Program.

(i) Factors for consideration for removal of quality measures. CMS will weigh whether to remove measures based on the following factors:

(A) Factor 1. Measure performance among REHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (“topped-out” measures);

(B) Factor 2. Performance or improvement on a measure does not result in better patient

outcomes;

(C) *Factor 3.* A measure does not align with current clinical guidelines or practice;

(D) *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(G) *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Criteria to determine topped-out measures.* For the purposes of the REHQR Program, a measure is considered to be topped-out under paragraph (e)(3)(i)(A) of this section when it meets both of the following criteria:

(A) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an REH's measure is within two times the standard error of the full data set); and

(B) A truncated coefficient of variation less than or equal to 0.10.

(iii) *Application of measure removal factors.* The benefits of removing a measure from the REHQR Program will be assessed on a case-by-case basis. Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor.

(f) *Public reporting of data under the REHQR Program.* Data that an REH submits for the REHQR Program will be made publicly available on a CMS website in an easily understandable format after providing the REH an opportunity to review the data to be made public. CMS will publicly display REH data by the CCN when data are submitted under the

CCNs.

(g) *Exception.* CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) *Upon request by the REH.* Specific requirements for submission of a request for an exception are available on a CMS website.

(2) *At the discretion of CMS.* CMS may grant exceptions to REHs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

39. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

40. Section 424.24 is amended by—

- a. Revising paragraphs (b);
- b. Adding paragraph (d), and
- c. Revising paragraph (e)(1)(i).

The revisions and addition read as follows:

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

* * * * *

(b) *General rule.* Medicare Part B pays for medical and other health services furnished by providers (and not exempted under paragraph (a) of this section) only if a physician certifies the content specified in paragraphs (c)(1), (c)(4), (d)(1), or (e)(1) of this section, as appropriate.

* * * * *

(d) *Intensive outpatient services: Content of certification and plan of treatment*

requirements -

(1) *Content of certification.* (i) The individual requires such services for a minimum of 9 hours per week.

(ii) The services are or were furnished while the individual was under the care of a physician.

(iii) The services were furnished under a written plan of treatment that meets the requirements of paragraph (d)(2) of this section.

(2) *Plan of treatment requirements.* (i) The plan is an individualized plan that is established and is periodically reviewed by a physician in consultation with appropriate staff participating in the program, and that sets forth -

(A) The physician's diagnosis;

(B) The type, amount, duration, and frequency of the services; and

(C) The treatment goals under the plan.

(ii) The physician determines the frequency and duration of the services taking into account accepted norms of medical practice and a reasonable expectation of improvement in the patient's condition.

(3) *Recertification requirements—(i) Signature.* The physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment.

(ii) *Timing.* Recertifications are required at intervals established by the provider, but no less frequently than every 60 days.

(iii) *Content.* The recertification must specify that the patient continues to require at least 9 hours of intensive outpatient services and describe the following:

(A) The patient's response to the therapeutic interventions provided by the intensive outpatient program.

(B) The patient's psychiatric symptoms that continue to place the patient at risk of relapse or hospitalization.

(C) Treatment goals for coordination of services to facilitate discharge from the intensive outpatient program.

(e) * * *

(1) * * *

(i) The individual requires such services for a minimum of 20 hours per week, and would require inpatient psychiatric care if the partial hospitalization services were not provided.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

41. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh).

42. Section 485.506 is amended by revising paragraphs (b) and (c) to read as follows:

§ 485.506 Designation and certification of REHs.

* * * * *

(b) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds located in a county (or equivalent unit of local government) that is considered rural (as defined in section 1886(d)(2)(D) of the Act); or

(c) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds that was treated as being located in a rural area that has had an active reclassification from urban to rural status as specified in § 412.103 of this chapter as of December 27, 2020.

43. Section 485.900 is amended by revising paragraphs (a)(1), (2), and (3) to read as follows:

§ 485.900 Basis and scope.

(a) * * *

(1) Section 1832(a)(2)(J) of the Act specifies that payments may be made under Medicare Part B for partial hospitalization services and intensive outpatient services furnished by a community mental health center (CMHC) as described in section 1861(ff)(3)(B) of the Act.

(2) Section 1861(ff) of the Act describes the items and services that are covered under Medicare Part B as “partial hospitalization services” and “intensive outpatient services” and the conditions under which the items and services must be provided. In addition, section 1861(ff) of the Act specifies that the entities authorized to provide partial hospitalization services and intensive outpatient services under Medicare Part B include CMHCs and defines that term.

(3) Section 1866(e)(2) of the Act specifies that a provider of services for purposes of provider agreement requirements includes a CMHC as defined in section 1861(ff)(3)(B) of the Act, but only with respect to providing partial hospitalization services and intensive outpatient services.

* * * * *

44. Section 485.904 is amended by revising paragraph (b)(5) and adding paragraph (b)(12) to read as follows:

§ 485.904 Condition of participation: Personnel qualifications.

* * * * *

(b) * * *

(5) *Mental health counselor.* An individual who meets the applicable education, training, and other requirements of § 410.54 of this chapter.

* * * * *

(12) *Marriage and family therapist.* An individual who meets the applicable education, training, and other requirements of § 410.53 of this chapter

* * * * *

45. Section 485.914 is amended by revising paragraphs (a)(2) and (d)(2) to read as

follows:

§ 485.914 Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client.

(a) * * *

(2) For clients assessed and admitted to receive partial hospitalization services and intensive outpatient services, the CMHC must also meet separate requirements as specified in §§ 485.918(f) and 485.918(g), as applicable.

* * * * *

(d) * * *

(2) For clients that receive PHP or IOP services, the assessment must be updated no less frequently than every 30 days.

* * * * *

46. Section 485.916 is amended by revising paragraph (d) to read as follows:

§ 485.916 Condition of participation: Treatment team, person-centered active treatment plan, and coordination of services.

* * * * *

(d) *Standard: Review of the person-centered active treatment plan.* The CMHC interdisciplinary treatment team must review, revise, and document the individualized active treatment plan as frequently as the client's condition requires, but no less frequently than every 30-calendar day. A revised active treatment plan must include information from the client's initial evaluation and comprehensive assessments, the client's progress toward outcomes and goals specified in the active treatment plan, and changes in the client's goals. The CMHC must also meet partial hospitalization program requirements specified under § 424.24(e) of this chapter or intensive outpatient service requirements as specified under § 424.24(d) of this chapter, as applicable, if such services are included in the active treatment plan.

* * * * *

47. Section 485.918 is amended by:

- a. Revising the section heading;
- b. Revising paragraph (b)(1)(iii);
- c. Redesignating paragraph (g) as paragraph (h); and
- d. Adding paragraph (g).

The revisions and addition read as follows:

§ 485.918 Condition of participation: Organization, governance, administration of services, partial hospitalization services and intensive outpatient services.

* * * * *

(b) * * *

(1) * * *

(iii) Provides day treatment, partial hospitalization services, or intensive outpatient services, other than in an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.

* * * * *

(g) *Standard: Intensive outpatient services.* A CMHC providing intensive outpatient services must –

- (1) Provide services as defined in § 410.2 of this chapter.
- (2) Provide the services and meet the requirements specified in § 410.44 of this chapter.
- (3) Meet the requirements for coverage as described in § 410.111 of this chapter.
- (4) Meet the content of certification and plan of treatment requirements as described in § 424.24(d) of this chapter.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

48. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302; and 1395hh.

49. Section 488.2 is amended by revising provision “1832(a)(2)(J)” to read as follows:

§ 488.2 Statutory basis.

* * * * *

1832(a)(2)(J)–Requirements for partial hospitalization services and intensive outpatient services provided by CMHCs.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

50. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh).

48. Section 489.2 is amended by revising paragraph (c)(2) to read as follows:

§ 489.2 Scope of part.

* * * * *

(c) * * *

(2) CMHCs may enter into provider agreements only to furnish partial hospitalization services and intensive outpatient services.

* * * * *

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 180 as set forth below:

PART 180—HOSPITAL PRICE TRANSPARENCY

51. The authority citation for part 180 continues to read as follows:

Authority: 42 U.S.C. 300gg-18, 42 U.S.C. 1302.

52. Section 180.20 is amended by—

a. Adding definitions for “CMS template”, “Consumer-friendly expected allowed charges”, “Encode”, and “Machine-readable file”.

b. In the definition “Machine-readable format” removing the sentence “Examples of machine-readable formats include, but are not limited to, XML, JSON and .CSV formats.”

The additions read as follows:

§ 180.20 Definitions.

* * * * *

CMS template means a CSV format or JSON schema that CMS makes available for purposes of compliance with 180.40(a).

Consumer-friendly expected allowed amount means the average dollar amount that the hospital estimates it will be paid by a third party payer for an item or service.

* * * * *

Encode means to enter data items into the fields of the CMS template.

* * * * *

Machine-readable file means a single digital file that is in a machine-readable format.

* * * * *

53. Section 180.50 is amended by--

a. Adding paragraph (a)(3);

b. Revising paragraphs (b) and (c);

c. Amending paragraph (d)(4) by removing the phrase “The digital file and standard charge information contained in that file must be” and adding in its place the phrase “The machine-readable file and standard charge information contained in that machine-readable file must be”.

d. Amending paragraph (d)(5) by:

i. Removing the phrase “The file must” and adding in its place the phrase “The

machine-readable file must”; and

ii.e.. Removing the phrase “[json|xml|csv]” and adding in its place the phrase “[json|csv]”.

f. Adding paragraph (d)(6).

g. Amending paragraph (e) by removing the second sentence.

The additions and revisions read as follows:

§ 180.50 Requirements for making public hospital standard charges for all items and services.

* * * * *

(a) * * *

(3) The hospital must include a statement in its machine-readable file affirming that the hospital, to the best of its knowledge and belief, has included all applicable standard charge information in accordance with the requirements of this section, and that the information displayed is true, accurate, and complete as of the date indicated in the file.

(b) Required data elements. Each hospital must encode in its machine-readable file all standard charge information, as applicable, for each of the following required data elements:

(1) General data elements:

(i) Hospital name, license number, and location name(s) and address(es) at which the public may obtain the items and service at the standard charge amount indicated in the machine-readable file; and

(ii) The version number of the CMS template and the date of most recent update of the standard charge information in the machine-readable file.

(2) Each type of standard charge as defined at § 180.20 (for example, gross charge, discounted cash price, payer-specific negotiated charge, de-identified

minimum negotiated charge, and de-identified maximum negotiated charge) and, for payer-specific negotiated charges, the following additional data elements:

(i) Payer and plan names; plan(s) may be indicated as categories (such as “all PPO plans”) when the established payer-specific negotiated charges are applicable to each plan in the indicated category.

(ii) Type of contracting method used to establish the standard charge; and

(iii) Whether the standard charge indicated should be interpreted by the user as a dollar amount, or if the standard charge is based on a percentage or algorithm. If the standard charge is based on a percentage or algorithm, the MRF must also specify what percentage or algorithm determines the dollar amount for the item or service, and the consumer-friendly expected allowed amount for that item or service.

(3) A description of the item or service that corresponds to the standard charge established by hospital, including:

(i) A general description of the item or service;

(ii) Whether the item or service is provided in connection with an inpatient admission or an outpatient department visit; and

(iii) For drugs, the drug unit and type of measurement.

(4) Any codes used by the hospital for purposes of accounting or billing for the item or service, modifier(s), and the code type(s).

(c) Format. The hospital’s machine-readable file must conform to the CMS template layout, data specifications, and data dictionary for purposes of making public the standard charge information required under paragraph (b) of this section.

(d) * * *

(6) The hospital must ensure that the public website it selects to host its machine-readable file establishes and maintains, in the form and manner specified by

CMS:

(i) A .txt file in the root folder that includes:

(A) The hospital location name that corresponds to the machine-readable file;

(B) The source page URL that hosts the machine-readable file;

(C) A direct link to the machine-readable file (the machine-readable file URL);

and

(D) Hospital point of contact information.

(ii) A link in the footer on its website, including but not limited to the homepage, that is labeled “Hospital Price Transparency” and links directly to the publicly available webpage that hosts the link to the machine-readable file.

54. Section 180.70 is amended by:

a. Revising paragraph (a) introductory text.

b. Revising paragraph (a)(2)(iii).

c. By adding paragraphs (a)(2)(iv) and (v).

d. By revising paragraph (b)(1); and

e. By adding paragraphs (c) and (d).

The additions and revisions read as follows:

§ 180.70 Monitoring and enforcement.

(a) *Monitoring and assessment.*

(1) * * *

(2) * * *

* * * * *

(iii) CMS audit and comprehensive review.

(iv) Requiring submission of certification by an authorized hospital official as to the accuracy and completeness of the data in the machine-readable file.

(v) Requiring submission of additional documentation as may be necessary to

make a determination of hospital compliance.

(b) * * *

(1) Provide a written warning notice to the hospital of the specific violation(s).

CMS will require that a hospital submit an acknowledgement of receipt of the warning notice in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital.

* * * * *

(c) *Actions to address noncompliance of hospitals in health systems.* In the event CMS takes an action to address hospital noncompliance (as specified in paragraph (b) of this section) and the hospital is determined by CMS to be part of a health system, CMS may notify health system leadership of the action and may work with health system leadership to address similar deficiencies for hospitals across the health system.

(d) *Publicizing assessments, compliance actions, and outcomes.* CMS may publicize on its website information related to the following:

(1) CMS' assessment of a hospital's compliance.

(2) Any compliance action taken against a hospital, the status of such compliance action, or the outcome of such compliance action.

(3) Notifications sent to health system leadership.

§ 180.90 [Amended]

55. In §180.90, amend paragraph (b)(2)(ii)(C) by removing the phrase “resulting from monitoring activities” and adding in its place the phrase “resulting from monitoring and assessment activities”.

Dated: July 7, 2023.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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