DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 416, 419, and 512

Office of the Secretary

45 CFR Part 180

[CMS–1753–P]

RIN 0938–AU43

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), Depatment 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 (CY) 2022 based on our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program, update Hospital Price Transparency requirements, and update and refine the design of the Radiation Oncology Model. Finally, this proposed rule includes a Request for Information (RFI) focusing on the health and safety standards, quality measures and reporting requirements, and payment policies for Rural Emergency Hospitals (REHs), a new Medicare provider type. The RFI will be used to inform future rulemaking for REHs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by September 17, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1753–P when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1753–P, P.O. Box 8010, Baltimore, MD 21244–1850.

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

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1753–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

FOR FURTHER INFORMATION CONTACT: 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 Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Cyra Duncan via email *Cyra.Duncan@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*.

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

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Au'Sha Washington via email at *AuSha.Washington@cms.hhs.gov*.

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

Hospital Inpatient Quality Reporting Program—Administration Issues, contact Julia Venanzi, *julia.venanzi@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Shaili Patel via email *Shaili.Patel@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, contact the Hospital Price Transparency email box at *PriceTransparencyHospitalCharges@cms.hhs.gov*.

Inpatient Only (IPO) Procedures List, contact Au'Sha Washington via email at *Ausha.Washington@cms.hhs.gov*, or Allison Bramlett via email *Allison.Bramlett@cms.hhs.gov*, Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*, or Abigail Cesnik at *Abigail.Cesnik@cms.hhs.gov*.

Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule), 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*.

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

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

OPPS 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) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov*.

Rural Hospital Payments, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

Skin Substitutes, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

Supervision of Outpatient Therapeutic Services in Hospitals and CAHs, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

RO Model, contact *RadiationTherapy@cms.hhs.gov* or at 844–711–2664, Option 5.

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: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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*.

Current Procedural Terminology (CPT) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2019 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR and Defense Federal Acquisition Regulations (DFAR) apply.

Table of Contents

I. Summary and Background
- A. Executive Summary of This Document
- B. Legislative and Regulatory Authority for the Hospital OPPS
- C. Excluded OPPS Services and Hospitals
- D. Prior Rulemaking
- E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)
- F. Public Comments Received on the CY 2021 OPPS/ASC Final Rule with Comment Period

II. Proposed Updates Affecting OPPS Payments
- A. Proposed Recalibration of APC Relative Payment Weights
- B. Proposed Conversion Factor Update
- C. Proposed Wage Index Changes
- D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)
- 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 2021
- F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2021
- G. Proposed Hospital Outpatient Outlier Payments
- H. Proposed Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment
- I. Proposed Beneficiary Copayments

III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
- A. Proposed OPPS Treatment of New and Revised HCPCS Codes
- B. Proposed OPPS Changes—Variations Within APCs
- C. Proposed New Technology APCs
- D. Proposed OPPS APC-Specific Policies

IV. Proposed OPPS Payment for Devices
- A. Proposed Pass-Through Payments for Devices
- B. Proposed Device-Intensive Procedures

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals
- A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals
- B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices
- A. Background
- B. Proposed Estimate of Pass-Through Spending

VII. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

VIII. Payment for Partial Hospitalization Services
- A. Background
- B. Proposed PHP APC Update for CY 2021
- C. Proposed Outlier Policy for CMHCs

IX. Proposed Services That Would Be Paid Only as Inpatient Services
- A. Background
- B. Proposed Changes to the Inpatient Only (IPO) List
- C. Comment Solicitation

X. Proposed Nonrecurring Policy Changes
- A. Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)
- B. Proposed Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2021 and Subsequent Years

XI. Proposed CY 2021 OPPS Payment Status and Comment Indicators
- A. Proposed CY 2021 OPPS Payment Status Indicator Definitions
- B. Proposed CY 2021 Comment Indicator Definitions

XII. MedPAC Recommendations
- A. Proposed OPPS Payment Rates Update
- B. Proposed ASC Conversion Factor Update
- C. Proposed ASC Cost Data

XIII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System
- A. Background
- B. Proposed ASC Treatment of New and Revised Codes
- C. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services
- D. Proposed Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services

E. Proposed New Technology Intraocular Lenses (NTIOLs)
F. Proposed ASC Payment and Comment Indicators
G. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor
XIV. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Outpatient Quality Programs—Request for Information
XV. Proposed Requirements for the Hospital Outpatient Quality Reporting (OQR) Program
A. Background
B. Proposed Hospital OQR Program Quality Measures
C. Administrative Requirements
D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program
E. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2021 Payment Determination
XVI. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program
A. Background
B. Proposed ASCQR Program Quality Measures
C. Administrative Requirements
D. Form, Manner, and Timing of Data Submitted for the ASCQR Program
E. Proposed Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements
XVII. Request for Information on Rural Emergency Hospitals
A. Background
B. Solicitation of Public Comments
C. RO Model Proposed Regulations
XVIII. Radiation Oncology Model
A. Introduction
B. Background
XIX. Proposed Updates to Requirements for Hospitals To Make Public a List of Their Standard Charges
A. Introduction and Overview
B. Proposal To Increase the Civil Monetary Penalty Using a Scaling Factor
C. Proposal To Deem Certain State Forensic Hospitals as Having Met Requirements
D. Proposals Prohibiting Additional Barriers To Accessing the Machine-Readable File
E. Clarifications and Requests for Comment
XX. Additional Hospital Inpatient Quality Reporting (IQR) Program Policies
XXI. Additional Medicare Promoting Interoperability Program Policies
XXII. Files Available to the Public via the Internet
XXIII. Collection of Information Requirements
A. Statutory Requirement for Solicitation of Comments
B. ICRs for the Hospital OQR Program
C. ICRs for the ASCQR Program
D. ICRs for [placeholder for any rider]
E. Total Reduction in Burden Hours and in Costs
XXIV. Response to Comments
XXV. Economic Analyses
A. Statement of Need
B. Overall Impact for the Provisions of This Proposed Rule
C. Detailed Economic Analyses
D. Regulatory Review Costs
E. Regulatory Flexibility Act (RFA) Analysis
F. Unfunded Mandates Reform Act Analysis
G. Federalism Analysis

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, 2022. 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 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 practices, 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 and the ASC Quality Reporting (ASCQR) Program.

2. Summary of the Major Provisions

- *OPPS Update:* For 2022, we propose to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.3 percent. This increase factor is based on the proposed hospital inpatient market basket percentage increase of 2.5 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) 2022 would be approximately $82.704 billion, an increase of approximately $10.757 billion compared to estimated CY 2021 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 CY 2022 OPPS/ASC Ratesetting:* To set CY 2022 OPPS and ASC payment rates, we would normally use the most updated claims and cost report data available. However, because the CY 2020 claims data includes services furnished during the COVID–19 PHE, which significantly affected outpatient service utilization, we have determined that CY 2019 data would better approximate expected CY 2022 outpatient service utilization than CY 2020 data. As a result, we are proposing to utilize CY 2019 data to set CY 2022 OPPS and ASC payment rates.
- *Partial Hospitalization Update:* For the CY 2022 OPPS/ASC proposed rule, CMS is proposing to use the CMHC and hospital-based PHP (HB PHP) geometric mean per diem costs, consistent with existing methodology, but with a cost floor that would maintain the per diem costs finalized in CY 2021. CMS is also proposing to use CY 2019 claims and cost report data for each provider type. This proposal is consistent with a broader CY 2022 OPPS ratesetting proposal to use claims and cost report data prior to the PHE.
- *Changes to the Inpatient Only (IPO) List:* For 2022, we propose to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 against our longstanding criteria for removal, we propose to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022. CMS is also proposing to codify in regulation the five longstanding criteria used to determine whether a procedure or service should be removed from the IPO list. In addition, we solicit comment on several policy modifications including whether CMS should maintain the longer-term objective of eliminating the IPO list or maintain the IPO list but continue to systematically scale the list back so that inpatient only designations are consistent with current standards of practice.
- *Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule):* For CY 2022,

we propose to exempt procedures that are removed from the inpatient only (IPO) list under the OPPS beginning on or January 1, 2021, from site-of-service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organization (BFCC–QIO) referrals to Recovery Audit Contractor (RAC) for persistent noncompliance with the 2-midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service) for a time period of 2 years.

• 340B-*Acquired Drugs:* We propose to continue our current policy of paying an adjusted amount of ASP minus 22.5 percent for drugs and biologicals acquired under the 340B program. We are proposing to continue to exempt Rural SCHs, PPS-exempt cancer hospitals and children's hospitals from our 340B payment policy.

• *Device Pass-Through Payment Applications:* For CY 2022, we received eight applications for device pass-through payments. One of these applications (the Shockwave C² Coronary Intravascular Lithotripsy (IVL) catheter) received preliminary approval for pass-through payment status through our quarterly review process. We are soliciting public comment on all eight of these applications and final determinations on these applications will be made in the CY 2022 OPPS/ASC final rule.

• *Equitable Adjustment for Device Category, Drugs, and Biologicals with Expiring Pass-through Status:* As a result of our proposal to use CY 2019 claims data, rather than CY 2020 claims data, to inform CY 2022 ratesetting, we are proposing to use our equitable adjustment authority under 1833(t)(2)(E) to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose pass-through payment status will expire between December 31, 2021 and September 30, 2022.

• *Cancer Hospital Payment Adjustment:* For 2022, we propose to continue to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, we propose that a target PCR of 0.89 would be used to determine the CY 2022 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 0.89 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. Using the hospital market basket methodology, for CY 2022, we propose to increase payment rates under the ASC payment system by 2.3 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed increase is based on a hospital market basket percentage increase of 2.5 percent reduced by a proposed 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 2022 would be approximately 5.16 billion, a decrease of approximately 20 million compared to estimated CY 2021 Medicare payments.

• *ASC Payment Policy for Non-Opioid Pain Management Drugs and Biologicals under Section 6082 of the SUPPORT Act (Section 1833(t)(22) of the Social Security Act):* Under section 1833(t)(22)(A) of the Act, the Secretary was required to conduct a review (part of which may include a request for information) of payments 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. Section 1833(t)(22)(A)(ii) provides that the Secretary may, as the Secretary determines appropriate, conduct subsequent reviews of such payment.

In accordance with our review, for CY 2022, we are proposing to continue to pay separately for two drugs currently receiving separate payment in the ASC setting as non-opioid pain management drugs that function as surgical supplies. For CY 2022, we propose to modify the current non-opioid pain management payment policy and regulatory text to require that evidence-based non opioid alternatives for pain management must have Food and Drug Administration (FDA) approval, an FDA-approved indication for pain management or analgesia, and for the drugs and biologicals to have a per-day cost in excess of the OPPS drug packaging threshold, which is proposed at $130 for CY 2022 and described in section V.B.1.a., to qualify under this policy. Further, we are soliciting comment on potential additional requirements the Secretary should consider establishing for this policy as well as whether any additional products meet the proposed criteria for CY 2022.

• *Changes to the List of ASC Covered Surgical Procedures:* For CY 2022, we are proposing to re-adopt the ASC Covered Procedures List (CPL) criteria that were in effect in CY 2020 and to remove 258 of the 267 procedures that were added to the ASC CPL in CY 2021. We are requesting comments on whether any of the 258 procedures meet the CY 2020 criteria that we are proposing to reinstate. We are also proposing to change the notification process adopted in CY 2021 to a nomination process, under which stakeholders could nominate procedures they believe meet the requirements to be added to the ASC CPL. The formal nomination process would begin in CY 2023.

Hospital Outpatient Quality Reporting (OQR) Program: For the Hospital OQR Program, we are proposing changes for the CY 2023, CY 2024, CY 2025, and CY 2026 payment determinations and subsequent years. For the Hospital OQR Program measure set, we are proposing to: (1) Remove the OP–02: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival measure beginning with the CY 2025 payment determination; (2) remove the OP–03: Median Time to Transfer to Another Facility for Acute Coronary Intervention measure beginning with the CY 2025 payment determination; (3) adopt the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure beginning with the CY 2024 payment determination; (4) adopt the Breast Screening Recall Rates measure beginning with the CY 2023 payment determination; (5) adopt the ST-Segment Elevation Myocardial Infarction (STEMI) electronic clinical quality measure (eCQM) beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination; (6) make voluntary the reporting of the OP–37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with the CY 2023 reporting period and mandatory beginning with the CY 2024 reporting period/CY 2026 payment determination; and (7) make mandatory the reporting of the OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure beginning with the CY 2025 payment determination. In addition, we are proposing data submission

requirements for the OAS CAHPS Survey-based measures and the COVID–19 Vaccination Coverage Among HCP measure. Similarly, we are proposing data submission and certification requirements for eCQMs and expanding our Extraordinary Circumstances Exemption (ECE) policy to these measures.

Beginning with the CY 2024 payment determination, we are proposing three updates to our validation requirements by proposing to: (1) Use electronic file submissions for chart-abstracted measure medical record requests; (2) change the chart validation requirements and methods; and (3) update the targeting criteria. We are also requesting comment from stakeholders on: (1) The potential future development and inclusion of a patient-reported outcomes measure following elective total hip and/or total knee arthroplasty (THA/TKA); (2) the possibility of expanding our current disparities methods to include reporting by race and ethnicity; and (3) the possibility of hospital collection of standardized demographic information for quality reporting and measure stratification. We are also requesting feedback across programs on potential actions and priority areas that would enable the continued transformation of our quality measurement toward greater digital capture of data and use of the FHIR standard.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are proposing changes for the CY 2024, CY 2025, and CY 2026 payment determinations and subsequent years. For the ASCQR Program measure set, we are proposing to: (1) Adopt the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2024 payment determination; (2) resume data collection for four measures beginning with the CY 2025 payment determination: (a) ASC–1: Patient Burn; (b) ASC–2: Patient Fall; (c) ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and (d) ASC–4: All-Cause Hospital Transfer/Admission; (3) require the ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure beginning with the CY 2025 payment determination; and (4) require the ASC–15a-e: OAS CAHPS Survey-based measures with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination. In addition, we are proposing data submission requirements for the OAS CAHPS Survey-based measures and the COVID–19 Vaccination Coverage Among HCP measure.

We are requesting stakeholder comment on: (1) The potential future development and inclusion of a patient-reported outcomes measure following elective THA/TKA; (2) potential measurement approaches or social risk factors that influence health disparities in the ASC setting; and (3) the future inclusion of a measure to assess pain management surgical procedures performed in ASCs. In this proposed rule, we are also requesting feedback across programs on potential actions and priority areas that would enable the continued transformation of our quality measurement toward greater digital capture of data and use of the FHIR standard.

• *Hospital Inpatient Quality Reporting (IQR) Program Update:* In this proposed rule, we are requesting information from stakeholders on potential measure updates on reporting and submission requirements for the Safe Use of Opioids—Concurrent Prescribing eCQM.

• *Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges:* We are proposing to amend several hospital price transparency policies codified at 45 CFR part 180 in order to encourage compliance. We are proposing to: (1) Increase the amount of the penalties for noncompliance through the use of a proposed scaling factor based on hospital bed count; (2) deem state forensic hospitals that meet certain requirements to be in compliance with the requirements of 45 CFR part 180; and (3) prohibit certain conduct that we have concluded are barriers to accessing the standard charge information. In addition, we clarify the expected output of hospital online price estimator tools when hospitals choose to use an online price estimator tool in lieu of posting its standard charges for the required shoppable services in a consumer-friendly format. Finally, we seek comment on a variety of issues that we may consider in future rulemaking, including improving standardization of the data disclosed by hospitals.

• *Request for Information on Rural Emergency Hospitals (REHs):*

Congress enacted section 125 of the Consolidated Appropriations Act (CAA) of 2021, which establishes REHs as a new provider type. In accordance with the statutory requirements in the CAA, REHs will provide emergency department services, observation care, and, at the election of the REH, other medical and health services on an outpatient basis, as specified by the Secretary through rulemaking. Additionally, REHs must not provide acute care inpatient services, with the exception of skilled nursing facility services furnished in a distinct part unit. The REH must have a staffed emergency department 24 hours a day, 7 days a week, with staffing requirements similar to those for Critical Access Hospitals (CAHs). The CAA provides that the statutory provisions governing Medicare payment to REHs shall apply to items and services furnished on or after January 1, 2023. We are seeking public comment via a Request for Information on the health and safety standards, payment policies, the REH enrollment process, and quality measures and reporting requirements for REHs to inform our policy making as we establish this new provider type.

• *Radiation Oncology Model (RO Model):* Section 133 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260), enacted on December 27, 2020, included a provision that prohibits the RO Model from beginning before January 1, 2022. This law supersedes the RO Model delayed start date established in the CY 2021 OPPS/ASC final rule. In this proposed rule, we are proposing provisions related to the additional delayed implementation due to the CAA, 2021, as well as modifications to certain RO Model policies not related to the delay. These proposals if finalized would necessitate modifying 42 CFR 512.205, 512.210, 512.217, 512.220, 512.230, 512.240, 512.245, 512.250, 512.255, 512.275, 512.280, and 512.285 and add 42 CFR 512.292 and 512.294.

• *Comment Solicitation on Temporary Policies for the PHE for COVID–19:* In response to the COVID–19 pandemic, CMS undertook emergency rulemaking to implement a number of flexibilities to address the pandemic, such as preventing spread of the infection and supporting diagnosis of COVID–19. While many of these flexibilities will expire at the conclusion of the PHE, we are seeking comment on whether there are certain policies that should be made permanent. Specifically, we are seeking comment on services furnished by hospital staff to beneficiaries in their homes through use of communication technology, direct supervision when the supervising practitioner is available through two-way, audio/video communication technology, and code and payment for COVID–19 specimen collection.

• *Changes to Beneficiary Coinsurance for Colorectal Cancer Screening Test:* Section 122 of the Consolidated Appropriations Act (CAA) of 2021 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 propose that all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy could be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of determining the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter.

3. Summary of Costs and Benefit

In sections XXIV. and XXV. 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 OPPS Changes

Table U1 in section XXIV.B of this proposed rule displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2021 compared to all estimated OPPS payments in CY 2020. We estimate that the policies in this proposed rule would result in a 1.8 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2021, including beneficiary cost-sharing, to the approximately 3,662 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately $1.3 billion compared to CY 2020 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. 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 1.6 percent increase in CY 2021 payments to CMHCs relative to their CY 2020 payments.

b. Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY 2022 IPPS proposed rule wage indexes would result in no change for urban hospitals under the OPPS and no change for rural hospitals. These wage indexes include the continued implementation of the 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 Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2022 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural hospital payment adjustments. While we propose to implement the reduction to the cancer hospital payment adjustment for CY 2022 required by section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act, the target payment-to-cost ratio (PCR) for CY 2021 is 0.89, equivalent to the 0.89 target PCR for CY 2021, and therefore has no budget neutrality adjustment.

d. Impacts of the Proposed OPD Fee Schedule Increase Factor

For the CY 2021 OPPS/ASC, we propose to establish an OPD fee schedule increase factor of 2.3 percent and apply that increase factor to the conversion factor for CY 2021. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals will experience an increase in payments of approximately 2.3 percent and that rural hospitals would experience an increase in payments of 2.3 percent. Classifying hospitals by teaching status, we estimate nonteaching hospitals would experience an increase in payments of 2.5 percent, minor teaching hospitals would experience an increase in payments of 2.3 percent, and major teaching hospitals would experience an increase in payments of 2.2 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would experience an increase of 2.3 percent in payments, while hospitals with government ownership would experience an increase of 2.4 percent in payments. We estimate that hospitals with proprietary ownership would experience an increase of 2.5 percent in payments.

e. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2022 payment rates, compared to estimated CY 2021 payment rates, generally ranges between an increase of 2 and 4 percent, depending on the service, with some exceptions. We estimate the impact of applying the hospital market basket update to ASC payment rates would increase payments by $90 million under the ASC payment system in CY 2022.

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; and the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), enacted on December 27, 2020.

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

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

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

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

C. Excluded OPPS Services and Hospitals

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

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

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; 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 OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than

annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at: *https://www.cms.gov/Medicare/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 Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act, 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 or the 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 20, 2020, 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/AdvisoryPanelonAmbulatoryPayment ClassificationGroups.html.*

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 31, 2020. 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). As published in this notice, CMS is accepting nominations on a continuous basis.

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 31, 2020, meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the August 31, 2020 Panel meeting, namely APC assignments for certain CPT codes, a comprehensive APC for skin substitute products, a comprehensive APC for autologous hematopoietic stem cell transplantation, and packaging policies, were discussed in relevant specific sections in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85866). 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 *http://facadatabase.gov.*

F. Public Comments Received on the CY 2020 OPPS/ASC Final Rule With Comment Period

We received approximately 32 timely pieces of correspondence on the CY 2021 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on December 2, 2020 (85 FR 85866), most of which were

outside of the scope of the final rule. 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. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Use of CY 2019 Data in the CY 2022 OPPS Ratesetting

We primarily use two data sources in OPPS ratesetting: Claims data and cost report data. Our goal is always to use the best available data overall for ratesetting. Ordinarily, the best available full year of claims data would be 2 years prior to the calendar year that is the subject of the rulemaking. As discussed in further detail in Section X.E. of this CY 2022 OPPS/ASC proposed rule, given our concerns with CY 2020 data as a result of the COVID–19 PHE, in general, we are proposing to use CY 2019 claims data and the data components related to it in establishing the CY 2022 OPPS.

b. 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 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 2022 OPPS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2022, and before January 1, 2023 (CY 2022), using the same basic methodology that we described in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85873), using CY 2019 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 2022, 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, 2019, and before January 1, 2020, 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 2022 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) includes the proposed list of bypass codes for CY 2022. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2019 and, therefore, includes codes that were in effect in CY 2019 and used for billing. We propose to retain deleted bypass codes on the proposed CY 2022 bypass list because these codes existed in CY 2019 and were covered OPD services in that period, and CY 2019 claims data were used to calculate proposed CY 2022 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 2022 are identified by asterisks (*) in the fourth column of Addendum N.

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

For 2022, 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 CY 2022 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2019 claims data by comparing these claims data to hospital cost reports available for the CY 2021 OPPS/ASC final rule with comment period ratesetting, which, in most cases, are from CY 2019. For the proposed CY 2022 OPPS payment rates, we used the set of CY 2019 claims processed through June 30, 2020. 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 2019 (the year of claims data we used to calculate the proposed CY 2022 OPPS payment rates) and updates to the NUBC 2020 Data Specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

In accordance with our longstanding policy, we calculate CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of this proposed rule.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74840 through 74847), we finalized our policy of creating new cost centers and distinct CCRs for implantable devices, magnetic resonance imaging (MRIs), computed tomography (CT) scans, and cardiac catheterization. However, in response to comments we received from our CY 2014 OPPS/ASC proposed rule, we finalized a policy in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74847) to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs associated with the APCs for CT and MRI. As finalized in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61152), beginning in CY 2021, we use all claims with valid CT and MRI cost center CCRs, including those that use a ''square feet'' cost allocation method, to estimate costs for the CT and MRI APCs.

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

In this section of this proposed rule, we discuss the use of claims to calculate the OPPS payment rates for CY 2022.

The Hospital OPPS page on the CMS website on which this proposed rule is posted (*http://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, *http://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 OPPS Identifiable Data Set, including ICD–10–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2019 claims that were used to calculate the proposed payment rates for this CY 2022 OPPS/ASC proposed rule.

Previously, the OPPS established the scaled relative weights on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. For 2022, we propose to continue to use geometric mean costs to calculate the relative weights on which the proposed CY 2022 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPPS payment rates for CY 2022 shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier ''PN'', which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier ''PN'' from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2022 OPPS, we will continue to remove claim lines with modifier ''PN'' from the ratesetting process.

For details of the claims accounting process used in this proposed rule, we refer readers to the claims accounting narrative under supporting documentation for this CY 2022 OPPS/ASC proposed rule on the CMS website at: *http://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 OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

We propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, to address the differences in CCRs and to better reflect hospitals' costs, we propose to continue to simulate 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. We also propose to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports to simulate blood-specific CCRs for those hospitals. We propose to calculate the costs upon which the proposed CY 2022 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated blood-specific, CCR methodology 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. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that using this methodology in CY 2022 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that we defined a comprehensive APC (C–APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C–APCs. We propose to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C–APCs. Because the costs of blood and blood products would be reflected in the overall costs of the C–APCs (and, as a result, in the proposed payment rates of the C–APCs), we propose not to make separate payments for blood and blood products when they appear on the same claims as services assigned to the C–APCs (we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795 through 66796) for

more information about 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 refer readers to Addendum B of this proposed rule (which is available via the internet on the CMS website) for the proposed CY 2022 payment rates for blood and blood products (which are generally identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

For CY 2022, 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 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 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2022, except where otherwise indicated, we propose to use the costs derived from CY 2019 claims data to set the proposed CY 2022 payment rates for brachytherapy sources because CY 2019 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 2022 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and brachytherapy source C2636 (Brachytherapy linear source, non-stranded, palladium-103, per 1 mm), we propose to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we propose for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also propose to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). 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, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also propose to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010 by section 142 of Pub. L. 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2022 payment rates for brachytherapy sources are included in 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 mm^2. For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2. Our CY 2018 claims data available for the final 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 mm^2. In response to comments from stakeholders, we agreed with commenters that given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of 1.02 per mm^2 may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2020. Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021 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 to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2021.

As discussed in Section X.E. of this CY 2022 OPPS/ASC proposed rule, given our concerns with CY 2020 data as a result of the COVID–19 PHE, in general we are proposing to use CY 2019 claims data and the data components related to it in establishing the CY 2022 OPPS. Therefore, we are proposing to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2022.

Additionally, for CY 2022 and subsequent calendar years, as discussed in Section X.C., we are proposing to establish a Low Volume APC policy for New Technology APCs, clinical APCs, and brachytherapy APCs. For these

APCs with fewer than 100 single claims that can be used for ratesetting purposes in the existing claims year, we are proposing to use up to four years of claims data to establish a payment rate for each item or service as we currently do for low volume services assigned to New Technology APCs. Further, we propose to calculate the cost for Low Volume APCs based on the greatest of the arithmetic mean cost, median cost, or geometric mean cost. We are proposing to designate 5 brachytherapy APCs as Low Volume APCs for CY 2022. For more information on our Low Volume APC proposal, see Section X.C. of this CY 2022 OPPS/ASC proposed rule.

We continue to invite hospitals and other parties to submit recommendations to us 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 2022

(1) Background

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

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66810). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70332), we finalized 10 additional C–APCs to be paid under the existing C–APC payment policy and added 1 additional level to both the Orthopedic Surgery and Vascular Procedures clinical families, which increased the total number of C–APCs to 37 for CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584 through 79585), we finalized another 25 C–APCs for a total of 62 C–APCs. In the CY 2018 OPPS/ASC final rule with comment period, we did not change the total number of C–APCs from 62. In the CY 2019 OPPS/ASC final rule with comment period, we created 3 new C–APCs, increasing the total number to 65 (83 FR 58844 through 58846). In the CY 2020 OPPS/ASC final rule with comment period, we created two new C–APCs, increasing the total number to 67 C–APCs (84 FR 61158 through 61166). Most recently, in the CY 2021 OPPS/ASC final rule, we created two new C–APCs, increasing the total number to 69 C–APCs (85 FR 85885).

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

Services excluded from the C–APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 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).

In the interim final rule with request for comments (IFC) entitled, ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', published on November 6, 2020, we stated that, effective for services furnished on or after the effective date of the IFC and until the end of the PHE for COVID–19, there is an exception to the OPPS C–APC policy to ensure separate payment for new COVID–19 treatments that meet certain criteria (85 FR 71158 through 71160). Under this exception, any new COVID–19 treatment that meets the following two criteria will, for the remainder of the PHE for COVID–19, always be separately paid and will not be packaged into a C–APC when it is provided on the same claim as the primary C–APC service. First, the treatment must be a drug or biological product (which could include a blood product) authorized to treat COVID–19, as indicated in section ''I. Criteria for Issuance of Authorization'' of the FDA letter of authorization for the emergency use of the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID–19. Second, the emergency use authorization (EUA) for the drug or biological product (which could include a blood product) must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by the FDA to treat COVID–19 disease and not limit its use to the inpatient setting. For further information regarding the exception to the C–APC policy for COVID–19 treatments, please refer to the November 6, 2020 IFC (85 FR 71158 through 71160).

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period for the C–APCs 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'', 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''. 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 1 day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and
- Does not contain services described by a HCPCS code to which we have assigned status indicator ''J1''.

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

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

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

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 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.

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

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

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

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

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

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

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

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for 2022, we propose to 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 2022, along with all of the other proposed complexity adjustments, in Addendum J to this CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

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 are proposed to 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 4 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 are proposed to 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 stakeholders the opportunity to better assess the impact associated with the proposed reassignment 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 the procedures. 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 is 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 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 starting in CY 2020 (84 FR 61167). We proposed to continue to exclude 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'' or ''J2'' service assigned to a C–APC.

(3) Additional C–APCs for CY 2022

For CY 2022 and subsequent years, we propose to continue to apply the C–APC payment policy methodology. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we are not proposing to convert any standard APCs to C–APCs in CY 2022, thus we propose that the number of C–APCs for CY 2022 would be the same as the number for CY 2021, which is 69 C–APCs.

Table 1 lists the proposed C–APCs for CY 2022, all of which were established in past rules. 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 of the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information.

BILLING CODE 4120–01–P

TABLE 1: Proposed CY 2022 C-APCs

C-APC	CY 2022 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	
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	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5361	Level 1 Laparoscopy and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
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	

C-APC	CY 2022 APC Group Title	Clinical Family	New C-APC
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	
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

BILLING CODE 4120–01–C

c. Proposed Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service.

Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. (We note that, in the CY 2018 OPPS/ASC final rule with comment period, we finalized a policy to delete the composite APC 8001 (LDR Prostate Brachytherapy Composite) for CY 2018 and subsequent years.) We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241 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 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79588 through 79589), we finalized a policy to combine the existing Level 1 and Level 2 hospital-based PHP APCs into a single hospital-based PHP APC, and thereby discontinue APCs 5861 (Level 1—Partial Hospitalization (3 services) for Hospital-Based PHPs) and 5862 (Level—2 Partial Hospitalization (4 or more services) for Hospital-Based PHPs) and replace them with APC 5863 (Partial Hospitalization (3 or more services per day)).

In the CY 2018 OPPS/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 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. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

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 maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2022. In addition, we propose to set the proposed payment rate for composite APC 8010 at the same payment rate that we proposed for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the proposed payment rate for composite APC 8010.

(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 2022, 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 2022, except where otherwise indicated, we propose to use the costs derived from CY 2019 claims data to set the proposed CY 2022 payment rates. Therefore, for CY 2022, 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 2019 claims available for this CY 2022 OPPS/ASC proposed rule that qualified for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we have used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this CY 2022 OPPS/ASC 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 CY 2022 OPPS/ASC proposed rule.

For this CY 2022 OPPS/ASC proposed rule, we were able to identify approximately 1.04 million ''single session'' claims out of an estimated 2.2 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 47 percent of all eligible claims, to calculate the proposed CY 2022 geometric mean costs for the multiple imaging composite APCs. Table 2 of this CY 2022 OPPS/ASC 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 2022.

BILLING CODE 4120–01–P

TABLE 2: PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2022 APC 8004 (Ultrasound Composite)	**CY 2022 Approximate APC Geometric Mean Cost = $290.73**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2022 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2022 Approximate APC Geometric Mean Cost = $218.46**
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 2022 APC 8006 (CT and CTA with Contrast Composite)	**CY 2022 Approximate APC Geometric Mean Cost = $424.02**
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/dyc
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/dyc
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 2022 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2022 Approximate APC Geometric Mean Cost = $509.23**
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 2022 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2022 Approximate APC Geometric Mean Cost = $821.31**
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.	

BILLING CODE 4120–01–C

3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

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

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services

or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2000 OPPS final rule (65 FR 18434), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70343), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59250), the CY 2019 OPPS/ASC final rule with comment period (83 FR 58854), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 85894). As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

For CY 2022, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies.

For CY 2022, we propose no 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. Below we discuss a proposed change to an ASC payment system packaging policy for CY 2022 and solicit comment on potential additional changes to that policy and application of that policy to the OPPS.

b. Proposed Payment Policy for Non-Opioid Pain Management Drugs and Biologicals That Function as Surgical Supplies Under the ASC Payment System

(1) Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

In the CY 2018 OPPS/ASC proposed rule (82 FR 33588), within the framework of existing packaging categories, such as drugs that function as supplies in a surgical procedure or diagnostic test or procedure, we requested stakeholder feedback on common clinical scenarios involving currently packaged items and services described by HCPCS codes that stakeholders believe should not be packaged under the OPPS. We also expressed interest in stakeholder feedback on common clinical scenarios involving separately payable HCPCS codes for which payment would be most appropriately packaged under the OPPS. Commenters who responded to the CY 2018 OPPS/ASC proposed rule expressed a variety of views on packaging under the OPPS. While several commenters were in support of maintaining packaging policies, most of the public comments ranged from requests to unpackage most items and services that are unconditionally packaged under the OPPS, including drugs and devices, to specific requests for separate payment for a particular drug or device.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52485), we reiterated our position with regard to payment for Exparel®, a non-opioid analgesic that functions as a surgical supply, stating that we believed that payment for this drug is appropriately packaged with the primary surgical procedure. We also stated in the CY 2018 OPPS/ASC final rule with comment period that we would continue to explore and evaluate packaging policies under the OPPS and consider these policies in future rulemaking.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58855), we explained that, in addition to stakeholder feedback regarding OPPS packaging policies, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission)[1] had recently recommended that CMS examine payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments. The Commission was established in 2017 to study the scope and effectiveness of the Federal response to drug addiction and the opioid crisis and to make recommendations to the President for improving the Federal response to the crisis. The Commission's report included a recommendation for CMS to ". . . review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain. . . ." We explained that, as discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37068 through 37071), in response to stakeholder comments on the CY 2018 OPPS/ASC proposed rule and in light of the recommendations regarding payment policies for certain drugs, we had recently evaluated the impact of our packaging policy for drugs that function as a supply when used in a surgical

[1] *https://www.federalregister.gov/documents/2017/04/03/2017-06716/establishing-the-presidents-commission-on-combating-drug-addiction-and-the-opioid-crisis.*

procedure on the utilization of these drugs in both the hospital outpatient department and the ASC setting. We stated that, although we found increases in utilization of Exparel when it was paid under the OPPS, we noticed decreased utilization of Exparel under the ASC payment system. Accordingly, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58855 through 58860), 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 for CY 2019, due to decreased utilization in the ASC setting. Historically, we stated that 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).

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 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), which requires any adjustments to be made in a budget neutral manner. Section 1833(i)(8), 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 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. We used currently available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives, including drugs that function as a supply, nerve blocks, and neuromodulation products, to determine whether our packaging policies may have reduced the use 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 for CY 2020. 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 to 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 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 for CY 2021. For CY 2021, only two drug products met the criteria as non-opioid pain management drugs that function as surgical supplies in the ASC setting, and thus receive separate payment under the ASC payment system. These drugs are Exparel and Omidria.

(2) CY 2022 Evaluation of Payments for Opioids and Non-Opioid Alternatives for Pain Management and Comment Solicitation on Extending the Policy to the OPPS

As noted in the background above, over the past several years we have reviewed non-opioid alternatives and evaluated the impact of our packaging policies on access to these products. In our previous evaluations, we used currently available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives, including drugs that function as a supply, nerve blocks, and neuromodulation products, to determine whether our packaging policies may have reduced the use of non-opioid alternatives. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85896 to 85899), we stated that we would continue to analyze the issue of access to non-opioid pain management alternatives in the HOPD and the ASC settings as part of any reviews we conduct under section 1833(t)(22)(A)(ii), with a specific focus on whether there is evidence that our current payment policies are creating access barriers for other non-opioid pain management alternatives for which there is evidence-based support that these products help to deter or avoid prescription opioid use and opioid use disorder.

For CY 2022, we conducted a subsequent review of payments for opioids and non-opioid alternatives as authorized by section 1833(t)(22)(A)(ii). We analyzed utilization patterns in both the HOPD and ASC settings for multiple non-opioid pain management drugs, including the two drugs that are receiving separate payment when furnished in the ASC setting under our current policy for CY 2021: Exparel and Omidria. The results of our CY 2022 review were similar to the results of our

reviews in previous years. Generally, utilization of non-opioid pain management drugs continued to increase year after year in the HOPD setting, where payment for these non-opioid alternatives is packaged with the payment for the associated surgical procedure. In the ASC setting, where Exparel and Omidria are separately paid, we also saw utilization increases for these two drugs. However, in the ASC setting, the rate of increase in utilization is much more substantial than in the HOPD setting. In particular, in the HOPD setting where payment for Exparel is packaged, utilization of Exparel increased from 19.7 million units in 2019 to 21.8 million units in 2020, whereas utilization of Exparel increased from 1.5 million units in 2019 to 3.3 million units in 2020 in the ASC setting, where Exparel is separately paid. We note that a number of reasons could explain this discrepancy other than our policy to pay separately for Exparel under the ASC payment system, including evolving clinical practice in the ASC setting, which could increase the number of surgeries performed in ASCs for which Exparel is an appropriate pain management drug.

We have consistently explained, including as recently as in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85894), that our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item. We have not found conclusive evidence to support the notion that the OPPS packaging policy, under which non-opioid drugs and biologicals are packaged when they function as a supply in a surgical procedure, has created financial incentives to use opioids instead of evidence-based non-opioid alternatives for pain management. For example, we have not observed decreased utilization of non-opioid alternatives for pain management in the HOPD setting. Therefore, for CY 2022, we are proposing 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.

As explained earlier in this section, while packaging encourages efficiency and is a fundamental component of a prospective payment system, where there is an overriding policy objective to reduce disincentives for use of non-opioid products to the extent possible, we believe it may be appropriate to establish payment that reduces disincentives for use of non-opioid drugs and biologicals for pain management when there is evidence that use of those products reduces unnecessary opioid use. For these reasons, we are soliciting comment as to whether we should expand our current policy that only applies in the ASC setting—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—to the HOPD setting. We are interested in learning from stakeholders whether similar disincentives for the use of non-opioid pain management drugs and biologicals identified in the ASC setting exist in the HOPD setting. Previously, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59067), we identified several disincentives that were unique to the ASC setting compared to the HOPD setting, including the fact that ASCs tend to provide specialized care and a more limited range of services in comparison to hospital outpatient departments. Also, ASCs are paid, in aggregate, approximately 55 percent of the OPPS rate. Therefore, fluctuations in payment rates for specific services may affect these providers more acutely than hospital outpatient departments; and ASCs may be less likely to choose to furnish non-opioid postsurgical pain management treatments, which are typically more expensive than opioids, as a result. Additionally, we are seeking comment on what evidence supports the expansion of this policy to the HOPD setting, including the clinical benefit that Medicare beneficiaries may receive from the availability of separate or modified payment for these products in the HOPD setting.

Finally, we are seeking comment on if we should treat products the same depending on the setting, ASC or HOPD. For example, we are seeking comment on whether products should have the same eligibility requirements to qualify for revised payment in the ASC and the HOPD settings. We are additionally seeking comment on how the additional comment solicitations described below, which refer to the ASC setting, could also be applied to the HOPD setting.

(3) Proposed Criteria for Eligibility for Separate Payment Under the ASC Payment System for Non-Opioid Pain Management Drugs and Biologicals That Function as Surgical Supplies

As described in section 1833(t)(22)(A)(i) of the Act, the Secretary shall conduct a review of payments for opioids and evidence-based non-opioid alternatives for pain management with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. In any future reviews the Secretary may determine appropriate to conduct under section 1833(t)(22)(A)(ii) of the Act, we believe it is important to establish the evidence-base for non-opioid alternatives for pain management when evaluating whether current payment policies result in an incentive for providers to use opioids instead of such evidence-based non-opioid alternatives for pain management. Accordingly, for CY 2022 and subsequent years, we are proposing two criteria that non-opioid pain management drugs and biologicals would be required to meet to be eligible for a payment revision under the ASC payment system in accordance with section 1833(t)(22)(C). The proposed criteria are intended to identify non-opioid pain management drugs and biologicals that function as supplies in surgical procedures for which revised payment under the ASC payment system would be appropriate.

Specifically, for CY 2022, we are proposing the following criteria that non-opioid pain management drugs and biologicals would be required to meet to be eligible for separate payment under the ASC payment system in accordance with section 1833(t)(22)(C):

Criterion 1: FDA Approval and Indication for Pain Management or Analgesia

We propose that the drug or biological product must be safe and effective, as determined by the FDA. We propose that the drug must be approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), generic drug application under an abbreviated new drug application under section 505(j), or, in the case of a biological product, be licensed under section 351 of the Public Health Service Act. We further propose that the drug or biological must also have an FDA-approved indication for pain management or analgesia. We believe FDA approval is an appropriate requirement for a drug or biological to

be eligible for this policy because the FDA reviews drugs and biologicals for safety and effectiveness, which would allow us to identify safe and effective non-opioid products to which this separate payment policy should apply. Given that the FDA has an existing and detailed review process already in place to review drugs and biologicals, we believe it would be appropriate and administratively efficient to utilize FDA approval as a requirement to ensure that the drugs and biologicals approved under this policy are generally safe and effective for beneficiaries. We believe the vast majority of drugs and biologicals on the market have undergone FDA review and approval, and we do not anticipate this criterion would prevent otherwise eligible drugs or biologicals from qualifying. In addition, section 1833(t)(22)(C) of the Act, our current policy, and our proposed policy all focus on pain management products. Specifically, section 1833(t)(22)(C) of the Act refers to reviews of opioid and evidence-based non opioid products for pain management. Therefore, we propose to require an FDA-approved indication for pain management or analgesia for a drug or biological to qualify as a pain management product. The FDA approval process would allow us to confirm that a drug or biological is, in fact, a non-opioid. Drugs and biologicals that are approved as opioids or opioid agonists, or that receive an opioid-related approval from the FDA would not be eligible for separate payment under this policy.

Criterion 2: Cost of the Product

Currently, under the OPPS, drugs that are not policy-packaged are subject to the drug 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 at $50 per administration during CYs 2005 and 2006. We set the packaging threshold for establishing separate APCs for drugs and biologicals through annual notice and comment rulemaking. (Please see section V.B.1.a. of this proposed rule for additional details on the drug packaging threshold policy). The proposed per-day drug packaging threshold for CY 2022 is $130.

As our second criterion, we are proposing that a drug or biological would only be eligible for a payment revision under the ASC payment system in accordance with section 1833(t)(22)(C) if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this rule. We believe this is an appropriate requirement because we believe that not all non-opioid alternative treatments are equally disincentivized by our packaging policies. In particular, the cost of non-opioid drugs and biologicals below the packaging threshold of $130 per day does not generally have a significant impact on the overall procedure costs, and we believe use of these drugs and biologicals is unlikely to be disincentivized by CMS packaging policies. However, when the per-day cost of the drug is above the drug packaging threshold, the cost of these drugs or biologicals generally has a significant impact on the overall procedure costs. Section 1833(t)(22)(A)(i) of the Act discusses financial incentives to use opioids instead of non-opioid alternative treatments. As such, we do not believe non-opioid pain management drugs that are lower in cost are generally disincentivized by our packaging policies, as their cost is more easily absorbed into the payment for the primary procedure in which they are used when compared to drugs and biologicals above the threshold. We are proposing to use the existing OPPS drug packaging threshold as it is familiar to stakeholders and its application to drugs and biologicals under this policy creates uniformity across the OPPS and ASC payment systems. Therefore, CMS is proposing that drugs and biologicals would be required to have a per-day cost that exceeds the drug packaging threshold that CMS sets annually through notice and comment rulemaking.

We also believe the use of this threshold as an eligibility criterion for drugs under consideration for a payment revision under this policy is appropriate, as it conforms with the broader goals of the OPPS and ASC payment systems. Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies, including the drug packaging threshold, support our strategic goal of using larger payment bundles to maximize hospitals' incentives to provide care in the most efficient manner. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. For the reasons mentioned above, we believe it to be appropriate to package drugs under consideration for this policy which fall below the OPPS drug packaging threshold.

We propose that non-opioid drugs and biologicals currently receiving transitional drug pass-through status in the OPPS would not be candidates for this policy as they are already paid separately under the OPPS and ASC payment system. Please see section V.A., Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals, of this proposed rule for additional details on transitional pass-through payments for drugs and biologicals. We propose that once transitional drug pass-through status expires, the non-opioid drug or biological may qualify for separate payment under the ASC payment system if it meets the proposed eligibility requirements.

We seek comment on whether there are any other non-opioid drug or biological products that would meet the proposed criteria if finalized.

(4) Proposed Regulation Text Changes

We propose to codify our proposed criteria for separate payment for qualifying non-opioid pain management drugs and biologicals that function as surgical supplies in the regulation text for the ASC payment system in a new § 416.174. In particular, we propose to provide in a new § 416.174(a)(1) that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if they are approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), generic drug application under an abbreviated new drug application under section 505(j), or, in the case of a biological product, are licensed under section 351 of the Public Health Service Act. Section 416.174(a)(1) would also provide that the drug or biological must have an FDA-approved indication for pain management or analgesia. New § 416.174(a)(2) would require that the per-day cost of the drug or biological must exceed the OPPS drug packaging threshold set annually through notice and comment rulemaking.

We also propose to amend § 416.164(b)(6) to provide that 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 are ancillary items that are integral to a

covered surgical procedure and for which separate payment is allowed. We also propose to amend § 416.171(b)(1) to provide that the payment rate for 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 are paid an amount derived from the payment rate for the equivalent item or service under the OPPS, and if such a payment amount is unavailable, are contractor priced.

(5) Eligibility for Separate Payment in CY 2022 for Exparel, Omidria, and Other Non-Opioid Products for Pain Management

As discussed in the CY 2021 OPPS/ASC final rule with comment period, there are two products receiving separate payment in the ASC setting under our current policy to pay separately for non-opioid pain management treatments that function as surgical supplies when furnished in the ASC setting (85 FR 86171). These two products are Exparel (*HCPCS Code C9290, Injection, bupivacaine liposome, 1 mg*) and Omidria (HCPCS Code J1097, *phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*). Based on the current information available to us, as we explain below, we are proposing that both products would be eligible for separate payment in CY 2022 under our proposed policy. We have included our initial evaluation of these two products below.

(a) Eligibility for Separate Payment in CY 2022 for Exparel Under the Proposed Eligibility Criteria

We are proposing that Exparel would continue to receive separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply for CY 2022. Based on CMS's internal review, we believe Exparel meets criterion 1. Exparel was approved by the FDA with a New Drug Application (NDA #022496) on 10/28/2011.[2] Exparel's FDA-approved indication is ''in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia (1). In adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia''.[3] No component of Exparel is opioid-based. Accordingly, we propose that Exparel meets criterion one.

As discussed in section (3) above, for criterion two we are proposing that a drug or biological would only be eligible for separate payment under this policy if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this rule. The proposed per day cost threshold for CY 2022 is $130. Using the methodology described at V.B.1.a., the per day cost of Exparel exceeds the $130 per day cost threshold. Therefore, we propose that Exparel meets criterion two.

Therefore, we are proposing that Exparel meets criteria one and two, and should receive separate payment under the ASC payment system for CY 2022.

(b) Eligibility for Separate Payment for Omidria in CY 2022 Under the Proposed Eligibility Criteria

We are proposing that Omidria would continue to receive separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply for CY 2022. Based on our internal review, we believe Omidria would meet criterion one. Omidria was approved by the FDA with a New Drug Application (NDA #205388) on 5/30/2014.[4] Additionally, 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''.[5] No component of Omidria is opioid-based. Therefore, we propose that Omidria would meet proposed criterion one.

Using the methodology described at V.B.1.a., the per day cost of Omidria exceeds the $130 per day cost threshold. Therefore, we propose that Omidria meets criterion two. Therefore, we are proposing that Omidria meets criteria one and two, and should receive separate payment under the ASC payment system for CY 2022.

(6) Comment Solicitation on Policy Modifications and Potential Additional Criteria for Revised Payment for Non-Opioid Pain Management Treatments

In addition to the proposed eligibility criteria above, we are also soliciting comment on potential policy modifications and additional criteria that may help further align this policy with the intent of section 1833(t)(22) of the Act. Below we discuss potential additional criteria. We note that, depending on the public comments we receive and our continued consideration of these potential criteria, we may adopt these criteria as part of our final policy and include them in the final regulation text; accordingly, we are providing substantial details, explanations, and considerations about these potential criteria. We welcome input from stakeholders on these and any additional policy modifications or criteria they believe would enhance our proposed policy. We are also soliciting comment on other barriers to access to non-opioid pain management products that may exist, and to what extent our policies under the OPPS or ASC payment system could be modified to address these barriers.

(a) Utilization of the Product

We have historically used utilization as a metric to determine whether a change in our payment policy was necessary to determine whether our policies create a disincentive to use non-opioid alternatives. For example, as previously discussed, Exparel's decreasing utilization in the ASC setting caused us to propose to pay separately for non-opioid pain management drugs that function as surgical supplies in the ASC setting. We have used currently available claims data in prior years to analyze the payment and utilization patterns associated with specific non-opioid alternatives to determine whether our packaging policies may have reduced the use of non-opioid alternatives. We believe that higher utilization may be a potential indicator that the packaged payment is not causing an access to care issue and that the payment rate for the primary procedure adequately reflects the cost of the drug or biological. We also believe decreased utilization could potentially indicate that our packaging policy is discouraging use of drug or biological and that providers are choosing less expensive treatments. We note that it is difficult to attribute product-specific changes in utilization to our packaging policies alone. Nonetheless, while we acknowledge certain limitations of utilization data, we believe analyzing utilization either on a product-specific basis or on a broader basis could be an important criterion in determining whether separate payment is warranted for a non-opioid pain management alternative.

Therefore, we are soliciting comment on whether specific evidence of reduced utilization should be part of our evaluation and determination of whether a non-opioid pain management product should qualify for modified

[2] Exparel. FDA Letter. 28 October 2011. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022496s000ltr.pdf.*

[3] Exparel. FDA Package Insert. 22 March 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022496s035lbl.pdf.*

[4] Omidria. FDA Letter. 30 May 2014. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/205388Orig1s000ltr.pdf.*

[5] Omidria. FDA Package Insert. 08 December 2017. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.*

payment. This data may help to demonstrate that our packaging policies are causing an access issue for these products. Additionally, we realize that new products to the market may not have utilization data available, or reliable utilization data may be difficult to obtain for some products; therefore, we are also requesting comment on whether utilization data requirements should vary based on the newness of a product or its FDA marketing approval date.

(b) FDA Indication for Pain Management or Analgesia for the Drug or Biological Product

As previously discussed, section 1833(t)(22)(A) of the Act specifically refers to reviews of opioid and evidence-based non opioid products for pain management. We believe the majority of drugs and biologicals that would meet the requirements of our proposed policy would already have FDA approval as a pain management drug or as an analgesic. However, we acknowledge there may be other non-opioid products that would benefit from inclusion under this policy, but do not have a specific FDA-approved indication for pain management or analgesia, and would not satisfy criterion 1. Therefore, we are soliciting comment on whether we should allow certain FDA-approved drugs and biologicals to be eligible for separate payment under this policy without a specific FDA-approved indication for pain management or as an analgesic drug. In lieu of an FDA indication for pain management or analgesia, we are seeking comment on whether it would be appropriate to approve a product for inclusion under this policy if the pain-management or analgesia attributes of the drug or biological are recognized by a medical compendium. Similarly, we are seeking comment as to whether we should consider specialty society or national organization (such as a national surgery organization) recommendations of non-opioid pain management products that function as surgical supplies and reduce opioid use in the ASC setting, as evidence that a product meets criterion one, where a drug or biological does not have an FDA indication for pain management or analgesia.

(c) Peer-Reviewed Literature Requirement Comment Solicitation

We note that section 1833(t)(22)(B) requires the Secretary to focus on covered OPD services (or groups of services) assigned to a comprehensive ambulatory payment classification, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary that generally involve treatment for pain management. We are also soliciting comment as to whether we should only adopt a payment revision to drugs and biologicals that function as surgical supplies in the ASC setting when those products have evidence in peer reviewed literature supporting that the product actually decreases opioid. We believe this may be appropriate to ensure Medicare payment policies would not financially incentivize use of opioids rather than evidence-based non-opioid alternative treatments, as required by section 1833(t)(22)(A)(iii) of the Act. Specifically, we are seeking comment as to whether the drug or biological's use in a surgical procedure as a non-opioid pain management product should be supported by peer-reviewed literature demonstrating a clinically significant decrease in opioid usage compared to the standard of care, and we are seeking comment on whether such decreases in opioid usage should be sustained decreases that continue into the post-operative period.

Additionally, we are seeking input from commenters as to what they believe the requirements for peer-reviewed literature requirements should be. For example, we are seeking stakeholder feedback as to whether peer-reviewed literature should demonstrate that use of the drug or biological results in at least one, or several, of the following: Decreased post-operative opioid use following surgery; decreased opioid misuse following surgery; or decreased opioid use disorder and dependency following surgery.

Additionally, we ask stakeholders if specific thresholds are necessary to determine whether these decreases are statistically and clinically significant and whether the decreases should simply be measured against placebo or the standard of care. We also request information on how stakeholders would define the standard of care in these circumstances. When evaluating literature, we would expect to examine the study methods, sample size, limitations, possible conflicts of interest, patient populations studied, and how the evidence supports the conclusion that the product can serve as a non-opioid pain management product and provide a clinically significant reduction in opioid use that continues into the post-operative period. However, we welcome input from stakeholders about additional aspects of these studies that they believe CMS should focus on for this potential criterion. Additionally, we would expect to use our discretion to assess whether the submitted studies meet these criteria, as well as for clinical applicability, literature integrity, and potential biases in consultation with our clinical advisors.

In order to provide stakeholders with some examples of what supporting evidence CMS may consider for this potential criterion, we believe it would be helpful for CMS to receive literature demonstrating that use of a non-opioid drug or biological results in a statistically and clinically significant decreased day supply of outpatient opioids prescribed after surgery discharge compared to the generally accepted standard of care, or a statistically and clinically significant decreased morphine milligram equivalents (MME) per opioid dose prescribed after surgery discharge compared to the generally accepted standard of care. We would consider the generally accepted standard of care to include pain management therapy a patient would receive in the absence of the non-opioid alternative, such as the use of localized analgesia and/or an opioid. As previously discussed, we would then expect the use of a non-opioid pain management drug or biological to result in a decline in opioids used compared to the pain management therapy a patient would receive in the absence of the non-opioid alternative. We would expect this decline in opioids to include a decreased number of opioids received by a patient intraoperatively, post-operatively, and most significantly at discharge. We are soliciting comment on additional examples or measures that would be beneficial for CMS to take into consideration. Additionally, we are seeking comment on whether we should require a specific objective measure for this criterion. We also seek input on how to assess whether changes are statistically and clinically significant. We request comment on whether stakeholders believe evidence of statistical significance should be sufficient, or whether stakeholders believe the literature should also demonstrate clinically significant differences between treatment groups as well.

(d) Alternative Payment Mechanisms for Non-Opioid Drugs and Biologicals

As previously discussed, for CY 2022, we are proposing to pay separately at ASP plus 6 percent for non-opioid pain management drugs and biologicals that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and meet our other proposed

criteria. Section 1833(t)(22)(A)(iii) requires the Secretary to consider the extent to which revisions payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management. Accordingly, separate payment is not the only possible revision that may be appropriate. We seek comment on additional payment mechanisms that may be appropriate aside from separate payment. For instance, we request feedback from stakeholders as to whether a single, flat add-on payment, or separate APC assignment, for products or procedures that use a product that meets eligibility criteria would be preferable to separate payment. We note that any revisions the Secretary determines appropriate under section 1833(t)(22)(C) must be applied in a budget neutral manner under section 1833(t)(9)(B). We also seek input from stakeholders on any other innovative payment mechanisms for eligible non-opioid drugs and biologicals for pain management.

(e) Non-Drug Products

We are also interested in information on any non-opioid non-drug products that function as surgical supplies commenters believe should be eligible for separate payment under this policy. Although we have not currently identified any non-opioid pain management non-drug products that are disincentivized by CMS packaging policies based on utilization data, we believe it is reasonable to assume that if disincentives exist for the use of non-opioid pain management drugs and biological products under the ASC payment system, they may also exist for non-opioid, non-drug products under the ASC payment system. If this is the case, we would like to address these disincentives given the severity, and importance of combatting, the opioid epidemic, regardless of whether the non-opioid product is a drug, biological, or non-drug product. We remain interested as to whether there are any non-opioid, non-drug products that may meet the proposed eligibility criteria and should qualify for separate or modified payment as discussed in section (d) above, in the ASC setting. Similarly, we are also seeking comment on if there are unique qualities of non-drug products that would make revised payment in the HOPD setting appropriate instead of, or in addition to, the ASC setting.

We are also soliciting comment on whether it is appropriate to require non-drug products to meet the same criteria being proposed for drugs and biologicals. Additionally, we are seeking comment from stakeholders on whether they believe it would be appropriate to create a broad category for non-drug products, or if a more limited category, such as for devices, would be appropriate. Specifically, we are seeking comment on whether there is information in the FDA approval for devices that would be an appropriate criterion to determine eligibility for separate payment, similar to how we are proposing to require FDA approval with an indication for pain management or analgesia for drugs and biologicals. We are also seeking comment on whether, if the non-drug product is a ''device'' as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, the device should have received FDA premarket approval, grant of a de novo request, 510(k) clearance or meet an exemption from premarket review. We are soliciting comment on all aspects of an extension of our current policy to include appropriate products that are not drugs or biologicals.

We are also soliciting comment as to how peer-reviewed literature and utilization claims data could be used as potential criteria for a policy that would apply to non-drug products. Additionally, should a payment revision be determined necessary, we are seeking comment on appropriate payment mechanisms for non-opioid, non-drug products, including assigning the non-drug product to its own APC to ensure that the product is paid separately or establishing an add-on adjustment for the cost of the non-drug product in addition to the payment for the APC to which the non-drug product is assigned. Additionally, we seek comment on whether it would be appropriate to subject non-drug products to a cost threshold similar to the one we are proposing to apply to drugs and biologicals.

4. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85902 through 85903), we applied this policy and calculated the relative payment weights for each APC for CY 2021 that were shown in Addenda A and B to that 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 that final rule with comment period. For CY 2022, as we did for CY 2021, we propose to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2022 using geometric mean-based APC costs.

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

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2022, as we did for CY 2021, 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 OPPS services. For CY 2022, as we did for CY 2021, we propose to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

We note that in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61365 through 61369), we discuss our policy, implemented on January 1, 2019, to

control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus provider-based department (PBD) at a reduced rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the policy has a negligible effect on the scalar. Specifically, under this policy, there is no change to the relativity of the OPPS payment weights because the adjustment is made at the payment level rather than in the cost modeling. Further, under this policy, the savings that result from the change in payments for these clinic visits are not budget neutral. Therefore, the impact of this policy will generally not be reflected in the budget neutrality adjustments, whether the adjustment is to the OPPS relative weights or to the OPPS conversion factor. For a full discussion of this policy, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2022 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 2021 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2022 unscaled relative payment weights.

For CY 2021, we multiplied the CY 2021 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2019 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 2022, we propose to apply the same process using the estimated CY 2022 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2021 estimated aggregate weight by the unscaled CY 2022 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Click on the CY 2022 OPPS proposed rule link and open the claims accounting document link at the bottom of the page.

We propose to compare the estimated unscaled relative payment weights in CY 2022 to the estimated total relative payment weights in CY 2021 using CY 2019 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 2022 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2022 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4436 to ensure that the proposed CY 2022 relative payment weights are scaled to be budget neutral. The proposed CY 2022 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 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 proposed rule) is included in the budget neutrality calculations for the CY 2022 OPPS.

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 OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25435), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2020 forecast of the FY 2022 market basket increase, the proposed FY 2022 IPPS market basket update was 2.5 percent.

Specifically, 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 ''MFP adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment, and then revised this methodology, as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25435), the proposed MFP adjustment for FY 2022 was 0.2 percentage point.

Therefore, we propose that the MFP adjustment for the CY 2022 OPPS is 0.2 percentage point. We also propose that if more recent data become subsequently available after the publication of this proposed rule (for example, a more recent estimate of the market basket increase and/or the MFP adjustment), we will use such updated data, if appropriate, to determine the CY 2022 market basket update and the MFP 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, in the CY 2022 OPPS/ASC final rule.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we propose for CY 2022 an OPD fee schedule increase factor of 2.3 percent for the CY 2022 OPPS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 2.5 percent, less the proposed 0.2 percentage point MFP 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 OPPS 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 the proposed rule.

To set the OPPS conversion factor for 2022, we propose to increase the CY 2021 conversion factor of $82.797 by 2.3 percent. In accordance with section 1833(t)(9)(B) of the Act, we propose further to adjust the conversion factor for CY 2022 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We propose to calculate an overall budget neutrality factor of 1.0012 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2022 IPPS wage indexes to those payments using the FY 2021 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For the CY 2022 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 continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule. We propose to calculate a CY 2022 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2022 payments under section 1833(t) of the Act, including the proposed CY 2022 cancer hospital payment adjustment, to estimated CY 2022 total payments using the CY 2021 final cancer hospital payment adjustment, as required under section 1833(t)(18)(B) of the Act. The proposed CY 2022 estimated payments applying the proposed CY 2022 cancer hospital payment adjustment were the same as estimated payments applying the CY 2021 final cancer hospital payment adjustment. Therefore, we propose to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 1833(t)(18)(C), as added by section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255), we are applying a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we applied as stated in section II.F. of the proposed rule.

For this CY 2022 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2022 would equal approximately $1.03 billion, which represented 1.24 percent of total projected CY 2022 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.92 percent estimate of pass-through spending for CY 2021 and the 1.24 percent estimate of proposed pass-through spending for CY 2022, resulting in a proposed decrease to the conversion factor for CY 2022 of 0.32 percent.

Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2022. We estimate for the proposed rule that outlier payments would be 1.06 percent of total OPPS payments in CY 2021; the 1.00 percent for proposed outlier payments in CY 2022 would constitute a 0.06 percent decrease in payment in CY 2022 relative to CY 2021.

For this CY 2022 OPPS/ASC proposed rule, 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 0.3 percent (that is, the proposed OPD fee schedule increase factor of 2.3 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2022 of $82.810 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.647 in the conversion factor relative to hospitals that met the requirements).

In summary, for 2022, we propose to use a reduced conversion factor of $82.810 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.647 in the conversion factor relative to hospitals that met the requirements).

For 2022, we propose to use a conversion factor of $84.457 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 2.3 percent for CY 2022, the required proposed wage index budget neutrality adjustment of approximately 1.0012, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment of 0.32 percentage point of projected OPPS spending for the difference in pass-through spending that resulted in a proposed conversion factor for CY 2022 of $84.457.

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 OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We propose to continue this policy for the CY 2022 OPPS. 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), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2022 pre-reclassified wage index that we would use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an

adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For 2022, 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 2021 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; and for FY 2021, 85 FR 58765.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2022 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, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and an adjustment to the wage index for certain low wage index hospitals to help address wage index disparities between low and high wage index hospitals. In addition, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25405 through 25407), we proposed to implement section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) which reinstates the imputed floor wage index adjustment under the IPPS for hospitals in all-urban states effective for discharges on or after October 1, 2021 (FY 2022) using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act, as added by section 9831 of the American Rescue Plan Act, provides that for discharges occurring on or after October 1, 2021, the area wage index applicable under the IPPS to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. We further noted in the FY 2022 IPPS/LTCH PPS proposed rule that, given the recent enactment of section 9831 of Public Law 117–2 on March 11, 2021, there was not sufficient time available to incorporate the changes required by this statutory provision (the reinstatement of the imputed floor wage index) into the calculation of the IPPS provider wage index for the FY 2022 IPPS/LTCH PPS proposed rule, and we stated that we would include the imputed floor wage index adjustment in the calculation of the IPPS provider wage index in the FY 2022 IPPS/LTCH PPS final rule. We note that CMS posted, concurrent with the issuance of the FY 2022 IPPS/LTCH proposed rule, estimated imputed floor values by state in a separate data file on the FY 2022 IPPS Proposed Rule web page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. In addition, we stated in the FY 2022 IPPS/LTCH PPS proposed rule that, based on data available for the FY 2022 IPPS/LTCH PPS proposed rule, the following States would be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States would be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2022: New Jersey, Rhode Island, Delaware, Connecticut, and Washington, DC. We refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25396 through 25417) for a detailed discussion of all proposed changes to the FY 2022 IPPS wage indexes.

Furthermore, as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) and in each subsequent IPPS/LTCH PPS final rule, including the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755), the Office of Management and Budget (OMB) issued revisions to the labor market area delineations on February 28, 2013 (based on 2010 Decennial Census data) that included a number of significant changes, such as new Core Based Statistical Areas (CBSAs), urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart (OMB Bulletin 13–01). This bulletin can be found at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf*. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49985), for purposes of the IPPS, we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13–01, effective October 1, 2014. For purposes of the OPPS, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66826 through 66828), we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13–01, effective January 1, 2015, beginning with the CY 2015 OPPS wage indexes. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted revisions to statistical areas contained in OMB Bulletin No. 15–01, issued on July 15, 2015, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. For purposes of the OPPS, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79598), we adopted the revisions to the OMB statistical area delineations contained in OMB Bulletin No. 15–01, effective January 1, 2017, beginning with the CY 2017 OPPS wage indexes.

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. The attachments to OMB Bulletin No. 17–01 provided detailed information on the update to the statistical areas since July 15, 2015, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. For purposes of the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58863 through 58865), we adopted the updates set forth in OMB Bulletin No. 17–01,

effective January 1, 2019, beginning with the CY 2019 wage index.

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 No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. Typically, interim OMB bulletins (those issued between decennial censuses) have only contained minor modifications to labor market delineations. However, the April 10, 2018 OMB Bulletin No. 18–03 and the September 14, 2018 OMB Bulletin No. 18–04 included more modifications to the labor market areas than are typical for OMB bulletins issued between decennial censuses, including some new CBSAs, urban counties that became rural, rural counties that became urban, and some existing CBSAs that were split apart. In addition, some of these modifications had a number of downstream effects, such as reclassification changes. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. For purposes of the OPPS, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85907 through 85908), we adopted the updates set forth in OMB Bulletin No. 18–04 effective January 1, 2021, beginning with the CY 2021 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 18–04, we refer readers to the CY 2021 OPPS/ASC final rule with comment period.

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. The attachments to OMB Bulletin No. 20–01 provided detailed information on the updates to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017 and July 1, 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.*) In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area, one new component of an existing Combined Statistical Area and changes to New England City and Town Area (NECTA) delineations. As we stated in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25397), after reviewing OMB Bulletin No. 20–01, we determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the Medicare IPPS wage index for FY 2022. Specifically, the updates consisted of changes to NECTA delineations and the creation of a new Micropolitan Statistical Area, which was then added as a new component to an existing Micropolitan Statistical Area. The Medicare wage index does not utilize NECTA definitions, and, as most recently discussed in FY 2021 IPPS/LTCH PPS final rule (85 FR 58746), we include hospitals located in Micropolitan Statistical areas in each State's rural wage index. Therefore, consistent with our discussion in the FY 2022 IPPS/LTCH PPS proposed rule, while we propose to adopt the updates set forth in OMB Bulletin No. 20–01 consistent with our longstanding policy of adopting OMB delineation updates, we note that specific OPPS wage index updates would not be necessary for CY 2022 as a result of adopting these OMB updates. In other words, these OMB updates would not affect any hospital's geographic area for purposes of the OPPS wage index calculation for CY 2022.

For CY 2022, we would continue to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01, 17–01, and 18–04.

We note that, in connection with our adoption in FY 2021 of the updates in OMB Bulletin 18–04, we adopted a policy to place a 5 percent cap, for FY 2021, on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020 so that a hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58753 through 58755) for a complete discussion of this transition. As finalized in the FY 2021 IPPS/LTCH PPS final rule, this transition is set to expire at the end of FY 2021. However, as discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25397), given the unprecedented nature of the ongoing COVID–19 PHE, we sought comment in the FY 2022 IPPS/LTCH PPS proposed rule on whether it would be appropriate to continue to apply a transition for the FY 2022 IPPS wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04. For example, we stated that such an extended transition could potentially take the form of holding the FY 2022 IPPS wage index for those hospitals harmless from any reduction relative to their FY 2021 wage index. We further stated that if we were to apply a transition to the FY 2022 IPPS wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04, we also sought comment on making this transition budget neutral under the IPPS, as is our usual practice, in the same manner that the FY 2021 IPPS wage index transition was made budget neutral as discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58755).

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/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 OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2022, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

We propose to use the FY 2022 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment

rate and the copayment rate for CY 2022. Therefore, any adjustments for the FY 2022 IPPS post-reclassified wage index, including, but not limited to, the imputed floor adjustment and any transition that may be applied (as discussed previously), would be reflected in the final CY 2022 OPPS wage index beginning on January 1, 2022. (We refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25396 through 25417) and the proposed FY 2022 hospital wage index files posted on the CMS website.) With regard to budget neutrality for the CY 2022 OPPS wage index, we refer readers to section II.B. of this CY 2022 OPPS/ASC proposed rule. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index adjustments. In this CY 2022 OPPS/ASC proposed rule, we propose to continue this policy for CY 2022, and are including below a brief summary of the major proposed FY 2022 IPPS wage index policies and adjustments that we propose to apply to these hospitals under the OPPS for CY 2022. We referred readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25396 through 25417) for a detailed discussion of the proposed changes to the FY 2022 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2022, we propose to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). Furthermore, we propose that the wage index that would apply for CY 2022 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any 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 OPPS would include any transition we may finalize for the FY 2022 IPPS wage index as discussed previously.

For CMHCs, for CY 2022, 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 CMHCs for CY 2022 would continue to include the rural floor adjustment and any adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to CMHCs would include any transition we may finalize for the FY 2022 IPPS wage index as discussed above. 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 2022 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 2022 IPPS/LTCH PPS proposed rule (available for download via the website above) identifies IPPS hospitals that would receive the out-migration adjustment for FY 2022. We are including the outmigration adjustment information from Table 2 associated with the FY 2022 IPPS/LTCH PPS proposed rule as Addendum L to this CY 2022 OPPS/ASC proposed rule with the addition of non-IPPS hospitals that would receive the section 505 outmigration adjustment under this proposed rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index*. At this link, readers will find a link to the proposed FY 2022 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 to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the CY 2022 OPPS proposed rule Claims Accounting Narrative that is posted on our website. We propose to calculate the default ratios for CY 2022 using cost report data from the same set of cost reports we originally used in the CY 2021 OPPS ratesetting, consistent with the broader proposal regarding 2022 OPPS ratesetting discussed in section X.E. of this proposed rule.

We no longer publish a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS proposed rule and final rule with comment period. These CCRs with the upper limit will be available for download with each OPPS 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 web page.

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 2022

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

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Public Law 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 2021. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For CY 2022, we propose to continue the current policy of a 7.1 percent payment adjustment that is done in a budget neutral manner 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.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2021

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 hospital 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 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 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, 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 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 3 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2021.

TABLE 3: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT-TO-COST RATIOS (PCRs), CY 2012 THROUGH CY 2021

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

2. Proposed Policy for CY 2022

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 final PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals, using the most recent submitted or settled cost report data that were available at the time of the development of the proposed rule, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act. We are not proposing an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) for CY 2022.

Under our established policy, to calculate the proposed CY 2022 target PCR, we would use the same extract of cost report data from HCRIS used to estimate costs for the CY 2022 OPPS which would be the most recently available hospital cost reports which, in most cases, would be from CY 2020. However, as discussed in Section II.A.1.a of this proposed rule, given our concerns with CY 2020 claims data as a result of the PHE, we believe a target PCR based on CY 2020 claims and the most recently available cost reports may provide a less accurate estimation of cancer hospital PCRs and non-cancer hospital PCRs than the data used for the CY 2021 rulemaking cycle. Therefore, for CY 2022, we are proposing to continue to use the CY 2021 target PCR of 0.89. This proposed CY 2022 target PCR of 0.89 includes the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2022. For a description of the CY 2021 target PCR calculation, we refer readers to the CY 2021 OPPS/ASC final rule with comment period (84 FR 85912 through 85914).

Table 4 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2022, due to the cancer hospital payment adjustment policy. The actual amount of the CY 2022 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2022 payments and costs. 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 4: ESTIMATED CY 2022 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2022 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	31.3%
050660	USC Norris Cancer Hospital	9.9%
100079	Sylvester Comprehensive Cancer Center	16.5%
100271	H. Lee Moffitt Cancer Center & Research Institute	20.8%
220162	Dana-Farber Cancer Institute	34.3%
330154	Memorial Sloan-Kettering Cancer Center	38.1%
330354	Roswell Park Cancer Institute	14.0%
360242	James Cancer Hospital & Solove Research Institute	16.4%
390196	Fox Chase Cancer Center	11.2%
450076	M.D. Anderson Cancer Center	51.4%
500138	Seattle Cancer Care Alliance	46.5%

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2021, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $5,300 (the fixed-dollar amount threshold) (85 FR 85914 through 85916). If the cost of 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 cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2019 OPPS payments, using CY 2019 claims available for this CY 2022 OPPS/ASC proposed rule, is approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2019, we estimated that we paid the outlier target of 1.0 percent of total aggregated OPPS payments. Using an updated claims dataset for this CY 2022 OPPS/ASC proposed rule, we estimate that we paid approximately 0.92 percent of the total aggregated OPPS payments in outliers for CY 2019.

For this CY 2022 OPPS/ASC proposed rule, using CY 2019 claims data and CY 2021 payment rates, we estimated that the aggregate outlier payments for CY 2021 would be approximately 1.06 percent of the total CY 2021 OPPS payments. We provided estimated CY 2021 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 2022

For CY 2022, 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. We propose to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under APC 5853 (Partial

Hospitalization for CMHCs), exceeds 3.40 times the payment rate for proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC 5853 payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this CY 2022 OPPS/ASC proposed rule.

To ensure that the estimated CY 2022 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 $6,100.

We calculated the proposed fixed-dollar threshold of $6,100 using the standard methodology most recently used for CY 2021 (85 FR 85914 through 85916). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2020 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2022 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2019 claims using the same inflation factor of 1.20469 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25718). We used an inflation factor of 1.13218 to estimate CY 2021 charges from the CY 2019 charges reported on CY 2019 claims. The methodology for determining this charge inflation factor is discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we propose to apply the same CCR inflation adjustment factor that we propose to apply for the FY 2022 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2022 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2022, we propose to apply an adjustment factor of 0.94964 to the CCRs that were in the April 2020 OPSF to trend them forward from CY 2020 to CY 2022. The methodology for calculating the proposed adjustment is discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25717 through 25719).

To model hospital outlier payments for this proposed rule, we applied the overall CCRs from the April 2021 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.94964 to approximate CY 2022 CCRs) to charges on CY 2019 claims that were adjusted (using the proposed charge inflation factor of 1.20469 to approximate CY 2022 charges). We simulated aggregated CY 2021 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 2021 OPPS payments. We estimated that a proposed fixed-dollar threshold of $6,100, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we propose that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 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 will 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 OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we propose to continue the policy that we implemented in CY 2010 that the hospitals' costs will 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 basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2022 OPPS/ASC proposed rule, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this proposed rule and the relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the internet on the CMS website) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available via the internet on the CMS website) was calculated by multiplying the proposed CY 2022 scaled weight for the APC by the CY 2022 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 (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) 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.

We demonstrate the steps used to determine the APC payments that will be made in a CY under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''Q4'', ''R'', ''S'', ''T'', ''U'', or ''V'' (as defined in Addendum D1 to the 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 will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to the 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 2022 OPPS fee schedule increase factor.

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

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

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

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

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that, for the CY 2021 OPPS wage index (85 FR 85907 through 85908), we adopted the updated OMB delineations based on OMB Bulletin No. 18–04 and related IPPS wage index adjustments finalized in the FY 2021 IPPS/LTCH PPS final rule. 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 2022 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 2022 OPPS wage index any adjustments for the FY 2022 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 2022 OPPS, 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 Public Law 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 2022 IPPS wage index, which are listed in Table 2 associated with the FY 2022 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website at: *http://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 2022 IPPS Proposed Rule Home Page'' and select ''FY 2022 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).

$X_a = .60 *$ (national unadjusted payment rate) * applicable wage index.

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

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

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

$Y = .40 *$ (national unadjusted payment rate).

Adjusted Medicare Payment = $Y + X_a$.

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.

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will 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 2022 full national unadjusted payment rate for APC 5071 is $638.48. The proposed reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $626.03. This proposed reduced rate is calculated by multiplying the reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

The proposed FY 2022 wage index for a provider located in CBSA 35614 in New York, which includes the proposed adoption of IPPS 2022 wage index policies, is 1.3404. The labor-related portion of the proposed full national unadjusted payment is approximately $513.49 (.60 * $638.48 * 1.3404). The labor-related portion of the proposed reduced national unadjusted payment is approximately $503.48 (.60 * $626.03 * 1.3404). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $255.39 (.40 * $638.48). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $250.41 (.40 * $626.03). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $768.88 ($513.49 + $255.39). The sum of the portions of the proposed reduced national adjusted payment is approximately $753.89 ($503.48 + $250.41).

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. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, may be found in section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. Proposed OPPS Copayment Policy

For CY 2022, we propose to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (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, 2022 are included in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

As discussed in section XIV.E. of this proposed rule, for CY 2022, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

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

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

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in

an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

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 this rule for additional details.

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 payment rate. For example, using APC 5071, $127.70 is approximately 20 percent of the full national unadjusted payment rate of $638.48. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

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

B is the beneficiary payment percentage.

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

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

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

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

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

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

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

The proposed unadjusted copayments for services payable under the OPPS that will be effective January 1, 2022, are shown in Addenda A and B to proposed rule (which are available via the internet on the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the CY 2022 OPD fee schedule increase factor discussed in section II.B. of 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. 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 maintained by the American Medical Association (AMA), and consists of Category I, II, and III CPT codes. Level II, 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. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alphanumeric codes), which are used primarily to identify drugs, devices, ambulance services, durable medical equipment, orthotics, prosthetics, supplies, temporary surgical procedures, and medical services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes and makes the

codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe the items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. Those items, procedures, or services not exclusively paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section XI. of this proposed rule (Proposed CY 2022 OPPS Payment Status and Comment Indicators), we discuss the various proposed status indicators used under the OPPS. We also provide a complete list of proposed status indicators and their definitions in Addendum D1 to this CY 2022 OPPS/ASC proposed rule.

1. April 2021 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2021 update, 26 new HCPCS codes were established and made effective on April 1, 2021. These codes and their long descriptors are listed in Table 5 below. Through the April 2021 OPPS quarterly update CR (Transmittal 10666, Change Request 12175, dated March 8, 2021), we recognized several new HCPCS codes for separate payment under the OPPS. In this CY 2022 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the codes listed Table 5. 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. These new codes that are effective April 1, 2021 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 that comments will be accepted on their interim APC assignments. Also, 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, Addendum D1, and Addendum D2 are available via the internet on the CMS website.

BILLING CODE 4120–01–P

TABLE 5.—NEW HCPCS CODES EFFECTIVE APRIL 1, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
A9592	Copper cu-64, dotatate, diagnostic, 1 millicurie	NP	G	9383
C9074*	Injection, lumasiran, 0.5 mg	NP	D	N/A
C9776	Intraoperative near-infrared fluorescence imaging of major extra-hepatic bile duct(s) (e.g., cystic duct, common bile duct and common hepatic duct) with intravenous administration of indocyanine green (icg) (list separately in addition to code for primary procedure)	NP	N	N/A
C9777	Esophageal mucosal integrity testing by electrical impedance, transoral (list separately in addition to code for primary procedure)	NP	N	N/A
G2020	Services for high intensity clinical services associated with the initial engagement and outreach of beneficiaries assigned to the sip component of the pcf model (do not bill with chronic care management codes)	NP	A	N/A
G2172	All inclusive payment for services related to highly coordinated and integrated opioid use disorder (oud) treatment services furnished for the demonstration project	NP	A	N/A
J1427	Injection, viltolarsen, 10 mg	NP	G	9386
J1554	Injection, immune globulin (asceniv), 500 mg	NP	G	9392
J7402	Mometasone furoate sinus implant, (sinuva), 10 micrograms	NP	G	9346
J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	NP	G	9384
J9349	Injection, tafasitamab-cxix, 2 mg	NP	G	9385
K1013	Enema tube, any type, replacement only, each	NP	Y	N/A
K1014	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control	NP	Y	N/A
K1015	Foot, adductus positioning device, adjustable	NP	Y	N/A

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
K1016	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve	NP	Y	N/A
K1017	Monthly supplies for use of device coded at K1016	NP	Y	N/A
K1018	External upper limb tremor stimulator of the peripheral nerves of the wrist	NP	Y	N/A
K1019	Monthly supplies for use of device coded at K1018	NP	Y	N/A
K1020	Non-invasive vagus nerve stimulator	NP	Y	N/A
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	NP	G	9391
0242U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements	NP	A	N/A
0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia	NP	Q4	N/A
0244U	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffinembedded tumor tissue	NP	A	N/A
0245U	Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage	NP	A	N/A
0246U	Red blood cell antigen typing, DNA, genotyping of at least 16 blood groups with phenotype prediction of at least 51 red blood cell antigens	NP	A	N/A
0247U	Obstetrics (preterm birth), insulin-like growth factor–binding protein 4 (IBP4), sex hormone–binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous	NP	Q4	N/A

HCPCS code C9074, which was effective April 1, 2021, was deleted June 30, 2021 and replaced with HCPCS code J0224 (Injection, lumasiran, 0.5mg) effective July 1, 2021.

2. July 2021 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the July 2021 update, 55 new codes were established and made effective July 1, 2021. The codes and long descriptors are listed in Table 6 below. Through the July 2021 OPPS quarterly update CR (Transmittal 10825, Change Request 12316, dated June 11, 2021), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. In this CY 2022 OPPS/ASC proposed rule, we are

soliciting public comments on the proposed APC and status indicator assignments for the codes implemented on July 1, 2021, all of which are listed in Table 6. 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. These new codes that are effective July 1, 2021 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 that comments will be accepted on their interim APC assignments. Also, 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, Addendum D1, and Addendum D2 are available via the internet on the CMS website.

TABLE 6.—NEW HCPCS CODES EFFECTIVE JULY 1, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	NP	G	9409
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	NP	G	9410
C1761	Catheter, transluminal intravascular lithotripsy, coronary	NP	H	2033
C9075	Injection, casimersen, 10 mg	NP	G	9412
C9076	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	NP	G	9413
C9077	Injection, cabotegravir and rilpivirine, 2mg/3mg	NP	G	9414
C9078	Injection, trilaciclib, 1 mg	NP	G	9415
C9079	Injection, evinacumab-dgnb, 5 mg	NP	G	9416
C9080	Injection, melphalan flufenamide hydrochloride, 1 mg	NP	G	9417
C9778	Colpopexy, vaginal; minimally invasive extra-peritoneal approach (sacrospinous)	NP	J1	5414
G0327	Colorectal cancer screening; blood-based biomarker	NP	A	N/A
J0224*	Injection, lumasiran, 0.5 mg	NP	G	9407
J1951	Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg	NP	K	9419
J7168	Prothrombin complex concentrate (human), kcentra, per i.u. of factor ix activity	NP	K	9132
J9348	Injection, naxitamab-gqgk, 1 mg	NP	G	9408
J9353	Injection, margetuximab-cmkb, 5 mg	NP	G	9418
Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	NP	G	9411
0640T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition, interpretation and report, each flap or wound	NP	M	N/A
0641T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition only, each flap or wound	NP	T	5732
0642T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of	NP	M	N/A

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
	deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); interpretation and report only, each flap or wound			
0643T	Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach	NP	E1	N/A
0644T	Transcatheter removal or debulking of intracardiac mass (eg, vegetations, thrombus) via suction (eg, vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed	NP	J1	5192
0645T	Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed	NP	E1	N/A
0646T	Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	NP	E1	N/A
0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report	NP	J1	5302
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	NP	S	5523
0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	NP	N	N/A

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional	NP	Q1	5741
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report	NP	T	5301
0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	NP	T	5301
0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple	NP	T	5301
0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter	NP	J1	5302
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging	NP	J1	5374
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments	NP	C	N/A
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments	NP	C	N/A
0658T	Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score	NP	S	5733
0659T	Transcatheter intracoronary infusion of supersaturated oxygen in conjunction with percutaneous coronary revascularization during acute myocardial infarction, including catheter placement, imaging guidance (eg, fluoroscopy), angiography, and radiologic supervision and interpretation	NP	C	N/A
0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach	NP	E1	N/A
0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant	NP	E1	N/A
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	NP	S	5732

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (list separately in addition to code for primary procedure)	NP	N	N/A
0664T	Donor hysterectomy (including cold preservation); open, from cadaver donor	NP	E1	N/A
0665T	Donor hysterectomy (including cold preservation); open, from living donor	NP	E1	N/A
0666T	Donor hysterectomy (including cold preservation); laparoscopic or robotic, from living donor	NP	E1	N/A
0667T	Donor hysterectomy (including cold preservation); recipient uterus allograft transplantation from cadaver or living donor	NP	E1	N/A
0668T	Backbench standard preparation of cadaver or living donor uterine allograft prior to transplantation, including dissection and removal of surrounding soft tissues and preparation of uterine vein(s) and uterine artery(ies), as necessary	NP	E1	N/A
0669T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; venous anastomosis, each	NP	E1	N/A
0670T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; arterial anastomosis, each	NP	E1	N/A
0248U	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug	NP	A	N/A
0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report	NP	Q4	N/A
0250U	Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden	NP	A	N/A
0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma	NP	Q4	N/A
0252U	Fetal aneuploidy short tandem–repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy	NP	A	N/A

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive)	NP	A	N/A
0254U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy, per embryo tested	NP	A	N/A

*HCPCS code C9074, which was effective April 1, 2021, was deleted June 30, 2021 and replaced with HCPCS code J0224 effective July 1, 2021.

BILLING CODE 4120–01–C

3. October 2021 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2022 OPPS/ASC Final Rule With Comment Period

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, 2021 in the CY 2022 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2023 OPPS/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2021 OPPS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2022, we are proposing 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 are effective October 1, 2021 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 2022 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2023 OPPS/ASC final rule with comment period.

4. January 2022 HCPCS Codes

a. New Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2022 OPPS/ASC Final Rule With Comment Period

Consistent with past practice, we will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2022 in the CY 2022 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2023 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 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 2022, we propose to include in Addendum B to the CY 2022 OPPS/ASC final rule with comment period the new Level II HCPCS codes effective January 1, 2022 that would be incorporated in the January 2022 OPPS quarterly update CR. These codes will be released to the public through the January OPPS quarterly update CRs and via the CMS HCPCS website (for Level II HCPCS codes).

For CY 2022, we are proposing 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, 2022 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 2022 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2023 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This Proposed Rule

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 2022 OPPS update, we received the CPT codes that will be effective January 1, 2022 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 2022 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) so that the public can adequately comment on our proposed APCs and status indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled ''CY 2022 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code''. The final CPT code numbers will be included in the CY 2022 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2022 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2022. 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 are proposing to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2022 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

Finally, in Table 7 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.

BILLING CODE 4120–01–P

TABLE 7.—COMMENT TIMEFRAME FOR NEW AND REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2021	HCPCS (CPT and Level II codes)	April 1, 2021	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
July 2021	HCPCS (CPT and Level II codes)	July 1, 2021	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
October 2021	HCPCS (CPT and Level II codes)	October 1, 2021	CY 2022 OPPS/ASC final rule with comment period	CY 2023 OPPS/ASC final rule with comment period
January 2022	CPT Codes	January 1, 2022	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2022	CY 2022 OPPS/ASC final rule with comment period	CY 2023 OPPS/ASC final rule with comment period

BILLING CODE 4120–01–C

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. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

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

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2022, 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 HOP Panel recommendations for specific services for the CY 2022 OPPS update will be discussed in the relevant specific sections throughout the CY 2022 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 2022, 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 2022 OPPS update, we have identified the APCs with violations of the 2 times rule. Therefore, we propose changes to the procedure codes assigned to these APCs 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 CY 2022 OPPS/ASC 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/index.html*. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity, 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 procedure code reassignments and associated APC reconfigurations for CY 2022 included in this proposed rule are related to changes in costs of services that were observed in the CY 2019 claims data available for CY 2022 ratesetting. Addendum B to this CY 2021 OPPS/ASC 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, 2021 OPPS Addendum B Update (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.html*).

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we propose to make for CY 2022, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. 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.

Based on the CY 2019 claims data available for this CY 2022 proposed rule, we found 23 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we propose to make exceptions under the 2 times rule for CY 2022, and found that all of the 23 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2019 claims data available for this proposed rule. 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.

We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we may accept the HOP Panel's recommendation because those recommendations are based on explicit consideration (that is, a review of the latest OPPS claims data and group discussion of the issue) of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 8 of this proposed rule lists the 23 APCs for which we propose to make an exception under the 2 times rule for CY 2021 based on the criteria cited above and claims data submitted between January 1, 2019, and December 31, 2019, and processed on or before June 30, 2020, and updated 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: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

BILLING CODE 4120–01–P

TABLE 8.—PROPOSED CY 2022 APC EXCEPTIONS TO THE 2 TIMES RULE

Proposed CY 2022 APC	Proposed CY 2022 APC Title
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5101	Level 1 Strapping and Cast Application
5112	Level 2 Musculoskeletal Procedures
5161	Level 1 ENT Procedures
5301	Level 1 Upper GI Procedures
5311	Level 1 Lower 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
5571	Level 1 Imaging with Contrast
5593	Level 3 Nuclear Medicine and Related Services
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673	Level 3 Pathology
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

BILLING CODE 4120–01–C

C. Proposed New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

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

For CY 2021, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) through 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 OPPS. 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 OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital market basket increase reduced by the productivity adjustment. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and are adequate to ensure access to services (80 FR 70374).

For many emerging technologies, there is a transitional period during

which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payments under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

We note that, in a budget-neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2022, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

2. Establishing Payment Rates for Low-Volume New Technology Services

Services that are assigned to New Technology APCs are typically new services that do not have sufficient claims history to establish an accurate payment for the services. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new service so that it can be assigned to an appropriate clinical APC. Some services that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. We consider services with fewer than 100 claims annually to be low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. In addition, services with fewer than 100 claims per year are not generally considered to be a significant contributor to the APC ratesetting calculations and, therefore, are not included in the assessment of the 2 times rule. As we explained in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58890), we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS service code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the service for these low-volume services.

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. As described earlier, assigning a service to a New Technology APC allows us to gather claims data to price the service and assign it to the APC with services that use similar resources and are clinically comparable. However, 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 determined in the CY 2019 OPPS/ASC final rule with comment period that it was appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determined the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). We have utilized our equitable adjustment authority at 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 estimate an appropriate payment amount for low-volume new technology services in the past (82 FR 59281). Although we have used this adjustment authority on a case-by-case basis in the past, we stated in the CY 2019 OPPS/ASC final rule with comment period that we believed it was appropriate to adopt an adjustment for low-volume services assigned to New Technology APCs in order to mitigate the wide payment fluctuations that have occurred for new technology services with fewer than 100 claims and to provide more predictable payment for these services.

For purposes of this adjustment, we stated that we believed that it was appropriate to use up to 4 years of claims data in calculating the applicable payment rate for the prospective year, rather than using solely the most recent available year of claims data, when a service assigned to a New Technology APC has a low annual volume of claims, which, for purposes of this adjustment, we defined as fewer than 100 claims annually. We adopted a policy to consider services with fewer than 100 claims annually as low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. We explained that we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS procedure code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the low-volume service. Using multiple years of claims data will potentially allow for more than 100 claims to be used to set the payment rate, which would, in turn, create a more statistically reliable payment rate.

In addition, to better approximate the cost of a low-volume service within a New Technology APC, we stated that we believed using the median or arithmetic mean rather than the geometric mean (which ''trims'' the costs of certain claims out) could be more appropriate in some circumstances, given the extremely low volume of claims. Low claim volumes increase the impact of ''outlier'' claims; that is, claims with either a very low or very high payment

rate as compared to the average claim, which would have a substantial impact on any statistical methodology used to estimate the most appropriate payment rate for a service. We also explained that we believed having the flexibility to utilize an alternative statistical methodology to calculate the payment rate in the case of low-volume new technology services would help to create a more stable payment rate. Therefore, 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 seek public comments on which statistical methodology should be used for each low-volume service assigned to a New Technology APC. In the preamble of each annual rulemaking, we stated that we would present the result of each statistical methodology and solicit public comment on which methodology should be used to establish the payment rate for a low-volume new technology service. In addition, we explained that we would use our assessment of the resources used to perform a service and guidance from the developer or manufacturer of the service, as well as other stakeholders, to determine the most appropriate payment rate. Once we identified the most appropriate payment rate for a service, we would assign the service to the New Technology APC with the cost band that includes its payment rate.

For CY 2022, we propose to continue to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using up to four years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC. However, we propose to utilize our equitable adjustment authority through our proposed universal low volume APC policy described in section X.C. of this proposed rule. Our proposed universal low volume APC policy is similar to our current New Technology APC low volume policy with the difference between the two policies being that the universal low volume APC policy would apply to clinical APCs and brachytherapy APCs, in addition to New Technology APCs, and would use the highest of the geometric mean, arithmetic mean, or median based on up to four years of claims data to set the payment rate for the APC. For New Technology APCs with fewer than 100 single claims at the procedure level that can be used for ratesetting, we would apply our proposed methodology for determining a low volume APC's cost, choosing the ''greatest of'' the median, arithmetic mean, or geometric mean at the procedure level, to apply to the individual services assigned to New Technology APCs and provide the final New Technology APC assignment for each procedure. We propose to end our separate New Technology APC low volume policy if we adopt the proposed universal low volume APC policy, as it also applies to New Technology APCs.

3. Procedures Assigned to New Technology APC Groups for CY 2022

As we described in the CY 2002 OPPS final rule with comment period (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 2022, 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 not 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. Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving the use of the Argus® II Retinal Prosthesis System. This first retinal prosthesis was approved by FDA in 2013 for adult patients diagnosed with severe to profound retinitis pigmentosa. For information on the utilization and payment history of the Argus® II procedure and the Argus® II device prior to CY 2020, please refer to the CY 2021 OPPS final rule (85 FR 85937 through 85938).

For CY 2020, we identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2015 through CY 2018. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $146,059, the arithmetic mean cost to be approximately $152,123, and the median cost to be approximately $151,267. All of the resulting estimates from using the three statistical methodologies fell within the same New Technology APC cost band ($145,001–$160,000), where the Argus® II procedure was assigned for CY 2019. Consistent with our policy stated in section III.C.2, we presented the result of each statistical methodology in the proposed rule, and we sought public comments on which method should be used to assign procedures described by CPT code 0100T to a New Technology APC. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fell within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000. Accordingly, we assigned CPT code 0100T in APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2020.

For CY 2021, the number of reported claims for the Argus® II procedure continued to be very low with a substantial fluctuation in cost from year to year. The high annual variability of the cost of the Argus® II procedure continued to make it difficult to establish a consistent and stable payment rate for the procedure. As previously mentioned, in accordance with section 1833(t)(2)(B) of the Act, we are required to establish that services classified within each APC are comparable clinically and with respect to the use of resources. We identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2016 through CY 2019. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $148,148, the arithmetic mean cost to be approximately $153,682, and the median cost to be approximately $151,974. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fell within

the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000, and accordingly, we assigned the Argus II procedure to New Technology APC 1908 for CY 2021.

For 2022, we propose to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to establish the universal low volume APC policy described in section X.C. of this proposed rule. Consistent with this proposed policy, we calculated the geometric mean, arithmetic mean, and median costs using multiple years of claims data to select the appropriate payment rate for purposes of assigning the Argus® II procedure (CPT code 0100T) to a New Technology APC. We propose to use claims data from CY 2016 through CY 2019, which are the last four years of available OPPS claims data that we believe are appropriate for ratesetting, to determine the proposed payment rate for the Argus® II procedure for CY 2022. The claims data are the same 35 claims that were used to determine the payment rate for CPT code 0100T in CY 2021, and the estimates of the geometric mean ($148,148), the arithmetic mean ($153,682), and the median ($151,974) are the same as the estimates for CY 2021. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure are within the cost band for New Technology APC 1908, with the proposed payment rate being between $145,001 and $160,000. Accordingly, we propose to continue to assign the Argus® II procedure to New Technology APC 1908 for CY 2022. Please see Table 9 below for the proposed OPPS APC and status indicator for the Argus® II procedure (CPT code 0100T) for CY 2022.

TABLE 9: CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR THE ARGUS® II PROCEDURE (CPT CODE 0100T) ASSIGNED TO NEW TECHNOLOGY APC

CY 2022 HCPCS Code	Long Descriptor	Proposed CY 2022 OPPS SI	Proposed CY 2022 OPPS APC	Proposed CY 2022 OPPS Payment Rate
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy	T	1908	$152,500.50

b. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1561)

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 HCPCS code 67036. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology—Level 24 ($3001–$3500)). This procedure may be used to describe the administration of CPT code J3398 (*Injection, voretigene neparvovec-rzyl, 1 billion vector genomes*). This procedure was previously discussed in the CY 2021 OPPS/ASC Final Rule with comment period (85 FR 85939–85940).

CPT code J3398 (*Injection, voretigene neparvovec-rzyl, 1 billion vector genomes*) is a gene therapy for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®), was approved by FDA in December of 2017, and is indicated as 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 through a subretinal injection, which stakeholders 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.''

Stakeholders, including the manufacturer of Luxturna®, recommended HCPCS code 67036 (*Vitrectomy, 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 HCPCS code 67036 (*Vitrectomy, mechanical, pars plana approach*) does not account for the administration itself.

CMS recognized the need to accurately describe the unique administration procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC proposed rule (85 FR 48832), we proposed to establish a new HCPCS code, C97X1 (*Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent*) to describe this process. We stated that we believed that this new HCPCS code accurately described the unique service associated with intraocular administration of HCPCS code J3398. We recognized that HCPCS code 67036 represents a clinically similar procedure and process that approximates similar resource utilization that is associated with 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 HCPCS 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

[6] Luxturna. FDA Package Insert. Available: *https://www.fda.gov/media/109906/download.*

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

a cost band that contains the geometric mean cost for HCPCS code 67036. The placeholder code C97X1 was replaced by C9770 in the final rule. For CY 2021, we finalized our proposal to create C9770 (*Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent*), and we assigned this code to APC 1561 (New Technology—Level 24 ($3001–$3500)) using the geometric mean cost of HCPCS code 67036. See Table 10 for the finalized descriptor and APC assignment of HCPCS code C9770 for CY 2021.

For CY 2022, we are proposing to continue our policy from CY 2021 to assign the services described by HCPCS code C9770 to a New Technology APC with a cost band that contains the geometric mean cost for HCPCS code 67036. We propose to continue to assign the services described by C9770 to a New Technology APC with a payment band based on the geometric mean cost for HCPCS code 67036 based on its geometric mean cost using CY 2019 claims data for CY 2022. Based on this data, the geometric mean cost of HCPCS code 67036 is $3,434.91. Therefore, we propose to assign C9770 to the corresponding New Technology APC payment band, APC 1561 New Technology—Level 24 ($3001–$3500) with a payment rate of $3250.50. Please see Table 10 below for the proposed OPPS APC and status indicator for HCPCS code C9770 for CY 2022.

TABLE 10: CY 2021 FINALIZED AND CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9770 ASSIGNED TO NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	Finalized CY 2021 OPPS SI	Finalized CY 2021 OPPS APC	Proposed CY 2022 OPPS SI	Proposed CY 2022 OPPS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1561	T	1561

c. Bronchoscopy With Transbronchial Ablation of Lesion(s) by Microwave Energy

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3–D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (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 OPPS, 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 OPPS/ASC final rule with comment period, there were 4 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 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 calculate 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 and provided a reasonable estimate of the midpoint cost of the three claims that have been paid for this service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we assigned HCPCS code C9751 to APC 1562 for CY 2021.

For CY 2022, the only available claims for HCPCS code C9751 are from CY 2019. Therefore, we are proposing given the low number of claims for this procedure to 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 calculate an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC, consistent with our proposed universal low volume APC policy. Because we are using the same claims as we did for CY 2021, we found the same values for the geometric mean cost, arithmetic mean cost, and the median cost for CY 2022. Once again, the median was the statistical methodology that estimated the highest cost for the service and provides a reasonable estimate of the midpoint cost of the three claims that have been paid for this service. The payment rate calculated using this methodology falls again within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we propose to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3,501–$4,000)), with a proposed payment rate of $3,750.50 for CY 2022. Details regarding HCPCS code C9751 are included in Table 11.

TABLE 11: CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9751 ASSIGNED TO NEW TECHNOLOGY APC

CY 2022 HCPCS Code	Long Descriptor	Proposed CY 2022 OPPS SI	Proposed CY 2022 OPPS APC	Proposed CY 2022 OPPS Payment Rate
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 (eg, aspiration[s]/biopsy[ies]	T	1562	$3,750.50

d. Fractional Flow Reserve Derived From Computed Tomography (FFRCT)

Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow procedure is intended for clinically stable symptomatic patients with coronary artery disease, and, in many cases, may avoid the need for an invasive coronary angiogram procedure. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether or not patients should undergo further invasive testing (that is, a coronary angiogram).

For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the primary service. However, in CY 2018, we determined that HeartFlow should receive a separate payment because the service is performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan. We assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50 based on pricing information provided by the developer of the procedure that indicated the price of the procedure was approximately $1,500. We did not have Medicare claims data in CY 2019 for CPT code 0503T, and we continued to assign the service to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50.

CY 2020 was the first year for which we had Medicare claims data to calculate the cost of HCPCS code 0503T. For the CY 2020 OPPS/ASC final rule, there were 957 claims with CPT code 0503T of which 101 of the claims were single frequency claims that were used to calculate the geometric mean of the procedure. We planned to use the geometric mean to report the cost of HeartFlow. However, the number of single claims for CPT code 0503T was below the low-volume payment policy threshold for the proposed rule, and this number of single claims was only two claims above the threshold for the New Technology APC low-volume policy for the final rule. Therefore, we decided to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using the CY 2018 claims data to determine an appropriate payment rate for HeartFlow using our New Technology APC low-volume payment policy. While the number of single frequency claims was just above our threshold to use the low-volume payment policy, we still had concerns about the normal cost distribution of the claims used to calculate the payment rate for HeartFlow, and we decided the low-volume payment policy would be the best approach to address those concerns.

Our analysis found that the geometric mean cost for CPT code 0503T was $768.26, the arithmetic mean cost for CPT code 0503T was $960.12, and the median cost for CPT code 0503T was $900.28. Of the three cost methods, the highest amount was for the arithmetic mean. The arithmetic mean fell within the cost band for New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) with a payment rate of $950.50. The arithmetic mean helped to account for some of the higher costs of CPT code 0503T identified by the developer and other stakeholders that may not have been reflected by either the median or the geometric mean.

For CY 2021, we observed a significant increase in the number of claims billed with CPT code 0503T. Specifically, using CY 2019 data, we identified 3,188 claims billed with CPT code 0503T including 465 single frequency claims. These totals are well above the threshold of 100 claims for a procedure to be evaluated using the New Technology APC low-volume policy. Therefore, we used our standard methodology rather than the low-volume methodology we previously used to determine the cost of CPT code 0503T. Our analysis found that the geometric mean for CPT code 0503T was $804.35, and the geometric mean cost for the service fell within the cost band for New Technology APC 1510 (New Technology—Level 10 ($801–$900)). However, providers and other stakeholders have noted that the FFRCT service costs $1,100 and that there are additional staff costs related to the submission of coronary CT image data for processing by HeartFlow.

We noted that HeartFlow is one of the first procedures utilizing artificial intelligence to be separately payable in the OPPS, and providers are still

learning how to accurately report their charges to Medicare when billing for artificial intelligence services (85 FR 85943). This is especially the case for allocating the cost of staff resources between the HeartFlow procedure and the coronary CT imaging services. Therefore, we decided it would be appropriate to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2021 as in CY 2020 in order to provide payment stability and equitable payment for providers as they continue to become more familiar with the proper cost reporting for HeartFlow and other artificial intelligence services. Accordingly, we assigned CPT code 0503T to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) with a payment rate of $950.50 for CY 2020, and we continued to assign CPT code 0503T to New Technology APC 1511 for CY 2021.

For CY 2022, we propose to use claims data from CY 2019 to estimate the cost of the HeartFlow service. Because we are using the same claims data as in CY 2021, these data continue to reflect that providers were learning how to accurately report their charges to Medicare when billing for artificial intelligence services. Therefore, we propose to continue to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2022 as in CY 2020 and CY 2021: New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)), with a payment rate of $950.50 for CY 2022, which is the same payment rate for the service as in CY 2020 and CY 2021. Please see Table 12 below for the proposed OPPS APC and status indicator for CPT code 0503T for CY 2022.

TABLE 12: CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR CPT CODE 0503T ASSIGNED TO NEW TECHNOLOGY APC

CY 2022 HCPCS Code	Long Descriptor	Proposed CY 2022 OPPS SI	Proposed CY 2022 OPPS APC	Proposed CY 2022 OPPS Payment Rate
0503T	Noninvasive estimated coronary fractional flow reserve (ffr) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated ffr model	S	1511	$950.50

e. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies

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. Table 13 lists the code descriptors, status indicators, and APC assignments for these CPT codes. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 ($2,001–$2,500)) with a payment rate of $2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 ($2,501–$3,000)) with a payment rate of $2,750.50. We did not receive any claims data for these services for CY 2021. Therefore, we continued to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2,001–$2,500)) with a payment rate of $2,250.50. Likewise, CPT codes 78432 and 78433 continued to be assigned to APC 1523 (New Technology—Level 23 ($2,501–$3,000)) with a payment rate of $2,750.50.

For CY 2022, we propose to use CY 2019 claims data to determine the payment rates for CPT codes 78431, 78432, and 78433. Because these codes did not become active until CY 2020, there are no claims for these three services. Accordingly, we propose to continue to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2,001–$2,500)) with a payment rate of $2,250.50. Likewise, we propose that CPT codes 78432 and 78433 would continue to be assigned to APC 1523 (New Technology—Level 23 ($2,501–$3,000)) with a payment rate of $2,750.50. Table 13 lists code descriptors, status indicators, and APC assignments for these CPT codes. The proposed CY 2022 payment rates for CPT codes 78431, 78432, and 78433 can be found in Addendum B to the CY 2022 OPPS/ASC proposed rule.

BILLING CODE 4120–01–P

TABLE 13: CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR CPT CODES 78431, 78432, AND 78433 ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2021 OPPS SI	OPPS CY 2021 APC	Proposed CY 2022 OPPS SI	Proposed OPPS CY 2022 APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	S	1522
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);	S	1523	S	1523
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 (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	S	1523	S	1523

f. V-Wave Medical Interatrial Shunt Procedure

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 have 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)).

We stated in the CY 2021 OPPS final rule that we believe that similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure (85 FR 85946). Therefore, the difference in the payment for HCPCS codes C9758 and C9760 is 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. Accordingly, for CY 2021, we reassigned HCPCS code C9758 to New Technology APC 1590, which reflects the cost of having surgery

every time and receiving the interatrial shunt one-half of the time when the procedure is performed.

For CY 2022, we are using the same claims data that we did for CY 2021. Because there are no claims reporting HCPCS code C9758, we are proposing to continue to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2022.

Details about the HCPCS code and its APC assignment are shown in Table 14. The proposed CY 2022 payment rate for C9758 can be found in Addendum B to the CY 2022 OPPS/ASC proposed rule.

TABLE 14: CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR BLINDED INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	Proposed 2022 OPPS SI	Proposed 2022 OPPS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1590

g. Corvia Medical Interatrial Shunt Procedure

Corvia Medical is currently conducting its pivotal trial for their interatrial shunt procedure. The trial started in Quarter 1 of CY 2017 and is scheduled to continue through CY 2021.[8] 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 the implantation of the Corvia Medical interatrial shunt.

As we stated in the CY 2021 OPPS final rule, we believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure (85 FR 85947). Therefore, the difference in the payment for HCPCS codes C9760 and C9758 is based on how often the interatrial shunt is implanted when each code is billed. The Corvia Medical interatrial shunt is implanted every time 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. For CY 2022, we propose to use the same claims data as in CY 2021 to establish payment rates for services. Therefore, there are no claims for HCPCS code C9760, and we propose to continue to assign HCPCS code C9760 to New Technology APC 1592.

Details about the HCPCS code and its APC assignment are shown in Table 15. The proposed CY 2022 payment rate for C9760 can be found in Addendum B to the proposed rule.

[8] *https://clinicaltrials.gov/ct2/show/NCT03088033?term=NCT03088033&rank=1.*

TABLE 15: CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR NON-RANDOMIZED, NON-BLINDED INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	Proposed 2022 OPPS SI	Proposed 2022 OPPS APC
C9760	Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (eg, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	T	1592

h. Supervised Visits for Esketamine Self-Administration (HCPCS Codes G2082 and G2083 APCs 1508 and 1511)

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 Spravato administration, and the potential for abuse and 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.

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 would require either two (2) devices (for a 56 mg dose) or three (3) devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product, Spravato is only available through a restricted distribution system under a REMS; patients must be monitored by a health care provider for at least 2 hours after receiving their Spravato dose; the prescriber and patient must both sign a Patient Enrollment Form; and the product will only be administered in a certified medical office where the health care provider can monitor the patient. Please refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine 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 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 and includes 2 hours post-administration observation. 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. HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) with a payment rate of $950.50.

For CY 2022, we are using CY 2019 claims data to determine the payment rates for HCPCS codes G2082 and G2083. Since these codes did not become active until CY 2020, there are no claims for these two services. Therefore, for CY 2022, we propose to continue to assign HCPCS code G2082 to New Technology APC 1508 (New Technology—Level 8 ($601–$700)) and to assign HCPCS code G2083 to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)).

Details about the HCPCS codes and their APC assignments are shown in Table 16. The proposed CY 2022 payment rate for esketamine self-administration can be found in Addendum B to the proposed rule.

TABLE 16: CY 2021 PROPOSED OPPS APC AND STATUS INDICATOR FOR ESKETAMINE SELF-ADMINISTRATION HCPCS CODES ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2021 OPPS SI	OPPS CY 2021 APC	Proposed CY 2022 OPPS SI	Proposed OPPS CY 2021 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	1508	S	1508
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	1511	S	1511

BILLING CODE 4120–01–C

D. Proposed OPPS APC-Specific Policy: Stromal Vascular Fraction (SVF) Therapy

SVF therapy is intended to treat knee osteoarthritis. To process SVF, the patient's own body fat (usually from the abdomen), is recovered, and then processed to isolate a cellular product, referred to in CPT codes as an autologous cellular implant, and then injected into the knee for pain relief. SVF therapy is currently described by CPT codes 0565T and 0566T, which were effective January 1, 2020. The long descriptors for both codes are as follows:

- 0565T: Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation.
- 0566T: Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral.

For CY 2021, CPT code 0565T is assigned to APC 5733 (Level 3 Minor Procedures) with a payment rate of $55.66, and CPT code 0566T is assigned to APC 5441 (Level 1 Nerve Injections) with a payment rate of $261.17. Based on recent information from the FDA, we found there is no current FDA-approved autologous cellular product derived from autologous body fat (referred to in CPT code 0565T and 0566T as ''autologous cellular implant'') associated with SVF therapy. In addition, review of the clinical trials.gov website indicate that SVF therapy is currently under clinical trial (ClinicalTrials.gov Identifiers: NCT04440189 and NCT02726945), and has not received CMS approval as investigational device exemption (IDE) studies. We note that IDE studies that have been approved and met CMS' standards for coverage are listed on the CMS Approved IDE Studies website, specifically, at *https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.*

Consequently, for CY 2022, we are proposing not to pay under the OPPS for either code. Specifically, we are revising the status indicator for CPT code 0565T from ''Q1'' (conditionally packaged; separately payable) to ''E1'' to indicate that the code is not payable by Medicare. Similarly, we are revising the status indicator for CPT code 0566T from ''T'' (separately payable) to ''E1'' to indicate that the code is not payable by Medicare and deleting the APC assignment for this code.

We note that the CY 2022 proposed status indicators for CPT codes 0565T and 0566T can also be found in Addendum B to this proposed rule with comment period. In addition, we refer readers to Addendum D1 of this proposed rule with comment period for the status indicator (SI) definitions for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

IV. OPPS 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 OPPS 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.

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. There currently are 11 device categories eligible for pass-through payment: C1823-Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads); C1824-Generator, cardiac contractility modulation (implantable); C1982-Catheter, pressure-generating, one-way valve, intermittently occlusive; C1839-Iris prosthesis; C1734-Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable); C2596-Probe, image-guided, robotic, waterjet ablation; C1748-Endoscope, single-use (that is disposable), Upper GI, imaging/illumination device (insertable); C1052-Hemostatic agent, gastrointestinal, topical, C1062-Intravertebral body fracture augmentation with implant (for example, metal, polymer); C1825-Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s); and C1761-Catheter, transluminal intravascular lithotripsy, coronary.

Below, we detail the expiration dates of pass-through payment status for each of the 11 devices currently receiving device pass-through payment.

The pass-through payment status of the device category for HCPCS code C1823 is scheduled to expire on December 31, 2021. Typically, we would propose to package the costs of the device described by C1823 into the costs related to the procedure with which the device is reported in the hospital claims data for CY 2022. The data for the CY 2022 OPPS proposed rule ratesetting for the procedure reported with C1823 would have been set using CY 2020 outpatient claims data processed through December 31, 2020, however, as described in section IV.A.3 of this proposed rule, due to the effects of the COVID–19 PHE, we are proposing to use CY 2019 claims data instead of CY 2020 claims data in establishing the CY 2022 OPPS rates and to use cost report data from the same set of cost reports originally used in final rule 2021 OPPS ratesetting. Therefore, we are proposing to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide separate payment for C1823 for four quarters of CY 2022 to end on December 31, 2022. This would allow for CY 2021 claims data to inform CY 2023 rate setting for the procedure reported with C1823. This is the only device whose costs would typically be packaged into the related procedure in CY 2022 using CY 2020 claims data for ratesetting and is the only device to which this proposed policy would apply. A full discussion of this proposed policy is included in section IV.A.3 of this proposed rule.

The pass-through payment status of the device category for HCPCS code C1823 will end on December 31, 2021. The pass-through payment status of the device categories for HCPCS codes C1824, C1982, C1839, C1734, and C2596 is set to expire on December 31, 2022. The pass-through payment status of the device category for HCPCS code C1748 is set to expire on June 30, 2023. The pass-through payment status of the device category for HCPCS codes C1052, C1062, and C1825 is set to expire on December 31, 2023 and the pass-through payment status of the device category for HCPCS code C1761 is set to expire on June 30, 2024. Table 17 shows the expiration of transitional pass-through payments for these devices.

BILLING CODE 4120–01–P

Table 17: EXPIRATION OF TRANSITIONAL PASS-THROUGH PAYMENTS FOR CERTAIN DEVICES

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2021
C1824	Generator, cardiac contractility modulation (implantable	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023
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

BILLING CODE 4120–01–C

2. New Device Pass-Through Applications

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 might be most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629). We note that, as discussed in section IV.A.4. of this CY 2022 OPPS/ASC proposed rule, we created an alternative pathway in the CY 2020 OPPS/ASC final rule that granted fast-track device pass-through payment under the OPPS for devices approved under the FDA Breakthrough Device Program for OPPS device pass-through payment applications received on or after January 1, 2020. We refer readers to section IV.A.4. of this CY 2022 OPPS/ASC proposed rule for a complete discussion of this pathway.

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 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 the 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.

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 will be 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 Food and Drug Administration (FDA) marketing authorization. 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, and meet the other criteria in the regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: *http://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 discuss research trial design in advance of any device pass-through application or to discuss application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Payment for CY 2022

We received eight complete applications by the March 1, 2021 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2022 OPPS/ASC proposed rule. We received three of the applications in the third quarter of 2020, two of the applications in the fourth quarter of 2020, and three of the applications in the first quarter of 2021. One of the applications was approved for device pass-through payment during the quarterly review process: The Shockwave C² Coronary Intravascular Lithotripsy (IVL) catheter, which received fast-track approval under the alternative pathway effective July 1, 2021. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle. Therefore, the Shockwave C² Coronary Intravascular Lithotripsy (IVL) catheter is discussed below in section IV.2.b.1.

Applications received for the later deadlines for the remaining 2021 quarters (June 1, September 1, and December 1), if any, will be discussed

in the CY 2023 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed in light 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*.

A discussion of the applications received by the March 1, 2021 deadline is included below.

1. Alternative Pathway Device Pass-Through Applications

We received two device pass-through applications by the March 2021 quarterly application deadline for devices that have received Breakthrough Device designation from FDA and FDA marketing authorization, and therefore are eligible to apply under the alternative pathway. As stated above in section IV.2.a of this proposed rule, under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but need to meet the other requirements for pass-through payment status in our regulation at § 419.66.

(1) RECELL System

AVITA Medical submitted an application for a new device category for transitional pass-through payment status for the RECELL System (RECELL) for CY 2022. According to the applicant, RECELL is used to process autologous donor tissue into a cell suspension autograft that is then immediately applied to the surgically prepared acute thermal burn wound.

The applicant stated RECELL is a stand-alone, single-use, battery-powered device used to process and apply an autologous skin cell suspension. According to the applicant, RECELL is a Category III medical device indicated for the treatment of acute partial-thickness and full-thickness/mixed depth thermal burn wounds and is not categorized as a skin substitute.

According to the applicant, the autograft procedure utilizing the RECELL system involves harvesting a small graft from the patient's healthy skin and placing it into the RECELL System for immediate processing into an autologous skin cell suspension. The applicant asserts that a significantly smaller autograft harvest is needed for procedures involving RECELL when compared to procedures involving a split-thickness skin graft (STSG) without RECELL; where typical STSG expansion ranges from 2:1 to 6:1, RECELL may expand skin by up to 80:1. The applicant adds the entire procedure takes place in the operating room, including surgically preparing the acute burn wound, harvesting the autograft, processing the skin cell suspension through a disaggregation process, and applying the cell suspension autograft to the wound with no culturing in a laboratory.

The applicant described the RECELL procedure in 27 steps: (1) The autograft site is identified; (2) the patient is anesthetized and prepared; (3) the nurse opens and transfers the sterile RECELL System to the operative field; (4) a self-test is performed; (5) the nurse prepares and dispenses the enzyme into the incubation well; (6) the buffer solution is drawn and dispensed into the buffering and rinsing well; (7) the RECELL processing unit is activated to heat the enzyme; (8) a thin epidermal autograft is harvested; (9) the harvested skin graft is placed in the enzyme; (10) the donor graft incubates for 15–20 minutes; (11) the sample is placed dermal side down in the mechanical scraping tray; (12) a scalpel is used to scrape the edges of the skin sample; (13) once ready, the donor skin is rinsed in the buffer solution; (14) the skin is returned to the mechanical scraping tray; (15) buffer is applied to the skin sample; (16) the skin sample is held in place with forceps; (17) the surgeon scrapes the epidermal cells; (18) the buffer syringe is used to rinse the disaggregated skin cells; (19) the surgeon draws up the autologous skin cell suspension from the tray into a syringe; (20) the suspension is then dispensed through the cell strainer to filter the suspension; (21) the filtered autologous skin cell suspension is drawn into a new 10 ml syringe; (22) the cell suspension autograft is prepared; (23) the burn wound is debrided; (24) the primary dressing (non-adherent, non-absorbent, small pore) is fixed or held only at the lower aspect of the burn wound; (25) the cell suspension autograft is applied by either spraying or dripping over the prepared wound bed; (26) after application, the primary dressing is immediately secured over the wound bed; and (27) absorbent and protective dressings are then applied as needed.

The applicant states the autologous skin cell suspension prepared using the RECELL System contains keratinocytes, fibroblasts and melanocytes. According to the applicant, keratinocytes are the primary cells of the epidermis that are responsible for healing; fibroblasts enable the creation of new extracellular matrix proteins; and melanocytes produce melanin to allow restoration of normal pigmentation. The applicant asserts the unique delivery system allows for broad and even distribution of the cell suspension autograft directly onto a prepared wound surface or in combination with a meshed skin graft.

According to the applicant, there is one commercially available product (Epicel) that is also used to create an autograft from the patient's skin that is then applied to treat acute thermal burns. The applicant's claims regarding the differences between the two products are summarized in the following Table 18:

BILLING CODE 4120–01–P

TABLE 18 – DIFFERENCES BETWEEN RECELL AND EPICEL ACCORDING TO APPLICANT

RECELL	Epicel
Indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older	Indicated for use in adult and pediatric patients who have deep dermal or full thickness burns
Used to treat acute thermal burns up to 50% total body surface area (TBSA)	Used to treat acute thermal burns with TBSA greater than or equal to 30%
Class III device approved under PMA process. Includes electromagnetic warnings to include that it should not be used in presence of flammable anesthetic.[9] Contraindicated for treatment of infected or necrotic tissue, in those hypersensitive to trypsin or sodium lactate solution.[10]	Approved under a Humanitarian Device Exception (HDE). HDE devices are exempt from the effectiveness requirements for PMAs.[11] Includes a black box warning noting a serious risk of squamous cell carcinoma.[12] Contraindicated in those with history of hypersensitivity following exposure to vancomycin, amikacin, or amphotericin or those with sensitivities to bovine or murine materials.[13]
Requires a single operative session to treat the patient.	Surgical procedures separated by a period of two or more weeks are required for harvesting and placement of cultured tissue sheets. Multiple operative sessions may also be required for cultured tissue sheet placements.
Cell suspension autograft prepared in the operating room and immediately applied	Harvested autograft cultured in an off-site laboratory, taking approximately 17 days to culture for application at a later date[14]
No blood samples needed	Blood samples must be taken and archived on the date of the procedure per FDA protocol

With respect to the newness criterion at § 419.66(b)(1), RECELL received FDA Breakthrough Designation effective January 1, 2020. The applicant states that RECELL received premarket approval (PMA) on September 20, 2018. The applicant adds that RECELL is a Class III medical device indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. We received the application for a new device category for transitional pass-through payment status for RECELL on August 7, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the RECELL meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, RECELL is integral to the service provided, 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. The applicant also claimed that RECELL meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. However, given the applicant's description of RECELL as a device that processes tissue into an autograft, it appears that the RECELL system may

[9] Instructions for use—RECELL® Autologous Cell Harvesting Device. Food and Drug Administration. *https://www.fda.gov/media/116382/download.*

[10] Ibid.

[11] Humanitarian Device Exemption (HDE) Program—Guidance for Industry and FDA Staff. U.S. Department of Health and Human Services. Food and Drug Administration. Issued September 6, 2019. Accessed on March 30, 2021 and available at: *https://www.fda.gov/media/74307/download.*

[12] Manufacturer Important Drug Warning: Serious Risk with Use of Epicel (cultured epidermal autografts): Squamous Cell Carcinoma (SCC). June 2014. Food and Drug Administration. Accessed on March 30, 2021 and available at: *https://www.fda.gov/media/102746/download.*

[13] Directions for Use—Epicel (cultured epidermal autografts). Food and Drug Administration. *https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/epicel-cultured-epidermal-autografts.*

[14] Epicel Surgical Guidelines. Epicel website. Accessed on March 30, 2021 and available at: *https://www.epicel.com/pdfs/Epicel%20SurgicalGuide%202018%20DIGITAL.pdf.*

not be surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion. We believe the product of the RECELL system, the suspension, may be applied on a wound, but we are not certain that this suspension qualifies as a device. We are inviting public comments on whether RECELL meets the eligibility criteria at § 419.66(b).

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. We have not yet identified an existing pass-through payment category that describes RECELL. We are inviting public comment on whether RECELL meets the device category criterion.

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. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization in the CY 2020 OPPS/ASC final rule (84 FR 61295). The RECELL System has a Breakthrough Device designation and marketing authorization from the FDA and therefore is not evaluated for substantial clinical improvement. We note that the applicant has applied for the New Technology Add-on Payment under the Alternative Pathway for Breakthrough devices in the FY 2022 IPPS/LTCH proposed rule (86 FR 25385 through 25388).

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 RECELL would be reported with the HCPCS codes listed in the following Table 19:

TABLE 19 – HCPCS CODES REPORTED WITH RECELL

HCPCS Code	Short Descriptor	SI	APC
Epidermal Autograft Procedures			
15110	Epidrm autogrft trnk/arm/leg	T	5054
15111	Epidrm autogrft t/a/l add-on	N	
15115	Epidrm a-grft face/nck/hf/g	T	5054
15116	Epidrm a-grft f/n/hf/g addl	N	
Split-Thickness Skin Graft Procedures			
15100	Skin splt grft trnk/arm/leg	T	5054
15101	Skin splt grft t/a/l add-on	N	
15120	Skn splt a-grft fac/nck/hf/g	T	5055
15121	Skn splt a-grft f/n/hf/g add	N	
Surgical Preparation Procedures			
15002	Wound prep trk/arm/leg	T	5054
15003	Wound prep addl 100 cm	N	
15004	Wound prep f/n/hf/g	T	5053
15005	Wnd prep f/n/hf/g addl cm	N	

BILLING CODE 4120–01–C

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. For our calculations, we used APC 5054—Level 4 Skin Procedures, which had a CY 2020 payment rate of $1,622.74 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 15110 had a device offset amount of $13.47 at the time the application was received. According to the applicant, the cost of the RECELL is $7,500.

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 $7,500 for RECELL is 462 percent of the applicable APC payment amount for the service related to the category of devices of $1,622.74 ((7,500/1,622.74) × 100 = 462.2 percent). Therefore, we believe RECELL 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 $7,500 for RECELL is 55,679 percent of the cost of the device-related portion of the APC payment amount for the related service of $13.47 (($7,500/$13.47) × 100 = 55,679.3 percent). Therefore, we believe that RECELL 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 $7,500 for RECELL and the portion of the APC payment amount for the device of $13.47 is 461 percent of the APC payment amount for the related service of $1,622.74 ((($7,500 − $13.47)/$1,622.74) × 100 = 461.4 percent). Therefore, we believe that RECELL meets the third cost significance requirement.

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

(2) Shockwave C² Coronary Intravascular Lithotripsy (IVL) Catheter

Shockwave Medical submitted an application for a new device category for transitional pass-through payment status for the Shockwave C² Coronary Intravascular Lithotripsy (IVL) catheter (Coronary IVL) for CY 2022. The applicant asserts the Coronary IVL catheter is a proprietary lithotripsy device delivered through the coronary arterial system of the heart to the site of an otherwise difficult to treat calcified stenosis, including calcified stenosis that is anticipated to exhibit resistance to full balloon dilation or subsequent uniform coronary stent expansion. According to the applicant, energizing the lithotripsy device generates intermittent sound waves within the target treatment site, disrupting calcium within the lesion and allowing subsequent dilation of a coronary artery stenosis using low balloon pressure. According to the applicant, the Coronary IVL System is comprised of the following components:

(1) IVL Generator—a portable, rechargeable power source that is capital equipment and reusable.

(2) IVL Connect Cable—a reusable cable used to connect the IVL Generator to the IVL Catheter.

(3) Coronary IVL Catheter—a sterile, single-use catheter that delivers intravascular lithotripsy within the target coronary lesion.

According to the applicant, during a percutaneous coronary intervention (PCI) procedure, the physician determines that a lesion has severe calcification. The applicant states the Coronary IVL catheter is introduced into the lesion where lithotripsy is delivered to crack the calcification to facilitate the optimal dilatation of the vessel and placement of a coronary stent. The applicant adds that the catheter is removed, and the physician then implants a coronary stent to treat the lesion.

The applicant asserts that Coronary IVL is different from other devices used during PCI procedures as it delivers localized lithotripsy to crack the calcified lesion prior to the placement of a coronary stent. According to the applicant there are other devices that may be utilized to remove calcium within the vessel (that is, atherectomy), however, these devices utilize some form of cutting or laser to remove or ablate the calcium and can only address the calcium nearest to the vessel lumen. According to the applicant, Coronary IVL addresses the calcium within the lumen as well as within the vessel walls.

According to the applicant, Coronary IVL is used to treat a subset of patients identified for a PCI procedure to treat their coronary artery disease where approximately 15 percent of lesions in patients being eligible for a PCI procedure have severe calcification. The applicant adds the Shockwave C² Coronary IVL catheter is utilized during PCI procedures and does not replace any devices currently utilized to complete the procedure (for example, guidewires, angioplasty balloons, stent(s), vascular closure, etc.) that are packaged into the APC payment rate. According to the applicant, based on the FDA labeling for the Coronary IVL catheter, it will be utilized prior to the placement of a coronary stent.

With respect to the newness criterion at § 419.66(b)(1), the Coronary IVL received FDA premarket approval (PMA) for the Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C² Coronary Intravascular Lithotripsy (IVL) Catheter on February 12, 2021 and is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting. The Coronary IVL received FDA Breakthrough Device designation on August 19, 2019, and is indicated for lithotripsy-enabled, low-pressure dilatation of calcified, stenotic de novo coronary arteries prior to stenting. We received the application for a new device category for transitional pass-through payment status for the Coronary IVL on February 26, 2021, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the Coronary IVL meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Coronary IVL is integral to the service provided, is used for one patient only, comes in contact with human tissue and is surgically inserted in a patient until the procedure is completed. The applicant also claimed that Coronary IVL meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether Coronary IVL meets the eligibility criteria at § 419.66(b).

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 identified five established categories which they believe are not appropriate representatives of the Coronary IVL: (1) C1714 and C 1724 include devices that use mechanical cutting tools, (2) C1725 includes balloon angioplasty, (3) C1885 which uses laser, beams of light to break up vessel obstructions, and (4) C2623 which includes a drug coated balloon. We have not identified an existing pass-through payment category that describes Coronary IVL and we are inviting public comment on this issue.

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. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization in the CY 2020 OPPS/ASC final rule (84 FR 61295). Coronary IVL has a Breakthrough Device designation and marketing authorization from the FDA and therefore is not evaluated for substantial clinical improvement. We note that the applicant has applied for the New Technology Add-on Payment under the Alternative Pathway for Breakthrough devices in the FY 2022 IPPS/LTCH proposed rule (86 FR 25388 through 25389).

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 Coronary IVL would be reported with the HCPCS codes listed in the following Table 20:

TABLE 20 – HCPCS CODES REPORTED WITH CORONARY IVL

HCPCS Code	Short Descriptor	SI	APC
92928	Prq card stent w/angio 1 vsl	J1	5193
92929	Prq card stent w/angio addl	N	
92933	Prq card stent/ath/angio	J1	5194
92934	Prq card stent/ath/angio	N	
92941	Prq card revasc mi 1 vsl	C	
92943	Prq card revasc chronic 1vsl	J1	5193
92944	Prq card revasc chronic addl	N	
C9600	Perc drug-el cor stent sing	J1	5193
C9601	Perc drug-el cor stent bran	N	
C9602	Perc d-e cor stent ather s	J1	5194
C9603	Perc d-e cor stent ather br	N	
C9606	Perc d-e cor revasc w ami s	C	
C9607	Perc d-e cor revasc chro sin	J1	5194
C9608	Perc d-e cor revasc chro add	N	

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. For our calculations, we used APC 5193—Level 3 Endovascular Procedures, which had a CY 2021 payment rate of $10,042.94 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 92928 had a device offset amount of $3,607.42 at the time the application was received.

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 for Coronary IVL of $5,640 is 56 percent of the applicable APC payment amount for the service related to the category of devices of $10,042.94 (($5,640/10,042.94) × 100 = 56 percent). Therefore, we believe Coronary IVL 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 for Coronary IVL of $5,640 is 156 percent of the cost of the device-related portion of the APC payment amount for the related service of $3,607.42 (($5,640/$3,607.42) × 100 = 156 percent). Therefore, we believe that Coronary IVL meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $5,640 for Coronary IVL and the portion of the APC payment amount for the device of $3,607.42 is 20 percent of the APC payment amount for the related service of $10,042.94 (($5,640 − $3,607.42)/$10,042.94) × 100= 20 percent. Therefore, we believe that Coronary IVL meets the third cost significance requirement.

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

As specified above, the Coronary IVL application was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2021. We are inviting public comment on whether the Coronary IVL should continue to receive transitional pass-through payment under the alternative pathway for devices that are FDA market authorized and that have an FDA Breakthrough Device designation.

2. Traditional Device Pass-Through Applications

(1) AngelMed Guardian® System

Angel Medical Systems submitted an application for a new device category for transitional pass-through payment status for the AngelMed Guardian® System (Guardian®) for CY 2022. The applicant asserted that the Guardian® is a proactive diagnostic technology that monitors a patient's heart's electrical activity for changes that may indicate an Acute Coronary Syndrome (ACS) event (that is, STEMI, NSTEMI, or unstable angina) related to blockage of a coronary artery which prevents the heart muscle from receiving sufficient oxygen. The Guardian® is a device implanted in the upper left chest and connects to an active fixation intracardiac lead attached to the apex of the right ventricle. The applicant asserts the Guardian® consists of an implantable medical device (IMD) which is composed of the header with an antenna for communication and the can with circuitry, radio, vibratory motor, and battery. According to the applicant, the Guardian® system also includes an external device that communicates with the IMD and provides redundant patient notification using auditory and visual alarms. Lastly, the applicant states the Guardian® system includes a physician programmer, a capital device, used to program the IMD and download cardiac data captured by the IMD.

According to the applicant, the Guardian® system relies upon the gold standard of changes to the ST-segment of a patient's heartbeat to diagnose a heart attack. According to the applicant, the Guardian® system uses an intracardiac lead to sense cardiac data and proprietary machine learning algorithms to assess acute changes to the ST-segment on a continuous, real-time basis. The applicant asserts these changes are compared to a patient's normal baseline reference that is computed over the prior twenty-four hours of monitored heart activity. According to the applicant, if the Guardian® detects a statistically abnormal acute change relative to this baseline, it notifies the patient to the potential ACS event by providing an alarm: The implanted device will vibrate, and the external device will flash and beep. According to the applicant, patients are instructed to seek urgent medical assistance when the system activates, even in the absence of ACS symptoms.

According to the applicant, the Guardian® system implantation will typically be an outpatient procedure and, following 10–14 days, is programmed in the physician office. The applicant asserts the patient undergoes training on the Guardian® and has follow-up visits every six months to review the device data. The applicant states that the emergency alarm is intended to be used as an adjunct to symptoms; in the absence of an emergency alarm patients are instructed not to ignore symptoms of an ACS event. The applicant asserts that while current technologies detect and provide therapy for cardiac medical conditions related to abnormal heart rate and rhythm, the AngelMed Guardian® system is the only FDA approved technology for providing detection and patient notification of ACS events so that patients more reliably and urgently seek medical care.

With respect to the newness criterion at § 419.66(b)(1), the AngelMed Guardian® system first received FDA 510(k) clearance on April 9, 2018 under premarket approval (PMA) number P150009. The manufacturers received a Category B Investigational Device Exemption (IDE) as of January 27, 2020 for the use of the device in their continued access study, AngelMed for Early Recognition and Treatment of STEMI (ALERTS). According to the applicant, the device is anticipated for U.S. market availability in quarter three of 2021. We received the application for a new device category for transitional pass-through payment status for the Guardian® system on February 28, 2021, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comment on whether the Guardian® system meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Guardian® is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted temporarily. The applicant also claimed that Guardian® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether Guardian® meets the eligibility criteria at § 419.66(b).

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. We have not yet identified an existing pass-through payment category that describes Guardian®. We are inviting public comment on whether Guardian® meets the device category criterion.

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.

The applicant stated that Guardian® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant asserted that Guardian® offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than is currently possible and this earlier diagnosis results in better outcomes.[15] In support of this claim the applicant submitted two published articles, the first by Gibson et al. and the second by Holmes et al.[16] [17]

[15] 66 FR 55852, November 2, 2001.

[16] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[17] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients with Acute Coronary Syndrome Events. JACC, 74(16), 2047–2055.

The first study is a randomized control trial with 907 subjects who were implanted with the Guardian® system and randomized 1:1 to either active or deactivated alarms.[18] According to the authors, all subjects received education regarding the importance of minimizing symptom-to-door time in the presence of chest pain or ischemic equivalents, regardless of alarm status. The authors state that patients were not blinded to their randomization status. After randomization patients returned for follow-up visits at 1, 3, 6, and every six months thereafter. In all patients, the Guardian® system captured electrogram data up to 24 hours before and 8 hours after a triggered alarm for later review. According to the authors, the primary safety endpoint was the absence of system-related complications that required a system revision or invasive intervention to resolve in at least 90 percent of subjects through six months. The primary efficacy endpoint was a composite of: (1) Cardiac or unexplained death; (2) new Q-wave MI; and (3) detection-to-presentation time >2 h for a documented coronary occlusion event. Electrocardiogram (ECG) tracings were obtained prior to implantation, at randomization, at 1, 3, and 6 months, and at every emergency presentation to evaluate for a Q-wave MI not present at baseline. An exploratory dual baseline ECG analysis was performed, according to the authors, because Q-waves may be transient between implantation and randomization. The dual baseline ECG analysis evaluates for the presence of new Q waves across subsequent ECGs. At the start of the trial, 456 patients were identified as controls and 451 as treated; at six months, 446 controls remained and 437 treated remained. The authors stated that subject enrollment ceased after 900 subjects were randomized and therefore an alpha penalty of 0.25 was taken for the interim look at event rates after 600 subjects.

According to the authors, the control and treatment groups were well matched at baseline.[19] The primary safety endpoint was met with 96.7 percent freedom (posterior probability >0.999) with a total of 31 system-related complications in 30 (3.3 percent) subjects with infections being the predominant cause of complications. The authors stated that ACS events occurrence was low. At 7, 30, 50, 70, and 90 days there were no statistical differences between the control and treated groups on the primary composite efficacy endpoint. At each time interval, the treated group had lower rates of the primary endpoint than the control group. Statistical differences were observed between treated and control groups in the dual baseline ECG exploratory analysis particularly at 50, 70, and 90 days after a confirmed occlusive event favoring the treated group. At the pre-specified 7-day look back window, the median time from Guardian® notification to arrival at a medical facility was 51 minutes for the treated subjects as compared to 30.6 hours for control subjects (Pr [pt < pc] >0.999). Subject arrival within 2 hours of a detected and confirmed coronary occlusion occurred in 85 percent (29 of 34) of the treatment group compared with only 5 percent of the control group, with the majority of patients in the control arm presenting after 7 days. However, the authors asserted that despite a numerical reduction in new Q-wave MI using single and dual baseline ECGs at any of the pre-specified look-back windows, the posterior probability of superiority did not reach statistical significance. The applicant added that 22 percent (42/193) of the confirmed ACS events were detected due to Emergency Department (ED) visits prompted by alarms in the absence of symptoms; that silent MIs typically account for approximately 30 percent of all MIs and are historically associated with increased rates of morbidity and mortality.[20]

The second article expanded on the previously discussed study with a post hoc analysis of two coprimary efficacy endpoints: Superiority of positive predictive value (PPV) and noninferiority of false positive rate for ED visits prompted by alarms compared to symptoms-only.[21] According to the authors, these primary endpoints were assessed by comparing ED visits for an Alarms OFF group (control subjects during the randomized 6-month period) to those of an Alarms ON group (including both the treatment subjects during the first 6 months and all implanted patients beyond 6 months with alarms activated). The authors stated the expanded analysis adjudicated ED visits into either true or false-positive ACS events based on independent review of cardiac test data. The authors stated that the annual rate for Clinical Events Committee (CEC)—adjudicated ACS events was 0.151 (33 of 218.15) in the Alarms OFF group and 0.124 (193 of 1,557.64) in the Alarms ON group. In the Alarms OFF group, of the 181 ED visits, the CEC adjudicated 33 (18 percent) as ACS events (MI = 22 [67 percent]; unstable angina (UA) ¼ 11 [33 percent]), with the remaining visits adjudicated as due to either stable CAD or indeterminate etiology. The median symptom-to-door time for Alarms OFF ACS events was 8.0 h (95 percent confidence interval [CI]: 3.2 to 47.5 h). In Alarms ON subjects, of the 970 ED visits, the CEC adjudicated 193 (20 percent) as ACS events, with the remainder classified as stable CAD, indeterminate events, and/or a false-positive alarm. Of the 193 ACS events, 89 events (46 percent) were prompted by alarms (with or without symptoms; MI ¼ 40 [45 percent]; UA ¼ 49 [55 percent]). The remaining 104 visits (54 percent) were prompted by symptoms only (MI ¼ 60 [58 percent]; UA ¼ 44 [42 percent]). An overall median arrival time of 1.7 h was found for the Alarms ON group composite including all 3 prompt types for ED arrival (alarms only, alarms þ symptoms, or symptoms only), which was significantly shorter than the 8.0 h delay of the Alarms OFF group (p < 0.0001). The applicant asserts that the Guardian® system allows patients with asymptomatic ACS events to respond to the ED faster with a median pre-hospital delay of 1.4 hours.

The applicant further asserts that the Guardian® system offers more rapid beneficial resolution of the disease process treated because of the use of the device. According to the applicant, the Guardian® system increases the likelihood that a patient will correctly seek medical care for an ACS event in a timely manner that reduces pre-hospital delay and associated risk of heart damage (for example, larger infarct size, ejection fraction decrement)[22 23 24]

[18] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[19] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[20] Gibson, C. M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[21] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients with Acute Coronary Syndrome Events. JACC, 74(16), 2047–2055.

[22] Weaver WD, Cerqueira M, Hallstrom AP, et al. Prehospital-Initiated vs Hospital-Initiated Thrombolytic Therapy: The Myocardial Infarction

and associated downstream sequelae. More specifically, the applicant asserts that based on the results of the second discussed study, the Guardian® system Alarms ON group showed reduced pre-hospital delays, with 55 percent (95 percent confidence interval [CI]: 46 percent to 63 percent) of Emergency department visits for ACS events <2 hours compared with 10 percent (95 percent CI: 2 percent to 27 percent) in the Alarms OFF group ($p < 0.0001$).[25] The applicant adds that results were similar when restricted to myocardial infarction (MI) events.[26] The applicant states the median pre-hospital delay for MI was 12.7 hours for Alarms OFF compared to 1.6 hours in Alarms ON subjects ($p < 0.0089$) as reported in Holmes et al. (2019).[27] The applicant asserts that it is clinically recognized, due to numerous lines of evidence, that shorter total ischemia time is associated with better outcomes for ACS events.[28 29 30 31] The applicant asserts that prompt responsiveness to symptoms and decreased pre-hospital delay is a universally understood benefit which improves the health outcomes of ACS events. According to the applicant, the American Heart Association (Mission Lifeline), American College of Cardiology (Door to Balloon (D2B) Alliance), Society for Angiographic Intervention (Seconds Count™ program) and the National Heart, Lung, and Blood Institute have organized task forces and launched national programs with the goal of improving patient awareness and response to symptoms which are indicative of potential ACS events and reducing total ischemia time (that is, prehospital delay and in-hospital delay) to improve outcomes.

The applicant next asserts the device offers more rapid beneficial resolution of the disease process because the use of the Guardian® system, as compared to the standard of care relying on symptoms alone, being in the Alarm ON group was associated with a reduction in the rate of new onset of left ventricular dysfunction.[32]

Lastly the applicant asserts the use of the Guardian® system will decrease the number of future hospitalizations or physician visits. According to the applicant, the Guardian® system reduces the annual false positive rate (FPR) of Emergency Department visits (that is, spurious ED visits where no ACS is found) by 26 percent.[33] The applicant states that the FPR for all alarms on emergency visits was 0.499 per patient-year compared to 0.678 for alarms off ($p <0.001$).[34]

Based on the evidence submitted with the application, we have the following observations. Much of the claims for substantial clinical improvement are derived from two primary studies identified by the applicant and discussed above.[35 36] We note that the first study (Gibson et al. 2019) did not demonstrate statistically significant superiority of the intervention during the pre-determined study window. The authors noted a lower than expected frequency of events and the study was terminated early, two factors which may have affected these results. The results from the second study are based entirely on a post hoc analysis of data from the first article. We note that the findings presented are valuable but we seek comment on whether a post hoc analysis provides sufficient evidence to support the claim of substantial clinical improvement. Furthermore, we note that the primary efficacy endpoint was a composite of three outcomes. We are not certain that this endpoint is an appropriate measure with which to evaluate substantial clinical improvement among patients experiencing ACS events. We invite public comments on whether the Guardian® system meets the substantial clinical improvement criterion.

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 Guardian® would be reported with the HCPCS codes listed in the following Table 21:

Triage and Intervention Trial. JAMA. 1993;270(10):1211–1216.

[23] Hasche ET, Fernandes C, Freedman SB, Jeremy RW. Relation between ischemia time, infarct size, and left ventricular function in humans. Circulation. 1995;92:710–719.

[24] Liem AL, van 't Hof AW, Hoorntje JC, de Boer MJ, Suryapranata H, Zijlstra F. Influence of treatment delay on infarct size and clinical outcome in patients with acute myocardial infarction treated with primary angioplasty. J Am Coll Cardiol. 1998;32:629–633.

[25] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[26] Holmes, D.R., Jr, Krucoff, M. W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[27] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M. S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[28] Guerchicoff A, Brener SJ, Maehara A, et al. Impact of delay to reperfusion on reperfusion success, infarct size, and clinical outcomes in patients with ST-segment elevation myocardial infarction: the INFUSE–AMI Trial (INFUSE-Anterior Myocardial Infarction). JACC Cardiovasc Interv. 2014;7(7):733–740.

[29] Flynn A, Moscucci M, Share D, et al. Trends in door-to-balloon time and mortality in patients with ST elevation myocardial infarction undergoing primary percutaneous coronary intervention. Arch Intern Med. 2010;170(20):1842–1849.

[30] De Luca G, Suryapranata H, Zijlstra F, et al. Symptom-onset-to-balloon time and mortality in patients with acute myocardial infarction treated by primary angioplasty. J Am Coll Cardiol. 2003;42(6):991–997.

[31] Gersh BJ, Stone GW. Pharmacological facilitation of coronary intervention in ST-segment elevation myocardial infarction: Time is of the essence. JACC Cardiovasc Interv. 2010;3(12):1292–1294.

[32] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[33] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[34] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[35] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[36] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

TABLE 21 – HCPCS CODES REPORTED WITH GUARDIAN®

HCPCS Code	Short Descriptor	SI	APC
0525T	Insj/rplcmt compl iims	J1	5223
0526T	Insj/rplcmt iims eltrd only	J1	5222
0527T	Insj/rplcmt iims implt mntr	J1	5222
0528T	Prgrmg dev eval iims ip	Q1	5741
0529T	Interrog dev eval iims ip	Q1	5741
0530T	Removal complete iims-	Q1	5222
0531T	Removal iims electrode only	Q1	5221
0532T	Removal iims implt mntr only	Q1	5221

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. For our calculations, we used APC 5222—Level 2 Pacemaker and Similar Procedures, which had a CY 2021 payment rate of $8,152.58 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 0527T was assigned to APC 5222 and had a device offset amount of $1,598.72 at the time the application was received.

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 for Guardian is 126 percent of the applicable APC payment amount for the service related to the category of devices of $8,152.58. Therefore, we believe Guardian® 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 for Guardian® is 641 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,598.72. Therefore, we believe that Guardian® 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 for Guardian® and the portion of the APC payment amount for the device of $1,598.72 is 106 percent of the APC payment amount for the related service of $8,152.58. Therefore, we believe that Guardian® meets the third cost significance requirement. We are inviting public comment on whether the Guardian® meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(2) BONEBRIDGE Bone Conduction Implant System

MED–EL Corporation submitted an application for a new device category for transitional pass-through payment status for the BONEBRIDGE Bone Conduction Implant System (hereinafter referred to as the BONEBRIDGE) by the March 2021 quarterly deadline for CY 2022. The BONEBRIDGE is a transcutaneous, active auditory osseointegrated device that replaces the function of the damaged outer or middle ear and can help people for whom hearing aids are ineffective or not recommended. According to the applicant, the device consists of a bone conduction implant and electronics components, and an externally worn audio processor. The bone conduction implant is called the BONEBRIDGE Bone Conduction Implant (BCI 602) and the externally worn audio processor is called the SAMBA 2 Audio Processor. The BCI 602 consists of two main sections, the coil section and the transducer section. The BCI 602 consists of a magnet surrounded by the receiver coil, the transition, the Bone Conduction Floating Mass Transducer (BC–FMT), and the electronics package in a hermetic housing. The SAMBA 2 Audio Processor is 30.4 mm × 36.4 mm × 10.2 mm and weighs 9.3 g, including the battery and magnet (strength 1). It

has an 18-band digital equalizer, 18 independent compression channels, and an audio frequency range of 250 Hz to 8 kHz. The audio processor is powered by a non-rechargeable 675 zinc-air button cell with a nominal 1.4-volt supply and 600 mA-Hrs of capacity offering the user up to 133 hours (8 to 10 days) on a single battery.

The applicant stated that the bone conduction implant is surgically attached to the skull, subcutaneous, and is connected to the external audio processor by transcutaneous magnetic attraction. The external audio processor picks up sound from the environment and converts those sounds to a radiofrequency (RF) signal that that can be transmitted across the skin to the implant. The implant converts the signal to controlled vibrations which are conducted via the skull and perceived as sound. More specifically, the applicant stated that the BCI 602 is activated by placing the external audio processor over the magnet of the BCI 602. The signal and the energy to drive the BC–FMT are transferred via an inductive link to the internal coil, and then relayed to the BC–FMT. The BC–FMT transduces the signal into mechanical vibrations, which are conducted to the skull via the cortical titanium screws. These vibrations stimulate the auditory system through the bone conduction pathway to allow the patient to hear.

With respect to the newness criterion at § 419.66(b)(1), the FDA granted a *de novo* request classifying the BONEBRIDGE as a Class II device under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act on July 20, 2018. The BONEBRIDGE is indicated for use in the following patients: (1) Patients 12 years of age or older; and (2) patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL; (3) Bilateral fitting of the BONEBRIDGE is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies; (4) Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (that is, single-sided deafness or ''SSD''). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz); (5) The BONEBRIDGE for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS. Prior to receiving the device, it is recommended that an individual have experience with appropriately fit air conduction or bone conduction hearing aids. We received the application for a new device category for transitional pass-through payment status for the BONEBRIDGE on December 10, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the BONEBRIDGE meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the BONEBRIDGE is integral to the service provided, is used for one patient only, comes in contact with human skin and is surgically implanted or inserted. The applicant also claimed that the BONEBRIDGE meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. Additionally, the BONEBRIDGE is not subject to the hearing aid exclusion at § 411.15(d)(1). The BONEBRIDGE Bone Conduction Implant (BCI 602) component is an osseointegrated implant, surgically attached to the skull that converts a radiofrequency signal from an external audio processor to controlled vibrations which are conducted via the skull to the cochlea. Therefore, we believe the BONEBRIDGE meets the criterion at § 411.15(d)(2)(i) and is not subject to the hearing aid exclusion. In accordance with the Medicare Benefit Policy Manual, Chapter 16 ''General Exclusions from Coverage,'' section 100, certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices. These include osseointegrated implants, that is, devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer. We believe the BONEBRIDGE device meets the criteria of this benefit category. We are inviting public comments on whether the BONEBRIDGE meets the eligibility criteria at § 419.66(b) as well as the criterion at § 411.15(d)(2)(i).

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 stated that the previous category, L8690—Auditory osseointegrated device, includes all internal and external components, which was effective from January 1, 2007-December 31, 2008 did not include the BONEBRIDGE. The applicant stated that at the time the category was established, BONEBRIDGE did not exist and the devices described by the category included auditory osseointegrated implant (AOI) devices or bone-anchored hearing aids (BAHA). The applicant claimed that AOI devices and BAHAs are distinct from the BONEBRIDGE because they are implant systems composed of an external sound processor connected via a percutaneous abutment to a titanium implant that is implanted in the skull. In these devices, the titanium implant protrudes through the skin creating a titanium post, which directly attaches to an external sound processor. The system replaces the function of the middle ear by transmitting mechanical energy from the external transducer/sound processor directly to the titanium implant to the cochlea thereby resulting in better hearing. The applicant stated that the titanium abutment used by percutaneous systems permanently pierce the skin to allow the sound processor to transmit sound and create vibrations within the skull that stimulate the nerve fibers of the inner ear. The applicant also stated that in the percutaneous systems, the external component (sound processor) receives and processes the sound and generates the vibrations.

The applicant claimed that the BONEBRIDGE is a new technology compared to the AOI devices and BAHAs and unlike these devices, it does not use a percutaneous abutment. The applicant described BONEBRIDGE as an active, transcutaneous device that consists of a completely implanted transducer and electronics components, and an externally worn audio processor. The active implant is surgically attached to the skull, is subcutaneous, and is connected to the external audio processor by transcutaneous magnetic attraction. The external audio processor picks up sound from the environment and converts those sounds to a radiofrequency (RF) signal that can be transmitted across the skin to the implant. The implant converts the

signal to controlled vibrations, which are conducted via the skull and perceived as sound. The applicant proposed the device pass-through category descriptor ''Auditory osseointegrated device, transcutaneous, with implanted transducer and radiofrequency link to external sound processor'' and suggested that L8690 be revised to read, ''Auditory osseointegrated device, percutaneous, includes all internal and external components''. The applicant stated that the Cochlear Osia™ 2 System, which also submitted a device pass-through application for CY 2022, would also be described by the proposed additional category.

We believe that the BONEBRIDGE is described by L8690—Auditory osseointegrated device, includes all internal and external components. The applicant has noted differences between the BONEBRIDGE and the devices that were described by L8690, specifically percutaneous, auditory osseointegrated devices, regarding the connection between the implanted transducer and the external audio processor (percutaneous abutment vs. transcutaneous magnetic attraction). However, we believe that there is a similar mechanism of action for all these devices specifically, vibratory stimulation of the skull to stimulate the receptors in the cochlea (inner ear). Further, we believe that the broad descriptor for L8690 of ''Auditory osseointegrated device, includes all internal and external components'' includes the applicant's device.

We are inviting public comment on whether the BONEBRIDGE meets the device category criterion.

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. With respect to the substantial clinical improvement criterion, the applicant stated that the BONEBRIDGE represents a substantial clinical improvement because it provides a reduced rate of device-related complications and a more rapid beneficial resolution of the disease process treated because of the use of the device compared to currently available treatments. The applicant submitted six studies to support these claims. The applicant also submitted references for four retrospective case studies of complications with percutaneous devices, specifically bone-anchored hearing aids, including infections, pain, soft tissue hypertrophy, loss of osseointegration, and need for further surgery. These studies did not involve the applicant's device.

In support of the claim that the BONEBRIDGE reduced the rate of device-related complications compared to currently available treatments, the applicant submitted a white paper that reviewed the literature reporting on safety outcomes in bone conduction implants authored by the manufacturer of the BONEBRIDGE, MED–EL.[37] The review included five products used to treat conductive hearing loss, mixed hearing loss or single side deafness, which were either percutaneous systems that had an abutment that permanently pierced through the skin or transcutaneous systems without permanent skin penetration. The authors further defined the products as either active or passive, depending on the placement of the vibrating (or active) device component. According to the authors, active bone conduction systems, the active device component, is located within the implantable part of the system. According to the authors, passive bone conduction systems, the vibrating device component, is located outside of the skull.[38]

The literature review compared the safety outcomes of the BAHA Connect and the Ponto, (passive, percutaneous systems,) the BONEBRIDGE, (an active, transcutaneous systems), and the Sophono Alpha and the BAHA Attract, (passive, transcutaneous systems). In total, 156 studies were included in the literature review. There were seven studies with 234 patients reported on the Ponto, thirteen studies with 175 patients reported on the BONEBRIDGE, twelve publications with 143 patients reported on the Sophono Alpha, seven studies reported on the BAHA Attract system with 114 patients, and 117 studies reported on the BAHA Connect system with a total of 6,965 patients. Of all reported adverse events, 38 percent were major and 62 percent were minor. Major adverse events reported in the review included revision surgery, explantation, removal at patient request, implant loss, implant device failure, skin revision surgery or skin infection. Minor adverse events included skin infections, soft tissue reactions, and healing difficulties. The results showed that 9.8 percent of patients using the BONEBRIDGE system experienced an adverse event (major or minor), compared to 68.4 percent of BAHA Attract patients, 46.9 percent of Sophono Alpha patients, 44.0 percent of Ponto system patients and 51.7 percent of BAHA Connect patients. When comparing the percentage of patients who experienced a major adverse event, 2.9 percent of BONEBRIDGE patients had a major adverse event compared to 1.8 percent of BAHA Attract patients, 4.2 percent of Sophono Alpha patients, 5.1 percent of Ponto system patients, and 21.1 percent of BAHA Connect patients.

To support the claim that the BONEBRIDGE reduced the rate of device-related complications compared to currently available treatments, the applicant also submitted a systematic review of the current literature on safety, efficacy and subjective benefit after implantation with the BONEBRIDGE device.[39] The systematic review assessed 39 publications and included randomized controlled trials, clinical controlled trials and cohort studies, case series and case reports investigating subjective and objective outcomes. In the 39 publications included in the review, 487 participants were evaluated; 303 participants had conductive hearing loss, 67 participants had mixed hearing loss, and 53 participants had single-sided deafness. The mean age of the patients in the included studies was 35.6 ± 16.9 years. Using the guidelines available from the Cochrane Collaboration, a search strategy and review protocol was developed using PubMed (MEDLINE) and Cochrane databases to identify all publications on the BONEBRIDGE from 2012 to October 31, 2018. The researchers excluded studies that assessed a device or treatment other than the BONEBRIDGE, did not include human participants, focused on a type of hearing loss other than the losses that BONEBRIDGE is indicated for (that is, conductive hearing loss, mixed hearing loss or single-sided deafness), did not report on safety or performance/quality of life data, were not related to hearing loss or treatment thereof, lacked

[37] MED–EL Medical Electronics. (2019). Safety outcomes of bone conduction implants: A systematic review [White paper].

[38] Ibid.

[39] Magele, A., Schoerg, P., Stanek, B. *et al.* (2019). Active transcutaneous bone conduction hearing implants: Systematic review and meta-analysis. *PLoS ONE* 14(9); e0221484 *https://doi.org/10.1371/journal.pone.0221484.*

sufficient information for evaluation, and included overlapping samples.

The outcomes extracted from the studies were assessed via meta-analysis. The safety of the device was assessed by collecting information on complications during surgery and adverse events in the postoperative period. Of the 39 identified studies, there were 25 studies that reported on safety during a mean period of 11.7 months (range 3–36 months). The reported complications were categorized into minor and major complications, with a major complication described as requiring surgical attention leading to revision surgery or explantation. Minor complications included skin edema or erythema, skin infections, and hematomas. Out of 286 ears implanted with the device, there were no complications in 259 ears (90.6 percent). Minor complications occurred in 22 ears (7.7 percent) over a cumulative period of reported mean follow-up of 12.7 years (mean: 11.7 months ± 4.5). Major complications occurred in three studies comprising five ears (1.7 percent).[40]

The applicant submitted an additional study by Schmerber, et al. to support the claim that the BONEBRIDGE reduced the rate of device-related complications compared to currently available treatments.[41] The study of 28 participants was a multicenter, prospective study with intra-subject measurements with the purpose of the study to validate the safety and efficacy of the BONEBRIDGE 12 months after implementation. The study included nine university hospitals, seven in France and two in Belgium. Sixteen participants with conductive or mixed hearing loss with bone-conduction hearing thresholds under the upper limit of 45 dB HL for each frequency from 500 to 4,000 Hz, and 12 participants with SSD (contralateral hearing within normal range) were enrolled in the study. Three of the 28 participants (with mixed or conductive hearing loss) did not complete the study; one requested that the device be removed (due to ''severe psychological problems'') and two were lost to follow up. The skin safety of the participants was evaluated by the surgeon who implanted the device up to 12 months post-operatively using an ordinal scale (''very good'', ''good'', ''acceptable'', ''bad skin condition'') and a visual analogue scale (between 1 and 10 from ''very bad'' to ''excellent'') to rate cutaneous tolerance. In the study, no complications or device failures occurred, no revision surgery was necessary and no skin injury was reported. The scoring was judged as 'excellent' or 'good' for all subjects (n = 25), corresponding to scores 8 to 10 on the scale. No complication (0 percent) was observed [95 percent confidence interval = (0 percent − 14.9 percent)]. The authors stated that there was a lower rate of complications for the BONEBRIDGE device compared to percutaneous systems, like the BAHA, whose complication rate was up to 24 percent in a large series of 602 ears and a revision surgery rate of 12 percent.[42 43]

The applicant also submitted a study by Siegel et al. as evidence to support the claim that the BONEBRIDGE reduced the rate of device-related complications compared to currently available treatments.[44] The study was a retrospective review that included 37 adult patients with conductive/mixed hearing loss who met the indications for use and were implanted with BONEBRIDGE over a five-year period from April 2013 to May 2018. Patient charts were reviewed for surgical outcomes and complications over the 6-year period. The mean time of follow-up was 32 months (range: 9–71 months). There were no events of surgical complications in the patients included in the study, specifically no instances of dural injury, cerebrospinal fluid (CSF) leak, or intracranial bleeding. There were also no skin complications and no postoperative symptoms of tinnitus/vertigo or dizziness.[45]

In support of the assertion that the use of BONEBRIDGE resulted in a more rapid beneficial resolution of the disease process compared to currently available treatments, the applicant also referenced the Magele et al., and Siegel et al. studies as well as a study conducted by Yang et al.[46 47 48]

As previously noted, the Magele et al. study assessed 39 publications that included 487 participants; 303 participants had conductive hearing loss, 67 participants had mixed hearing loss, and 53 participants had single-sided deafness.[49] Functional gain was available for analysis from 14 articles and was measured as the difference between unaided and aided (with the BONEBRIDGE) warble tone thresholds. On average, functional gain of 32.7 dB ± 16 dB was observed. Overall, the results showed a 30.89 dB (95 percent CI 27.53 dB − 34.24 dB) improvement at speech presentation level; for the 30 conductive hearing loss patients, the improvement was 39.48 dB (95 percent CI 35.25 dB − 43.71 dB); for the mixed hearing loss group, the improvement was 29.08 dB (95 percent CI 26.32 dB − 31.83 dB) and the improvement was 28.94 dB (95 percent CI 16.92 dB − 40.96 dB) for the 10 subjects with single-sided deafness.

The applicant also noted the study by Siegel et al. to support the claim that the use of BONEBRIDGE resulted in a more rapid beneficial resolution of the disease process compared to currently available treatments.[50] As previously stated, in this study, 37 adult patients with conductive/mixed hearing loss who met the indications for use were implanted with BONEBRIDGE over a six-year period. The patients' charts were reviewed for surgical outcomes and complications over the six-year period. Preoperative air conduction (AC), preoperative bone conduction (BC), and 3-month postoperative aided thresholds were recorded. Speech perception was assessed using two different tests, consonant-nucleus-consonant (CNC) words and AzBio sentences. Pure-tone averages (PTAs; measured at 0.5, 1.0, 2.0 and 3.0 kHz), air-bone gap (ABG), and functional gain (FG) were calculated. The preoperative air-bone gap was calculated as the difference between AC thresholds and BC thresholds of the implanted ear. The postoperative ABG was calculated as the difference between the preoperative BC and postoperative BONEBRIDGE aided thresholds measured at 3 months postoperatively. Functional gain was

[40] Ibid.

[41] Schmerber, S., Deguine, O., Marx, M. *et al.* (2017). Safety and effectiveness of the Bonebridge transcutaneous direct-drive bone-conduction hearing implant at 1-year device use. *Eur Arch Otorhinolaryngol* 274: 1835–1851 doi 10.1007/s00405–016–4228–6.

[42] Schmerber, S., Deguine, O., Marx, M. *et al.* (2017). Safety and effectiveness of the Bonebridge transcutaneous direct-drive bone-conduction hearing implant at 1-year device use. *Eur Arch Otorhinolaryngol* 274: 1835–1851 doi 10.1007/s00405–016–4228–6.

[43] Hobson, J.C., Roper, A.J., Andrew, R., Rothera, M.P., Hill, P., Green, K.M. (2010) Complications of bone-anchored hearing aid implantation. *J Laryngol Otol* 124(2):132–136. doi:10.1017/S0022215109991708.

[44] Siegel, L.H., You, P., Zimmerman, K. *et al.* (2020). Active transcutaneous bone conduction implant: Adiometric outcomes following a novel middle fossa approach with self-drilling screws. *Otol Neurotol* 41(5): 605–613. *doi: 10.1097/MAO.0000000000002597.*

[45] Siegel, L.H., You, P., Zimmerman, K. *et al.* (2020). Active transcutaneous bone conduction implant: Audiometric outcomes following a novel middle fossa approach with self-drilling screws. *Otol Neurotol* 41(5): 605–613. *doi: 10.1097/MAO.0000000000002597.*

[46] Ibid.

[47] Ibid.

[48] Ibid.

[49] Ibid.

[50] Siegel, L.H., You, P., Zimmerman, K. *et al.* (2020). Active transcutaneous bone conduction implant: Audiometric outcomes following a novel middle fossa approach with self-drilling screws. *Otol Neurotol* 41(5): 605–613. *doi: 10.1097/MAO.0000000000002597.*

calculated as the difference between preoperative AC thresholds and BONEBRIDGE aided thresholds measured 3 months postoperatively.

The results of this study showed audiological improvement in the 37 patients with a functional gain (averaged over 4 frequencies, 500 kHz to 3,000 kHz) of 40.3 dB (± 19.0 dB) for air conduction 3 months postoperatively. The difference between the average air to bone conduction gap fell from 44.9 dB preoperative to 4.6 dB three months after surgery. The postoperative air conduction thresholds for the 21 patients with mixed hearing loss ranged between 30–40 dB and the air conduction thresholds for the 16 patients with conductive hearing loss ranged between 20–30 dB. For patients with mixed hearing loss, nearly a full ABG closure was achieved at all frequencies by 3 months postoperatively.

In the same study, speech perception testing was available for 21 patients (57 percent). At activation, mean speech perception results for CNC words (13 patients) and AzBio sentences (14 patients) were 79 and 93 percent, respectively. At six months postoperatively, CNC words (17 patients) and AzBio sentences (21 patients) were 81 and 93 percent, respectively. The authors stated that the results of the study were comparable with what has been accomplished using traditional percutaneous conduction devices and passive transcutaneous bone conduction devices.

Lastly, to support the claim that the use of the BONEBRIDGE resulted in a more rapid beneficial resolution of the disease process, the applicant submitted a study that compared the use of the BONEBRIDGE with a non-implantable bone conduction hearing aid (BCHA).[51] This single center, prospective study involved 100 patients in Beijing, China with bilateral congenital microtia-atresia (CMA). The patients had a mean age of 11.9 ± 6.0 years old at the time the BONEBRIDGE was implanted. All patients had worn the passive bone anchored hearing aid for at least a year prior to the implantation of the BONEBRIDGE and patients were tested an average of 25 weeks after surgery. Measured outcomes in the study included sound field thresholds (SFT), functional gain (FG) [aided threshold minus the unaided threshold], word recognition, speech reception thresholds (SRT), preoperative and postoperative bone and air conduction and patient subjective satisfaction. Bone conduction of pure tones at any frequency did not change significantly from preoperative to postoperative testing. The mean bone-conduction pure-tone threshold (PTA) before implantation was 8.7 ± 6.1 dB HL and after surgery was 8.9 ± 5.6 dB HL ($p > .745$, paired t-test). Furthermore, bone conduction did not significantly change at any frequency after surgery ($p > .05$, t-test). The mean SFT of the BONEBRIDGE (61.6 ± 7.1 dB HL) was significantly higher than the BCHA (31.3 ± 6.1 dB HL) (paired t-test, $p < .001$) and the SFT was significantly better with BONEBRIDGE at 500, 1,000, 2,000, and 4,000 Hz sound frequencies (paired t-test, $p < .002$). Further, the FG of the BONEBRIDGE (31.2 ± 9.5 dB HL) was significantly better than the FG of the BCHA (26.5 ± 10.3 dB HL) (paired t-test, $p < .001$). The FG measured at 250 Hz in the two aided conditions had less improvement compared to other frequencies ($p < .001$). A comparison of BCHA and BONEBRIDGE resulted in a significant difference in word recognition (68.0 percent for monosyllabic words and 79.0 percent for disyllabic words with the BCHA vs. 78.0 percent for monosyllabic and 84.0 percent for disyllabic words with the BONEBRIDGE) in favor of the BONEBRIDGE ($p < .001$).

Regarding the applicant's evidence of substantial clinical improvement, we note that the studies submitted did not involve a direct comparison to other currently available treatments, namely percutaneous or passive, transcutaneous auditory osseointegrated devices. Therefore, it was difficult to determine whether the BONEBRIDGE provided a substantial clinical improvement over existing devices. Also, the studies submitted included a small number of participants which may affect the generalizability of the data provided in support of the device.

In the white paper by MED–EL, the authors compared the complication rates associated with various studies that differed by design, population characteristics and follow-up time. We are not confident that differences seen or elucidated by the applicant are due to the differences in treatments or instead due to differences in study characteristics. Additionally, although the overall, both major and minor, adverse event ratio was significantly lower for the BONEBRIDGE device (9.8 percent) versus other bone conduction hearing devices in the study, when comparing the percent of patients who experienced a major adverse event, BONEBRIDGE patients had a major adverse event (2.9 percent) that was more comparable to other devices included in the paper. With regard to the Yang et al. study, given the young age of the patients and the congenital nature of the hearing loss being treated, we are concerned that these results may not be generalizable to the Medicare population, which tends to be significantly older in age and potentially less likely to have hearing loss related to congenital causes. We invite public comments on whether BONEBRIDGE meets the substantial clinical improvement criterion.

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 there were no specific CPT codes that currently describe the implantation of BONEBRIDGE. To demonstrate that the requested category met the cost criterion, the applicant submitted the HCPCS codes used to describe implantation of a percutaneous device, included in the following Table 22.

[51] Yang, J., Chen, P., Zhao, C. *et al.* 2020. Audiological and subjective outcomes of 100 implanted transcutaneous bone conduction devices and preoperative bone conduction hearing aids in patients with bilateral microtia-atresia. *Acta Oto-Laryngologica* 140(6): 667–673 *https://doi.org/10.1080/00016489.2020.1762929.*

TABLE 22 – HCPCS CODES REPORTED WITH BONEBRIDGE

HCPCS Code	Short Descriptor	SI	APC
69714	Implant temple bone w/stimul	J1	5115
69715	Temple bne implnt w/stimulat	J1	5116
69717	Temple bone implant revision	J1	5114
69718	Revise temple bone implant	J1	5115

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5115—Level 5 Musculoskeletal Procedures, which had a CY 2020 payment rate of $11,900.71 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 69714 had a device offset amount of $7,742.60 at the time the application was received. According to the applicant, the cost of the BONEBRIDGE is $11,500.

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 $11,500 for BONEBRIDGE is 97 percent of the applicable APC payment amount for the service related to the category of devices of $11,900.71 (($11,500/$11,900.71) × 100 = 96.6 percent). Therefore, we believe BONEBRIDGE meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $11,500 for BONEBRIDGE is 149 percent of the cost of the device-related portion of the APC payment amount for the related service of $7,742.60 (($11,500/$7,742.60) × 100 = 148.5 percent). Therefore, we believe that BONEBRIDGE 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 $11,500 for BONEBRIDGE and the portion of the APC payment amount for the device of $7,742.60 is 31.6 percent of the APC payment amount for the related service of $11,900.71 ((($11,500 − $7,742.60)/$11,900.71) × 100 = 31.6 percent). Therefore, we believe that BONEBRIDGE meets the third cost significance requirement.

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

(3) Eluvia™ Drug-Eluting Vascular Stent System

Boston Scientific Corporation submitted an application for device pass-through status for the Eluvia™ Drug-Eluting Vascular Stent System (Eluvia™ system) for CY 2022. According to the applicant, the Eluvia™ system is a combination product composed of an implantable endoprosthesis, a non-bonded freely dispersed drug layer (a formulation of paclitaxel contained in a polymer matrix), and a stent delivery system indicated for the treatment of symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery (PPA).

According to the applicant, the Eluvia™ system stent is a laser-cut self-expanding stent composed of nickel titanium alloy with radiopaque markers made of tantalum on the proximal and distal ends. The applicant states that the 6-French delivery system is a triaxial design with an outer shaft to stabilize the stent delivery system, a middle shaft to protect and constrain the stent, and an inner shaft to provide a guidewire lumen. The delivery system is compatible with 0.035 in (0.89mm) guidewires and is offered in two working lengths (75 and 130 cm).

According to the applicant, peripheral artery disease (PAD) occurs when fatty or calcified material (plaque) builds up in the walls of the arteries and makes them narrower, thus restricting blood flow. The applicant asserts that when this occurs, the muscles in the legs cannot get enough blood and oxygen, especially during exertion such as exercise or walking. According to the applicant, the main symptoms of PAD are pain, burning sensation, or general discomfort in the muscles of the feet, calves, or thighs. As the disease progresses, plaque accumulation may significantly reduce blood flow through the arteries, resulting in claudication and increasing disability, with severe cases often leading to amputation of the affected limb. The applicant states that according to the Centers for Disease Control and Prevention approximately 8.5 million people age 40 and older in the United States have PAD, including 6–26 percent of individuals older than age 60.[52] According to the applicant,

[52] Centers for Disease Control and Prevention. *https://www.cdc.gov/heartdisease/pad.htm.*

PAD disproportionately affects African American and American Indian populations [53] and nonrevascularized lower extremity PAD is among the most common causes of lower extremity amputation.

According to the applicant, the Eluvia™ system is designed to restore blood flow in the peripheral arteries above the knee, specifically the superficial femoral artery and proximal popliteal artery. The applicant states that the stent features a unique drug-polymer combination intended to facilitate sustained elution of the drug paclitaxel that can prevent narrowing (restenosis) of the vessel. The applicant adds that restenosis is often the cause of pain and disability for patients diagnosed with PAD.

The applicant asserts that no other endovascular technologies that are approved for the treatment of PAD provide sustained elution of a drug over at least 12 months to prevent restenosis. According to the applicant, two of the most common endovascular treatments for PAD are angioplasty and stenting. The applicant states that following an intervention within the SFA or PPA, these arteries elicit a healing response that leads to restenosis starting with inflammation, followed by smooth muscle cell proliferation and matrix formation.[54] According to the applicant, because of the unique mechanical forces in the SFA and PPA, the restenotic process can continue well beyond 12 months from the initial intervention. The applicant asserts the Eluvia™ system is designed to elute anti-restenotic drug paclitaxel beyond 12 months, which is longer than the two-month duration of drug applied from drug-coated balloons and the drug-coated stent Zilver PTX.

With respect to the newness criterion at § 419.66(b)(1), the Eluvia™ system received FDA premarket approval (PMA) on September 18, 2018. The application for a new device category for transitional pass-through payment status for the Eluvia™ system was received on February 26, 2021, which is within 3 years of the date of the initial FDA approval or clearance. We invite public comments on whether the Eluvia™ system meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Eluvia™ system is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically impacted or inserted. The applicant also claimed that the Eluvia™ system meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. Previously, we invited public comment and subsequently determined that Eluvia™ system device meets the eligibility criterion (84 FR 61286). We invite public comments on whether the Eluvia™ system continues to meet the eligibility criterion at § 419.66(b).

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. We have not identified an existing pass-through payment category that describes the Eluvia™ system. The applicant proposed a category descriptor for the Eluvia™ system of ''Stent, non-coronary, polymer matrix, minimum 12-month sustained drug release, with delivery system.'' Previously, we invited public comment and subsequently determined that Eluvia™ system device meets the device category eligibility criterion. For a complete discussion of comments received, please see the CY 2020 OPPS/ASC final rule with comment period (84 FR 61286–61287). We invite public comments on whether the Eluvia™ system continues to meet this criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines 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. With respect to this criterion, the applicant claims the Eluvia™ system provides a substantial clinical improvement over existing technologies for the following reasons: (1) The Eluvia™ system achieves superior primary patency; (2) the Eluvia™ system achieves reduced lesion revascularization, leading to a reduced rate of subsequent therapeutic interventions at one year and a statistically significant reduction of target lesion revascularization (TLR) at two years; (3) the Eluvia™ system decreases the number of future hospitalizations or physician visits; (4) the Eluvia™ system reduces hospital readmission rates; (5) Eluvia reduces the rate of device related complications; and (6) the Eluvia™ system achieves similar functional outcomes and quality of life index values while associated with half the rate of TLRs.

Many of the assertions made by the applicant are derived from the IMPERIAL trial which is reported in three citations supplied by the applicant.[55] [56] [57] We discuss results from the MAJESTIC study and then these publications from the IMPERIAL study to provide context for the assertions made by the applicant.

The first article, by Müller-Hülsbeck et al., discusses the three-year results of the MAJESTIC study, the first-in-human prospective, single-arm, multicenter, clinical trial involving 57 patients with symptomatic lower limb ischemia and lesions in the superficial femoral artery or proximal popliteal artery.[58] Patients who were treated with the Eluvia™ system were followed for a three-year time period during which they took acetylsalicylic acid as an antiplatelet therapy. At 24 months, patients received a duplex ultrasound, ankle-brachial index, and Rutherford classification at a clinical visit. At 36 months patients completed a telephone or clinical visit which included adverse event and antiplatelet medication assessments. The authors report that long-term results from the MAJESTIC study of the Eluvia™ system continue to demonstrate good technical and clinical outcomes (assessed through 2 years) and

[53] Virani SS, et al. AHA Statistical Update: Heart Disease and Stroke Statistics—2020 Update, A Report from the American Heart Association. Circulation. 2020;141:e139–e596.

[54] Forrester JS, et al. A paradigm for restenosis based on cell biology: Clues for the development of new preventive therapies. J Am Coll Cardiol. 1991 Mar 1;17(3):758–69.

[55] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[56] Müller-Hülsbeck S et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent. Cardiovasc Intervent Radiol. 2021;44:368–375.

[57] Golzar J et al. Effectiveness and Safety of a Paclitaxel-Eluting Stent for Superficial Femoral Artery Lesions up to 190 mm: One-Year Outcomes of the Single-Arm IMPERIAL Long Lesion Substudy of the Eluvia Drug-Eluting Stent. Journal of Endovascular Therapy. 2020;27(2):296–303.

[58] Müller-Hülsbeck S, Keirse K, Zeller T, Schroe H, Diaz-Cartelle J. Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Followup. Cardiovasc Interv Ther. 2017;40(12):1832–1838.

a low reintervention rate (through 3 years).

The second article, by Gray et al., discusses the IMPERIAL trial, a prospective randomized (2:1) (Eluvia™ system vs. Zilver PTX), single-blind, non-inferiority study in 465 patients with symptomatic lower-limb ischemia manifesting as claudication with atherosclerotic lesions in the native superficial femoral artery or proximal popliteal artery across 65 centers and multiple countries.[59] Of the 465 patients enrolled, 309 were assigned to the Eluvia™ system and 156 were assigned to Zilver PTX. The authors state the overall sample size in the randomised trial was selected to preserve adequate statistical power for non-inferiority testing of the primary efficacy and safety endpoints at a prespecified, one-sided significance level of 5 percent for each, without adjustment for multiplicity.

The authors state baseline demographic, clinical, and angiographic characteristics were similar between the two study groups, indicative of successful randomization. The primary efficacy endpoint of the trial was primary vessel patency at 12 months which was a binary endpoint based on a duplex ultrasound peak systolic velocity ratio of 2.4 or lower in the absence of clinically driven target lesion revascularization or bypass of the target lesion. Secondary endpoints at 12 months were technical success, procedural success, adverse events, stent integrity, major adverse events, and clinical outcomes. The authors note that the funder of the study was involved in study design, data collection, data analysis, data interpretation, and writing of the report. To identify statistically meaningful results for the non-inferiority test, the authors used a test such as the Farrington-Manning method, to estimate the lower bound for the 95 percent CI of the difference between treatment groups.[60] According to the authors, if this lower bound was greater than the non-inferiority margin of −10 percent, the Eluvia™ system would be considered non-inferior to Zilver PTX in terms of device efficacy. For all other statistical comparisons, the authors used a p value of less than 0.05 as indicative of a significant difference.

According to the authors, the primary non-inferiority analyses were done when 409 patients (276 in the Eluvia group and 133 in the Zilver PTX group) had completed 12 months of follow-up or had a primary efficacy or safety endpoint event.[61] Primary patency was observed for 231 (87 percent) of 266 patients in the Eluvia™ system group and for 106 (82 percent) of 130 patients in the Zilver PTX stent group (difference 5.3 percent [one-sided lower bound of 95 percent CI −0.66]; p<0·0001). 259 (95 percent) of 273 patients in the Eluvia group and 121 (91 percent) of 133 patients in the Zilver PTX group had not had a major adverse event at 12 months (difference 3.9 percent [one-sided lower bound of 95 percent CI −0·46]; p<0·0001). According to the authors, superiority of the Eluvia™ system over Zilver PTX (primary patency in 86.8 percent vs. 77.5 percent respectively, p = 0.0144) was met in the post-hoc analysis of 12 month primary patency data in the full-analysis cohort. The authors summarize by stating the proportions of patients with stent thrombosis or clinically driven target lesion revascularisation in the Eluvia stent group were about half those in the Zilver PTX group while both groups showed improvements in clinical symptoms and walking function and the occurrence of stent fracture was low.[62]

The third article, by Golzar et al, discusses the one-year follow up of the single-arm long lesion substudy portion of the IMPERIAL trial.[63] Fifty patients were enrolled in the study where 20 patients had diabetes, 16 were current smokers, 35 had moderately or severely calcified lesions, and 16 lesions were total occlusions. To be eligible, patients needed a lesion ranging from 140 mm to 190 mm which required two overlapping Eluvia stents. At 12 months, no deaths, stent thrombosis, or target limb amputation had occurred. The primary patency rate was 87.0 percent at 12 months which exceeded the 60 percent performance goal. Forty-three patients (91 percent) had Rutherford category improvement without the need for TLR. The authors concluded that one year patency with the Eluvia™ system was independent of lesion length.

The fourth article, by Müller-Hülsbeck et al., discusses the two-year follow up to the IMPERIAL trial.[64] The authors found that through 24 months, the patency rates and Rutherford category improvements were largely sustained, with a significantly lower clinically driven TLR rate for Eluvia versus Zilver PTX at 2 years. At two years the TLR rate for patients treated with Eluvia was 12.7 percent as compared to patients treated with Zilver PTX at 20.1 percent (P = 0.0495). As with the previous citation, both study arms show sustained clinical improvement (that is improvement in Rutherford classification by one or more categories as compared with baseline and without TLR) of 84.4 percent for patients treated with Eluvia and 78.2 percent for patients treated with Zilver PTX (p = 0.140). For all-cause mortality, Eluvia (7.1 percent) and Zilver PTX (8.3 percent) did not statistically differ (p = 0.6649). The authors conclude that the IMPERIAL trial provides support for the benefit of drug-eluting treatment in this population.

According to the applicant, the Eluvia™ system achieves superior primary patency compared to Zilver PTX. The applicant states that, based on the IMPERIAL trial, the Eluvia™ system demonstrated superior primary patency over Zilver PTX, 86.8 percent vs. 77.5 percent respectively (p=0.0144) based on pre-specific post-hoc analysis. The applicant further states that at 12 months, the Eluvia™ system had greater primary patency than Zilver PTX at 88.5 percent vs. 79.5 percent respectively (p=0.0119). According to the applicant, these results are consistent with the 96.4 percent primary patency rate at 12 months in the MAJESTIC study, the single-arm first-in-human study of the Eluvia™ system.[65] Furthermore, in regard to this point, the applicant asserts among patients 65 and older, the primary patency rate in the Eluvia™ system was 92.6 percent

[59] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[60] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[61] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[62] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[63] Golzar J et al. Effectiveness and Safety of a Paclitaxel-Eluting Stent for Superficial Femoral Artery Lesions up to 190 mm: One-Year Outcomes of the Single-Arm IMPERIAL Long Lesion Substudy of the Eluvia Drug-Eluting Stent. Journal of Endovascular Therapy. 2020;27(2):296–303.

[64] Müller-Hülsbeck S et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent. Cardiovasc Intervent Radiol. 2021;44:368–375.

[65] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

compared to 75.0 percent in Zilver PTX (p=0.0386). Lastly, the application states that among 50 patients with an average lesion length of 162.8 mm (long lesions), each treated with two Eluvia stents, there was a 12 month primary patency of 87 percent and a TLR of 6.5 percent.[66]

According to the applicant, the Eluvia™ system reduced subsequent therapeutic interventions at one year and a reduction of target lesion revascularization at two years. Based on the IMPERIAL trial, the applicant asserts the Eluvia™ system achieved a substantial reduction in re-intervention with a target lesion revascularization (TLR) of 4.5 percent compared to 9.0 percent (p=0.0672) in the Zilver PTX group.[67] The applicant states that at two years the Eluvia™ system had a statistically significantly lower rate of TLRs than Zilver PTX of 12.7 percent vs. 20.1 percent respectively (p=0.0495).[68] The applicant notes that the published analysis presented in this application has a slightly different clinically-driven TLR rate at two years than internal analysis provided in the Eluvia CY 2020 device pass-through application (12.7 percent and 20.1 percent (p=0.0495) vs. 12.9 percent and 20.5 percent (p=0.0472), respectively). We note that the applicant provides a table which compares TLR rates between the Eluvia™ system and Zilver PTX by all patients 65 and older, US patients 65 and older, and patients with diabetes.

The applicant asserts that patients treated with the Eluvia™ system required fewer days of hospital care than in the Zilver PTX group. According to the applicant, patients treated with the Eluvia™ system had fewer days in the hospital as compared to Zilver PTX for all adverse events (13.9 vs. 17.7 respectively), TLR (2.8 vs. 7.1 respectively), and procedure and device related adverse events (2.7 vs. 4.5 respectively). We note that statistical significance was not assessed.

The applicant asserts that patients treated with the Eluvia™ system had reduced hospital readmission rates compared to those treated with Zilver PTX at 12 months at 3.9 percent and 7.1 percent respectively (p=0.1369).[69]

The applicant asserts that while rates of adverse events were similar in total between treatment arms in the IMPERIAL trial, device-related adverse-events were reported in 8 percent of patients treated with the Eluvia™ system as compared to 14 percent of patients treated with Zilver PTX.[70]

Lastly, the applicant asserts that the Eluvia™ system is able to achieve similar functional outcomes to Zilver PTX while associated with half the rate of TLRs. The applicant states while functional outcomes appear similar between the Eluvia Stent System and Zilver PTX groups at 12 months, these improvements for the Zilver PTX group are associated with twice as many TLRs to achieve similar EQ–5D index values.[71] The applicant provides multiple tables which show similar improvements in walking, distance, speed, stair climbing, and health related quality of life (EQ–5D) between the Eluvia™ system and Zilver PTX.

For a complete discussion of the applicant's previous submission regarding substantial clinical improvement please see the CY 2020 OPPS/ASC final rule with comment period (84 FR 61287–61292). We note that we did not approve the Eluvia™ system for CY 2020 device transitional payment due to the potential increased long-term mortality signal that the FDA was at the time evaluating. We further note that in the FY 2021 IPPS/LTCH final rule (85 FR 58657), we stated that the FDA August 7, 2019 update, which concluded that the benefits of paclitaxel-coated devices (for example, reduced reinterventions) should be considered in individual patients along with potential risks (for example, late mortality) as well as for individual patients judged to be at particularly high risk for restenosis and repeat femoropopliteal interventions, clinicians may determine that the benefits of using a paclitaxel-coated device outweigh the risk of late mortality. The applicant asserts that the Eluvia™ system has demonstrated substantial clinical improvement over Zilver PTX in the IMPERIAL trial to include no increase in all-cause mortality. In response to this new information, we no longer have concerns regarding the increased long-term mortality signal we described in the CY 2020 OPPS/ASC final rule with comment period.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61289) we noted that the IMPERIAL study, which showed significant differences in primary patency at 12 months, was designed for noninferiority and not superiority. Therefore, we were concerned that results showing primary patency at 12 months may not be valid given the study design. In response, the applicant stated that a non-inferiority study is consistent with accepted research methodology and is typical of many head-to-head trials of medical devices. For the complete response please see the CY 2020 OPPS/ASC final rule with comment period (84 FR 61290). We invite public comments on whether the Eluvia™ Drug-Eluting Vascular Stent System meets the substantial clinical improvement criterion with respect to a finding of substantial clinical improvement for the Eluvia™ system.

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 Eluvia™ system would be reported with the HCPCS codes in the following Table 23:

[66] Golzar J et al. Effectiveness and Safety of a Paclitaxel-Eluting Stent for Superficial Femoral Artery Lesions up to 190 mm: One-Year Outcomes of the Single-Arm IMPERIAL Long Lesion Substudy of the Eluvia Drug-Eluting Stent. Journal of Endovascular Therapy. 2020;27(2):296–303.

[67] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[68] Müller-Hülsbeck S et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent. Cardiovasc Intervent Radiol. 2021;44:368–375. Published online 22 November 2020.

[69] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[70] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[71] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

TABLE 23 – HCPCS CODES REPORTED WITH ELUVIA ™ SYSTEM

HCPCS Code	Short Descriptor	SI	APC
37226	Fem/popl revasc w/ stent	J1	5193
37227	Fem/popl revasc stnt & ather	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. For our calculations, we used APC 5193—Level 3 Endovascular Procedures, which had a CY 2021 payment rate of $10,042.94 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 37226 had a device offset amount of $4,843.71 at the time the application was received.

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 Eluvia™ system is 56 percent of the applicable APC payment amount for the service related to the category of devices of $10,042.94. Therefore, we believe the Eluvia™ system meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost for the Eluvia™ system is 117 percent of the cost of the device-related portion of the APC payment amount for the related service of $4,843.71. Therefore, we do not believe that the Eluvia™ system meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost for the Eluvia™ system and the portion of the APC payment amount for the device of $4,843.71 is 8 percent of the APC payment amount for the related service of $10,042.94. Therefore, we do not believe that Eluvia™ system meets the third cost significance requirement.

We invite public comment on whether the Eluvia™ system meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(4) Cochlear™ Osia® 2 System

Cochlear Americas submitted an application for a new device category for transitional pass-through payment status for the Cochlear™ Osia® 2 System (hereinafter referred to as the Osia® 2 System) by the December 2020 quarterly deadline for CY 2022. The Osia® 2 System is a transcutaneous, active auditory osseointegrated device that replaces the function of the middle ear by providing mechanical energy to the cochlea. According to the applicant, the device consists of four components including: (1) An external sound processor, the Osia 2 Sound Processor; (2) the Osia OSI200 Implant Piezo Power™ transducer; (3) the BI300 osseointegrated implant for anchoring and single point transmission; and (4) a fixation screw for attaching the OSI200 implant to the BI300 implant which is implanted in the skull.

The external sound processor captures environmental sounds and converts the sound signal into a digital signal transmitted as a radiofrequency. The external sound processor also contains a magnet and a battery (rechargeable 675 zinc air button 1.4Volt; 600 mA-hrs capacity). The magnets couple the external and internal components across the skin. The transducer (Piezo Power™) detects the radiofrequency signals after they pass through the intact skin and transforms the signal to vibrations, which are then transmitted to the bone-implanted fixation screw. The screw vibrates the skull bone (temporal portion) which stimulates the cochlea (inner ear) to transmit the information to the brain so that the vibrations are perceived as sounds. The implanted portion is 7.2 cm × 3 cm × 0.49 cm. The system has a fitting range of 55 dB sensory neural hearing loss. The applicant stated that unlike hearing aids, which make sounds louder, an auditory osseointegrated device, such as the Osia® 2 System can improve clarity of hearing and improve hearing at higher frequencies.

With respect to the newness criterion at § 419.66(b)(1), the Osia® 2 System received FDA 510(k) clearance on November 15, 2019, based on a determination of substantial equivalence to a legally marketed predicate device. The Osia® 2 System is intended for the following patients and indications: (1) Patients 12 years of age or older; (2) patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dBHL; (3) Bilateral fitting of the Osia® 2 System is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies; (4) patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (that is, single-sided deafness or ''SSD''). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz). The Osia® 2 System for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS. Prior to receiving the device, it is recommended that an individual have experience with appropriately fitted air conduction or bone conduction hearing aids.

We received the application for a new device category for transitional pass-through payment status for the Osia® 2 System on December 1, 2020, which is

within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the Osia® 2 System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Osia® 2 System is integral to the service provided, is used for one patient only, comes in contact with human skin and is surgically implanted or inserted. The applicant also claimed that the Osia® 2 System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. Additionally, the Osia® 2 System is not subject to the hearing aid exclusion at § 411.15(d)(1). As described in the application, the implanted components of the Osia® 2 System consist of a piezoelectric transducer (OSI200) that is attached directly to an osseointegrated implant (BI300) with a fixation screw. Sound received by an external processor (the Osia® 2 System) is converted to a digital radiofrequency signal which is received and transformed into mechanical vibrations by the OSI200 implant, which are transferred directly to the BI300 osseointegrated implant. These vibrations are conducted via the skull to the cochlea. Therefore, we believe the Osia® 2 System meets the criterion at § 411.15(d)(2)(i) and is not subject to the hearing aid exclusion.

In accordance with the Medicare Benefit Policy Manual, Chapter 16 ''General Exclusions from Coverage,'' § 100, certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices. These include osseointegrated implants, that is, devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer. We believe the Osia® 2 System as described by the application meets the criteria for this benefit category. We are inviting public comments on whether the Osia® 2 System meets the eligibility criteria at § 419.66(b) as well as the criterion at § 411.15(d)(2)(i).

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 stated that the Osia® 2 System differs significantly from the devices that were included in the previous category for auditory osseointegrated devices (L8690—Auditory osseointegrated device, includes all internal and external components) which was effective from effective from January 1, 2007 through December 31, 2008. The applicant claimed that the devices that were described by this category include a transducer/actuator and sound processor that is worn externally with the transducer/actuator connected to the skull by a percutaneous post or abutment that penetrates the skin. In these devices, the sound processor converts sound into a digital signal which the transducer/actuator converts to vibrations that are transmitted to the skull through the abutment. The vibrations are transmitted directly to the inner ear and are reproduced as sound.

The applicant stated that the Osia® 2 System is distinct from devices with a percutaneous connection between the transducer and the sound processor because the transducer/actuator for the Osia® 2 system is surgically implanted and has a magnetic transcutaneous attachment to the external sound processor. The applicant also claimed that the percutaneously coupled osseointegrated devices included in the previous device pass-through category convert sound to mechanical vibrations in the external sound processor/actuator, then transmit the vibrations to the internal components. The applicant claimed that the Osia® 2 system instead converts the sound to mechanical vibrations after it has reached the internal components. The applicant claimed that the technology to fully implant the transducer/actuator did not exist when the previous device pass-through category was established. The applicant proposed the device pass-through category descriptor ''Auditory osseointegrated device, including implanted transducer/actuator with radiofrequency link to external sound processor''. The applicant stated that the BONEBRIDGE Bone Conduction Implant System, which also submitted a device pass-through application for CY 2022 and is described in this section under number (2) above, would also be described by the proposed additional category.

We believe that the Osia® 2 system is described by L8690—Auditory osseointegrated device, includes all internal and external components. The applicant has noted differences between the Osia® 2 system and the devices that were described by L8690, specifically percutaneous, auditory osseointegrated devices, regarding the connection between the implanted transducer and the external audio processor (percutaneous abutment vs. transcutaneous magnetic attraction) however, we believe that there is a similar mechanism of action for all these devices specifically, vibratory stimulation of the skull to stimulate the receptors in the cochlea (inner ear). Further, we believe that the broad descriptor for L8690 of ''Auditory osseointegrated device, includes all internal and external components'' includes the applicant's device. We are inviting public comment on whether the Osia® 2 system meets the device category criterion.

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. With respect to the substantial clinical improvement criterion, the applicant stated that the Osia® 2 system represents a substantial clinical improvement because it provides a reduced rate of device-related complications compared to currently available treatments. The applicant submitted five references to retrospective case series that studied the long-term complications associated with percutaneous osseointegrated bone conduction hearing devices, specifically bone-anchored hearing aids.[72] [73] [74] [75] [76]

[72] Kraai T, Brown C, Neeff M, Fisher K. Complications of bone-anchored hearing aids in pediatric patients. Int J Pediatr Otorhinolaryngol. 2011 Jun;75(6):749–53.

[73] Badran K, Arya AK, Bunstone D, Mackinnon N. Long-term complications of bone-anchored hearing aids: A 14-year experience. J Laryngol Otol. 2009 Feb;123(2):170–6.

[74] House JW, Kutz JW Jr. Bone-anchored hearing aids: Incidence and management of postoperative complications. Otol Neurotol. 2007 Feb;28(2):213–7.

[75] Asma A, Ubaidah MA, Hasan SS, Wan Fazlina WH, Lim BY, Saim L, Goh BS. Surgical outcome of bone anchored hearing aid (baha) implant surgery: A 10 years experience. Indian J Otolaryngol Head Neck Surg. 2013 Jul;65(3):251–4.

[76] Shirazi MA, Marzo SJ, Leonetti JP. Perioperative complications with the bone-

The applicant stated that complications associated with bone-anchored hearing aids include irritation and/or infection of the skin surrounding the abutment, skin flap necrosis, wound dehiscence, bleeding or hematoma formation, soft tissue overgrowth and persistent pain.[77 78 79 80 81] Additionally, the applicant also submitted five references to clinical studies and case series involving the use of transcutaneous osseointegrated bone conduction hearing devices. Of these five references, three of these studies involved the use of the BONEBRIDGE device and have been previously discussed in this section, one study that involved the use of the BAHA Attract device, and one study that involved the use of the Osia® system, an earlier version of the Osia® 2 system.

In support of their claim that the Osia® 2 system reduced the rate of device-related complications compared to currently available treatments, the applicant submitted a multicenter prospective within-subject study conducted at five centers in Europe, Australia, and USA. This study investigated clinical performance, safety, and benefit of the Osia® system and included 51 adult subjects with mixed and conductive hearing loss (MHL/CHL, n = 37) and single-sided sensorineural deafness (SSD, n = 14). In regard to safety outcomes, patients experienced the following minor adverse events including pain (n = 7), numbness (n = 1), vertigo (n = 3), swelling (n = 3), tension implant site (n = 1), warmth at the SP site (n = 3), headache (n = 3), hematoma/bleeding (n = 2).[82] One participant developed an implant-site infection three days after implantation, which subsequently developed into skin necrosis and dehiscence. The implant had to be removed 55 days after implantation.

We are concerned that the applicant did not submit studies that involved the use of the Osia® 2 system to demonstrate substantial clinical improvement of the device. The applicant submitted one study that investigated the Osia® system that utilizes an earlier model of the device. We are also concerned that the evidence of substantial clinical improvement submitted by the applicant did not directly compare the Osia® 2 system to other currently available treatments, namely percutaneous or passive, transcutaneous auditory osseointegrated devices. Therefore, we are concerned that we are unable to determine a substantial clinical improvement of the Osia 2 system as compared to existing devices. We would be interested in any additional studies that involve the use of the Osia® 2 system and compare the device to other currently available auditory osseointegrated devices. We invite public comments on whether the Osia® 2 system meets the substantial clinical improvement criterion.

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 Osia® 2 system would be reported with the HCPCS codes listed in the following Table 24:

TABLE 24 – HCPCS CODES REPORTED WITH OSIA® 2 SYSTEM

HCPCS Code	Short Descriptor	SI	APC
69714	Implant temple bone w/stimul	J1	5115
69715	Temple bne implnt w/stimulat	J1	5116
69717	Temple bone implant revision	J1	5114
69718	Revise temple bone implant	J1	5115

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5115—Level 5 Musculoskeletal Procedures, which had a CY 2020 payment rate of $11,900.71 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 69714 had a device offset amount of $7,742.60 at the time the application was received.

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 the Osia® 2 system is 88 percent of the applicable APC payment amount for the service related to the category of devices of $11,900.71. Therefore, we believe the Osia® 2 system meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost for the Osia® 2 system is 136 percent of the cost of the device-related portion of the APC payment amount for the related

anchored hearing aid. Otolaryngol Head Neck Surg. 2006 Feb;134(2):236–9.

[77] Ibid.

[78] Ibid.

[79] Ibid.

[80] Ibid.

[81] Ibid.

[82] Mylanos, E.A.M., Hua, H., Arndt, S. 2020. Multicenter clinical investigation of a new active osseointegrated steady-state implant system. *Otol Neurotol* 41: 1249–1257.

service of $7,742.60. Therefore, we believe that the Osia® 2 system meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of the Osia® 2 system and the portion of the APC payment amount for the device of $7,742.60 is 23 percent of the APC payment amount for the related service of $11,900.71. Therefore, we believe that the Osia® 2 system meets the third cost significance requirement.

We invite public comment on whether the Osia® 2 system meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(5) Pure-Vu® System

Motus GI submitted an application for a new device category for transitional pass-through payment status for the Pure-Vu® System (Pure-Vu®) for CY 2022. The applicant asserted that the Pure-Vu® System helps to avoid aborted and delayed colonoscopy procedures due to poor visualization of the colon mucosa by creating a unique High Intensity, Pulsed Vortex Irrigation Jet that consists of a mixture of air and water to break-up fecal matter, blood clots, and other debris, and scrub the walls of the colon while simultaneously removing the debris through two suction channels. The applicant stated that the suction channels have a sensor to detect the formation of a clog in the channels, triggering the system to automatically purge and then revert to suction mode once the channel is clear. According to the applicant, this combination of the agitation of the fluid in the colon via the pulsed vortex irrigation and simultaneous removal of the debris allows the physician to visualize the colon and achieve a successful colonoscopy or other advanced procedure through the colonoscope even if the patient is not properly prepped and has debris either blocking the ability to navigate the colon or covering the colon wall obscuring the mucosa and any pathology that may be present. The applicant asserted that the constant volume suction pumps do not cause the colon to collapse, which allows the physician to continue to navigate the colon while cleansing and avoids the need to constantly insufflate the colon, which may be required with other colonoscopy irrigation systems.

The applicant stated that the Pure-Vu® System is comprised of a workstation that controls the function of the system, a disposable oversleeve that is mounted on a colonoscope and inserted into the patient, and a disposable connector with tubing (umbilical tubing with main connector) that provides the interface between the workstation, the oversleeve, and off the shelf waste containers.

The applicant explained that the workstation has two main functions: cleansing via irrigation and evacuation, and acting as the user interface of the system. The applicant explained that the irrigation into the colon is achieved by an electrical pump that supplies pressurized gas (air) and a peristaltic pump that supplies the liquid (water or saline). According to the applicant, the pressurized gas and liquid flow through the ''main connector'' and are mixed upon entry into the umbilical tubing that connects to the oversleeve. The applicant explained that the gas pressure and flow are controlled via regulators and the flow is adjusted up or down depending on the cleansing mode selected. The applicant stated that a foot pedal connected to the user interface activates the main functions of the system so that the user's hands are free to perform the colonoscope procedure in a standard fashion.

The applicant stated that the evacuation mode (also referred to as suction) removes fecal matter and fluids out of the colon. The applicant noted that the evacuation function is active during cleansing so that fluid is inserted and removed from the colon simultaneously. The applicant explained that the evacuation pumps are designed in a manner that prevents the colon from collapsing when suctioning, which facilitates the ability to simultaneously irrigate and evacuate the colon. According to the applicant, during evacuation, the system continuously monitors the pressure in the evacuation channels of the oversleeve and if the pressure drops below pre-set limits the pumps will automatically reverse the flow. The applicant explained that the clog sensor triggers the system to automatically purge the material out of the channel and back into the colon where it can be further emulsified by the Pulsed Vortex Irrigation Jet, and then automatically reverts back into evacuation mode once the channel is cleared. The applicant stated that the evacuation (suction) that drains fecal matter and fluids out of the colon is generated by peristaltic pumps that can rotate in both directions, either to evacuate fluids and fecal matter from the colon through the evacuation tubes and into a waste container, or while in the reverse direction, to purge the evacuation tubes. The applicant claimed the suction created by this type of pump creates a constant volume draw of material from the colon and therefore prevents the colon from collapsing rapidly. According to the applicant, purging of evacuation tubes may be activated in two ways: the purging cycle is automatically activated when low pressure is noted by the evacuation-line sensor (it is also activated for the first 0.5 seconds when evacuation is activated to make sure the line is clear from the start); or a manual purge may be activated by the user by pushing the ''manual purge'' button on the foot pedal. The applicant claimed the pressure-sensing channel is kept patent by using an air perfusion mechanism where an electrical pump is used to perfuse air through the main connector and into the oversleeve, while the sensor located in the workstation calculates the pressure via sensing of the channel.

The applicant explained the Pure-Vu® System is loaded over a colonoscope and that the colonoscope with the Pure-Vu® Oversleeve is advanced through the colon in the same manner as a standard colonoscopy. The applicant stated that the body of the oversleeve consists of inner and outer sleeves with tubes intended for providing fluid path for the cleansing irrigation (2X), the evacuation of fluids (2X), the evacuation sensor (1X) and that the flexible head is at the distal end of the oversleeve and is designed to align with the colonoscope's distal end in a consistent orientation. The applicant explained that the distal cleansing and evacuation head contains the irrigation ports, evacuation openings, and a sensing port. According to the applicant, the system gives the physician the control to cleanse the colon as needed based on visual feedback from the colonoscope to make sure they have an unobstructed view of the colon mucosa to detect and treat any pathology. The applicant noted that since the Pure-Vu® System does not interfere with the working channel of the colonoscope, the physician is able to perform all diagnostic or therapeutic interventions in a standard fashion with an unobstructed field of view.

With respect to the newness criterion at § 419.66(b)(1), the Pure-Vu® System first received FDA 510(k) clearance on September 22, 2016 under 510(k) number K60015. Per the applicant, this initial device was very cumbersome to set up and required direct support from

the company and therefore was not viable for a small company with limited resources to market the device. The applicant noted that the initial device could have been sold starting on January 27, 2017 when the first device came off the manufacturing line. Per the applicant, the device was allocated for clinical evaluations but 10 institutions throughout the country did purchase the device outside of any true clinical study, mostly based on the fact that physicians wanted to try the product prior to committing to a clinical trial. The applicant further noted that minor modifications were made to the Pure-Vu® System in additional 510(k) clearances dated December 12, 2017 and June 21, 2018. The current marketed Pure-Vu® System was then granted 510(k) clearance on June 6, 2019 under 510(k) number K191220. Per the applicant, this clearance changed the entire set-up of the device, redesigned the user interface, and reduced the size, among other changes. According to the applicant, this updated version was commercially available as of September 19, 2019. We have not identified an existing pass-through payment category that describes the Pure-Vu® System. We are inviting public comment on whether the Pure-Vu® System meets the device category criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Pure-Vu® is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted temporarily. The applicant also claimed that Pure-Vu® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether Pure-Vu® meets the eligibility criteria at § 419.66(b).

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. We have not identified an existing pass-through payment category that describes Pure-Vu®. We are inviting public comment on whether Pure-Vu® meets the device category criterion.

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. The applicant stated that Pure-Vu® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant submitted studies that examined the impact of Pure-Vu® on endoscopic hemostasis outcomes, rebleeding occurrence, and mortality. We note that the applicant has applied for the New Technology Add-on Payment in the FY 2022 IPPS/LTCH proposed rule (86 FR 25299 through 25304).

According to the applicant, the Pure-Vu® System offers the ability to achieve rapid beneficial resolution of the disease process treatment by achieving rapid and full visualization of the colon, which will improve diagnostic yield and the effectiveness of treatment of diseases of the bowel. The applicant claimed that Pure-Vu® is indicated for use in emergent issues such as acute lower gastrointestinal (GI) bleeding, unknown abdominal pain, foreign body removal, chronic disease management, and preventive medicine such as screening and surveillance. The applicant states these procedures are typically performed using a colonoscope to visualize the colon and provide a conduit to deliver therapeutic treatments. According to the applicant, the current standard of care requires the colon to be cleansed to ensure the success of any procedure. The applicant asserts that in the case where pre-procedural preparations are not adequate to achieve proper visualization, current technology provides limited ability to remove debris from the colon during the procedure to facilitate the process. The applicant states that regardless of indication, the bowel preparation remains the constant across patients who may have a wide range of comorbidities which may limit patient tolerability. According to the applicant the consumption of a purgative and the dietary restriction to be on clear liquids for approximately 24 hours can be problematic for the diabetic and elderly populations.[83]

In support of its application, the applicant submitted three outpatient clinical studies to demonstrate the Pure-Vu® System's capability to convert patients to adequate preparation where preparation was previously inadequate and the visualization was poor based on the Boston Bowel Preparation Scale (BBPS). In the first study, Perez J., et al. conducted an outpatient prospective pilot study using the Pure-Vu® System.[84] The study observed 50 patients with poorly prepared colons undergoing colonoscopy at two outpatient clinical sites in Spain and Israel, respectively. The applicant claimed study patients underwent a reduced bowel preparation consisting of the following: No dried fruits, seeds, or nuts starting 2 days before the colonoscopy, a clear liquid diet starting 18 to 24 hours before colonoscopy, and a split dose of 20mg oral bisacodyl. The study found the number of patients with an adequate cleansing level (BBPS ≥2 in each colon segment) increased significantly from 31 percent (15/49) prior to use of the Pure-Vu System (baseline) to 98 percent (48/49) after use of the Pure-Vu® System ($P<0.001$), with no serious adverse events reported.

In the second study provided by the applicant, van Keulen, et al. also conducted a single-arm, prospective study on 47 patients with a median age of 61 years in the outpatient setting in the Netherlands using the Pure-Vu® System.[85] Within the study, cecal intubation was achieved in 46/47 patients. This multicenter feasibility study found that the Pure-Vu® System significantly improved the proportion of patients with adequate bowel cleansing from 19.1 percent prior to the use of the Pure-Vu® System to 97.9 percent after its use ($P<0.001$) and median BBPS score (from 3.0 [IQR 0.0–5.0] to 9.0 [IQR 8.0–9.0]).

In the third study provided by the applicant that directly evaluated the Pure-Vu® System in a clinical setting, Bertiger G., et al. performed a United States-based single center, prospective,

[83] Parra-Blanco A, Ruiz A, Alvarez-Lobos M, Amoros A, Gana JC, Ibanez P, et al. Achieving the best bowel preparation for colonoscopy. World J Gastroenterol. 2014;20(47):17709–26.

[84] Perez Jimenez J, Diego Bermudez L, Gralnek IM, Martin Herrera L, Libes M. An Intraprocedural Endoscopic Cleansing Device for Achieving Adequate Colon Preparation in Poorly Prepped Patients. J Clin Gastroenterol. 2019;53(7):530–4.

[85] Van Keulen KE, Neumann H, Schattenberg JM, Van Esch AAJ, Kievit W, Spaander MCW, Siersema PD. A novel device for intracolonoscopy cleansing of inadequately prepared colonoscopy patients: A feasibility study. Endoscopy. 2019 Jan;51(1):85–92. doi: 10.1055/a–0632–1927. Epub 2018 Jul 11.

outpatient study investigating regimes of reduced outpatient bowel preparations, which included low doses of over-the-counter laxatives, and eliminating the typical 24 hour clear liquid diet restriction, which was replaced by a low residue diet the day before the procedure.[86] In this study, 46 of a possible 49 patients received a colonoscopy, 8 of which took the over-the-counter laxative (''MiraLAX arm''), 21 patients ingested two doses of 7.5oz Magnesium Citrate (MgC) each taken with 19.5oz of clear liquid (''Mag Citrate 15oz arm''), and 18 patients ingested 2 doses of 5oz MgC taken with 16oz of clear liquid (''Mag Citrate 10oz arm''). Of the 46 subjects, 59 percent were males and there was a mean age of 61 ± 9.48 years. The study found that each of the 3 study arms revealed significant differences in BBPS score between the baseline preparation and post-cleansing via Pure-Vu®. All the preparation regimens resulted in inadequately prepped colons. Comparing the mean BBPS rating for both pre- and post-Pure-Vu® use, the MiraLAX arm was inferior ($P<0.05$) to both Mag Citrate arms. For the MiraLAX arm, the mean BBPS Score improved from 1.50 to 8.63. For the Mag Citrate 15oz arm, the mean BBPS score improved from 3.62 to 8.95. For the Mag Citrate 10oz arm, the mean BBPS Score improved from 4.76 to 9.0.

The applicant also provided a self-sponsored, U.S.-based, multicenter, prospective, single arm study in the inpatient setting, analyzing 94 patients, 65 of which (68 percent) had a GI bleed.[87] Of the 94 patients (41 percent females/59 percent males), the mean age was 62 years. According to the applicant, the study's primary endpoint was the rate of improved bowel cleansing level from baseline to after use of the Pure-Vu® System per colon segment using the BBPS. The BBPS score was recorded for each colorectal segment (left colon, transverse colon, and right colon segments) both prior to (baseline) and after colon cleansing with the Pure-Vu® System. An adequate cleansing level was *a priori* defined as a BBPS ≥2 in all evaluated colon segments. The study found that in 79 of the 94 patients (84 percent), the physician was able to successfully diagnose or rule out a GI bleed in the colon per the patients' colonoscopy indication using only the Pure-Vu® System. The analysis showed statistically significant visualization improvement in each colon segment after Pure-Vu® use with a mean BBPS score in the descending colon, sigmoid, and rectum of 1.74 pre-Pure-Vu® use and 2.89 post-Pure-Vu® use ($P<0.001$); in the transverse colon of 1.74 pre-Pure-Vu® use and 2.91 post Pure-Vu® use ($P<0.001$); and the ascending colon and cecum of 1.50 pre-Pure-Vu® use and 2.86 post Pure-Vu® use ($P<0.001$). The study found only 2 percent of cases where the diagnosis could not be achieved due to inadequate preparation. Overall, the 84 (89.4 percent) patients that received the Pure-Vu® System within the study improved BBPS scores from 38 percent (95 percent CI 28, 49) to 96 percent (95 percent CI 90, 99) in segments evaluated. The study noted one procedure related perforation which required surgical repair, and the patient was discharged 48 hours post operatively and recovered fully.

In addition to the previously discussed studies, the applicant also submitted two case studies to highlight the various clinical presentations of lower gastrointestinal bleed (LGIB) with the use of the Pure-Vu® System. In the first case, the applicant described a patient with a history of scleroderma and chronic constipation who was referred for a surveillance colonoscopy after a prior endoscopic mucosal resection due to a large polyp. The applicant states this was the patient's third colonoscopy in twelve months due to a history of poor preparation in the prior exams. Despite an aggressive prep regime, the applicant states the patient still had solid stool and debris throughout the colon. The applicant states the Pure-Vu® system was used extensively and the physician was able to fully cleanse the colon during which the physician was able to uncover a poorly defined over 1 cm sessile serrated polyp that could not be appreciated before cleansing with Pure-Vu®. The applicant states a successful polypectomy was performed.

In the second case, the applicant described a patient presenting with hemorrhagic shock and acute kidney injury six days after a colonoscopy where nine polyps were removed, including two polyps greater than 2cm. The applicant states angiographic control of the bleeding was not considered because of the patient's acute kidney injury with a rising creatinine. According to the applicant, the physician elected to use Pure-Vu® to immediately exam the patient without any preparation doing a bedside colonoscopy in the ICU. The applicant states, the physician was able to cleanse the colon, locate the source of the bleed and create hemostasis by placing two clips on the bleed. According to the applicant, the entire colon was visualized to confirm there were no other sources of bleeding, the physician was able to downgrade the patient out of the ICU that same day, and the patient was discharged from the hospital the following day.

The applicant concludes that based on the provided evidence, Pure-Vu® has the ability to improve adenoma detection rates which can reduce the rate of colorectal cancer (CRC) and diagnose and treat emergent patients in a more expeditious fashion by removing the need to have successful pre-procedural preparation that can take time and be very burdensome to the most needy and fragile patients. According to the applicant, Pure-Vu® can minimize the number of aborted and early repeat colonoscopies that carry inherent risks and add unnecessary costs to the healthcare system.

Based on the evidence submitted with the application, we have the following observations. While the studies provided in support of the Pure-Vu® System measure improvement of bowel preparation using the BBPS, the applicant did not provide data indicating that the improved BBPS directly leads to improved clinical outcomes (for example, reduction of blood loss in LGIB or reduction of missed polyps) based on use of the Pure-Vu® System. Additionally, we note that the applicant has not provided any studies comparing the efficacy of the Pure-Vu® System to other existing methods or products for irrigation in support of its claims that the product is superior at removing debris from the colon while simultaneously preventing the colon from collapsing, allowing use of the working channel, or improving outcomes. Furthermore, we note that many of the provided studies were based on small sample sizes, which may affect the quality and reliability of the data provided in support of the technology.

In addition, we note that it is unclear whether this device would have less utility in the outpatient setting as compared to the inpatient setting, given that patients will typically have time to adequately prepare for scheduled outpatient procedures. We further note that this device may not be broadly applicable in the outpatient setting and are seeking comment for situations in which this device will have a substantial clinical benefit for patients

[86] Bertiger, Gerald MD Optimizing the Preparation Regimen Prior to Colonoscopy Procedure With the Pure-Vu® System, American Journal of Gastroenterology: October 2018—Volume 113—Issue—p S119–S120.

[87] Helmut Neumann ML, Tim Zimmermann, Gabriel Lang, Jason B. Samarasena, Seth A. Gross, Bhaumik Brahmbhatt, Haleh Pazwash, Vladimir Kushnir. Evaluation of bowel cleansing efficacy in hospitalized patient population using the pure-vu system. Gastrointestinal Endoscopy. 2019;89(6).

or subpopulations of patients. For instance, in the outpatient setting, we are not certain that it would be appropriate to use this device in the case of a patient with a poorly prepared bowel as opposed to simply rescheduling the appointment.

Lastly, we note that the Helmut et al. study noted one procedure-related perforation which required surgical repair and we invite public comments regarding the concern of procedure-related perforation.[88] Based upon the evidence presented, we are inviting public comments on whether the Pure-Vu® meets the substantial clinical improvement criterion.

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 Pure-Vu® would be reported with the HCPCS codes listed in the following Table 25:

TABLE 25 – HCPCS CODES REPORTED WITH PURE-VU®

HCPCS Code	Short Descriptor	SI	APC
45378	Diagnostic colonoscopy	T	5311
45379	Colonoscopy w/fb removal	T	5312
45380	Colonoscopy and biopsy	T	5312
45381	Colonoscopy submucous njx	T	5312
45382	Colonoscopy w/control bleed	T	5312
45384	Colonoscopy w/lesion removal	T	5312
45385	Colonoscopy w/lesion removal	T	5312
45388	Colonoscopy w/ablation	T	5312
45390	Colonoscopy w/resection	J1	5313

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. For our calculations, we used APC 5311—Level 1 Lower GI Procedures, which had a CY 2020 payment rate of $763.88 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 45378 had a device offset amount of $1.07 at the time the application was received. According to the applicant, the cost of the Pure-Vu® is $975.

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 $975 for Pure-Vu® is 128 percent of the applicable APC payment amount for the service related to the category of devices of $763.80 (($975/$763.88) × 100 = 127.7 percent). Therefore, we believe Pure-Vu® 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 $975 for Pure-Vu® is 91,122 percent of the cost of the device-related portion of the APC payment amount for the related service of $1.07 (($975/$1.07) × 100 = 91,121.5 percent). Therefore, we believe that Pure-Vu® 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 $975 for Pure-Vu® and the portion of the APC payment amount for the device of $1.07 is 128 percent of the APC payment amount for the related service of $763.88 ((($975 − $1.07)/$763.80) × 100 = 127.5 percent). Therefore, we believe that Pure-Vu® meets the third cost significance requirement.

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

(6) Xenocor Xenoscope™

Xenocor Inc. submitted an application for a new device category for transitional pass-through payment status for the Articulating Xenoscope Laparoscope (hereinafter referred to as the Xenoscope™) by the March 2021 quarterly deadline for CY 2022. The applicant described the Xenoscope™ as a disposable laparoscope which consists of a high-definition camera chip on the tip of a composite shaft, paired with led lights with a handle comprised of a clamshell design and made with molded plastic. The applicant stated that the Xenoscope™ provides visualization in the abdominal and thoracic cavities through small, minimally invasive incisions for diagnostic and therapeutic laparoscopic procedures in a similar fashion to established, reusable versions of laparoscopes. It is paired with an image processing unit, the Xenobox, that can plug into any HD monitor to

[88] Helmut Neumann ML, Tim Zimmermann, Gabriel Lang, Jason B. Samarasena, Seth A. Gross, Bhaumik Brahmbhatt, Haleh Pazwash, Vladimir Kushnir. Evaluation of Bowel Cleansing Efficacy in Hospitalized Patient Population Using the Pure-Vu System. Gastrointestinal Endoscopy. 2019;89(6).

display anatomy in the abdomen, pelvis or chest. The Xenobox uses pre-installed firmware that is upgradable.

The applicant claimed that the Xenoscope™ is the first disposable laparoscope. The applicant also claimed that the use of the Xenoscope™ reduces the number of cords in the operating room, eliminates intraoperative fogging and associated image compromise and eliminates up-front capital enditures associated with reusable laparoscopes.

With respect to the newness criterion, the Xenoscope™ received FDA 510(k) clearance on January 27, 2020, based on a determination of substantial equivalence to a legally marketed predicate device. The Xenoscope™ is indicated for use in diagnostic and therapeutic procedures for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. We received the application for a new device category for transitional pass-through payment status for the Xenoscope™ on August 6, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the Xenoscope™ meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the Xenoscope™ is integral to the service, is used for one patient only, comes in contact with human skin, and is surgically implanted or inserted into the patient. Specifically, the applicant explained that the Xenoscope™ is plugged into the Xenobox image processing unit (which is connected to an HD monitor and an A/C power source). A surgeon then makes a small incision and a trocar (tube-like device with a seal to maintain abdominal pressure) is inserted to gain access to the body cavity. The Xenoscope™ is then inserted through the trocar in order to provide a full view of the anatomy for diagnostic and therapeutic procedures.

The applicant also claimed the Xenoscope™ meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether the Xenoscope™ meets the eligibility criteria at § 419.66(b).

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 Xenoscope™ as disposable laparoscope. The applicant reported that it does not believe that the Xenoscope™ is described by an existing category and requested category descriptor ''Single-use laparoscopes.'' The applicant also stated that the currently existing category, C1748—Endoscope, single-use (that is, disposable), upper gi, imaging/illumination device (insertable), did not describe this device because it is limited to single-use duodenoscopes inserted orally, to reach the small intestine versus minimally invasive abdominal surgery (laparoscopy). We have not identified an existing pass-through payment category that is applicable to the Xenoscope™. We are inviting public comments on this issue.

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.

With respect to the substantial clinical improvement criterion, the applicant stated that the Xenoscope™ provides a substantial clinical improvement over reusable laparoscopes because of its single-use nature. Specifically, the applicant claimed, that because the Xenoscope™ is a disposable, single-use device, the Xenoscope™ provides for less risk of scope-related cross-contamination and infection from improperly handled or reprocessed scopes compared to traditional laparoscopy.

The applicant also claimed that the Xenoscope™ includes a fog-free scope and provides a substantial clinical improvement over currently available laparoscopes which, according to the applicant, fog often, and can put patients at risk for surgical errors and more time under anesthesia. Additionally, the applicant claimed that the Xenoscope™ reaches 104 degrees Fahrenheit at the tip, eliminating risk of patient burns and drape fires associated with hotter Xenon bulbs used in currently available laparoscopes.

Lastly, that applicant stated that there can be significant economic benefits through the use of the Xenoscope™ due to the processing costs and up-front capital expenditures required for reusable laparoscopes.

In support of the assertion that the Xenoscope™ reduces the risk of cross-contamination from improperly cleaned reusable laparoscopic instruments, the applicant referenced two articles. The first article was published in 2002 and describes the problem of surgical site infection (SSI), the Centers for Disease Control (CDC) guidelines for SSI, and some cases of SSI related to improper cleaning of reusable laparoscopic instruments. The article also discusses practices to avoid these infections.[89] The applicant also submitted a draft of a manuscript titled ''Novel Laparoscopic System for Quality Improvement and Increased Efficiency'' that summarizes some of the evidence that laparoscopy, in general, is superior to open surgical approaches in terms of pain management and infection risk.[90]

In support of the claim that the Xenoscope™ eliminates the risk of patient burns and drape fires associated with Xenon bulbs used by currently available laparoscopes, the applicant submitted two articles. The first was an article published in 2011 that discusses the problem of laparoscopic related burn injuries and a potential solution using Active Electrode Monitoring (AEM).[91] AEM instruments reportedly use a ''shielded and monitored'' design to prevent the risk of stray energy burn injury from insulation failure and capacitive coupling. According to the article, the AEM technology is currently licensed by Intuitive Surgical's da Vinci® Surgical Systems. The applicant does not compare the Xenoscope™ to AEM technology in terms of burn injury reduction. The second article examined the variation and extent of thermal injuries that could be induced by laparoscopic light sources to porcine tissue. In the study, the maximum temperature at the tip of the optical cable varied between 119.5 degrees C and 268.6 degrees C. When surgical

[89] Hewitt, A. (2002, November 1). *Laparoscopic Instruments: Handle with Care.* Infection Control Today. *https://www.infectioncontroltoday.com/view/laparoscopic-instruments-handle-care.*

[90] Elliott, K.W. & Heilbraun, E. (2020). *Novel Laparoscopic System for Quality Improvement and Increased Efficiency.* Manuscript submitted for publication.

[91] Encision Inc. (2011, April 1*). Method of Reducing Stray Energy Burns in Laparoscopic Surgery.* Medical Design Briefs. *https://www.medicaldesignbriefs.com/component/content/article/mdb/tech-briefs/9500.*

drapes were exposed to the tip of the light source, the time to char was 3–6 seconds. The degree and volume of injury increased with longer exposure times, and significant injury was recorded with the optical cable 3 mm from the skin.[92]

In support of the claim that there could be significant economic benefits realized through the use the Xenoscope™ compared to reusable laparoscopes, the applicant also referenced the manuscript entitled ''Novel Laparoscopic System for Quality Improvement and Increased Efficiency''.[93] In this study, a three-page survey was created to collect data regarding laparoscope-related practices and costs. The survey was completed by three different institutions, including an ambulatory surgery center (ASC), a rural hospital and a suburban hospital. The sites provided the capital equipment cost required at the time of purchase at their facility which ranged from $837,184 to $2,786,348. The average cost per use for one surgical procedure involving a reusable laparoscope was $1,019.24 across the three institutions.

We are concerned that the application and the articles submitted as evidence of substantial clinical improvement discuss potential adverse effects from laparoscopic procedures, but do not appear to directly show any clinical improvement that result from the use of the Xenoscope™. The applicant has provided evidence which seems to rely on indirect inferences from other sources of data. The articles provided did not involve the clinical use of the Xenoscope™ and did not compare the device to an appropriate comparator, such as a reusable laparoscope. Therefore, it is difficult to determine whether the Xenoscope™ offers substantial clinical improvement over standard, reusable laparoscopes based on the information provided. 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 are invite public comment on whether the Xenoscope™ meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Xenoscope™ would be reported with HCPCS codes listed in the following Table 26:

TABLE 26 – HCPCS CODES REPORTED WITH XENOSCOPE™

HCPCS Code	Short Descriptor	SI	APC
49320	Diag laparo separate proc	J1	5361
49321	Laparoscopy biopsy	J1	5361
47562	Laparoscopic cholecystectomy	J1	5361
44970	Laparoscopy appendectomy	J1	5361
49650	Lap ing hernia repair init	J1	5361
49651	Lap ing hernia repair recur	J1	5361
49652	Lap vent/abd hernia repair	J1	5361
58661	Laparoscopy remove adnexa	J1	5361
58570	Tlh uterus 250 g or less	J1	5362
43281	Lap paraesophag hern repair	J1	5362
43282	Lap paraesoph her rpr w/mesh	J1	5362

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. For our calculations, we used APC 5361 Level 1 Laparoscopy and Related Services, which had a CY 2020 payment rate of $4,833.71. Beginning in CY 2017, we calculated the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 49320 had a device offset amount of $107.79 at the time the application was received. According to the applicant, the cost of the Xenoscope™ is $1,500.

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 $1,500 for the Xenoscope™ is 31 percent of the applicable APC payment amount for the service related to the category of devices of Xenoscope™ (($1,500/$4,833.71) × 100 = 31.0 percent). Therefore, we believe Xenoscope™ meets the first cost significance requirement.

[92] Hindle, A. K., Brody, F., Hopkins, V., Rosales, G., Gonzalez, F., & Schwartz, A. (2009). Thermal injury secondary to laparoscopic fiber-optic cables. *Surgical endoscopy, 23*(8), 1720–1723. *https://doi.org/10.1007/s00464-008-0219-z.*

[93] Ibid.

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 $1,500 for the Xenoscope™ is 1,392 percent of the cost of the device-related portion of the APC payment amount for the related service of $107.79 (($1,500/$107.79) × 100 = 1,391.6 percent). Therefore, we believe that the Xenoscope™ 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 $1,500 for the Xenoscope™ and the portion of the APC payment amount for the device of $107.79 is 29 percent of the APC payment amount for the related service of $4,833.71 (($1,500 − $107.79)/$4,833.71) = 28.8 percent). Therefore, we believe that the Xenoscope™ meets the third cost significance requirement.

We invite public comment on whether the Xenoscope™ meets the device pass-through payment criteria discussed in this section, including the cost criterion.

B. Proposed Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs and is discussed in detail in section IV.B.4. of this CY 2022 OPPS/ASC 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 CY 2022 OPPS/ASC proposed rule. For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, under the device-intensive methodology we assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria 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 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APC designations were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.B.1.b. of this CY 2022 OPPS/ASC 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.B.3. and IV.B.4. of this CY 2022 OPPS/ASC proposed rule, respectively.

b. Use of the Three Criteria To Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy—which includes the three criteria listed previously—to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. 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 stakeholders that the criteria excluded some procedures that stakeholders believed should qualify as device-intensive procedures. Specifically, we were persuaded by stakeholder 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 ensive 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 little 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 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent 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 OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

As discussed in Section X.E of this proposed rule, given our concerns regarding CY 2020 data as a result of the COVID–PHE, we are proposing to use CY 2019 claims data to establish CY 2022 prospective rates. While we continue to believe CY 2019 represents the best full year of claims data for ratesetting, we believe our policy of temporarily assigning a higher offset percentage if warranted by additional information would provide a more accurate device offset percentage for certain procedures. Specifically, for procedures that were assigned device-intensive status, but were assigned a default device offset percentage of 31 percent or a device offset percentage based on claims from a clinically-similar code in the absence of CY 2019 claims data, we are proposing to assign a device offset percentage for such procedures based on CY 2020 data if CY 2020 claims information is available. While we believe that CY 2019 claims data is a better basis for CY 2022 OPPS rates overall, because we have specifically noted that we would consider using more recent data than the data available for ratesetting in a given year to determine device offset percentages for services that do not have any claims data in the year used for ratesetting, we believe it would be consistent with this policy for us to use CY 2020 claims data to determine the device offset percentage for services that meet the above criteria.

For CY 2022, our proposal would assign device offset percentages using CY 2020 claims data to the following 11 procedures:

- 0266T (Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed));
- 0414T (Removal and replacement of permanent cardiac contractility modulation system pulse generator only);
- 0511T (Removal and reinsertion of sinus tarsi implant);
- 0587T (Percutaneous implantation or replacement 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);
- 0600T (Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous);
- 0614T (Removal and replacement of substernal implantable defibrillator pulse generator);
- 66987 (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 ansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation);
- 66988 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation);
- C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar);
- C9765 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed); and
- C9767 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed).

We are soliciting comments on our proposal to establish the CY 2022 device offset percentage using CY 2020 claims data for device-intensive procedures with no claims in the CY 2019 claims data. The full listing of the proposed CY 2022 device-intensive procedures can be found in Addendum P to this CY 2022 OPPS/ASC 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 2022 OPPS/ASC proposed rule on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015

device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is ''Implantable/insertable device, not otherwise classified''.

We are not proposing any changes to this policy for CY 2022.

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

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including Chapter 4, Section 61.3.6 of the Medicare Claims Processing Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017 through 86018, 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We are not proposing any changes to our policies regarding payment for no cost/full credit and partial credit devices in CY 2022.

5. Payment Policy for Low-Volume Device-Intensive Procedures

In CY 2016, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act and used the median cost (instead of the geometric mean cost per our standard methodology) to calculate the payment rate for the implantable miniature telescope procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which is the only code assigned to APC 5494 (Level 4 Intraocular Procedures) (80 FR 70388). We noted that, as stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45656), we proposed to reassign the procedure described by CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) for CY 2017, but it would be the only procedure code assigned to APC 5495. The payment rates for a procedure described by CPT code 0308T (including the predecessor HCPCS code C9732) were $15,551 in CY 2014, $23,084 in CY 2015, and $17,551 in CY 2016. The procedure described by CPT code 0308T is a high-cost device-intensive surgical procedure that has a very low volume of claims (in part because most of the procedures described by CPT code 0308T are performed in ASCs). We believe that the median cost is a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for this procedure because the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. We stated that, in future rulemaking, we would consider proposing a general policy for the payment rate calculation for very low-volume device-intensive APCs (80 FR 70389).

For CY 2017, we proposed and finalized a payment policy for low-volume device-intensive procedures that is similar to the policy applied to the procedure described by CPT code 0308T in CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79660 through 79661), we established our current policy that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost, for the reasons described previously for the policy applied to the procedure described by CPT code 0308T in CY 2016. For CYs 2019 through 2021, we continued our policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC by using the median cost instead of the geometric mean (85 FR 86019).

As discussed in further detail in Section X.C of this proposed rule, we are proposing to establish a universal low volume APC policy for clinical APCs, brachytherapy APCs, and New Technology APCs with fewer than 100 single claims in the claims data used for ratesetting (for CY 2022 rates, this is proposed to be the CY 2019 claim data). For APCs designated as low volume APCs (those with fewer than 100 single claims in the claims year) under our proposed policy, we propose to establish a payment rate using the highest of the median cost, arithmetic mean cost, or the geometric mean cost. In conjunction with our new, broader low volume APC proposal for clinical APCs, brachytherapy APCs, and New Technology APCs, we are proposing to eliminate our payment policy for low-volume device-intensive procedures for CY 2022 and subsequent calendar years. Currently, CPT code 0308T is the only code subject to our low-volume device-intensive policy. Given that our proposed universal low volume APC policy would utilize a greater number of claims and provide additional cost metric alternatives for ratesetting than our existing low-volume device-intensive policy, we believe that the cost and ratesetting issues previously discussed with respect to CPT code 0308T would be appropriately addressed under our broader universal low volume APC proposal.

We are soliciting comments on our proposal to eliminate our payment policy for low-volume device-intensive procedures and address low-volume, device-intensive procedures through our broader proposal to designate low volume APCs among eligible clinical APCs, brachytherapy APCs, and New Technology APCs.

V. Proposed OPPS Payment Changes 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 Public Health Service 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 2022 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In 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: *http://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

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 newly 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 newly 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 whose pass-through payment status is ending during the calendar year will continue to be included in the quarterly OPPS Change Request transmittals.

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2021

There are 25 drugs and biologicals whose pass-through payment status will expire during CY 2021, as listed in Table 27. Most of these drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2018, through December 31, 2020. In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals newly 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 $130 for CY 2022), as discussed further in section V.B.1. of this proposed rule. We proposed that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would 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 proposed to provide separate payment at the applicable ASP-based payment amount (which is proposed at ASP+6 percent for non-340B drugs for CY 2022, as discussed further in section V.B.2. of this proposed rule).

BILLING CODE 4120–01–P

TABLE 27.--DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL EXPIRE BETWEEN MARCH 31, 2021 AND DECEMBER 31, 2021

CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018	03/31/2021
J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	03/31/2021
J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018	03/31/2021
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	03/31/2021
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	04/01/2018	03/31/2021
J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	9174	04/01/2018	03/31/2021
J9311	lnjection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	03/31/2021
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9035	04/01/2018	03/31/2021
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018	03/31/2021
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	03/31/2021

CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018	06/30/2021
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	07/01/2018	06/30/2021
J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018	06/30/2021
J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	06/30/2021
Q9991	Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg	G	9073	07/01/2018	06/30/2021
Q9992	Injection, buprenorphine extended-release (sublocade), greater than 100 mg	G	9239	07/0/2018	06/30/2021
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	09/30/2021
Q5105	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018	09/30/2021
Q5106	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018	09/30/2021
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9339	01/01/2019	12/31/2021
J0222	Injection, Patisiran, 0.1 mg	G	9180	01/01/2019	12/31/2021
J0291	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2021
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2021
J2798	Injection, risperidone, (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2021
J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021

BILLING CODE 4120–01–C

4. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in CY 2022

We propose to end pass-through payment status in CY 2022 for 26 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status between April 1, 2019, and January 1, 2020, are listed in Table 28. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2022, are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

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 2022, we propose to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2022. We propose that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals that are not policy-packaged as described in Section V.B.1.c. under the CY 2022 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+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 ASP+6 percent for CY 2022 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.

We propose to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2022 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2022, consistent with our CY 2021 policy for diagnostic and therapeutic radiopharmaceuticals, we propose 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 2022, 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 proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we propose to provide pass-through payment at WAC+3 percent (consistent with our proposed 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+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.

BILLING CODE 4120–01–P

TABLE 28: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING DURING CY 2022

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J7169	J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	03/31/2022
C9046	C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	03/31/2022
J0642	J0642	Injection, levoleucovorin 0(khapzory), 0.5 mg	G	9334	01/01/2020	03/31/2022
J1095	J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	G	9172	04/01/2019	03/31/2022
J3031	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)	G	9197	04/01/2019	03/31/2022
J3245	J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	03/31/2022
J7208	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	03/31/2022
J9119	J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	03/31/2022
J9313	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	03/31/2022
Q5108	Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	03/31/2022
Q5110	Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	03/31/2022
Q5111	Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	03/31/2022
C9047	C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	06/30/2022

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0121	J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	06/30/2022
J1096	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	06/30/2022
J1303	J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312	07/01/2019	06/30/2022
J9036	J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	G	9313	07/01/2019	06/30/2022
J9210	J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	06/30/2022
J9269	J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	06/30/2022
J3111	J3111	Injection, romosozumab-aqqg, 1 mg	G	9327	10/01/2019	09/30/2022
J9356	J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	G	9314	10/01/2019	09/30/2022
C9054	J0691	Injection, lefamulin (xenleta), 1 mg	G	9332	01/01/2020	12/31/2022
C9055	J1632	Injection, brexanolone, 1mg	G	9333	01/01/2020	12/31/2022
J9309	J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331	01/01/2020	12/31/2022
Q5107	Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
Q5117	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022

BILLING CODE 4120–01–C

5. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Continuing in CY 2022

We propose to continue pass-through payment status in CY 2022 for 46 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2020, and April 1, 2021, are listed in Table 29. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will continue after December 31, 2022, are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

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 2023, we propose to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and+ biologicals would receive in the physician's office setting in CY 2022. We propose that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals that are not policy-packaged as described in Section V.B.1.c. under the CY 2022 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+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 ASP+6 percent for CY 2022 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.

We propose to continue to update pass-through payment rates on a quarterly basis on our website during CY 2022 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2022, consistent with our CY 2021 policy for diagnostic and therapeutic radiopharmaceuticals, we propose 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 2023, 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 proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we propose to provide pass-through payment at WAC+3 percent (consistent with our proposed 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+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.

The drugs and biologicals that we propose to have pass-through payment status expire after December 31, 2022, are shown in Table 29.

BILLING CODE 4120–01–P

TABLE 29: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING AFTER CY 2022

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0179	J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
C9056	J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
C9053	J0791	Injection, crizanlizumab-tmca, 1 mg	G	9359	04/01/2020	03/31/2023
C9057	J1201	Injection, cetirizine hydrochloride, 1 mg	G	9361	04/01/2020	03/31/2023
J7331	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
C9058	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
C9059	J1738	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
C9061	J3241	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
C9063	J3032	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023
C9122	J7402	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354	07/01/2020	06/30/2023
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q5116	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5118	Q5118	Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg	G	9348	07/01/2020	06/30/2023
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023
C9060	A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	9370	10/01/2020	09/30/2023
C9062	J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj	G	9378	10/01/2020	09/30/2023
C9064	J9281	Mitomycin pyelocalyceal instillation, 1 mg	G	9374	10/01/2020	09/30/2023
C9065	C9065	Injection, romidepsin, non-lyophilized (e.g. liquid), 1mg	G	9379	10/01/2020	09/30/2023
C9066	J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	G	9376	10/01/2020	09/30/2023
C9067	C9067	Gallium ga-68, dotatoc, diagnostic, 0.01 mCi	G	9323	10/01/2020	09/30/2023
J7351	J7351	Injection, bimatoprost, intracameral implant, 1 microgram	G	9351	10/01/2020	09/30/2023
J9227	J9227	Injection, isatuximab-irfc, 10 mg	G	9377	10/01/2020	09/30/2023
Q5112	Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	G	9382	10/01/2020	09/30/2023
Q5113	Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	G	9349	10/01/2020	09/30/2023
Q5121	Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381	10/01/2020	09/30/2023
J1437	J1437	Injection, ferric derisomaltose, 10 mg	G	9388	01/01/2021	12/31/2023
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387	01/01/2021	12/31/2023
C9068	A9592	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9383	01/01/2021	12/31/2023

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9069	J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384	01/01/2021	12/31/2023
C9070	J9349	Injection, tafasitamab-cxix, 2 mg	G	9385	01/01/2021	12/31/2023
C9071	J1427	Injection, viltolarsen, 10 mg	G	9386	01/01/2021	12/31/2023
C9072	J1554	Injection, immune globulin (Asceniv), 500 mg	G	9392	01/01/2021	12/31/2023
C9073	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
N/A	J0693	Injection, cefiderocol, 5 mg	G	9380	01/01/2021	12/31/2023
N/A	J9316	Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg	G	9390	01/01/2021	12/31/2023
N/A	J9223	Injection, lurbinectedin, 0.1 mg	G	9389	01/01/2021	12/31/2023
Q5122	Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	12/31/2023
N/A	C9074	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024
N/A	J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024

6. 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), nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged in the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Also under the regulation at 42 CFR 419.2(b), nonpass-through drugs and biologicals that function as supplies in a surgical procedure are packaged in the OPPS. This category includes skin substitutes and other surgical-supply drugs and biologicals. 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 OPPS/ASC final rule with comment period (80 FR 70430 through 70432). For CY 2022, as we did in CY 2021, 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. The proposed 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 30.

TABLE 30: PROPOSED APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2022

CY 2022 APC	CY 2022 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

BILLING CODE 4120–01–C

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* 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 $130 for CY 2021 (84 FR 61312 through 61313).

Following the CY 2007 methodology, for this CY 2022 OPPS/ASC proposed rule, we used 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 2022 and rounded the resulting dollar amount ($132.44) to the nearest $5 increment, which yielded a figure of $130. 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 CMS' Office of the Actuary. For this CY 2022 OPPS/ASC proposed rule, based on these calculations using the CY 2007 OPPS methodology, we propose a packaging threshold for CY 2022 of $130.

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

To determine the proposed CY 2022 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 (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2019 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2019 claims processed through June 30, 2020 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 the proposed rule, or for the following policy-packaged items that we propose to continue to package in CY 2022: 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 2022, we use the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we propose for separately payable drugs and biologicals (other than 340B drugs) for CY 2022, as discussed in more detail in section V.B.2.b. of the proposed rule) to calculate the CY 2022 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2020 (data that were used for payment purposes in the physician's office setting, effective April 1, 2021) to determine the proposed rule per day cost. While the CY 2020 ASP data was collected during the PHE, ASP data are not affected by changes in utilization the way non-drug services are for setting payment rates, and so we believe ASP data continues to be representative of the price of drugs in the market. We have continued to use ASP data from CY 2020 to report quarterly drug rates for CY 2020 and CY 2021.

As is our standard methodology, for 2022, we propose to use payment rates based on the ASP data from the fourth quarter of CY 2020 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the 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 proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2021. 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 2019 hospital claims data to determine their per day cost.

We propose to package items with a per day cost less than or equal to $130, and identify items with a per day cost greater than $130 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2019 HCPCS codes that were reported to the CY 2021 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the internet on the CMS website) for proposed payment in CY 2022.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the 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 CY 2022 OPPS/ASC proposed rule, we proposed to use ASP data from the fourth quarter of CY 2020, 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, 2021, along with updated hospital claims data from CY 2019. We note that we also propose to use these data for budget neutrality estimates and impact analyses for this CY 2022 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of the final rule with comment period will be based on ASP data from the second quarter of CY 2021. 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, 2021. These payment rates would then be updated in the January 2022 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2022. For items that do not currently have an ASP-based payment rate, we proposed to recalculate their mean unit cost from all of the CY 2019 claims data and update cost report information available for the CY 2022 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the 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 proposed 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 2022 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2021. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2022, consistent with our historical practice, we proposed to apply the following policies to these 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 2021 and that are proposed for separate payment in CY 2022, and that then have per day costs equal to or less than the CY 2022 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2022 final rule, would continue to receive separate payment in CY 2022.
- HCPCS codes for drugs and biologicals that were packaged in CY 2021 and that are proposed for separate payment in CY 2022, and that then have per day costs equal to or less than the CY 2022 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2022 final rule, would remain packaged in CY 2022.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2022 but that then have per-day costs greater than the CY 2022 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2022 final rule, would receive separate payment in CY 2022.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are 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 OPPS/ASC final rule with comment period: ''We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy'' (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals, 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).

d. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we propose to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2022.

For CY 2022, 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 2019 claims data and our pricing information at ASP+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 CY 2022 OPPS/ASC 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 2019 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+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 the estimated per day cost of each drug or biological at less than or equal to the proposed CY 2022 drug packaging threshold of $130 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2022 drug packaging threshold of $130 (so that 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 2022 is displayed in Table 31.

BILLING CODE 4120–01–P

TABLE 31: HCPCS CODES TO WHICH THE CY 2022 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2022 HCPCS Code	CY 2022 Long Descriptor	CY 2022 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 2022 HCPCS Code	CY 2022 Long Descriptor	CY 2022 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

BILLING CODE 4120–01–C

2. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is 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+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.[94]

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. In this CY 2022 OPPS/ASC proposed rule, we proposed 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

[94] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: *http://www.medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.*

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 OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+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 2021.

b. Proposed CY 2022 Payment Policy

For 2022, we propose to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals, with the exception of 340B-acquired drugs, at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We propose to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent (as described in section V.B.6). We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055) for more information about our current payment policy for drugs and biologicals acquired with a 340B discount.

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 is not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the 6-percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). For CYs 2020 and 2021, we adopted a policy to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act pursuant to our authority under section 1833(t)(14)(A)(iii)(II) (84 FR 61318 and 85 FR 86039). For 2022, we propose to continue 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, 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 propose to apply this provision to non-SCOD separately payable drugs. Because we propose to establish the average price for a drug paid based on WAC under section 1847A of the Act as WAC+3 percent instead of WAC+6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. We propose that, if finalized, our proposal to pay for drugs or biologicals at WAC+3 percent, rather than WAC+6 percent, would apply whenever WAC-based pricing is used for a drug or biological under 1847A(c)(4). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the payment amount for these drugs (proposed as a rate of WAC minus 22.5 percent) would continue to apply. We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy.

We propose that payments for separately payable drugs and biologicals would be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also propose that the budget neutral weight scalar would not be 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 via the internet on the CMS website), which illustrate the proposed CY 2022 payment of ASP+6 percent for separately payable nonpass-through drugs and biologicals and ASP+6 percent 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, 2021, or WAC, AWP, or mean unit cost from CY 2019 claims data and updated cost report information available for this proposed rule. In general, these published payment rates are not the same as the actual January 2022 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2022 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2021 (July 1, 2021 through September 30, 2021) will be used to set the payment rates that are released for the quarter beginning in January 2022 near the end of December 2021. In addition, payment rates for drugs and biologicals in Addenda A and B to the proposed rule for which there was no ASP information available for April 2021 are based on mean unit cost in the available CY 2019 claims data. If ASP information becomes available for payment for the quarter beginning in January 2022, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for the proposed rule (reflecting April 2021 ASP data) that do not have ASP information available for the quarter beginning in January 2022. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2019 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to the proposed rule are not for January 2022 payment purposes and are only illustrative of the CY 2022 OPPS payment methodology using the most recently available information at the time of issuance of the proposed rule.

c. Biosimilar Biological Products

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 OPPS/ASC proposed rule (82

FR 33630), for CY 2018, we proposed to continue this same payment policy for biosimilar biological products.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), we noted that, with respect to comments we received regarding OPPS payment for biosimilar biological products, in the CY 2018 PFS final rule, CMS finalized a policy to implement separate HCPCS codes for biosimilar biological products. Therefore, consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, HCPCS coding for biosimilar biological products is based on the policy established under the CY 2018 PFS final rule.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), after consideration of the public comments we received, we finalized our proposed payment policy for biosimilar biological products, with the following technical correction: All biosimilar biological products are eligible for pass-through payment and not just the first biosimilar biological product for a reference product. In the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

In addition, in CY 2018, we adopted a policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid the ASP of the biosimilar minus 22.5 percent of the reference product's ASP (82 FR 59367). We adopted this policy in the CY 2018 OPPS/ASC final rule with comment period because we believe that biosimilars without pass-through payment status acquired under the 340B Program should be treated in the same manner as other drugs and biologicals acquired through the 340B Program. As noted earlier, biosimilars with pass-through payment status are paid their own ASP+6 percent of the reference product's ASP. Separately payable biosimilars that do not have pass-through payment status and are not acquired under the 340B Program are also paid their own ASP plus 6 percent of the reference product's ASP. If a biosimilar does not have ASP pricing, but instead has WAC pricing, the WAC pricing add-on of either 3 percent or 6 percent is calculated from the biosimilar's WAC and is not calculated from the WAC price of the reference product.

As noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), several stakeholders raised concerns to us that the payment policy for biosimilars acquired under the 340B Program could unfairly lower the OPPS payment for biosimilars not on pass-through payment status because the payment reduction would be based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, thus resulting in a more significant reduction in payment than if the 22.5 percent was calculated based on the biosimilar's ASP. We agreed with stakeholders that the current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program. In addition, we noted that we believed that these changes would better reflect the resources and production costs that biosimilar manufacturers incur. We also stated that we believe this approach is more consistent with the payment methodology for 340B-acquired drugs and biologicals, for which the 22.5 percent reduction is calculated based on the drug or biological's ASP, rather than the ASP of another product. In addition, we explained that we believed that paying for biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP, rather than 22.5 percent of the reference product's ASP, will more closely approximate hospitals' acquisition costs for these products.

Accordingly, in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), we proposed changes to our Medicare Part B drug payment methodology for biosimilars acquired under the 340B Program. Specifically, for CY 2019 and subsequent years, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP. This proposal was finalized without modification in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58977).

For 2022, we propose to continue our policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We also propose to continue our current policy of paying for nonpass-through biosimilars acquired under the 340B program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2022, we propose to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that 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 in CY 2022. Therefore, we propose for CY 2022 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also propose to rely on CY 2019 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP 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 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 2022 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

4. Payment for Blood Clotting Factors

For CY 2021, 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 (85 FR 86041). That is, for CY 2021, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2021 updated furnishing fee was $0.238 per unit.

For 2022, we propose to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay a furnishing fee for blood clotting factors under the OPPS 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 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/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 OPPS/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 OPPS/ASC final rule with comment period (72 FR 66765), we propose to 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: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

We propose to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website.

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

For CY 2022, we propose to continue to use the same payment policy as in CY 2021 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data, which describes how we determine the payment rate for drugs, biologicals, or radiopharmaceuticals without an ASP. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2022 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this proposed rule, which is available via the internet on the CMS website.

6. CY 2022 OPPS Payment Methodology for 340B Purchased Drugs

a. Overview and Background

Under the OPPS, payment rates for drugs are typically based on their average acquisition cost. This payment is governed by section 1847A of the Act, which generally sets a default rate of average sales price (ASP) plus 6 percent for certain drugs; however, the Secretary has statutory authority to adjust that rate under the OPPS. 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, which was based on findings of the GAO and MedPAC that hospitals were acquiring drugs at a significant discount under HRSA's 340B Drug Pricing Program. As described in the following sections, in December 2018, the United States District Court for the District of Columbia (the district court) concluded that the Secretary lacks the authority to bring the default rate in line with average acquisition cost unless the Secretary obtains survey data from hospitals on their acquisition costs. On July 10, 2019, the district court entered final judgment. The agency appealed to the United States Court of Appeals for the District of Columbia Circuit (hereinafter referred to as ''the D.C. Circuit''), and on July 31, 2020 the court entered an opinion reversing the district court's judgment in this matter. Following the D.C. Circuit's reversal of the lower's court decision, appellees' petition for panel rehearing and petition for rehearing en banc were denied on October 16, 2020. For CY 2021, CMS continued its policy of paying for drugs and biologicals acquired through the 340B Program at ASP minus 22.5 percent.

On January 10, 2021, the appellees filed a petition for a writ of certiorari in the United States Supreme Court. On July 2, 2021, the Supreme Court granted their petition for a writ of certiorari, and directed the parties to argue whether the petitioners' suit challenging HHS's 340B drugs payment adjustment is precluded by section 1833(t) (12).[95]

Background

In the CY 2018 OPPS/ASC proposed rule (82 FR 33558 through 33724), we proposed changes to the OPPS payment methodology for drugs and biologicals (hereinafter referred to collectively as ''drugs'') acquired under the 340B Program. We proposed these changes to better, and more accurately, reflect the resources and acquisition costs that these hospitals incur. We stated our belief that such changes would allow Medicare beneficiaries (and the Medicare program) to pay a more appropriate amount when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program. Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal and adjusted the payment rate for separately payable drugs and biologicals (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. We stated that our goal was to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs, while recognizing the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Congress created the 340B Drug Pricing Program so that the eligible entities, safety net providers, identified in statute, could stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. By

[95] *https://www.supremecourt.gov/orders/courtorders/070221zor_4gc5.pdf*. Accessed July 8, 2021.

design, the 340B Program increases the resources available to these safety net providers by providing discounts on covered outpatient drugs that generate savings that can be used to support patient care or other services. When the program was created, there was an understanding that many of the patients seen by these safety net providers were Medicare and Medicaid beneficiaries. This rule aims to fulfill the goals of different Federal programs, each of which helps ensure access to care for vulnerable populations. Critical access hospitals are not paid under the OPPS, and therefore are not subject to the OPPS payment policy for 340B-acquired drugs. We also excepted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment in CY 2018. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which are excluded from the 340B Program.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79706), we implemented section 603 of the Bipartisan Budget Act of 2015. As a general matter, applicable items and services furnished in certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered outpatient services for purposes of payment under the OPPS and are paid ''under the applicable payment system,'' which is generally the Physician Fee Schedule (PFS). However, consistent with our policy to pay separately payable, covered outpatient drugs and biologicals acquired under the 340B Program at ASP minus 22.5 percent, rather than ASP+6 percent, when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in non-excepted off-campus PBDs paid under the PFS. We adopted this payment policy effective for CY 2019 and subsequent years.

We clarified in the CY 2019 OPPS/ASC proposed rule (83 FR 37125) that the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and that it has been our policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment since the policy was first adopted. The 340B payment adjustment for WAC-priced drugs is WAC minus 22.5 percent. 340B-acquired drugs that are priced using AWP are paid an adjusted amount of 69.46 percent of AWP. The 69.46 percent of AWP is calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we apply the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which is similar to either ASP minus 22.5 percent or WAC minus 22.5 percent.

As discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), to effectuate the payment adjustment for 340B-acquired drugs, we implemented modifier ''JG'', effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as critical access hospitals), or excepted from the 340B drug payment policy for CY 2018, were required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals were excepted from the 340B payment adjustment. These hospitals were required to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and use of modifiers ''JG'' and ''TB''.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), we continued the Medicare 340B payment policies that were implemented in CY 2018 and adopted a policy to pay for nonpass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than of the reference product's ASP. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321), we continued the 340B policies that were implemented in CY 2018 and CY 2019.

Our CY 2018 and 2019 OPPS payment policies for 340B-acquired drugs have been the subject of ongoing litigation. On December 27, 2018, in the case of *American Hospital Association, et al.* v. *Azar, et al.,* the district court concluded in the context of reimbursement requests for CY 2018 that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent for that year.[96] In that same decision, the district court recognized the '' 'havoc that piecemeal review of OPPS payment could bring about' in light of the budget neutrality requirement,'' and ordered supplemental briefing on the appropriate remedy.[97] On May 6, 2019, after briefing on remedy, the district court issued an opinion that reiterated that the 2018 rate reduction exceeded the Secretary's authority, and declared that the rate reduction for 2019 (which had been finalized since the Court's initial order was entered) also exceeded his authority.[98] Rather than ordering HHS to pay plaintiffs their alleged underpayments, however, the district court recognized that crafting a remedy is ''no easy task, given Medicare's complexity,'' [99] and initially remanded the issue to HHS to devise an appropriate remedy while also retaining jurisdiction. The district court acknowledged that ''if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services.'' [100] *Id.* at 19. ''And because HHS has already processed claims under the previous rates, the Secretary would potentially be required to recoup certain payments made to providers; an expensive and time-consuming prospect.'' [101]

We respectfully disagreed with the district court's understanding of the scope of the Secretary's adjustment authority. On July 10, 2019, the district court entered final judgment. The agency appealed to the United States Court of Appeals for the District of Columbia Circuit, (hereinafter referred to as ''the D.C. Circuit''), and on July 31, 2020 the court entered an opinion reversing the district court's judgment in this matter. Following the D.C. Circuit's decision, appellees' petition for panel rehearing and petition for rehearing en banc were denied on October 16, 2020. On January of 2021, appellees petitioned the United States Supreme Court for a writ of certiorari. On July 2, 2021, the Court granted the petition.

Before the D.C. Circuit upheld our authority to pay ASP minus 22.5

[96] *American Hosp. Ass'n, et al.* v. *Azar, et al.,* No. 1:18–cv–2084 (D.D.C. Dec. 27, 2018).

[97] *Id.* at 35 (quoting *Amgen, Inc.* v. *Smith,* 357 F.3d 103, 112 (D.C. Cir. 2004) (citations omitted)).

[98] *See* May 6, 2019 Memorandum Opinion, Granting in Part Plaintiffs' Motion for a Permanent Injunction; Remanding the 2018 and 2019 OPPS Rules to HHS at 10–12.

[99] *Id.* at 13.

[100] *Id.* at 19.

[101] *Id.* (citing Declaration of Elizabeth Richter).

percent, we stated in the CY 2020 OPPS/ASC final rule with comment period that we were taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. Notably, after the CY 2020 OPPS/ASC proposed rule was issued, we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for certain quarters in CY 2018 and 2019. We stated that such survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for cost years going forward, and also may be used to devise a remedy for prior years if the district court's ruling was upheld on appeal. The district court itself acknowledged that CMS may base the Medicare payment amount on average acquisition cost when survey data are available.[102] No 340B hospital disputed in the rulemakings for CY 2018 and 2019 that the ASP minus 22.5 percent formula was a conservative adjustment that represented the minimum discount that hospitals receive for drugs acquired through the 340B program, which is significant because 340B hospitals have internal data regarding their own drug acquisition costs. We stated in the CY 2020 OPPS/ASC final rule with comment period that we thus anticipated that survey data collected for CY 2018 and 2019 would confirm that the ASP minus 22.5 percent rate is a conservative amount that overcompensates covered entity hospitals for drugs acquired under the 340B program. We also explained that a remedy that relies on such survey data could avoid the complexities referenced in the district court's opinion. For a complete discussion of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Outpatient Drugs, we refer readers to the CY 2021 OPPS/ASC Proposed Rule (85 FR 48882 through 48891) and the CY 2021 OPPS/ASC Final Rule with comment period (85 FR 86042 through 86055).

We proposed a payment rate for 340B drugs of ASP minus 28.7 percent based on survey data, and also proposed in the alternative that the agency could continue its current policy of paying ASP minus 22.5 percent for CY 2021. We explained that we adopted the OPPS 340B payment policy based on the average minimum discount for 340B-acquired drugs being approximately ASP minus 22.5 percent. The estimated discount was based on a MedPAC analysis identifying 22.5 percent as a conservative minimum discount that 340B entities receive when they purchase drugs under the 340B program, which we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52496). We emphasized that we continue to believe that ASP minus 22.5 percent is an appropriate payment rate for 340B-acquired drugs under the authority of section 1833(t)(14)(A)(iii)(II) for the reasons we stated when we adopted this policy in CY 2018 (82 FR 59216). We pointed out that on July 31, 2020, the D.C. Circuit reversed the decision of the district court, holding that this interpretation of the statute was reasonable. Therefore, we also proposed in the alternative that the agency could continue the current Medicare payment policy for CY 2021. If adopted, we stated that this proposed policy would continue the current Medicare payment policy for CY 2021.

Based on feedback from stakeholders, we stated that we believed maintaining the current payment policy of paying ASP minus 22.5 percent for 340B drugs was appropriate in order to maintain consistent and reliable payment for these drugs both for the remainder of the PHE and after its conclusion to give hospitals some certainty as to payments for these drugs. We explained that continuing our current policy also gives us more time to conduct further analysis of hospital survey data for potential future use for 340B drug payment. We also noted that any changes to the current 340B payment policy would be adopted through public notice and comment rulemaking.

Finally, we stated that while we believe our methods to conduct the 340B Drug Acquisition Cost Survey, as well as the methodology we used to calculate the proposed average or typical discount received by 340B entities on 340B drugs, are valid, we nonetheless recognize the comments that we received from stakeholders. Utilization of the survey data is complex, and we emphasized that we wish to continue to evaluate how to balance and weigh the use of the survey data, the necessary adjustments to the data, and the weighting and incorporation of ceiling prices—all to determine how best to take the relevant factors into account for potentially using the survey to set Medicare OPPS drug payment policy. We stated that we would continue to assess commenters' feedback as we explore whether survey data should be considered hospital acquisition cost data for purposes of paying for drugs acquired under section 1833(t)(14)(A)(iii)(I).

CY 2022 Proposed 340B Drug Payment Policy

For CY 2022, we are proposing to continue our current policy without modification of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs paid under the PFS. We are proposing, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, to pay for separately payable Medicare Part B drugs and biologicals (assigned status indicator ''K''), other than vaccines and drugs on pass-through status, that are acquired through the 340B Program at ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. We propose to continue our current policy for calculating payment for 340B-acquired biosimilars, which is discussed in section V.B.2.c. of the CY 2019 OPPS/ASC final rule with comment period, and would continue the policy we finalized in CY 2019 to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS.

We are also proposing to continue the 340B payment adjustment for WAC-priced drugs, which is WAC minus 22.5 percent. 340B-acquired drugs that are priced using AWP would continue to be paid an adjusted amount of 69.46 percent of AWP. Additionally, we are proposing to continue to exempt rural sole community hospitals (as described under the regulations at § 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment. These hospitals will continue to report informational modifier ''TB'' for 340B-acquired drugs, and will continue to be paid ASP plus 6 percent. We may revisit our policy to exempt rural SCHs, as well as other hospital types, from the 340B drug payment reduction in future rulemaking.

We are also continuing to require hospitals to use modifiers to identify 340B-acquired drugs. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and the requirements for use of modifiers ''JG'' and ''TB''. We believe maintaining the current policy of paying ASP minus 22.5 percent for 340B drugs is appropriate given the July 31, 2020 D.C. Circuit decision, which reversed the district court's decision and found that the interpretation of the statute was reasonable when the 340B drug

[102] *See American Hosp. Assoc.* v. *Azar,* 348 F. Supp. 3d 62, 82 (D.D.C. 2018).

payment policy was implemented in CY 2018. We note that any changes to the current 340B payment policy would be adopted through public notice and comment rulemaking.

While we believe the Secretary has discretion to propose a payment rate for 340B drugs based on the 2020 survey results, we also continue to believe that the current payment rate of ASP minus 22.5 percent represents the minimum discount that 340B covered entities receive, which more closely aligns the payment rate with the resources expended by 340B hospitals to acquire such drugs compared to a payment rate of ASP plus 6 percent, while also recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Additionally, we continue to believe it is important to provide consistency and reliable payment for these drugs both for the remainder of the Public Health Emergency (PHE) and after its conclusion to give hospitals some certainty as to payments for these drugs.

7. High Cost/Low Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933).

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 2021, the payment rate for APC 5053 (Level 3 Skin Procedures) was $524.17, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,715.36, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $3,522.15. This information also is available in Addenda A and B of the CY 2021 OPPS/ASC final rule with comment period, as issued with the final rule correction notice (86 FR 11428) (the correction notice and corrected Addenda A and B are available via the internet on the CMS website).

We have continued the high cost/low cost categories policy since CY 2014, and we propose to continue it for CY 2022. 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 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/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 OPPS/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 does not exceed either the MUC threshold or the PDC threshold to the low cost group (85 FR 86059).

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 stakeholders 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 stakeholders requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and also requested that CMS consider 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+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 stakeholders about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPS/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 OPPS/ASC final rule with comment

period (82 FR 59347). We stated in the CY 2018 OPPS/ASC proposed rule that the goal of our proposal to retain the same skin substitute cost group assignments in CY 2018 as in CY 2017 was to maintain similar levels of payment for skin substitute products for CY 2018 while we study our skin substitute payment methodology to determine whether refinements to the existing policies are consistent with our policy goal of providing payment stability for skin substitutes.

We stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347) that we would continue to study issues related to the payment of skin substitutes and take these comments into consideration for future rulemaking. We received many responses to our request for comments in the CY 2018 OPPS/ASC proposed rule about possible refinements to the existing payment methodology for skin substitutes that would be consistent with our policy goal of providing payment stability for these products. In addition, several stakeholders have made us aware of additional concerns and recommendations since the release of the CY 2018 OPPS/ASC final rule with comment period. As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58967 through 58968), we identified four potential methodologies that have been raised to us that we encouraged the public to review and provide comments on. We stated in the CY 2019 OPPS/ASC final rule with comment period that we were especially interested in any specific feedback on policy concerns with any of the options presented as they relate to skin substitutes with differing per day or per episode costs and sizes and other factors that may differ among the dozens of skin substitutes currently on the market.

For CY 2020, we sought more extensive comments on the two policy ideas that generated the most comment from the CY 2019 comment solicitation. One of the ideas was to establish a payment episode between 4 to 12 weeks where a lump-sum payment would be made to cover all of the care services needed to treat the wound. There would be options for either a complexity adjustment or outlier payments for wounds that require a large amount of resources to treat. The other policy idea would be to eliminate the high cost and low cost categories for skin substitutes and have only one payment category and set of procedure codes for the application of all graft skin substitute products. Please refer to the CY 2019 OPPS final rule (83 FR 58967 to 58968) and the CY 2020 OPPS final rule (84 FR 61328 to 61331) for a detailed summary and discussion of the comments we received in response to these comment solicitations. We are continuing to consider the comments we received in response to these comment solicitations.

b. Proposals for Packaged Skin Substitutes for CY 2022

For CY 2022, 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 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. Consistent with the methodology as established in the CY 2014 through CY 2018 final rules with comment period, we analyzed CY 2019 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 2022 MUC threshold is $48 per cm^2 (rounded to the nearest $1) and the proposed CY 2022 PDC threshold is $949 (rounded to the nearest $1). We also propose that our definition of skin substitutes includes synthetic skin substitute products in addition to biological skin substitute products as described in section V.B.7.d. of this proposed rule. We also want to clarify that the availability of an 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 2022, as we did for CY 2021, 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 with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group. For CY 2022, we propose that any skin substitute product that was assigned to the high cost group in CY 2021 would be assigned to the high cost group for CY 2022, regardless of whether it exceeds or falls below the CY 2022 MUC or PDC threshold. This policy was established in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59346 through 59348).

For 2022, 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+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we propose to use WAC+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+3 percent instead of WAC+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+3 percent for separately payable drugs and biologicals that do not have ASP data available. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2022 MUC and PDC thresholds. We also propose to continue to include synthetic products in addition to biological products in our description of skin substitutes. For a discussion of our existing policy under which we assign skin substitutes without pricing information to the low cost category until pricing information is available, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70436). For a discussion of how we determined that synthetic skin graft sheet products can be reported with graft skin substitute procedure codes, we refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86064 to 86067). Table 32 displays the final CY 2022 cost category assignment for each skin substitute product.

BILLING CODE 4120–01–P

TABLE 32: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2022

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Proposed CY 2022 High/Low Cost Assignment
C1849	Skin substitute, synthetic	High	High
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*

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Proposed CY 2022 High/Low Cost Assignment
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	Low	Low
Q4135	Mediskin	Low	Low
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High
Q4146	Tensix, 1cm	High	High
Q4147	Architect ccm 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

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Proposed CY 2022 High/Low Cost Assignment
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	Low	High
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	Low	Low
Q4173	Palingen or palingen xplus	High	High
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Flowcramniopatch, 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	Low	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	Low	High
Q4190	Artacent ac 1 sq cm	Low	High

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Proposed CY 2022 High/Low Cost Assignment
Q4191	Restorigin 1 sq cm	Low	Low
Q4193	Coll-e-derm 1 sq cm	Low	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	Low	High
Q4200	Skin te 1 sq cm	Low	High
Q4201	Matrion 1 sq cm	Low	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	Low	High
Q4210	Axolotl graf dualgraf sq cm	Low	Low
Q4211	Amnion bio or axobio sq cm	Low	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	Low
Q4217	Woundfix biowound plus xplus	Low	Low
Q4218	Surgicord per sq cm	Low	Low
Q4219	Surgigraft dual per sq cm	Low	High
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	Low

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Proposed CY 2022 High/Low Cost Assignment
Q4222	Progenamatrix, per sq cm	Low	High
Q4226	Myown harv prep proc sq cm	High	High
Q4227	Amniocore per sq cm	Low	High
Q4228	Bionextpatch, per sq cm	Low	Low
Q4229	Cogenex amnio memb per sq cm	Low	Low
Q4232	Corplex, per sq cm	Low	High
Q4234	Xcellerate, per sq cm	High	High
Q4235	Amniorepair or altiply sq cm	Low	Low
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	Low	High
Q4238	Derm-maxx, per sq cm	Low	High
Q4239	Amnio-maxx or lite per sq cm	Low	High
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	Low	Low
Q4249	Amniply, per sq cm	Low	High
Q4250	AmnioAMP-MP per sq cm	Low	Low
Q4254	Novafix dl per sq cm	Low	Low
Q4255	Reguard, topical use per sq	Low	Low

* These products do not exceed either the proposed MUC or PDC threshold for CY 2022, but are assigned to the high cost group because they were assigned to the high cost group in CY 2021.

BILLING CODE 4120–01–C

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the

applicable percentage and the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2022 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 2022. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2021 or beginning in CY 2022. The sum of the proposed CY 2022 pass-through spending estimates for these two groups of device categories equaled the proposed total CY 2022 pass-through spending estimate for device categories with pass-through payment status. We based the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the proposed rule, we propose to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2022, 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. Our estimate of drug and biological pass-through payment for CY 2022 for this group of items is $462.4 million, as discussed below, because we propose that most non pass-through separately payable drugs and biologicals would be paid under the CY 2022 OPPS at ASP+6 percent with the exception of 340B-acquired separately payable drugs, which we propose would be paid at ASP minus 22.5 percent, and because we propose to pay for CY 2022 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A. of this CY 2022 OPPS/ASC proposed rule.

Furthermore, 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 will not be 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 drugs and biologicals, as discussed in section V.B.1.c. of this CY 2022 OPPS/ASC proposed rule. We propose that all of these policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2022. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2022 is not $0, as discussed below. In section V.A.6. of this proposed rule, we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we propose to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. 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 this 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 2022. 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 2021 or beginning in CY 2022. The sum of the CY 2022 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2022 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending

For 2022, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2022, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2021 (85 FR 86068).

For the first group, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2022, there are 9 active categories for CY 2022. The active categories are described by HCPCS codes C2596, C1734, C1982, C1824, C1839, C1748, C1825, C1052, and C1062. Based on the information from the device manufacturers, we estimate that HCPCS code C2596 will cost $11.3 million in pass-through expenditures in CY 2022, HCPCS C1734 will cost $36.9 million in pass-through

expenditures in CY 2022, HCPCS code C1982 will cost $116.3 million in pass-through expenditures in CY 2022, HCPCS code C1824 will cost $46 million in pass-through expenditures in CY 2022, HCPCS code C1839 will cost $500,000 in pass-through expenditures in CY 2022, HCPCS code C1748 will cost $39.1 million in pass-through expenditures in CY 2022, HCPCS code C1825 will cost $3.5 million in pass-through expenditures in CY 2022, HCPCS code C1052 will cost $40 million in pass-through expenditures in CY 2022, and HCPCS code C1062 will cost $14.3 million in pass-through expenditures in CY 2022. Therefore, we propose an estimate for the first group of devices of $307.9 million.

In estimating our proposed CY 2022 pass-through spending for device categories in the second group, we included: Device categories that we assumed at the time of the development of this proposed rule will be newly eligible for pass-through payment in CY 2022; additional device categories that we estimated could be approved for pass-through status after the development of the proposed rule and before January 1, 2022; and contingent projections for new device categories established in the second through fourth quarters of CY 2022. For CY 2022, we propose to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. The proposed estimate of CY 2022 pass-through spending for this second group of device categories is $244.4 million.

To estimate proposed CY 2022 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 2022, we propose to use the CY 2019 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 those drugs or biologicals to project the CY 2022 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2022, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for non pass-through drugs and biologicals that will be separately paid. Separately payable drugs are paid at a rate of ASP+6 percent with the exception of 340B-acquired drugs, for which we propose to pay ASP minus 22.5 percent. Therefore, the payment rate difference between the pass-through payment amount and the non pass-through payment amount is $462.4 million for this group of drugs. Because payment for policy-packaged drugs and biologicals is packaged if the product was not paid separately due to its pass-through payment status, we proposed to include in the CY 2022 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment, which we estimate for CY 2022 for the first group of policy-packaged drugs to be $0 since there are currently no policy-packaged drugs for which we have cost data that will be on pass-through in CY 2022.

To estimate proposed CY 2022 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 the proposed rule were newly eligible or recently became eligible for pass-through payment in CY 2022, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2022 and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2022), 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 2022 pass-through payment estimate. We also propose to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2022 pass-through payments for this second group of drugs, we calculate a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

We estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2022 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2022 would be approximately $1,024.7 million (approximately $552.3 million for device categories and approximately $472.4 million for drugs and biologicals) which represents 1.24 percent of total projected OPPS payments for CY 2022 (approximately $83 billion). Therefore, we estimate that pass-through spending in CY 2022 will not amount to 2.0 percent of total projected OPPS CY 2022 program spending.

As discussed in section X.E. of this proposed rule, due to the effects of the COVID–19 PHE, we are proposing to generally use CY 2019 claims data instead of CY 2020 claims data in establishing the CY 2022 OPPS rates and to use cost report data from the same set of cost reports originally used in CY 2021 final rule OPPS ratesetting. If our proposal to use CY 2019 data, rather than CY 2020 data, to inform CY 2022 ratesetting, is finalized, we would effectively remove approximately one year of pass-through data collection time for ratesetting purposes. Therefore, for CY 2022, in section X.E. of this proposed rule, we are proposing to use our equitable adjustment authority under 1833(t)(2)(E) to provide up to four quarters of separate payment for 21 drugs and biologicals whose pass-through payment status will expire on March 31, 2022, June 30, 2022, or September 30, 2022 and six drugs and biologicals and one device category whose pass-through payment status will expire on December 31, 2021. This would ensure that we have a full year of claims data from CY 2021 to use for CY 2023 ratesetting and would allow us to avoid using CY 2020 data to set rates for these pass-through drugs, biologicals, and the device category for CY 2022.

We estimated the spending for the drugs, biologicals, and device category for which we are proposing to provide separate payment for the remainder of CY 2022 using our equitable adjustment authority. To estimate proposed CY 2022 spending for the one device pass-through category with pass-through status expiring on December 31, 2021, we also used the general methodology

described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778). For this device category, we calculate a proposed spending estimate of $3.5 million. To estimate proposed CY 2022 spending for the six drugs with pass-through status expiring on December 21, 2021 and the 18 drugs and three biologicals with pass-through status expiring on March 30, 2022, June 30, 2022, and September 30, 2022 we performed an analysis similar to the analysis for the first group of drugs and biologicals described earlier in this section where we estimated the pass-through payment amount as the difference between ASP+6 percent and the payment rate for non pass-through drugs and biologicals that will be separately paid. For this group, we calculate a proposed spending estimate for CY 2022 of $61.5 million. We estimate that total spending for these 27 drugs and biologicals and one device category would be approximately $65 million for CY 2022. The drugs, biologicals, and device category for which we propose to provide separate payment for one to four quarters in CY 2022 are listed in table 33 below.

BILLING CODE 4120–01–P

TABLE 33:
DEVICE CATEGORY, DRUGS, AND BIOLOGICALS WITH EXPIRING PASS-THROUGH STATUS THAT WOULD RECEIVE SEPARATE PAYMENT FOR ONE TO FOUR QUARTERS IN CY 2022

HCPCS Code	Long Descriptor	Pass-Through Status Effective Date	Pass-Through Status Expiration End Date	Proposed Adjustment Equivalent to an Extension of Pass-through Status (number of quarters)
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads)	01/01/2019	12/31/2021	4
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	01/01/2019	12/31/2021	4
J0222	Injection, Patisiran, 0.1 mg	01/01/2019	12/31/2021	4
J0291	Injection, plazomicin, 5 mg	01/01/2019	12/31/2021	4
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	01/01/2019	12/31/2021	4
J2798	Injection, risperidone, (perseris), 0.5 mg	01/01/2019	12/31/2021	4
J9204	Injection, mogamulizumab-kpkc, 1 mg	01/01/2019	12/31/2021	4
J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	04/01/2019	03/31/2022	3
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	04/01/2019	03/31/2022	3
J0642	Injection, levoleucovorin 0(khapzory), 0.5 mg	01/01/2020	03/31/2022	3
J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	04/01/2019	03/31/2022	3
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)	04/01/2019	03/31/2022	3
J3245	Injection, tildrakizumab, 1 mg	04/01/2019	03/31/2022	3
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	04/01/2019	03/31/2022	3
J9119	Injection, cemiplimab-rwlc, 1 mg	04/01/2019	03/31/2022	3

J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	04/01/2019	03/31/2022	3
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	04/01/2019	03/31/2022	3
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	04/01/2019	03/31/2022	3
Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	04/01/2019	03/31/2022	3
C9047	Injection, caplacizumab-yhdp, 1 mg	07/01/2019	06/30/2022	2
J0121	Injection, omadacycline, 1 mg	07/01/2019	06/30/2022	2
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	07/01/2019	06/30/2022	2
J1303	Injection, ravulizumab-cwvz, 10 mg	07/01/2019	06/30/2022	2
J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	07/01/2019	06/30/2022	2
J9210	Injection, emapalumab-lzsg, 1 mg	07/01/2019	06/30/2022	2
J9269	Injection, tagraxofusp-erzs, 10 micrograms	07/01/2019	06/30/2022	2
J3111	Injection, romosozumab-aqqg, 1 mg	10/01/2019	09/30/2022	1
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	10/01/2019	09/30/2022	1

BILLING CODE 4120–01–C

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2022, we propose to continue with our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of the current clinic and ED hospital outpatient visits policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also propose to continue our payment policy for critical care services for CY 2022. For a description of the current payment policy for critical care services, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). In this proposed rule, we are seeking public comments on any changes to these codes that we should consider for future rulemaking cycles. We continue to encourage commenters to provide the data and analysis necessary to justify any suggested changes.

We are continuing the clinic visit payment policy for CY 2022 and beyond. We will 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 excepted off-campus provider-based departments. The PFS-equivalent rate for CY 2022 is 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate). Under this policy, these departments will be paid approximately 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that is applied in CY 2022) for the clinic visit service in CY 2022. We will continue to monitor the effect of this change in Medicare payment policy, including the volume of these types of OPD services.

VIII. Payment for Partial Hospitalization Services

A. 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 guidance regarding PHP.

In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule (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 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016, 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 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381, and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352). We refer readers to section VIII.D. of this proposed rule for a discussion of the proposed updates and the applicability for CY 2021.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized our proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID–19 Public Health Emergency (PHE), hospital and CMHC staff are 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. These provisions apply only for the duration of the COVID–19 PHE.

In the CY 2021 final rule (85 FR 86073 through 86080), we finalized a CMHC geometric mean per diem cost of $136.14 and a final hospital-based PHP geometric mean per diem cost of $253.76 using the most recent updated claims and cost data. In the CY 2021 proposed rule (85 FR 48901 through 48905), we had proposed, for CY 2021 and subsequent years, to use the CY 2021 CMHC geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for CMHCs of $121.62 that was calculated for CY 2020 ratesetting (84 FR 61339 through 61344), as the basis for developing the CY 2021 CMHC APC per diem rate. We had also proposed, for CY 2021 and subsequent years, to use the CY 2021 hospital-based geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for hospital-based providers of $222.76 that was calculated for CY 2020 ratesetting (84 FR 61344 through 61345). We explained in the final rule that the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor,

therefore a floor was not necessary at the time, and we did not finalize the proposed cost floors in the CY 2021 OPPS/ASC final rule with comment period.

B. Proposed PHP APC Update for CY 2022

1. Proposed PHP APC Geometric Mean Per Diem Costs

In summary, for CY 2022 only, we propose to use the CY 2022 CMHC geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for CMHCs of $136.14, which is the final CMHC geometric mean per diem cost calculated last year for CY 2021 ratesetting (85 FR 86080), as the basis for developing the CY 2022 CMHC APC per diem rate. We also propose, for CY 2022 only, to use the CY 2022 hospital-based geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for hospital-based providers of $253.76 calculated last year for CY 2021 ratesetting (85 FR 86080). Following this methodology, we propose to use the cost floor value of $136.14 for CMHCs as the basis for developing the CY 2022 CMHC APC per diem rate, and to use the cost floor value of $253.76 as the basis for developing the CY 2021 hospital-based APC per diem rate. As discussed in section VIII.B.2 of this proposed rule, we propose to use the latest available CY 2019 claims and cost data from the CY 2021 rulemaking to determine CY 2022 geometric mean per diem costs in this proposed rule, and we propose that if the final CY 2022 cost for CMHCs or hospital-based PHPs is calculated to be above the proposed floor for that provider type, we would use the final calculated cost instead of the floor. The rationale behind this proposal is discussed in greater detail in sections VIII.B.2.a and VIII.B.2.b of this proposed rule.

Lastly, in accordance with our longstanding policy, we propose to continue to use CMHC APC 5853 (Partial Hospitalization (three or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (three or More Services Per Day)). These proposals are discussed in more detail below.

2. Development of the Proposed PHP APC Geometric Mean Per Diem Costs

In preparation for CY 2022, we followed the PHP ratesetting methodology described in section VIII.B.2. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to calculate the PHP APCs' geometric mean per diem costs and payment rates for APCs 5853 and 5863, incorporating the modifications made in the CY 2017 OPPS/ASC final rule with comment period. As discussed in section VIII.B.1. of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687), the geometric mean per diem cost for hospital-based PHP APC 5863 is based upon actual hospital-based PHP claims and costs for PHP service days providing three or more services. Similarly, the geometric mean per diem cost for CMHC APC 5853 is based upon actual CMHC claims and costs for CMHC service days providing three or more services. In addition, for this CY 2022 proposed rulemaking, we used 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). We discuss this proposed change in greater detail in section VIII.B.2.a of this OPPS/ASC proposed rule.

As discussed in section X.E of this OPPS/ASC proposed rule, we analyzed OPPS cost and claims information from CY 2019 and CY 2020 to better understand the effects of the COVID–19 PHE on outpatient services, including PHP, and to identify which data would be the best available for ratesetting. As discussed in that section, we observed a number of changes, likely as a result of the COVID–19 PHE, in the CY 2020 OPPS claims that we would ordinarily use for ratesetting, and this includes changes in the claims for partial hospitalization. For PHP services in particular, we identified that for hospital-based PHPs, the number of PHP days in our trimmed CY 2020 claims dataset was approximately 53 percent less than the number of PHP days in our trimmed CY 2019 claims dataset; and for CMHCs, the number of PHP days in our trimmed CY 2020 claims dataset was approximately 45 percent less than the number of PHP days in our trimmed CY 2019 claims dataset.

For this CY 2022 ratesetting, we are proposing to use CY 2019 claims and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking. We believe this is appropriate and necessary for PHP services, because of the substantial decrease in the number of PHP days in the CY 2020 claims dataset, which we would normally use for ratesetting. Furthermore, there was a substantial decrease in the number of PHP providers in the CY 2020 data. Our trimmed CY 2020 claims dataset contains cost and claim information from 35 fewer hospital-based PHP providers than are in the CY 2019 data. These significant decreases in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims lead us to believe that CY 2020 data are not the best overall approximation of expected PHP services in CY 2022. We believe that CY 2019 data, as the most recent complete calendar year of data prior to the COVID–19 PHE, are a better approximation of expected CY 2022 PHP services. Therefore, as discussed in section X.E of this OPPS/ASC proposed rule, and consistent with what CMS is proposing to do for other APCs under the OPPS, we are proposing to use CY 2019 claims and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 CMHC and hospital-based PHP APC per diem costs.

The CMHC or hospital-based PHP APC per diem costs are the provider-type specific costs derived from the latest updated CY 2019 claims and cost data from the CY 2021 rulemaking. The CMHC or hospital-based PHP APC per diem payment rates are the national unadjusted payment rates calculated from the CMHC or hospital-based PHP APC geometric mean per diem costs, after applying the OPPS budget neutrality adjustments described in section XX of this proposed rule.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this CY 2022 OPPS/ASC proposed rule, we prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465). However, as discussed above, we propose to use CY 2019 claims data and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 CMHC PHP APC per diem cost.

For this CY 2022 proposed rule, we also used cost and charge information from HCRIS as the basis for determining the CMHC CCRs used to calculate the geometric mean per diem cost for CMHC APC 5853. Following the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462), we calculated the CCR based on Medicare costs and charges. However, we note that CMHCs are now reporting their costs using the newer cost

reporting form, Form CMS 2088–17, which has different lines and columns than the ones described in the CY 2016 OPPS/ASC final rule for Form CMS 2088–92. Therefore, to calculate each CMHC's CCR for this proposed rulemaking, we divided costs from Worksheet C, Line 50, Column 5 by charges from Worksheet C, Line 50, Column 4.

As noted above, prior to this year's proposed rulemaking, our longstanding methodology for calculating CCRs for CMHCs has been to use the CCRs from the OPSF. As discussed in the CY 2004 OPPS/ASC final rule (68 FR 63468), a Program Memorandum was issued on January 17, 2003, which directed the fiscal intermediaries to recalculate hospital and CMHC cost-to-charge ratios and to update the cost-to-charge ratios on an ongoing basis in the OPSF, which was used as the basis for the CCRs used in calculating the geometric mean per diem costs for CMHCs. Subsequently, in the CY 2009 OPPS/ASC final rule (73 FR 68690), commenters addressed the fact that cost report information for CMHCs was not at that time included in HCRIS, and recommended that CMS base its calculations only in the cost report information that the agency can verify directly and not on data provided by the fiscal intermediary. CMS responded in the same OPPS/ASC final rule that it was working to include CMHC cost reports in the system, but that the CCRs from the OPSF continued to be the best available data for ratesetting. In the CY 2011 OPPS/ASC final rule (75 FR 71993 through 71994), commenters requested that CMHC cost report information be included in HCRIS, and CMS explained that CMHC cost reports would begin to be available in HCRIS starting in early 2011. Since that time, CMHC cost reports have become available in HCRIS. Because the data is now available and consistently populated based on the cost reports that CMHCs submit, we believe that using cost information from HCRIS would be more consistent with the methodology for calculating most other OPPS services, including hospital-based PHP services. Therefore, we are proposing for CY 2022 and future years to use HCRIS as the source for CMHC cost information used for calculating the geometric mean per diem cost for CMHC APC 5853.

Prior to calculating the proposed geometric mean per diem cost for CMHC APC 5853, we prepare the data by first applying trims and data exclusions, and assessing CCRs as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), so that ratesetting is not skewed by providers with extreme data. Before any trims or exclusions were applied, there were 40 CMHCs in the PHP claims data file. Under the ±2 standard deviation trim policy, we exclude any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day was more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. In applying this trim for CY 2022 ratesetting, one CMHC had geometric mean costs per day below the trim's lower limit of $32.84, and one had geometric mean costs per day above the trim's upper limit of $491.85. Therefore, we are excluding data for ratesetting from these 2 CMHCs because of the ±2 standard deviation trim.

In accordance with our PHP ratesetting methodology (80 FR 70465), we also remove service days with no wage index values, because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). For this CY 2022 proposed rule ratesetting, no CMHC was missing wage index data for all of its service days and, therefore, no CMHC was excluded. We also exclude providers without any days containing 3 or more units of PHP-allowable services. One provider is excluded from ratesetting because it had no days containing 3 or more units of PHP-allowable services. In addition to our trims and data exclusions, before calculating the PHP APC geometric mean per diem costs, we also assess CCRs (80 FR 70463). Our longstanding PHP OPPS ratesetting methodology defaults any CMHC CCR that is not available or any CMHC CCR greater than one to the statewide hospital CCR associated with the provider's urban/rural designation and their state location (80 FR 70463). For this CY 2022 OPPS/ASC proposed rule ratesetting, there are 3 CMHCs with CCRs greater than one, and 12 CMHCs with missing CCR information. Therefore, we are defaulting the CCRs for these 15 CMHCs for ratesetting to the applicable statewide hospital CCR for each CMHC based on its urban/rural designation and its state location.

In summary, these data preparation steps adjusted the CCR during our ratesetting process for 15 CMHCs having either a CCR greater than one or having no CCR. We are also excluding one CMHC because it had no days containing 3 or more services and 2 CMHCs for failing the ±2 standard deviation trim, resulting in the inclusion of 37 CMHCs. There were 564 CMHC claims removed during data preparation steps due to the ±2 standard deviation trim or because they either had no PHP allowable- codes or had zero payment days, leaving 10,370 CMHC claims in our CY 2022 proposed rule ratesetting modeling. After applying all of the previously listed trims, exclusions, and adjustments, we followed the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79688, and 79691), using the CMHC CCRs calculated based on the cost information from HCRIS as discussed in this OPPS/ASC proposed rule, to calculate the CMHC APC geometric mean per diem cost.[103] The calculated CY 2022 geometric mean per diem cost for all CMHCs for providing three or more services per day (CMHC APC 5853) is $130.41, a decrease from $136.14 calculated last year for CY 2021 ratesetting (85 FR 86080).

We considered whether a geometric mean per diem cost for CMHCs of $130.41 would be appropriate for calculating the CMHC APC 5853 per diem payment rate for CY 2022. As discussed above, we used the latest available CY 2019 claims and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 CMHC PHP APC per diem cost, because decreases that we observed in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims have led us to believe that the CY 2019 data, rather than the CY 2020 data, are the best overall approximation of expected PHP services in CY 2022. We considered what effect a decrease from the $136.14 calculated last year for the CY 2021 CMHC PHP APC might have on CMHCs

[103] Each revenue code on the CMHC claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the CMHC's overall CCR (or statewide CCR, where the overall CCR was greater than 1 or was missing) to estimate CMHC costs. Only the claims service lines containing PHP allowable HCPCS codes and PHP allowable revenue codes from the CMHC claims remaining after trimming are retained for CMHC cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. CMHC service days must have three or more services provided to be assigned to CMHC APC 5853. The final geometric mean per diem cost for CMHC APC 5853 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. CMHC service days with costs ±3 standard deviations from the geometric mean costs within APC 5853 are deleted and removed from modeling. The remaining PHP service days are used to calculate the final geometric mean per diem cost for each PHP APC by taking the *n*th root of the product of *n* numbers for days where three or more services were provided.

and Medicare beneficiaries. Recognizing the disruption that the ongoing COVID–19 PHE appears to be having on CMHCs' operations, we believe it is important for CMS to continue to support Medicare beneficiaries' access to critical PHP services during the COVID–19 PHE by helping maintain the stability of payments to PHP providers. We are concerned that a decrease in the geometric mean per diem cost for CMHC APC 5853 would result in a disruption to CMHC payments at a time when, despite the large decrease in the number of PHP days that we observed in our CY 2020 PHP claims data, the need for mental health services has increased.[104] Therefore, rather than proposing to calculate the CMHC APC 5853 payment rate based on the calculated geometric mean per diem cost of $130.41, we are instead proposing a cost floor to stabilize the geometric mean per diem costs finalized in the prior year, CY 2021. The final CY 2021 geometric mean per diem cost for CMHC APC 5853, which was calculated for the CY 2021 OPPS/ASC final rule based on CY 2019 claims, is $136.14, which we are proposing as the cost floor for CY 2022. Therefore, because the calculated geometric mean per diem cost for CMHC APC 5853 is below the cost floor, we are proposing to calculate the CY 2022 CMHC APC 5853 payment rate based on the cost floor of $136.14. We also propose that if the final CY 2022 geometric mean per diem cost is calculated to be higher than $136.14, then we would use the calculated geometric mean per diem cost.

As discussed earlier in this section, 3 CMHCs in our dataset had CCRs greater than 1, and 12 CMHCs had missing CCRs. We want to remind readers that our PHP ratesetting methodology depends heavily on provider-reported costs. We strongly encourage CMHCs to review cost reporting instructions to be sure they are reporting their costs correctly. These instructions are available in chapter 45 of the Provider Reimbursement Manual (PRM), Part 2, available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals*. We want to reiterate that it is a requirement for CMHCs, unless they are approved as a low-utilization or no-utilization provider in accordance with PRM–1, chapter 1, section 110 (42 CFR 413.24(g) and (h)), to file full cost reports, to help us capture accurate CMHC costs in rate setting. We furthermore encourage those CMHCs that do not file full cost reports to consider doing so.

We continue to recognize that because the CMHC ratesetting dataset is small (n=37), changes in costs from a small number of providers can influence the overall geometric mean per diem cost calculation. We are considering approaches to address cost fluctuations in future years, however, we are not proposing a methodology at this time.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this CY 2022 proposed rule, we prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for hospital-based PHP providers, which is similar to that used for CMHCs. However, as discussed above, we propose to use CY 2019 claims data and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 hospital-based PHP APC per diem cost. The CY 2019 PHP claims included data for 449 hospital-based PHP providers for our calculations in this CY 2022 OPPS/ASC proposed rule.

Consistent with our policies, as stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), we prepared the data by applying trims and data exclusions. We applied a trim on hospital service days for hospital-based PHP providers with a CCR greater than 5 at the cost center level. To be clear, the CCR greater than 5 trim is a service day-level trim in contrast to the CMHC ±2 standard deviation trim, which is a provider-level trim. Applying the CCR greater than 5 trim removed affected service days from one hospital-based PHP provider from our proposed ratesetting. However, 100 percent of the service days for this hospital-based PHP provider had at least one service associated with a CCR greater than 5, so the trim removed this provider entirely from our proposed ratesetting. In addition, 68 hospital-based PHPs were removed for having no days with PHP payment. Two hospital-based PHPs were removed because none of their days included PHP-allowable HCPCS codes. No hospital-based PHPs were removed for missing wage index data, and a single hospital-based PHP was removed by the OPPS ±3 standard deviation trim on costs per day. (We refer readers to the OPPS Claims Accounting Document, available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1717-P-2020-OPPS-Claims-Accounting.pdf*.

Overall, we removed 72 hospital-based PHP providers (1 with all service days having a CCR greater than 5) + (68 with no PHP payment) + (2 with no PHP-allowable HCPCS codes) + (1 provider with geometric mean costs per day outside the ± 3 SD limits)], resulting in 377 (449 total − 72 excluded) hospital-based PHP providers in the data used for calculating ratesetting.

After completing these data preparation steps, we calculated the CY 2022 geometric mean per diem cost for hospital-based PHP APC 5863 by following the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 and 79691).[105] The calculated CY 2022 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide three or more services per service day (hospital-based PHP APC 5863) is $253.08, which is a very slight decrease from $253.76 calculated last year for CY 2021 ratesetting (85 FR 86080).

As we discussed above, we observed a number of changes, likely as a result of the COVID–19 PHE, in the CY 2020 OPPS claims that we would ordinarily use for ratesetting, and this includes changes in the claims for partial hospitalization. We considered what effect this very slight decrease from the $253.76 calculated last year for the CY 2021 CMHC PHP APC might have on CMHCs and Medicare beneficiaries. In general, a decrease of this magnitude would not be unexpected due to normal variation in cost and claims data. However, recognizing the disruption

[104] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm.*

[105] Each revenue code on the hospital-based PHP claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the hospital's department-level CCR; in CY 2020 and subsequent years, that CCR is determined by using the PHP-only revenue-code-to-cost-center crosswalk. Only the claims service lines containing PHP-allowable HCPCS codes and PHP-allowable revenue codes from the hospital-based PHP claims remaining after trimming are retained for hospital-based PHP cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. Hospital-based PHP service days must have three or more services provided to be assigned to hospital-based PHP APC 5863. The final geometric mean per diem cost for hospital-based PHP APC 5863 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. Hospital-based PHP service days with costs ±3 standard deviations from the geometric mean costs within APC 5863 are deleted and removed from modeling. The remaining hospital-based PHP service days are used to calculate the final geometric mean per diem cost for hospital-based PHP APC 5863.

that the ongoing COVID–19 PHE appears to be having on the operations of hospital-based PHPs, we believe it is important for CMS to continue to support Medicare beneficiaries' access to critical PHP services during the COVID–19 PHE by helping to maintain the stability of payments to PHP providers. While the decrease in the geometric mean per diem cost for hospital-based PHP APC 5863 would be very slight based on the CY 2019 claims and cost data used for this CY 2022 OPPS/ASC proposed rule, we continue to believe, as we have stated before in recent years, that access is better supported when geometric mean per diem costs do not fluctuate greatly. The proposed cost floor would protect access to PHP services at hospital-based PHPs if the final CY 2022 calculated hospital-based PHP APC geometric mean per diem cost is significantly less. We are concerned that such a decrease may result in a disruption to hospital-based PHP payments at a time when, as discussed earlier in section VII.B.2.a of this OPPS/ASC proposed rule, the need for mental health services has increased. Therefore, we are proposing to calculate the hospital-based PHP APC 5863 payment rate based on a cost floor to maintain the geometric mean per diem costs finalized in the prior year, CY 2021. The final CY 2021 geometric mean per diem cost for hospital-based PHP APC 5863, which was calculated for the CY 2021 OPPS/ASC final rule based on CY 2019 claims, is $253.76, which we are proposing as the cost floor for CY 2022. Therefore, because the calculated geometric mean per diem cost for hospital-based PHP APC 5863 is below the cost floor, we are proposing to calculate the CY 2022 hospital-based PHP APC 5863 payment rate based on the cost floor of $253.76. We also propose that if the final CY 2022 geometric mean per diem cost is calculated to be higher than $253.76, then we would use the calculated geometric mean per diem cost.

We continue to recognize, as we have noted in past years, that changes in costs from a small number of providers can influence the overall geometric mean per diem cost calculation. We are considering approaches to address cost fluctuations in future years, however we are not proposing a methodology at this time.

These proposed CY 2022 PHP geometric mean per diem costs are shown in Table 34 and are used to derive the proposed CY 2022 PHP APC per diem rates for CMHCs and hospital-based PHPs. The proposed CY 2022 PHP 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*).[106]

TABLE 34: CY 2022 PHP APC Geometric Mean Per Diem Costs

CY 2022 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (three or more services per day) for CMHCs	$136.14
5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	$253.76

C. Proposed Outlier Policy for CMHCs

For 2022, we propose to continue to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed dollar-threshold according to previously established policies. These topics are discussed in more detail. We refer readers to section II.G.1 of this CY 2022 OPPS/ASC proposed rule for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 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 OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs. 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 OPPS/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 OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR

[106] As discussed in section XX. of this CY 2022 OPPS/ASC proposed rule, OPPS APC geometric mean per diem costs (including PHP APC geometric mean per diem costs) are divided by the geometric mean per diem costs for APC 5012 (Clinic Visits and Related Services) to calculate each PHP APC's unscaled relative payment weight. An unscaled relative payment weight is one that is not yet adjusted for budget neutrality. Budget neutrality is required under section 1833(t)(9)(B) of the Act, and ensures that the estimated aggregate weight under the OPPS for a calendar year is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To adjust for budget neutrality (that is, to scale the weights), we compare the estimated aggregated weight using the scaled relative payment weights from the previous calendar year at issue. We refer readers to the ratesetting procedures described in Part 2 of the OPPS Claims Accounting narrative and in section II. of this proposed rule for more information on scaling the weights, and for details on the final steps of the process that leads to final PHP APC per diem payment rates. The OPPS Claims Accounting narrative is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082).

We estimate CMHC per diem payments and outlier payments by using the most recent available utilization and charges from CMHC claims, updated CCRs, and the updated payment rate for APC 5853. 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 × Estimated Total OPPS Payments) = 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 this proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the CMHC PHP APC payment rate. If the provider's costs exceed the threshold, we multiply that excess by 50 percent, as described in section VIII.C.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.C.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 × 0.50) = Estimated CMHC Outlier Payment (before cap) = B. If B is greater than (0.08 × Provider's Total Estimated Per Diem Payments), then cap adjusted- B = (0.08 × 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, and we do not propose any changes to our current methodology for calculating the CMHC outlier percentage for CY 2022. Therefore, based on our CY 2022 payment estimates, CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2022, 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 is 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 exceeds 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 × (CMHC Cost − (3.4 × APC 5853 rate))]. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 through 58997), CY 2020 OPPS/ASC final rule with comment period (84 FR 61351) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082 through 86083). For CY 2022, 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. That is, for CY 2022, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the payment rate for CMHC APC 5853, the outlier payment will be calculated as [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))].

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that lead 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 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 2022. The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold (currently $500,000 for hospitals and any outlier payments for CMHCs) 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 (73 FR 68596 through 68599). 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 online at: *https://www.cms.gov/Regulations-and-*

Guidance/Guidance/Manuals/Downloads/clm104c04.pdf).

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). We finalized the CMHC outlier payment cap to be set at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695). 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 OPPS/ASC final rule with comment period (84 FR 61351), we finalized a proposal to continue this policy in CY 2020 and subsequent years. In this proposed rule, we are not proposing any changes to this policy.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/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. CMHC PHP APC 5853 is the only APC for which CMHCs may receive payment under the OPPS, and is for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APC 5853, it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed—dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083). We propose to continue this policy for CY 2022.

IX. Proposed Services That Will Be Paid Only as Inpatient Services

A. Background

Established in rulemaking as part of the initial implementation of the OPPS, 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 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, either because of the invasive nature of the procedures, the need for postoperative care, or the underlying physical condition of the patient who would require such surgery, 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 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 means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the outpatient setting (65 FR 18443). Conversely, the absence of a procedure from the list should not be interpreted as identifying those procedures as appropriately performed only in the outpatient setting (70 FR 68696).

As part of the annual update process, we have historically worked with interested stakeholders, 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. Stakeholders were 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).

Prior to CY 2021, we traditionally used five criteria to determine whether a procedure should be removed from the IPO list (65 FR 18455). As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we assessed whether a procedure or service met these criteria to determine whether or not it should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We have explained that a procedure is not required to meet all of the established criteria to be removed from the IPO list. The criteria for assessing procedures for removal from the IPO list prior to CY 2021 are the following:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be furnished in most outpatient departments.
- The procedure is related to codes that we have already removed from the IPO list.
- A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC list.

In the past, we have requested that stakeholders 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 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 medical advisors thoroughly reviewed all information submitted within the context of the established criteria and if, following this review, we determined that there was sufficient evidence to confirm that the code could be safely

and appropriately performed on an outpatient basis, we assigned the services to an APC and included it as a payable procedure under OPPS (67 FR 66740).

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 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). Prior to CY 2021, changes to the IPO list have been gradual. 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, therefore, that 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 or not any services should be removed from the list.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084 through 86088), we significantly adjusted our approach to the IPO list. As we stated in that final rule, we no longer saw the need for CMS to restrict payment for certain procedures by maintaining the IPO list to identify services that require inpatient care. In that final rule, we acknowledged the seriousness of the concerns regarding patient safety and quality of care that various stakeholders expressed regarding removing procedures from the IPO list or eliminating the IPO list altogether. But we stated that we believed that the developments in surgical technique and technological advances in the practice of medicine, as well as various safeguards, including, but not limited to, physician clinical judgment, state and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, CMS quality and monitoring initiatives and programs and other CMS initiatives would continue to ensure that procedures removed from the IPO list and provided in the outpatient setting could be performed safely on appropriately selected beneficiaries. We also stated that given our increasing ability to measure the safety of procedures performed in the outpatient setting and to monitor the quality of care, in addition to the other safeguards detailed above, we believed that quality of care was unlikely to be affected by the elimination of the IPO list. We noted that we do not require services that are not included on the IPO list to be performed solely in the outpatient setting and that services that were previously identified as inpatient only can continue to be performed in the inpatient setting. We emphasized that physicians should use their clinical knowledge and judgment, together with consideration of the beneficiary's specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required for the beneficiary, subject to the general coverage rules requiring that any procedure be reasonable and necessary. We also stated that the elimination of the IPO list would ensure maximum availability of services to beneficiaries in the outpatient setting. Finally, we stressed that as medical practice continues to develop, we believed that the difference between the need for inpatient care and the appropriateness of outpatient care has become less distinct for many services.

Accordingly, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084 through 86088), we finalized, with modification, our proposal to eliminate the IPO list over the course of three years (85 FR 86093). We revised our regulation at § 419.22(n) to state that, effective on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a three-year transition. As part of the first phase of this elimination of the IPO list, we removed 298 codes from the list beginning in CY 2021 and, because we proposed to eliminate the IPO list entirely, the removed procedures were not assessed against our longstanding criteria for removal (85 FR 86094).

B. Proposed Changes to the Inpatient Only (IPO) List

In this proposed rule, for CY 2022, we propose to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 as part of the first phase of eliminating the IPO list, we propose to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022. In accordance with this proposal, we propose to amend the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a three-year transition. We also propose to codify the five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation in a new § 419.23.

1. Stakeholder Feedback on Eliminating the IPO List

We received a significant number of stakeholder comments throughout the CY 2021 rulemaking cycle and following issuance of the final rule about eliminating the IPO list. Many commenters, including hospital associations and hospital systems, professional associations, and medical specialty societies, vociferously opposed eliminating the IPO list. These commenters primarily cited patient safety concerns, stating that the IPO list serves as an important programmatic safeguard and maintains a common standard of medical judgment in the Medicare program. Stakeholders stated that they support maintaining the IPO list and consider it an important tool to indicate which services may be appropriate to furnish in the outpatient setting (by virtue of the procedures not being on the IPO list) and to ensure that Medicare beneficiaries receive quality care. Commenters argued that many of the procedures that we designated as ''inpatient only'' are currently performed appropriately and safely only in the inpatient setting, and therefore, should remain on the IPO list. Additionally, commenters opposed eliminating the IPO list and stated that high-risk, invasive procedures that require post-operative monitoring would not be safe to perform on Medicare beneficiaries in an outpatient setting. While some commenters acknowledged that eliminating the IPO list would provide increased beneficiary access to care, these commenters were concerned that the increased access would be to lower quality care.

Many commenters who were opposed to eliminating the IPO list stated that CMS should retain the current methodology for evaluating and removing procedures from the IPO list through rulemaking. Alternatively, several commenters requested that instead of eliminating the IPO list, CMS should instead maintain the list specifically for a smaller number of procedures that are complex, surgically invasive, and that commenters believe should never be performed in the outpatient setting. The commenters suggested that these procedures be considered appropriate for inpatient

hospital admission and payment under Medicare Part A regardless of the expected length of stay.

While some commenters believed that eliminating the IPO list would remove regulatory barriers and provide patients with more choices for where to receive affordable care, other commenters expressed concerns that eliminating the IPO list would cause administrative and financial burdens for beneficiaries, hospitals, and payers given the number of transitioning codes and the speed with which they would be removed from the list.

A minority of commenters (including providers and trade associations) supported CMS eliminating the IPO list and stated that deference should be given to physicians' judgment on site-of-service decisions. These commenters stated that there is no clinical difference between a surgery performed on an inpatient versus an outpatient, and that eliminating the IPO list would create more flexibility for physicians and beneficiaries. The commenters also believed that eliminating the IPO list could potentially decrease overall healthcare costs and improve clinical outcomes for patients.

Commenters who supported delaying the elimination of the IPO list suggested various timeframes that ranged from three years to seven years. Several hospital associations recommended we delay eliminating the IPO list until we address patient safety concerns and provide national guidelines to identify patients who are appropriate candidates for care in the inpatient hospital versus outpatient hospital settings. During the 2021 rulemaking cycle, a few stakeholders suggested that we remove the proposed musculoskeletal services from the IPO list and then monitor the transition of those services to the outpatient hospital setting and the effect on beneficiary outcomes for a period of time before removing any additional services.

Following the CY 2021 OPPS/ASC final rule with comment period, stakeholders continued to express concerns regarding the pace at which the IPO list would be eliminated, the perceived lack of transparency in determining the order of removal of procedures over the course of the elimination process, and what stakeholders believed were insufficient details concerning rate setting for procedures for which payment would be made when furnished in the HOPD setting, as well as the accuracy of those rates for the HOPD setting. We have received stakeholder requests to reconsider the elimination of the IPO list, to reevaluate procedures removed from the IPO list due to safety and quality concerns, and to, at a minimum, extend the timeframe for eliminating the list.

2. Proposal To Halt the Elimination of the IPO List in CY 2022

After further consideration of the policy we adopted in last year's final rule with comment period and the concerns stakeholders have raised since the final rule was issued, we believe that we should halt the elimination of the IPO list to ensure that any service removed from the IPO list is evaluated against the previous longstanding criteria for removal from the IPO list before it is removed. We believe assessing whether a procedure or service meets the criteria for removal would allow for a more gradual removal of services from the IPO list—which would also allow stakeholders more time to evaluate the safety of the service in the HOPD and to prepare to safely furnish the services migrating off of the IPO list, if they so choose.

After further consideration, we continue to believe that the inpatient only list is a valuable tool for ensuring that the OPPS only pays for services that can safely be performed in the hospital outpatient setting, and we have reconsidered eliminating the inpatient only list at this time. We believe that there are many surgical procedures that cannot be safely performed on a typical Medicare beneficiary in the hospital outpatient setting, and therefore, it would be inappropriate for us to assign them separately payable status indicators and establish payment rates in the OPPS (78 FR 75055). We recognize that while physicians are able to make safety determinations for a specific beneficiary, CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries, that is, the typical Medicare beneficiary. While we want to afford physicians and hospitals the maximum flexibility in choosing the most clinically appropriate site of service for the procedure, as long as the characteristics of the procedure are consistent with the criteria listed above, we believe that the IPO list is a necessary safeguard that considers the broader Medicare population.

In the CY 2021 OPPS/ASC final rule with comment period, we recognized that stakeholders may need time to adjust to the removal of procedures from the list, especially given the significant number of services removed beginning in CY 2021 (85 FR 86085 and 86092). We recognized that providers may need time to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the IPPS or the OPPS (85 FR 86086). We also acknowledged that it will take time for clinical staff and providers to gain experience furnishing these services to the appropriate Medicare beneficiaries in the HOPD, and to develop comprehensive patient selection criteria and other protocols to identify whether a beneficiary can safely have these procedures performed in the outpatient setting (85 FR 86088).

Separately, we also acknowledged the numerous challenges that providers are facing due to the COVID–19 PHE (85 FR 86089). After further experience with the PHE and its impact on provider and beneficiary behavior, we recognize that the COVID–19 PHE has likely reduced providers' ability to prepare to furnish these services in the outpatient setting in the manner they would absent the PHE. We recognize that the COVID–19 PHE may have negatively impacted the time and resources that providers have to adapt to the removal of these procedures from the IPO list—making it more difficult for providers to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the IPPS or the OPPS. We also recognize that the COVID–19 PHE has negatively impacted clinical staff and providers' opportunity to develop the comprehensive patient selection criteria and other protocols necessary to identify whether a Medicare beneficiary could safely have these procedures performed in the outpatient setting while guaranteeing them appropriate quality of care.

After further consideration and review of the additional feedback from stakeholders, we recognize that the timeframe we finalized in the CY 2021 final rule with comment period for eliminating the IPO list did not, and would not, give us a sufficient opportunity to carefully assess whether a procedure should be payable in the HOPD setting, with considerations to beneficiary safety and medical advancements. We also recognize that the unprecedented removal of the 298 codes from the IPO list transpired quickly. Given the significant policy shift and work required to operationalize the elimination of the IPO list, we recognize that more time is required to separately evaluate and consider the inpatient only classification of each service and its potential APC assignment. In addition, we believe that we should continue to use the longstanding criteria for removing services from the IPO list to evaluate each service before proposing

to remove it from the list, and, as noted above, we propose to codify these criteria in the regulation in a new § 419.23.

CMS still believes that as medical practice continues to develop, the difference between the need for inpatient care and the appropriateness of outpatient care has become less distinct for many services. While we recognize that there are services currently classified as inpatient only that may be appropriate in the outpatient setting for some Medicare beneficiaries, CMS continues to strive to balance the goals of increasing physician and patient choice of setting of care with considerations to patient safety for all Medicare beneficiaries. We must also consider the timing with which we remove services from the IPO list and the availability of evidence that may support the removal of those services. We believe that with additional time stakeholders can provide supportive evidence to aid in the evaluations of each individual procedure's assignment to the IPO list, and where appropriate the APC assignment and corresponding payment for any codes as well, 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.

An initial review of 2021 billing data through May 21, 2021, supports our proposal to halt the elimination of the list, revealing that 131 of the 298 codes removed from the IPO list in last year's final rule appeared on either zero or one OPPS claims and 269 of the 298 codes appeared on fewer than 100 claims. These data indicate that fewer than 3 percent of the services removed from the IPO list in 2021 have seen notable volume in the outpatient setting following their removal from the IPO list. For perspective, we also note that even before we removed these codes from the IPO list, it was not uncommon to see at least some volume for these codes in the claims data. In CY 2020, when these codes were still not payable under the OPPS, 188 of the codes had at least one outpatient claim and 18 codes had greater than 100 claims, for reasons undetermined. As a result, it is likely that not all of the reported claims represent services provided in the outpatient setting due to these services being removed from the IPO list in CY 2021.

We propose to halt the elimination of the IPO list in order to allow for greater consideration of the impact removing services from the list has on beneficiary safety and to allow providers impacted by the COVID–19 PHE additional time to prepare to furnish appropriate services safely and efficiently before continuing to remove large numbers of services from the list. Below we solicit comments on the potential future elimination of the IPO list and what commenters believe the effects of that elimination would be. We also solicit comment on if CMS should maintain the IPO list but continue to systematically scale back the list by looking at groups of services that can safely and effectively be performed in the outpatient setting. Specifically, CMS is requesting comments on whether CMS should maintain the longer-term objective of eliminating the IPO list and if so, suggestions for a reasonable timeline for the elimination and what method should be employed to evaluate procedure removal. We request that commenters submit evidence on what effect, if any, they believe eliminating or scaling back the IPO list will have on beneficiary quality of care and what effect, if any, would the elimination or scaling back of the IPO list have on provider behavior, incentives, or innovation. We are also interested in stakeholders' viewpoints on the clinical, financial, and administrative impact of removing services from the IPO list. Additionally, we are interested in stakeholders' suggestions for refining the approach to inpatient only code evaluation to keep pace with advances in technology and surgical techniques that allow for more services to appropriately take place in the outpatient setting if we were to retain the IPO list.

We reiterate that the removal of a particular procedure from the IPO list does not require that all beneficiaries be treated in the hospital outpatient setting, but we are cognizant that it does require the physician and clinical care team to exercise complex medical judgment to determine the appropriate setting of care, in accordance with the two-midnight rule guidance. The services that we are proposing to maintain or add back to the IPO list reflect those services that we believe may pose increased safety risk to the typical Medicare beneficiary. However, we recognize that there may be a subset of Medicare beneficiaries who, on a case by case basis, may nonetheless be appropriate to treat in the outpatient setting; and we seek comment below on whether any services that were removed in CY 2021, but are being proposed to be added back to the IPO for CY 2022, should in fact, remain off the IPO list.

3. Proposal To Return Procedures Removed in CY 2021 to the IPO List for CY 2022

CMS continues to believe that physicians must use their clinical knowledge and judgment, together with consideration of the beneficiary's needs, to determine the appropriate site of service, but we recognize that the broad removal of services from the IPO list in CY 2021 did not assess whether procedures proposed for removal met the longstanding removal criteria that we have historically used in consideration of the typical Medicare beneficiary. We also recognize that given the clinical intensity of some of the services removed from the IPO list (which include, for example, amputations), the 298 codes that were removed from the list included services that clinically would not be expected to be performed in the outpatient setting and would be unlikely to meet the criteria. As discussed previously, to ensure beneficiary safety, we have historically used longstanding criteria to determine if a procedure should be removed from the IPO list, but the removed procedures were not assessed against these criteria as part of the broad removal of services from the IPO list in CY 2021 because we proposed to eliminate the IPO list entirely. After further consideration, we believe it is important to continue to assess whether services individually meet any of the criteria for removal from the IPO list before being removed. Further, CMS recognizes that the impact of the COVID–19 PHE on providers' ability to safely and comprehensively prepare to furnish these services in the outpatient setting may be greater than previously anticipated. After a clinical review and an evaluation using the five longstanding criteria for removing services from the IPO list discussed earlier in Section IX(A) we now believe that the services removed from the IPO list in CY 2021 do not currently meet our longstanding removal criteria and we propose to add them back to the IPO list for CY 2022.

As discussed earlier in Section IX(A), we typically evaluate whether a service should be removed from the IPO list using five criteria and, while a service does not need to meet all of the criteria to be removed from the IPO list, it should meet at least one criterion and the case for removing the service from the IPO list is strengthened with the more criteria the service meets. For CY 2021, in light of our proposal to eliminate the IPO list over a three-year transition, we proposed that musculoskeletal services would be the

first group of services removed from the IPO list. We stated that we proposed to remove this group of services first for several reasons. In recent years, due to new technologies and advances in surgical care protocols, expedited rehabilitation protocols, and significant enhancements in postoperative processes, we have removed TKA and THA, which are both musculoskeletal services, from the IPO list. During the process of proposing and finalizing removing TKA and THA from the IPO list, stakeholders have continuously requested that CMS remove other musculoskeletal services from the IPO list as well, citing shortened length of stay times, advancements in technologies and surgical techniques, and improved postoperative processes. Additionally, we noted that, more often than not, stakeholders historically requested that we remove musculoskeletal services from the IPO list more than other types of services. We also recognized that there is already a set of comprehensive APCs for musculoskeletal services for payment under the OPPS, which facilitates payment for these services and further supported their removal for CY 2021. Specifically, because we have previously removed codes from the IPO list that are similar clinically and in terms of resource cost and assigned them to these comprehensive APCs, we explained that these APCs generally describe appropriate ranges for the musculoskeletal codes removed in CY 2021, which we believed allowed for appropriate payment. We also proposed to remove additional related services that were recommended for removal by stakeholders during the annual HOP panel meeting.

As stated above, because these services were being removed from the IPO list as the first phase of the elimination of the list, we did not evaluate each of these services against the longstanding criteria for removing a service from the IPO list. While a number of commenters supported the removal of the 298 services, the vast majority of commenters were opposed to removing the services and shared concerns regarding their inability to properly review the clinical nature of this large number of procedures and to provide comprehensive feedback on their removal from the list. Some commenters were able to review the individual services and requested that specific CPT codes remain payable in the inpatient setting only, including CPT codes 27280 (Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed) and 22857 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar) due to concerns about the safety of these procedures if they are performed in the outpatient setting.

As previously stated in the CY 2021 final rule (85 FR 86087), an overwhelming number of stakeholders supported the previously established methodology for identifying appropriate changes to the IPO list. CMS received numerous requests to continue to use the established criteria to review and analyze services proposed for removal as opposed to removing large numbers of services in groups or categories. Commenters noted that they preferred the historical process for assessing services for removal from the IPO list using the five criteria, as they believed this process was more manageable for patients, providers, and other like stakeholders, allowing them to provide meaningful input on a procedure-by-procedure basis. Because we are proposing to halt elimination of the IPO list, we also believe it is appropriate to continue to evaluate services that we propose for removal against the longstanding criteria, and include with our proposals an in depth analysis of whether most outpatient departments are equipped to provide the services to the Medicare population; whether the simplest procedure described by the code may be performed in most outpatient departments; whether the procedure is related to codes that we have already removed from the IPO list; our determination of whether the procedure is being performed in numerous hospitals on an outpatient basis; and our determination of whether the procedure can be appropriately and safely performed in an ASC, is on the list of approved ASC procedures, or has been proposed by us for addition to the ASC list. Historically, we have included discussions of the individual codes proposed for removal in the proposed rule and stakeholders have had the opportunity to comment in kind with evidence in support of or opposition to the service's assignment to the IPO list, and we believe it is appropriate to continue to do so.

In light of ongoing stakeholder feedback, we have now, for CY 2022, reviewed each of the procedures removed from the IPO list in CY 2021 to determine whether they individually meet the longstanding criteria for removal from the list. Our review considered the clinical intensity and characteristics of the service, the underlying condition of the beneficiary who would require the service, peer-reviewed medical literature, case reports, clinical criteria sets, and utilization data. This review determined that none of the services removed in CY 2021 have sufficient supporting evidence that the service can be safely performed on the Medicare population in the outpatient setting, that most outpatient departments are equipped to provide the services to the Medicare population, or that the services are being performed safely on an outpatient basis. For a large number of the removed services, we did not find vignettes, claims or utilization data, or literature to support their removal under our longstanding criteria. For the few services that did have some data supporting their removal from the list, we found the data to be either incomplete or to be countered by conflicting data. For example, a few services, including CPT code 21627 (sternal debridement), showed increasing migration to the outpatient setting, but we could not locate supportive medical literature case studies, or outcomes data to support that the services are safe for the Medicare population in the outpatient setting. Some services, such as CPT code 22558 (Lumbar spine fusion) and CPT code 23472 (reconstruct shoulder joint), show increasing outpatient claims data, but have high length of stay times and extensive post-operative care needs that indicate these services may not be appropriate for the Medicare population in the outpatient setting. Other services, such as CPT code 22846 (Anterior instrumentation; 4 to 7 vertebral segments), lack medical literature or case studies, lack supportive claims data, and have conflicting stakeholder feedback for the safety of the service in the outpatient setting. We were unable to find literature and data for services that included outcomes specific to the Medicare population, particularly in the outpatient setting.

Given that our review of each of the services removed from the list in CY 2021 using the five criteria mentioned in Section IX(A) did not find sufficient evidence that any of these services would be safe to perform on the Medicare population in the outpatient setting, we do not believe it would be appropriate for Medicare to pay for these services when performed in an outpatient setting. In particular, we found that the simplest procedures described by the codes for these services cannot be furnished safely in most outpatient departments, most outpatient departments are not equipped to

provide these services to the Medicare population, and the procedures are not being performed in numerous hospitals on an outpatient basis. We also do not believe the services can be appropriately and safely furnished in an ASC.

As a result of this review, we are proposing to return all of the procedures removed in last year's final rule to the IPO list for CY 2022 because we do not believe they meet the previously established criteria for removal from the IPO list. Therefore, after further clinical review and additional consideration of safety and quality of care concerns for the group of services removed from the IPO list in the CY 2021 final rule, for CY 2022 we are proposing to return these 298 services to the IPO list, as shown in Table 35 below. The complete list of codes describing services that we propose to designate as inpatient-only services beginning in CY 2022 is included as Addendum E to this CY 2022 OPPS/ASC proposed rule, which is available via the internet on the CMS website.

We solicit public comment on whether there are services that were removed from the IPO list in CY 2021 that stakeholders believe do meet the longstanding criteria for removing services from the IPO list and should continue to be payable in the outpatient setting in CY 2022. If so, we request that commenters submit corresponding evidence—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—that the service meets the longstanding criteria for removal from the IPO list and is safe to perform on the average Medicare population in the outpatient setting.

As mentioned above, the services that we are proposing to add back to the IPO list reflect those services that we believe may pose increased safety risk to the typical Medicare beneficiary. However, we recognize that there may be a subset of Medicare beneficiaries who, on a case by case basis, may nonetheless be appropriate to treat in the outpatient setting and we seek comment below on whether any services that were removed in CY 2021, but are being proposed to be added back to the IPO for CY 2022, should in fact, remain off the IPO list.

Table 35 below contains the proposed additions to the IPO list for CY 2022.

BILLING CODE 4120–01–P

TABLE 35.—PROPOSED ADDITIONS TO THE INPATIENT ONLY (IPO) LIST FOR CY 2022

2022 CPT Code	CY 2022 Long Descriptor	CY 2021 APC Assignment	CY 2021 Status Indicator
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	N/A	N
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	N/A	N
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (list separately in addition to code for primary procedure)	N/A	N
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar	N/A	N

	(list separately in addition to code for primary procedure)		
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	N/A	N
0202T	Posterior vertebral joint(s) arthroplasty (for example, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine	5115	J1
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical	5115	J1
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic	5115	J1
20661	Application of halo, including removal; cranial	5113	Q1
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (for example, pediatric patients, hydrocephalus, osteogenesis imperfecta)	5113	Q1
20802	Replantation, arm (includes surgical neck of humerus through elbow joint), complete amputation	5116	J1
20805	Replantation, forearm (includes radius and ulna to radial carpal joint), complete amputation	5116	J1
20808	Replantation, hand (includes hand through metacarpophalangeal joints), complete amputation	5116	J1
20816	Replantation, digit, excluding thumb (includes metacarpophalangeal joint to insertion of flexor sublimis tendon), complete amputation	5114	J1
20824	Replantation, thumb (includes carpometacarpal joint to mp joint), complete amputation	5114	J1
20827	Replantation, thumb (includes distal tip to mp joint), complete amputation	5114	J1
20838	Replantation, foot, complete amputation	5116	J1
20955	Bone graft with microvascular anastomosis; fibula	5114	J1
20956	Bone graft with microvascular anastomosis; iliac crest	5114	J1
20957	Bone graft with microvascular anastomosis; metatarsal	5114	J1
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	5114	J1
20969	Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, metatarsal, or great toe	5114	J1
20970	Free osteocutaneous flap with microvascular anastomosis; iliac crest	5114	J1
21045	Excision of malignant tumor of mandible; radical resection	5165	J1

21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (for example, for long face syndrome), without bone graft	5165	J1
21142	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	5165	J1
21143	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	5165	J1
21145	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	5165	J1
21146	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	5165	J1
21147	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	5165	J1
21151	Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining autografts)	5165	J1
21154	Reconstruction of midface bones with bone graft Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); without LeFort I	5165	J1
21155	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I	5165	J1
21159	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I	5165	J1
21160	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I	5165	J1
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)	5165	J1
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)	5165	J1
21182	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting less than 40 sq cm	5165	J1
21183	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes	5165	J1

	obtaining grafts); total area of bone grafting greater than 40 sq cm but less than 80 sq cm		
21184	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm	5165	J1
21188	Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)	5165	J1
21194	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)	5165	J1
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	5165	J1
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (for example, for hemifacial microsomia)	5165	J1
21255	Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)	5165	J1
21268	Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; combined intra- and extracranial approach	5165	J1
21343	Open treatment of depressed frontal sinus fracture	5165	J1
21344	Open treatment of complicated (for example, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches	5165	J1
21347	Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches	5165	J1
21348	Open treatment of nasomaxillary complex fracture (lefort ii type); with bone grafting (includes obtaining graft)	5165	J1
21366	Open treatment of complicated (for example, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)	5165	J1
21422	Open treatment of palatal or maxillary fracture (lefort i type);	5165	J1
21423	Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches	5165	J1
21431	Closed treatment of craniofacial separation (lefort iii type) using interdental wire fixation of denture or splint	5165	J1
21432	Open treatment of craniofacial separation (lefort iii type); with wiring and/or internal fixation	5165	J1
21433	Open treatment of craniofacial separation (lefort iii type); complicated (for example, comminuted or	5165	J1

	involving cranial nerve foramina), multiple surgical approaches		
21435	Open treatment of craniofacial separation (lefort iii type); complicated, utilizing internal and/or external fixation techniques (for example, head cap, halo device, and/or intermaxillary fixation)	5165	J1
21436	Open treatment of craniofacial separation (lefort iii type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)	5165	J1
21510	Incision, deep, with opening of bone cortex (for example, for osteomyelitis or bone abscess), thorax	5114	J1
21602	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	5114	J1
21603	Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	5114	J1
21615	Excision first and/or cervical rib;	5114	J1
21616	Excision first and/or cervical rib; with sympathectomy	5114	J1
21620	Ostectomy of sternum, partial	5114	J1
21627	Sternal debridement	5114	J1
21630	Radical resection of sternum;	5114	J1
21632	Radical resection of sternum; with mediastinal lymphadenectomy	5114	J1
21705	Division of scalenus anticus; with resection of cervical rib	5114	J1
21740	Reconstructive repair of pectus excavatum or carinatum; open	5114	J1
21750	Closure of median sternotomy separation with or without debridement (separate procedure)	5114	J1
21825	Open treatment of sternum fracture with or without skeletal fixation	5114	J1
22010	Incision and drainage, open, of deep abscess (subfascial), posterior spine; cervical, thoracic, or cervicothoracic	5114	J1
22015	Incision and drainage, open, of deep abscess (subfascial), posterior spine; lumbar, sacral, or lumbosacral	5114	J1
22110	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical	5114	J1
22112	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic	5114	J1
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar	5114	J1
22116	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve	N/A	N

	root(s), single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)		
22206	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); thoracic	5114	J1
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); lumbar	5114	J1
22208	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); each additional vertebral segment (list separately in addition to code for primary procedure)	N/A	N
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical	5114	J1
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic	5114	J1
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar	5114	J1
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (list separately in addition to primary procedure)	N/A	N
22220	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical	5114	J1
22222	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic	5114	J1
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	5114	J1
22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	N/A	N
22318	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; without grafting	5115	J1
22319	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; with grafting	5115	J1
22325	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; lumbar	5115	J1
22326	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; cervical	5115	J1

22327	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; thoracic	5115	J1
22328	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; each additional fractured vertebra or dislocated segment (list separately in addition to code for primary procedure)	N/A	N
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	5116	J1
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	5116	J1
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (list separately in addition to code for primary procedure)	N/A	N
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-c1-c2 (atlas-axis), with or without excision of odontoid process	5116	J1
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	5116	J1
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	5116	J1
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace	5116	J1
22590	Arthrodesis, posterior technique, craniocervical (occiput-c2)	5116	J1
22595	Arthrodesis, posterior technique, atlas-axis (c1-c2)	5116	J1
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below c2 segment	5116	J1
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)	5116	J1
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	5116	J1
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)	N/A	N

22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments	5116	J1
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments	5116	J1
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments	5116	J1
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments	5116	J1
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments	5116	J1
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments	5116	J1
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments	5116	J1
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments	5116	J1
22830	Exploration of spinal fusion	5115	J1
22841	Internal spinal fixation by wiring of spinous processes (list separately in addition to code for primary procedure)	N/A	N
22843	Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (list separately in addition to code for primary procedure)	N/A	N
22844	Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (list separately in addition to code for primary procedure)	N/A	N
22846	Anterior instrumentation; 4 to 7 vertebral segments (list separately in addition to code for primary procedure)	N/A	N
22847	Anterior instrumentation; 8 or more vertebral segments (list separately in addition to code for primary procedure)	N/A	N
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (list separately in addition to code for primary procedure)	N/A	N
22849	Reinsertion of spinal fixation device	5116	J1
22850	Removal of posterior nonsegmental instrumentation (for example, harrington rod)	5115	J1
22852	Removal of posterior segmental instrumentation	5115	J1
22855	Removal of anterior instrumentation	5115	J1
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar	5116	J1

22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	5116	J1
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	5116	J1
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	5115	J1
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	5115	J1
23200	Radical resection of tumor; clavicle	5114	J1
23210	Radical resection of tumor; scapula	5114	J1
23220	Radical resection of tumor, proximal humerus	5114	J1
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (for example, total shoulder)	5073	J1
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (for example, total shoulder))	5115	J1
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	5115	J1
23900	Interthoracoscapular amputation (forequarter)	5115	J1
23920	Disarticulation of shoulder;	5115	J1
24900	Amputation, arm through humerus; with primary closure	5115	J1
24920	Amputation, arm through humerus; open, circular (guillotine)	5115	J1
24930	Amputation, arm through humerus; re-amputation	5114	J1
24931	Amputation, arm through humerus; with implant	5115	J1
24940	Cineplasty, upper extremity, complete procedure	5115	J1
25900	Amputation, forearm, through radius and ulna;	5115	J1
25905	Amputation, forearm, through radius and ulna; open, circular (guillotine)	5115	J1
25915	Krukenberg procedure	5114	J1
25920	Disarticulation through wrist;	5114	J1
25924	Disarticulation through wrist; re-amputation	5114	J1
25927	Transmetacarpal amputation;	5113	J1
26551	Transfer, toe-to-hand with microvascular anastomosis; great toe wrap-around with bone graft	5114	J1
26553	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, single	5114	J1
26554	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, double	5114	J1
26556	Transfer, free toe joint, with microvascular anastomosis	5114	J1
26992	Incision, bone cortex, pelvis and/or hip joint (for example, osteomyelitis or bone abscess)	5114	J1
27005	Tenotomy, hip flexor(s), open (separate procedure)	5114	J1

27025	Fasciotomy, hip or thigh, any type	5114	J1
27030	Arthrotomy, hip, with drainage (for example, infection)	5114	J1
27036	Capsulectomy or capsulotomy, hip, with or without excision of heterotopic bone, with release of hip flexor muscles (ie, gluteus medius, gluteus minimus, tensor fascia latae, rectus femoris, sartorius, iliopsoas)	5114	J1
27054	Arthrotomy with synovectomy, hip joint	5113	J1
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); superficial	5114	J1
27071	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); deep (subfascial or intramuscular)	5114	J1
27075	Radical resection of tumor; wing of ilium, 1 pubic or ischial ramus or symphysis pubis	5114	J1
27076	Radical resection of tumor; ilium, including acetabulum, both pubic rami, or ischium and acetabulum	5114	J1
27077	Radical resection of tumor; innominate bone, total	5115	J1
27078	Radical resection of tumor; ischial tuberosity and greater trochanter of femur	5115	J1
27090	Removal of hip prosthesis; (separate procedure)	5073	J1
27091	Removal of hip prosthesis; complicated, including total hip prosthesis, methylmethacrylate with or without insertion of spacer	5073	J1
27120	Acetabuloplasty; (for example, whitman, colonna, haygroves, or cup type)	5115	J1
27122	Acetabuloplasty; resection, femoral head (for example, girdlestone procedure)	5115	J1
27125	Hemiarthroplasty, hip, partial (for example, femoral stem prosthesis, bipolar arthroplasty)	5115	J1
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	5115	J1
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	5115	J1
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	5115	J1
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	5115	J1
27140	Osteotomy and transfer of greater trochanter of femur (separate procedure)	5115	J1
27146	Osteotomy, iliac, acetabular or innominate bone;	5114	J1
27147	Osteotomy, iliac, acetabular or innominate bone; with open reduction of hip	5114	J1
27151	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy	5114	J1

27156	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy and with open reduction of hip	5114	J1
27158	Osteotomy, pelvis, bilateral (for example, congenital malformation)	5114	J1
27161	Osteotomy, femoral neck (separate procedure)	5114	J1
27165	Osteotomy, intertrochanteric or subtrochanteric including internal or external fixation and/or cast	5114	J1
27170	Bone graft, femoral head, neck, intertrochanteric or subtrochanteric area (includes obtaining bone graft)	5114	J1
27175	Treatment of slipped femoral epiphysis; by traction, without reduction	5114	J1
27176	Treatment of slipped femoral epiphysis; by single or multiple pinning, in situ	5115	J1
27177	Open treatment of slipped femoral epiphysis; single or multiple pinning or bone graft (includes obtaining graft)	5114	J1
27178	Open treatment of slipped femoral epiphysis; closed manipulation with single or multiple pinning	5114	J1
27181	Open treatment of slipped femoral epiphysis; osteotomy and internal fixation	5114	J1
27185	Epiphyseal arrest by epiphysiodesis or stapling, greater trochanter of femur	5114	J1
27187	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate, femoral neck and proximal femur	5114	J1
27222	Closed treatment of acetabulum (hip socket) fracture(s); with manipulation, with or without skeletal traction	5111	J1
27226	Open treatment of posterior or anterior acetabular wall fracture, with internal fixation	5114	J1
27227	Open treatment of acetabular fracture(s) involving anterior or posterior (one) column, or a fracture running transversely across the acetabulum, with internal fixation	5114	J1
27228	Open treatment of acetabular fracture(s) involving anterior and posterior (two) columns, includes t-fracture and both column fracture with complete articular detachment, or single column or transverse fracture with associated acetabular wall fracture, with internal fixation	5114	J1
27232	Closed treatment of femoral fracture, proximal end, neck; with manipulation, with or without skeletal traction	5112	J1
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	5114	J1
27240	Closed treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with manipulation, with or without skin or skeletal traction	5112	J1

27244	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with plate/screw type implant, with or without cerclage	5114	J1
27245	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with intramedullary implant, with or without interlocking screws and/or cerclage	5114	J1
27248	Open treatment of greater trochanteric fracture, includes internal fixation, when performed	5114	J1
27253	Open treatment of hip dislocation, traumatic, without internal fixation	5113	J1
27254	Open treatment of hip dislocation, traumatic, with acetabular wall and femoral head fracture, with or without internal or external fixation	5113	J1
27258	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc);	5113	J1
27259	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc); with femoral shaft shortening	5113	J1
27268	Closed treatment of femoral fracture, proximal end, head; with manipulation	5113	J1
27269	Open treatment of femoral fracture, proximal end, head, includes internal fixation, when performed	5112	J1
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed	5116	J1
27282	Arthrodesis, symphysis pubis (including obtaining graft)	5115	J1
27284	Arthrodesis, hip joint (including obtaining graft);	5116	J1
27286	Arthrodesis, hip joint (including obtaining graft); with subtrochanteric osteotomy	5116	J1
27290	Interpelviabdominal amputation (hindquarter amputation)	5116	J1
27295	Detachment of hip joint	5116	J1
27303	Incision, deep, with opening of bone cortex, femur or knee (for example, osteomyelitis or bone abscess)	5114	J1
27365	Radical resection of tumor, femur or knee	5114	J1
27445	Arthroplasty, knee, hinge prosthesis (for example, walldius type)	5115	J1
27448	Osteotomy, femur, shaft or supracondylar; without fixation	5114	J1
27450	Osteotomy, femur, shaft or supracondylar; with fixation	5114	J1
27454	Osteotomy, multiple, with realignment on intramedullary rod, femoral shaft (for example, sofield type procedure)	5114	J1
27455	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus	5114	J1

	[bowleg] or genu valgus [knock-knee]); before epiphyseal closure		
27457	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); after epiphyseal closure	5114	J1
27465	Osteoplasty, femur; shortening (excluding 64876)	5114	J1
27466	Osteoplasty, femur; lengthening	5114	J1
27468	Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer	5114	J1
27470	Repair, nonunion or malunion, femur, distal to head and neck; without graft (for example, compression technique)	5114	J1
27472	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	5114	J1
27486	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	5115	J1
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component	5115	J1
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee	5114	J1
27495	Prophylactic treatment (nailing, pinning, plating, or wiring) with or without methylmethacrylate, femur	5114	J1
27506	Open treatment of femoral shaft fracture, with or without external fixation, with insertion of intramedullary implant, with or without cerclage and/or locking screws	5114	J1
27507	Open treatment of femoral shaft fracture with plate/screws, with or without cerclage	5114	J1
27511	Open treatment of femoral supracondylar or transcondylar fracture without intercondylar extension, includes internal fixation, when performed	5114	J1
27513	Open treatment of femoral supracondylar or transcondylar fracture with intercondylar extension, includes internal fixation, when performed	5114	J1
27514	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	5114	J1
27519	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	5114	J1
27535	Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	5114	J1
27536	Open treatment of tibial fracture, proximal (plateau); bicondylar, with or without internal fixation	5114	J1

27540	Open treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, includes internal fixation, when performed	5114	J1
27556	Open treatment of knee dislocation, includes internal fixation, when performed; without primary ligamentous repair or augmentation/reconstruction	5114	J1
27557	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	5114	J1
27558	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	5114	J1
27580	Arthrodesis, knee, any technique	5115	J1
27590	Amputation, thigh, through femur, any level;	5116	J1
27591	Amputation, thigh, through femur, any level; immediate fitting technique including first cast	5116	J1
27592	Amputation, thigh, through femur, any level; open, circular (guillotine)	5116	J1
27596	Amputation, thigh, through femur, any level; re-amputation	5114	J1
27598	Disarticulation at knee	5115	J1
27645	Radical resection of tumor; tibia	5114	J1
27646	Radical resection of tumor; fibula	5114	J1
27702	Arthroplasty, ankle; with implant (total ankle)	5115	J1
27703	Arthroplasty, ankle; revision, total ankle	5115	J1
27712	Osteotomy; multiple, with realignment on intramedullary rod (for example, sofield type procedure)	5115	J1
27715	Osteoplasty, tibia and fibula, lengthening or shortening	5115	J1
27724	Repair of nonunion or malunion, tibia; with iliac or other autograft (includes obtaining graft)	5114	J1
27725	Repair of nonunion or malunion, tibia; by synostosis, with fibula, any method	5114	J1
27727	Repair of congenital pseudarthrosis, tibia	5114	J1
27880	Amputation, leg, through tibia and fibula;	5116	J1
27881	Amputation, leg, through tibia and fibula; with immediate fitting technique including application of first cast	5114	J1
27882	Amputation, leg, through tibia and fibula; open, circular (guillotine)	5114	J1
27886	Amputation, leg, through tibia and fibula; re-amputation	5114	J1
27888	Amputation, ankle, through malleoli of tibia and fibula (for example, syme, pirogoff type procedures), with plastic closure and resection of nerves	5115	J1
28800	Amputation, foot; midtarsal (for example, chopart type procedure)	5113	J1

G0412	Open treatment of iliac spine(s), tuberosity avulsion, or iliac wing fracture(s), unilateral or bilateral for pelvic bone fracture patterns which do not disrupt the pelvic ring includes internal fixation, when performed	5114	J1
G0414	Open treatment of anterior pelvic bone fracture and/or dislocation for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation when performed (includes pubic symphysis and/or superior/inferior rami)	5115	J1
G0415	Open treatment of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation, when performed (includes ilium, sacroiliac joint and/or sacrum)	5115	J1
00192	Anesthesia for procedures on facial bones or skull; radical surgery (including prognathism)	N/A	N
00474	Anesthesia for partial rib resection; radical procedures (eg, pectus excavatum)	N/A	N
00604	Anesthesia for procedures on cervical spine and cord; procedures with patient in the sitting position	N/A	N
01756	Anesthesia for open or surgical arthroscopic procedures of the elbow; radical procedures	N/A	N
01638	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement	N/A	N
01636	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; interthoracoscapular (forequarter) amputation	N/A	N
01634	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; shoulder disarticulation	N/A	N
01150	Anesthesia for radical procedures for tumor of pelvis, except hindquarter amputation	N/A	N
01140	Anesthesia for interpelviabdominal (hindquarter) amputation	N/A	N
01212	Anesthesia for open procedures involving hip joint; hip disarticulation	N/A	N
01234	Anesthesia for open procedures involving upper two-thirds of femur; radical resection	N/A	N
01232	Anesthesia for open procedures involving upper two-thirds of femur; amputation	N/A	N
01404	Anesthesia for open or surgical arthroscopic procedures on knee joint; disarticulation at knee	N/A	N
01486	Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement	N/A	N

01274	Anesthesia for procedures involving arteries of upper leg, including bypass graft; femoral artery embolectomy	N/A	N
00904	Anesthesia for; radical perineal procedure	N/A	N
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral	5184	J1
35800	Exploration for postoperative hemorrhage, thrombosis or infection; neck	5184	J1
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation)	5193	J1
37617	Ligation, major artery (eg, post-traumatic, rupture); abdomen	5183	J1
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	5362	J1
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	5331	J1
44300	Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression) (separate procedure)	5302	J1
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)	5055	T
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)	5341	J1
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	5341	J1
44602	Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation	5303	J1
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	5341	J1
49255	Omentectomy, epiploectomy, resection of omentum (separate procedure)	5341	J1
51840	Anterior vesicourethropexy, or urethropexy (eg, marshall-marchetti-krantz, burch); simple	5415	J1
56630	Vulvectomy, radical, partial;	5415	J1
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	5194	J1

BILLING CODE 4120–01–C

4. Topics and Questions Posed for Public Comments

In addition to our proposal to halt the elimination of the IPO list and return services summarily removed from the IPO list last year that our clinicians have determined do not meet the criteria for removal from the IPO list, as provided in Table 35, we are also interested in feedback from stakeholders on whether CMS should maintain the longer-term objective of eliminating the IPO list or if CMS should maintain the IPO list but continue to systematically scale the list back to so that inpatient only designations are consistent with current standards of practice. Specifically, CMS is requesting comments on the following:

- Should CMS maintain the longer-term objective of eliminating the IPO list? If so, what is a reasonable timeline for eliminating the list? What method do stakeholders suggest CMS use to approach removing codes from the list?
- Should CMS maintain the IPO list but continue to streamline the list of services included on the list and, if so, suggestions for ways to systematically scale the list back to allow for the removal of codes, or groups of codes, that can safely and effectively be performed on a typical Medicare beneficiary in the hospital outpatient setting so that inpatient only designations are consistent with current standards of practice?
- What effect do commenters believe the elimination or scaling back of the IPO list would have on safety and quality of care for Medicare beneficiaries?
- What effect do commenters believe elimination or the scaling back of the IPO list would have on provider behavior, incentives, or innovation?
- What information or support would be helpful for providers and physicians in their considerations of site-of-service selections?
- Should CMS's clinical evaluation of the safety of a service in the outpatient setting consider the safety and quality of care for the typical Medicare beneficiary or a smaller subset of Medicare beneficiaries for whom the outpatient provision of a service may have fewer risk factors?
- Are there services that were removed from the IPO list in CY 2021 that stakeholders believe meet the longstanding criteria for removal from the IPO list and should continue to be payable in the outpatient setting in CY 2022? If so, what evidence supports the conclusion that the service meets the longstanding criteria for removal from the IPO list and is safe to perform on the Medicare population in the outpatient setting?

X. Proposed Nonrecurring Policy Changes

A. Proposed Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2022 and Subsequent Years

1. Background on the 2-Midnight Rule

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we clarified our policy regarding when an inpatient admission is considered reasonable and necessary for purposes of Medicare Part A payment. Under this policy, we established a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. Conversely, when a beneficiary enters a hospital for a surgical procedure not designated as an inpatient-only (IPO) procedure as described in 42 CFR 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A, regardless of the hour that the beneficiary came to the hospital or whether the beneficiary used a bed. With respect to services designated under the OPPS as IPO list procedures, we explained that because of the intrinsic risks, recovery impacts, or complexities associated with such services, these procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. We also indicated that there might be further ''rare and unusual'' exceptions to the application of the benchmark, which would be detailed in subregulatory guidance.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we also finalized the 2-Midnight presumption, which is related to the 2-Midnight benchmark but is a separate medical review policy. The 2-Midnight benchmark represents guidance to reviewers to identify when an inpatient admission is generally reasonable and necessary for purposes of Medicare Part A payment, while the 2-Midnight presumption relates to instructions to medical reviewers regarding the selection of claims for medical review. Specifically, under the 2-Midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are presumed to be appropriate for Medicare Part A payment and are not the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-Midnight presumption.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70538 through 70549), we revisited the previous rare and unusual exceptions policy and finalized a proposal to allow for case-by-case exceptions to the 2-Midnight benchmark, whereby Medicare Part A payment may be made for inpatient admissions where the admitting physician does not expect the patient to require hospital care spanning 2 midnights, if the documentation in the medical record supports the physician's determination that the patient nonetheless requires inpatient hospital care.

In the CY 2016 OPPS/ASC final rule with comment period, we reiterated our position that the 2-Midnight benchmark provides clear guidance on when a hospital inpatient admission is appropriate for Medicare Part A payment, while respecting the role of physician judgment. We stated that the following criteria will be relevant to determining whether an inpatient admission with an expected length of stay of less than 2 midnights is nonetheless appropriate for Medicare Part A payment:

- Complex medical factors such as history and comorbidities;
- The severity of signs and symptoms;
- Current medical needs; and
- The risk of an adverse event.

The exceptions for procedures on the IPO list and for ''rare and unusual'' circumstances designated by CMS as national exceptions were unchanged by the CY 2016 OPPS/ASC final rule with comment period.

As we stated in the CY 2016 OPPS/ASC final rule with comment period, the decision to formally admit a patient to the hospital is subject to medical review. For instance, for cases where the medical record does not support a reasonable expectation of the need for hospital care crossing at least 2 midnights, and for inpatient admissions not related to a surgical procedure specified by Medicare as an IPO procedure under 42 CFR 419.22(n) or for which there is not a national exception, payment of the claim under Medicare Part A is subject to the clinical judgment

of the medical reviewer. The medical reviewer's clinical judgment involves the synthesis of all submitted medical record information (for example, progress notes, diagnostic findings, medications, nursing notes, and other supporting documentation) to make a medical review determination on whether the clinical requirements in the relevant policy have been met. In addition, Medicare review contractors must abide by CMS' policies in conducting payment determinations, but are permitted to take into account evidence-based guidelines or commercial utilization tools that may aid such a decision. While Medicare review contractors may continue to use commercial screening tools to help evaluate the inpatient admission decision for purposes of payment under Medicare Part A, such tools are not binding on the hospital, CMS, or its review contractors. This type of information also may be appropriately considered by the physician as part of the complex medical judgment that guides their decision to keep a beneficiary in the hospital and formulation of the expected length of stay.

2. Current Policy for Medical Review of Inpatient Hospital Admissions for Procedures Removed From the Inpatient Only List

In the CY 2020 OPPS/ASC final rule with comment period we finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities to assess compliance with the 2-Midnight rule within the 2 calendar years following their removal from the IPO list. We stated that these procedures will not be considered by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) in determining whether a provider exhibits persistent noncompliance with the 2-Midnight rule for purposes of referral to the RAC nor will these procedures be reviewed by RACs for ''patient status.'' We explained that during this 2-year period, BFCC–QIOs will have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule, but claims identified as noncompliant will not be denied with respect to the site-of-service under Medicare Part A.

In CY 2021 we proposed to continue the 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. However, we finalized our proposal with modifications in the CY 2021 OPPS/ASC final rule with comment period. Instead of the 2-year exemption, procedures removed from the IPO list after January 1, 2021 were indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service). We stated that this exemption would last until we have Medicare claims data indicating that the procedure is more commonly performed in the outpatient setting than the inpatient setting. Thus, for the exemption to end for a specific procedure, in a single calendar year we would need to have Medicare claims data indicating that the procedure was performed more than 50 percent of the time in the outpatient setting. We stated that we would revisit in rulemaking whether an exemption for a procedure should be ended or whether we may consider additional metrics in the future that could assist us in determining when the exemption period should end for a procedure. Even during this exemption period, the BFCC–QIOs retain the authority to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule, but claims identified as noncompliant will not be denied with respect to the site-of-service under Medicare Part A. Additionally, we stated that we may still conduct medical review in cases in which we believe there is potential fraud or abuse occurring. We explained that the elimination of the IPO list was a large scale change that created brand new considerations in determining site-of-service for providers and beneficiaries. At the time we believed a change of this significance required us to reevaluate our stance on the exemption period for procedures removed from the IPO list.

Finally, in the CY 2021 OPPS/ASC final rule with comment period we amended 42 CFR 412.3 to clarify when a procedure removed from the IPO is exempt from certain medical review activities. We stated that for those services and procedures removed between January 1 and December 31, 2020, this exemption will last for 2 years from the date of such removal. For those services and procedures removed on or after January 1, 2021, this exemption will last until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting.

3. Medical Review of Inpatient Hospital Admissions for Procedures Removed From the Inpatient Only List for CY 2022 and Subsequent Years

As stated earlier in this section, services on the IPO list are not subject to the 2-Midnight rule for purposes of determining whether payment is appropriate under Medicare Part A. However, the 2-Midnight rule is applicable once services have been removed from the IPO list. Outside of the exemption periods discussed above, services that have been removed from the IPO list are subject to initial medical reviews of claims for short-stay inpatient admissions conducted by BFCC–QIOs.

BFCC–QIOs may also refer providers to the RACs for further medical review due to exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to:

- Having high denial rates;
- Consistently failing to adhere to the 2-Midnight rule; or
- Failing to improve their performance after QIO educational intervention.

However, as finalized in the CY 2021 OPPS/ASC final rule with comment period, procedures that have been removed from the IPO list January 1, 2021 or later were indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service). We stated that this exemption would last until we have Medicare claims data indicating that the procedure is more commonly performed in the outpatient setting than the inpatient setting.

As stated in section IX, CMS is proposing to halt the elimination of the IPO list. In accordance with this proposal, we are proposing to amend 42 CFR 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a three-year transition. We are also proposing to return 298 procedures removed from the IPO list in CY 2021 to the IPO list for CY 2022.

Regardless of the status of the IPO list, we believe that the 2-Midnight benchmark remains an important metric to help guide when Part A payment for inpatient hospital admissions is appropriate. As technology advances and more services may be safely performed in the hospital outpatient setting and paid under the OPPS, it is

increasingly important for physicians to exercise their clinical judgment in determining the generally appropriate clinical setting for their patient to receive a procedure, whether that be as an inpatient or on an outpatient basis. Importantly, removal of a service from the IPO list has never meant that a beneficiary cannot receive the service as a hospital inpatient—as always, the physician should use his or her complex medical judgment to determine the appropriate setting on a case by case basis.

As stated previously, our current policy regarding IPO list procedures is that they are appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. Halting the elimination of the IPO list would mean that this will remain true for all services that are still on the list. As in previous years, any services that are removed from the list in the future will be subject to the 2-Midnight benchmark and 2-Midnight presumption. This means that for services removed from the IPO list, under the 2-Midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after admission will be presumed to be appropriate for Medicare Part A payment and would not be the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-Midnight presumption. Additionally, under the 2-Midnight benchmark, services formerly on the IPO list will be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation.

As finalized in the CY 2021 OPPS/ASC final rule with comment period, procedures removed from the IPO list after January 1, 2021 were indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service). These procedures are not considered by the BFCC–QIOs in determining whether a provider exhibits persistent noncompliance with the 2-Midnight rule for purposes of referral to the RAC nor will claims for these procedures be reviewed by RACs for ''patient status.'' During the exemption period, BFCC–QIOs have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule, but claims identified as noncompliant are not denied with respect to the site-of-service under Medicare Part A. Again, information gathered by the BFCC–QIO when reviewing procedures as they are newly removed from the IPO list can be used for educational purposes and does not result in a claim denial during the exemption period.

Because we are proposing to halt the elimination of the IPO list and add 298 services that were removed back to the IPO list, we believe this proposed change requires us to reexamine the applicable exemption period. We noted in the CY 2021 OPPS/ASC final rule with comment period that we may shorten the exemption period for a procedure if necessary. We heard from many commenters last year that the 2-year exemption was appropriate when CMS was removing a smaller volume of procedures from the IPO list. However, commenters believed that the unprecedented volume of procedures becoming subject to the 2-Midnight rule with the phased elimination of the IPO list would necessitate a longer exemption period. While these commenters expressed their support for continuing the 2-year exemption, they further stated that a longer exemption period may be more appropriate. Some commenters suggested that anywhere between 3 to 6 years or indefinitely would be appropriate. Commenters expressed their belief that increasing the length of the exemption would be necessary to allow hospitals and practitioners sufficient time to adjust their billing and clinical systems, as well as processes used to determine the appropriate setting of care. For a full description of the comments received please refer to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86115).

We believe that the indefinite exemption was appropriate when the agency was removing an unprecedented volume of procedures from the IPO list in a short period of time. That would have resulted in a large number of procedures becoming subject to the 2-Midnight rule in a three-year span. However, should we finalize our proposal to halt the elimination of the IPO list, there will no longer be an unprecedented volume of procedures removed from the IPO list at once, and thus the indefinite exemption may no longer be appropriate. As we explained in the CY 2021 OPPS/ASC final rule with comment period, the indefinite exemption was necessary given the magnitude of the change for providers. Now, however, we are proposing to move toward a much smaller volume of procedures becoming subject to the 2-Midnight rule at one time. We believe that, in the event that we finalize the proposed halt in the elimination of the IPO list, an indefinite exemption from medical review activities related to the 2-Midnight rule will no longer be warranted.

We continue to believe that, in order to facilitate compliance with our payment policy for inpatient admissions, some exemption from certain medical review activities for services removed from the IPO list under the OPPS is appropriate. Accordingly, we propose to rescind the indefinite exemption and instead apply a 2-year exemption from two midnight medical review activities for services removed from the IPO list on or after January 1, 2021. As finalized in the CY 2020 OPPS/ASC final rule with comment period, and unchanged by the CY 2021 rulemaking, services removed from the IPO list between January 1 and December 30, 2020, are currently subject to a 2-year exemption. Accordingly, under this proposal, the same 2-year exemption would apply to all service removed from the IPO list on or after January 1, 2020. As we explained in the CY 2020 OPPS/ASC final rule with comment period, we believe that a 2-year exemption from certain medical review activities for procedures removed from the IPO list would allow sufficient time for providers to become more familiar with how to comply with the 2-Midnight rule and for hospitals and clinicians to become used to the availability of payment under both the hospital inpatient and outpatient setting for procedures removed from the IPO list. Should we finalize our proposal to halt the elimination of the IPO list, we believe that this rationale applies equally to the smaller number of services that may be removed from the list at any one time in the future, and thus that the same 2-year exemption period is appropriate.

As with the previous 2-year exemption period for services removed from the IPO list between January 1 and December 30, 2020, applying a 2-year exemption period to services removed from the IPO list on or after January 1, 2021, would allow providers time to gather information on procedures newly removed from the IPO list to help inform education and guidance for the broader provider community, develop patient selection criteria to identify which patients are, and are not, appropriate candidates for outpatient procedures, and to develop related policy protocols. We believe that this exemption period would aid in

compliance with our payment policy for inpatient admissions.

It is important to note that whether there is a limited timeframe or an indefinite exemption from the specified medical review activities, providers are still expected to comply with the 2-Midnight rule. It is also important to note that the 2-Midnight rule does not prohibit procedures from being performed or billed on an inpatient basis. Whether a procedure has an exemption or not does not change what site of service is medically necessary or appropriate for an individual beneficiary. Providers are still expected to use their complex medical judgment to determine the appropriate site of service for each patient and to bill in compliance with the 2-Midnight rule. The exemption is not from the 2-Midnight rule but from certain medical review procedures and site-of-service claim denials.

Absent the removal of an unprecedented number of services at once from the IPO list, we continue to believe that a 2-year exemption from BFCC–QIO referral to RACs and RAC ''patient status'' review of the setting for procedures removed from the IPO list under the OPPS and performed in the inpatient setting would be an adequate amount of time to allow providers to gain experience with application of the 2-Midnight rule to these procedures and the documentation necessary for Part A payment for those patients for which the admitting physician determines that the procedures should be furnished in an inpatient setting. Furthermore, it is our belief that the 2-year exemption from referrals to RACs, RAC patient status review, and claims denials would be sufficient to allow providers time to update their billing systems and gain experience with respect to newly removed procedures eligible to be paid under either the IPPS or the OPPS, while avoiding potential adverse site-of-service determinations. We solicit public comments regarding the appropriate period of time for this exemption. Commenters may indicate whether and why they believe the 2-year period is appropriate, or whether they believe a longer or shorter exemption period would be more appropriate.

In summary, for CY 2021 and subsequent years, we propose to return to the 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS on January 1, 2021 or later. Under this proposal, services removed beginning on January 1, 2021 would receive the same 2-year exemption from 2-Midnight medical review activities as currently applies to services removed between January 1 and December 30, 2020, and not the indefinite exemption finalized in the CY 2021 OPPS/ASC final rule with comment period. We encourage BFCC–QIOs to review these cases for medical necessity in order to educate themselves and the provider community on appropriate documentation for Part A payment when the admitting physician determines that it is medically reasonable and necessary to conduct these procedures on an inpatient basis. We note that we will monitor changes in site-of-service to determine whether changes may be necessary to certain CMS Innovation Center models. While we are proposing to halt the elimination of the IPO list, we are seeking comment on whether a 2-year time period is appropriate, or if a longer or shorter period may be more warranted. If we do not finalize our proposal to halt the elimination of the IPO list we may continue with the indefinite exemptions. Finally, we are proposing to amend § 412.3 of the Code of Federal Regulations to clarify when a procedure removed from the IPO list is exempt from certain medical review activities. For all services and procedures removed after January 1, 2020, this exemption will last for 2 years from the date of such removal. This would include those services and procedures removed on or after January 1, 2021, for which this exemption would also be for 2 years from the date of such removal.

B. Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests

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. The reduced coinsurance will be phased in beginning January 1, 2022. Currently, the addition of any procedure beyond a planned colorectal cancer screening test (for which there is no coinsurance), results in the beneficiary having to pay coinsurance.

Section 1861(pp) of the Act defines ''colorectal cancer screening tests'' and, under sections 1861(pp)(1)(B) and (C) of the Act, identifies ''screening flexible sigmoidoscopy'' and ''screening colonoscopy'' as two of the recognized procedures. During the course of either one of these two procedures, removal of tissue or other matter may become necessary for diagnostic purposes. Among other things, section 1861(pp)(1)(D) of the Act authorizes the Secretary to include in the definition, other tests or procedures and modifications to the tests and procedures described under this subsection, with such frequency and payment limits as the Secretary determines appropriate, in consultation with appropriate organizations. Section 1861(s)(2)(R) of the Act includes colorectal cancer screening tests in the definition of the medical and other health services that fall within the scope of Medicare Part B benefits described in section 1832(a)(1) of the Act. Section 1861(ddd)(3) of the Act includes colorectal cancer screening tests within the definition of ''preventive services.'' In addition, section 1833(a)(1)(Y) of the Act provides for payment for a preventive service under the PFS at 100 percent of the lesser of the actual charge or the fee schedule amount for these colorectal cancer screening tests, and under the OPPS at 100 percent of the OPPS payment amount, when the preventive service is recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B. As such, there is no beneficiary coinsurance for recommended colorectal cancer screening tests as defined in section 1861(pp)(1) of the Act.

Under these statutory provisions, we have issued regulations governing payment for colorectal cancer screening tests at § 410.152(l)(5). We pay 100 percent of the Medicare payment amount established under the applicable payment methodology for the setting for providers and suppliers, and beneficiaries are not required to pay Part B coinsurance for colorectal cancer screening tests (except for barium enemas, which are not recommended by the USPSTF with a grade of A or B).

In addition to colorectal cancer screening tests, which typically are furnished to patients in the absence of signs or symptoms of illness or injury, Medicare also covers various diagnostic tests (see § 410.32). In general, diagnostic tests must be ordered by the physician or practitioner who is treating the beneficiary and who uses the results of the diagnostic test in the management of the patient's specific medical

condition. Under Part B, Medicare may cover flexible sigmoidoscopies and colonoscopies as diagnostic tests when those tests are reasonable and necessary as specified in section 1862(a)(1)(A) of the Act. When these services are furnished as diagnostic tests rather than as screening tests, patients are responsible for the 20 percent of the Part B coinsurance associated with these services.

We define colorectal cancer screening tests in our regulation at § 410.37(a)(1) to include ''flexible screening sigmoidoscopies'' and ''screening colonoscopies, including anesthesia furnished in conjunction with the service.'' Under our current regulations, we exclude from the definition of colorectal screening services, colonoscopies and sigmoidoscopies that begin as screening services, but where a polyp or other growth is found and removed as part of the procedure. The exclusion of these services from the definition of colorectal cancer screening services is based upon longstanding provisions of the statute under section 1834(d)(2)(D) dealing with the detection of lesions or growths during procedures (See CY 1998 PFS final rule at 62 FR 59048, 59082).

Prior to the enactment of section 122 of the CAA, section 1834(d)(2)(D) of the Act provided that if, during the course of a screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening flexible sigmoidoscopy, but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal. Similarly, prior to the recent legislative change, section 1834(d)(3)(D) of the Act provided that if, during the course of a screening colonoscopy, a lesion or growth is detected that results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal. In these situations, Medicare pays for the flexible sigmoidoscopy and colonoscopy tests as diagnostic tests rather than as screening tests and the 100 percent payment rate for recommended preventive services under section 1833(a)(1)(Y) of the Act, as codified in our regulation at § 410.152(l)(5), has not applied. As such, beneficiaries currently are responsible for the usual 20 percent coinsurance that applies to the services.

Under section 1833(b) of the Act, before making payment under Medicare Part B for expenses incurred by a beneficiary for covered Part B services, beneficiaries must first meet the applicable deductible for the year. Section 4104 of the Affordable Care Act (that is, the Patient Protection and Affordable Care Act (Pub. L. 111–148, March 23, 2010), and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, March 30, 2010), collectively referred to as the ''Affordable Care Act'') amended section 1833(b)(1) of the Act to make the deductible inapplicable to expenses incurred for certain preventive services that are recommended with a grade of A or B by the USPSTF, including colorectal cancer screening tests as defined in section 1861(pp) of the Act. Section 4104 of the Affordable Care Act also added a sentence at the end of section 1833(b)(1) of the Act specifying that the exception to the deductible shall apply with respect to a colorectal cancer screening test 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 screening test. Although amendments made by the Affordable Care Act addressed the applicability of the deductible in the case of a colorectal cancer screening test that involves biopsy or tissue removal, they did not alter the coinsurance provision in section 1833(a) of the Act for such procedures. Although public commenters encouraged the agency to eliminate the coinsurance in these circumstances, the agency found that statute did not provide for elimination of the coinsurance (75 FR 73170 at 73431).

Beneficiaries have continued to contact us noting their concern that a coinsurance percentage applies (20 or 25 percent depending upon the setting) under circumstances where they expected to receive only a colorectal screening test to which coinsurance does not apply. Instead, these beneficiaries received what Medicare considers to be a diagnostic procedure because, for example, polyps were discovered and removed during the procedure. Similarly, physicians have expressed concern about the reactions of beneficiaries when they are informed that they will be responsible for coinsurance if polyps are discovered and removed during a procedure that they had expected to be a screening procedure to which coinsurance does not apply.

Section 122 of the CAA addresses this coinsurance issue by successively reducing, over a period of years, the percentage amount of coinsurance for which the beneficiary is responsible. Ultimately, for services furnished on or after January 1, 2030, the coinsurance will be zero.

To implement the amendments made by section 122 of the CAA, we are proposing in the CY 2022 PFS proposed rule to modify our regulations to reflect the changes to statute. As amended, the statute effectively provides that, for services furnished on or after January 1, 2022, a flexible sigmoidoscopy or a colonoscopy can be considered a screening flexible sigmoidoscopy or a screening colonoscopy test even if an additional procedure is furnished to remove tissue or other matter during the screening test. Specifically, section 122(a)(3) of the CAA added a sentence to the end of section 1833(a) of the Act to include as colorectal screening tests described in section 1833(a)(1)(Y) of the Act, a colorectal cancer screening test, 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 screening test. We note that only flexible screening sigmoidoscopies and screening colonoscopies are recognized currently as colorectal cancer screening tests that might involve removal of tissue or other matter. This new sentence added under section 1833(a) uses the same language that was used to amend the statute at section 1833(b)(1) of the Act to broaden the scope of colorectal cancer screening tests to which a deductible does not apply. Section 122(b)(1) of the CAA then limits application of the 100 percent Medicare payment rate (that is, no beneficiary coinsurance) under section 1833(a)(1)(Y) of the Act for the additional colorectal cancer screening tests (those that are not screening tests ''but for'' the new sentence at the end of section 1833(a) of the Act) by making payment for them subject to a new section 1833(dd) of the Act. Section 1833(dd) of the Act provides for a series of increases in the Medicare payment rate percentage for those services over successive periods of years through CY 2029. Thereafter, section 1833(dd) of the Act has no effect, so payment for all colorectal cancer screening tests would be made at 100 percent under section 1833(a)(1)(Y) of the Act.

To codify the amendments made by section 122 of the CAA in our regulations, we are proposing in the CY 2022 PFS proposed rule to make two modifications to current regulations.

At § 410.37, we propose in the CY 2022 PFS proposed rule to modify our

regulation where we define conditions for and limitations on coverage for colorectal cancer screening tests by adding a new paragraph (j). That paragraph would provide that, effective January 1, 2022, when a planned colorectal cancer screening test, that is, screening flexible sigmoidoscopy or colonoscopy screening test, requires a related procedure, including removal of tissue or other matter, furnished in connection with, as a result of, and in the same clinical encounter as the screening test, it is considered to be a colorectal cancer screening test.

At § 410.152(l)(5), we propose in the CY 2022 PFS proposed rule to modify our regulation. Here we describe payment for colorectal cancer screening tests. Effective January 1, 2022, we propose to provide for an increase in the Medicare payment percentage that is phased in over time. As the Medicare payment percentage increases, the beneficiary coinsurance percentage decreases. We propose to revise section 410.152(l)(5) to provide that Medicare payment in a specified year is equal to a specified percent of the lesser of the actual charge for the service or the amount determined under the fee schedule that applies to the test. The phased in Medicare payment percentages for colorectal cancer screening services described in the amendments we propose in the CY 2022 PFS proposed rule to our regulation at section 410.37(j) (and the corresponding reduction in coinsurance) are as follows:

- 80 percent payment for services furnished in CY 2022 (with coinsurance equal to 20 percent);
- 85 percent payment for services furnished in CY 2023 (with coinsurance equal to 15 percent);
- 90 percent payment for services furnished in 2027 through 2029 (with coinsurance equal to 10 percent); and
- 100 percent payment for services furnished from CY 2030 onward (with coinsurance equal to zero percent).

Thus, between CYs 2022 and 2030, the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter will be reduced from 20 or 25 percent to 0 percent. We refer readers to the CY 2022 Medicare Physician Fee Schedule (PFS) proposed rule for the full discussion of these proposed changes. Comments on this proposed policy, including the proposed changes to the regulations at §§ 410.37 and 410.152(l)(5), should be submitted in response to the CY 2022 PFS proposed rule.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72019 through 72020), we adopted a policy that all surgical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of implementing section 4104(c)(2) of the Affordable Care Act. We created the HCPCS modifier PT for providers to append to the diagnostic procedure code that is reported instead of the screening colonoscopy, screening flexible sigmoidoscopy HCPCS code, or as a result of the barium enema when the screening test becomes a diagnostic service. Where the modifier appears on a claim, the claims processing system does not apply the Part B deductible for all surgical services on the same date as the diagnostic test. We stated that we believed this interpretation was appropriate because we believe that it would be very rare for an unrelated surgery to occur on the same date as one of these scheduled screening tests (75 FR 72019). We also stated that we would reassess the appropriateness of the proposed definition of services that are furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test that becomes diagnostic in the event of a legislative change to this policy (for example, a statutory change that would remove the coinsurance for these related services in addition to the deductible).

As we did for purposes of implementing section 4104(c)(2) of the Affordable Care Act, to implement the amendments made by section 122 of the CAA we propose that all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy would be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of determining the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter. We believe this interpretation is appropriate because we continue to believe that it is very rare for an unrelated surgery to occur on the same date as a scheduled colorectal cancer screening. Providers must continue to report HCPCS modifier ''PT'' to indicate that a planned colorectal cancer screening service converted to a diagnostic service. We note that if this proposal is finalized, we will examine the claims data, monitor for any increases in surgical services unrelated to the colorectal cancer screening test performed on the same date as the screening test, and consider revising our policy through rulemaking if there is a notable increase.

C. Low Volume Policy for Clinical, Brachytherapy, and New Technology APCs

Historically, we have used our equitable adjustment authority at section 1833(t)(2)(E) of the Act on a case-by-case basis to adjust how we determine the costs for certain low volume services. In the CY 2016 OPPS/ASC final rule with comment period, we acknowledged that for low volume procedures with significant device costs, the median cost would be a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for low volume procedures (80 FR 70388 through 70389). We explained that the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. Therefore, in the CY 2016 OPPS/ASC final rule with comment period, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act to use the median cost, rather than the geometric mean, to calculate the payment rate for the procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) for CY 2016.

In the CY 2017 OPPS/ASC final rule with comment period, we adopted a payment policy for low-volume device-intensive procedures similar to the policy we applied to the procedure described by CPT code 0308T. Under this policy, we calculate the payment rate for any device-intensive procedure that is assigned to an APC with fewer than 100 single claims for all procedures in the APC using the median cost instead of the geometric mean cost (81 FR 79660 through 79661). We explained that we believed this policy would help mitigate to some extent the significant year-to-year payment rate fluctuations while preserving accurate claims data-based payment rates for these procedures.

In the CY 2019 OPPS/ASC final rule with comment period, we developed a policy for establishing payment rates for low-volume procedures assigned to New Technology APCs (83 FR 58892 through 58893). In that rule, we explained that procedures assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them (83 FR 58892). One of the objectives of

establishing New Technology APCs is to generate sufficient claims data for a new procedure so that it can be assigned to an appropriate clinical APC. We stated that some procedures that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. There is a higher probability that payment data for a procedure with fewer than 100 claims per year may not have a normal statistical distribution, which we were concerned could affect the quality of our standard cost methodology for assigning services to clinical APCs. We also noted that services with fewer than 100 claims per year are not generally considered to be significant contributors to the APC ratesetting calculations, and therefore, are not included in the assessment of the 2 times rule. For these low-volume procedures, we were concerned that the methodology we use to estimate the cost of a procedure under the OPPS—calculating the geometric mean for all separately paid claims for a HCPCS procedure code from the most recent available year of claims data—may not generate an accurate estimate of the actual cost of these procedures.

We noted that low utilization of services can lead to wide variation in payment rates from year to year. This volatility in payment rates from year to year can result in even lower utilization and potential barriers to access for these new technologies, which in turn limits our ability to assign the service to an appropriate clinical APC. To mitigate these issues, we believed that it was appropriate 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. We finalized a policy to calculate payment rates for low-volume procedures with fewer than 100 claims per year that are assigned to a New Technology APC by using up to 4 years of claims data to calculate the geometric mean, the median, and the arithmetic mean, to include the result of each statistical methodology in annual rulemaking, and to solicit comment on which methodology should be used to establish the payment rate. We explained that once we identify a payment rate for a low-volume service, we would assign the service to the New Technology APC with the cost band that includes its payment rate (83 FR 58893).

While we believe that the policies we have adopted to calculate payment rates for low-volume procedures have mitigated concerns regarding payment rates for new technologies and device-intensive procedures, we also believe that additional items and services may benefit from a policy that applies to clinical APCs with significantly low claims volume available for ratesetting purposes. In particular, we believe that where there are fewer than 100 single claims from the most recent year available for ratesetting for an APC, there is often significant volatility in the payment rate for those APCs that could be addressed with a low-volume adjustment policy similar to our low-volume policies for device-intensive procedures and New Technology APCs. For example, for CY 2022 ratesetting purposes, there are only 43 single claims from CY 2019 available for determining the geometric mean cost for APC 5244 (Level 4 Blood Product Exchange and Related Services) and the payment rate for this APC has fluctuated significantly from year to year. The geometric mean cost of APC 5244 was $30,424.15 in CY 2018 (based on CY 2016 claims), increased by 25.6 percent to $38,220.27 in CY 2019 (based on CY 2017 claims), and decreased by 18.9 percent to $31,015.17 in CY 2021 (based on CY 2019 claims).

Additionally, for CY 2022 ratesetting purposes, there are only 22 single claims from CY 2019 available for determining the geometric mean cost of APC 2632 (Iodine i-125 sodium iodide). The payment rates for this APC have also fluctuated significantly, with a geometric mean cost of $26.63 in CY 2018 (based on CY 2016 claims), which increased by 43.4 percent to $38.20 in CY 2019 (based on CY 2017 claims), and decreased by 31.8 percent to $26.04 in CY 2021 (based on CY 2019 claims).

We believe that APCs with low claims volume available for ratesetting could also benefit from a low-volume adjustment policy similar to the one we currently utilize to set payment rates for device-intensive procedures and procedures assigned to New Technology APCs. Specifically, we propose to designate clinical APCs, brachytherapy APCs, and New Technology APCs with fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year (the CY 2019 claims year for this CY 2022 proposed rule) as low volume APCs. While our proposed criterion for a clinical or brachytherapy APC to qualify as a low volume APC policy is that the APC have fewer than 100 single claims that can be used for ratesetting, we acknowledge that New Technology APCs are different from clinical APCs in that they contain procedures that may not be clinically similar to other procedures assigned to the same New Technology APC based on cost and are only assigned to a New Technology APC because there is not sufficient data to assign these procedures to a clinical APC. Therefore, we propose that for New Technology APCs with fewer than 100 single claims at the procedure level that can be used for ratesetting, we would apply our proposed methodology for determining a low volume APC's cost, choosing the ''greatest of'' the median, arithmetic mean, or geometric mean at the procedure level, to apply to the individual services assigned to New Technology APCs and provide the final New Technology APC assignment for each procedure.

We are proposing that the threshold for the low volume APC designation would be fewer than 100 single claims per year for the APC that can be used for ratesetting purposes, as this is how we have traditionally defined low volume under our existing policies. As previously mentioned, the threshold would be 100 single claims at the procedure level for New Tech APCs. We have defined low volume as fewer than 100 single claims under our existing policies as there is a higher probability that payment data for a procedure with fewer than 100 claims per year may not have a normal statistical distribution, which we were concerned could affect how we set payment rates for low volume APCs. For items and services assigned to APCs we propose to designate as low volume APCs, we are proposing to use up to 4 years of claims data to establish a payment rate for each item or service as we currently do for low volume services assigned to New Technology APCs. The availability of multiple years of claims data will allow for more claims to be used for ratesetting purposes and create a more statistically reliable payment rate for these APCs than setting rates for APCs with low claims volume based on one year of data alone. Further, using multiple years of claims data, we are proposing to use the greatest of the median, arithmetic mean, or geometric mean cost to approximate the cost of items and services assigned to a low volume APC. In previous years, we have received few to no public comments on which statistical methodology to use and have usually chosen the methodology that yields the highest rate to set the payment rate for procedures assigned to New Technology APCs. Going forward, we are proposing to formalize this approach for low volume New Technology, clinical, and brachytherapy APCs, as we believe using the greatest of these three methodologies provides a simple and consistent approach to determining the cost metric to be used for ratesetting for

these APCs and avoids uncertainty where multiple cost metrics could be used to set the APC's cost. Additionally, due to the payment volatility and low volume nature of these products, we believe that choosing the methodology that yields the highest rate will ensure that these products receive sufficient payment and that payment is not a barrier to access for these procedures.

Given the different nature of policies that affect the partial hospitalization program (PHP), we are not proposing to apply this low volume APC policy to APC 5853 Partial Hospitalization for CMHCs or APC 5863 Partial Hospitalization for Hospital-based PHPs. We are also not proposing to apply this low volume APC policy to APC 2698 (Brachytx, stranded, nos) or APC 2699 (Brachytx, non-stranded, nos), as we believe our current methodology for determining payment rates for non-specified brachytherapy sources, as discussed in Section II.A.2.a.(2) of this proposed rule, is appropriate. Further, as discussed in additional detail in Section IV.B.5 of this proposed rule, we are proposing to eliminate our low volume Device-Intensive Procedure policy, for which HCPCS code 0308T has been the only procedure subject to this policy, and subsume the ratesetting for HCPCS code 0308T within our broader low volume APC proposal.

For this CY 2022 OPPS/ASC proposed rule, we evaluated certain New Technology APCs to determine if such APCs meet our low volume APC criteria. As previously mentioned, we are proposing to use the ''greatest of'' the geometric mean, the median, or the arithmetic mean at the procedure level for determining the low volume APC cost of the individual services assigned to New Technology APCs, rather than soliciting comment on which methodology to use. In claims data available for this CY 2022 OPPS/ASC proposed rule, there were 5 claims for APC 1562 (which reflects the assignment of new technology procedure HCPCS code C9751 (bronchoscopy with transbronchial ablation of lesions by microwave energy)) and 35 claims for APC 1908 (New Technology—Level 52 ($145,001–$160,000)) which reflects the assignment of new technology procedure CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy).

Given the low volume of claims for HCPCS code C9751, we propose for CY 2022 to calculate the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning HCPCS code C9751 to a New Technology APC. We found the greatest cost metric for HCPCS code C9751 to be $3,707.76. Therefore, for this proposed rule, we are proposing to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3,501–$4,000)) and we are proposing to designate APC 1562 (New Technology—Level 25 ($3,501–$4,000)) as a low volume APC with a proposed APC cost and payment rate of $3,750.50. Details regarding APC 1562 are shown in Table 36.

Additionally, given the low volume of claims for APC 1908 (New Technology—Level 52 ($145,001–$160,000)) which reflects the assignment of new technology procedure CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy), we propose for CY 2022 to calculate the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning CPT code 0100T to a New Technology APC. We found the greatest cost metric for CPT code 0100T to be $155,412.90. Therefore, for this proposed rule, we are proposing to assign CPT code 0100T to APC 1908 (New Technology—Level 52 ($145,001–$160,000)) and we are proposing to designate APC 1908 (New Technology—Level 52 ($145,001–$160,000)) as a low volume APC with a proposed APC cost and payment rate of $152,500.50. Details regarding APC 1908 are shown in Table 36.

Further, for CY 2022, in addition to the 2 New Technology APCs we are proposing to designate as low volume APCs, we are also proposing to designate 4 clinical APCs and 5 brachytherapy APCs as low volume APCs under the OPPS. The 4 clinical APCs and 5 brachytherapy APCs meet our criteria of having fewer than 100 single claims in the claims year (CY 2019 for this CY 2022 OPPS/ASC proposed rule) and therefore, we propose that they would be subject to our new low volume APC policy, if finalized. Table 36 illustrates the APC geometric mean cost without the low volume APC designation, the median, arithmetic mean, and geometric mean cost using up to 4 years of claims data, as well as the statistical methodology we are proposing to use as the APC's cost for ratesetting purposes for CY 2022. As discussed in Section II.A.1.a of this proposed rule, given our concerns with CY 2020 claims data as a result of the PHE, the 4 years of claims data are based on CY 2016 claims through CY 2019 claims.

BILLING CODE 4120–01–P

Table 36. Cost Statistics for Proposed Low Volume APCs for CY 2022

APC	APC Description	Geometric Mean Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	CY 2022 Proposed APC Cost
1562	New Technology – Level 25 ($3,501 - $4,000)	$2,692.69	$3,707.76	$3,085.64	$2,692.69	$3,750.50
1908	New Technology – Level 52 ($145,001 - $160,000)	$155,412.90	$150,363.60	$154,321.70	$148,778.00	$152,500.50
2632	Iodine I-125 sodium iodide	$26.04	$30.24	$38.52	$34.16	$38.52
2635	Brachytx, non-str, HA, P-103	$44.37	$34.04	$43.53	$36.72	$43.53
2636	Brachy linear, non-str, P-103	$30.59	$24.78	$50.16	$36.43	$50.16
2645	Brachytx, non-str, Gold-198	$280.90	$61.85	$588.31	$131.86	$588.31
2647	Brachytx, NS, Non-HDRIr-192	$275.13	$145.36	$196.38	$94.24	$196.38
5244	Level 4 Blood Product Exchange and Related Services	$31,015.17	$34,287.01	$39,444.97	$34,399.17	$39,444.97
5494	Level 4 Intraocular Procedures	$14,621.42	$16,155.58	$14,951.58	$11,490.23	$16,155.58
5495	Level 5 Intraocular Procedures	$17,414.85	$17,414.85	$17,414.85	$17,414.85	$17,414.85

BILLING CODE 4120–01–C

Based on the number of available claims from the standard ratesetting methodology used for ASC ratesetting purposes, for CY 2022, under the ASC payment system, we propose to designate 2 New Technology APCs, 3 clinical APCs, and 5 brachytherapy APCs as Low Volume APCs that meet our criteria of having fewer than 100 single claims in the claims year (CY 2019 for this CY 2022 OPPS/ASC proposed rule) and would be subject to our new Low Volume APC. Under our proposed Low Volume APC policy, the payment rates for these APCs would be set at the highest amount among the geometric mean, median, or arithmetic mean, calculated using up to four years of data, which in the case of these APCs, would be claims data from 2016 through 2019.

As discussed in Section II.A.1.a of this proposed rule, given our concerns with CY 2020 claims data as a result of the PHE, the 4 years of claims data are based on claims from CY 2016 through CY 2019. We are soliciting comments from the public on our proposal to establish a Low Volume APC policy for clinical APCs, brachytherapy APCs, and New Technology APCs. This includes our criterion for designating an APC as a Low Volume APC, the use of the highest of the geometric mean, median, and arithmetic mean to determine the payment rate for clinical and brachytherapy APCs, as well as individual services assigned to New Technology APCs, and our use of claims data from CY 2016 through 2019 to calculate the geometric mean, median, and arithmetic mean for purposes of determining the CY 2022 payment rates for these APCs.

D. Comment Solicitation on Temporary Policies To Address the COVID–19 PHE

In response to the COVID–19 pandemic, CMS issued waivers and undertook emergency rulemaking to implement a number of temporary policies to address the pandemic, including policies to prevent spread of the infection and support diagnosis of COVID–19. Many of these flexibilities were available because certain statutory or regulatory provisions were waived. These waivers will expire at the conclusion of the PHE. We are seeking comment on the extent to which stakeholders utilized the flexibilities available under these waivers, as well as whether stakeholders believe certain of these temporary policies should be made permanent to the extent possible within our existing authority. Specifically, we are seeking comment on stakeholders' experience with hospital staff furnishing services remotely to beneficiaries in their homes through use of communications technology; providers furnishing services in which the direct supervision for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services requirement was met by the supervising practitioner being available through audio/video real-time communications technology; and the need for specific coding and payment to remain available under the OPPS for specimen collection for COVID–19.

1. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

Under the Physician Fee Schedule (PFS), Medicare makes payment to professionals and other suppliers for physicians' services, including certain diagnostic tests and preventive services. Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of Medicare telehealth services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunications technology. When furnished as Medicare telehealth services under section 1834(m), many of these services are still reported using codes that describe ''face-to-face'' services even though they are furnished using audio/video, real-time communications technology instead of in-person (82 FR 53006). Section 1834(m) of the Act specifies the types of health care professionals that can furnish and be paid by Medicare for telehealth services (referred to as distant site practitioners) and the types and locations of settings where a beneficiary can be located when receiving telehealth services (referred to as originating sites). In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare telehealth services list in accordance with section 1834(m)(4)(F)(ii) of the Act (42 CFR 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which we consider and review through the annual PFS rulemaking process. The regulation at § 410.78(a)(3) also defines the requirements for the interactive telecommunications systems that may be used to furnish Medicare telehealth services.

Due to the circumstances of the COVID–19 pandemic, particularly the need to maintain physical distance to avoid exposure to the virus, we anticipated that health care practitioners would develop new approaches to providing care using various forms of technology when they are not physically present with the patient. We have established several flexibilities to accommodate these changes in the delivery of care. For Medicare telehealth services, using waiver authority under section 1135(b)(8) of the Act in response to the PHE for the COVID–19 pandemic, we have removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as the restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE for the COVID–19 pandemic. We also used waiver authority to allow certain telehealth services to be furnished via audio-only communication technology during the PHE.

According to MedPAC's report, *Telehealth in Medicare after the Coronavirus Public Health Emergency,*[107] there were 8.4 million telehealth services paid under the PFS in April 2020, compared with 102,000 in February 2020. MedPAC also reported that during focus groups held in the summer of 2020, clinicians and beneficiaries supported continued access to telehealth visits with some combination of in-person visits. They cited benefits of telehealth, including improved access to care for those with physical impairments, increased convenience from not traveling to an office, and increased access to specialists outside of a local area. In their annual beneficiary survey, over 90 percent of respondents who had a telehealth visit reported being ''somewhat'' or ''very satisfied'' with their video or audio visit, and nearly two-thirds reported being ''very satisfied.''

Recently enacted legislation modified the circumstances under which Medicare makes payment for mental health services furnished via telehealth technology under the PFS following the PHE. Division CC, section 123 of the CAAremoved the geographic originating site restrictions and added the home of the individual as a permissible originating site for Medicare telehealth services when furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder.[108]

[107] *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_ch14_sec.pdf?sfvrsn=0.*

[108] There is a longstanding statutory payment exclusion that prohibits Medicare payment for services that are not furnished within the United

Continued

This change correlates with a growing acceptance of the use of technology in the provision of mental health care. According to the Commonwealth Fund,[109] the provision of mental and behavioral health services via communications technology, in particular, has a robust evidence base and numerous studies have demonstrated its effectiveness across a range of modalities and mental health diagnoses (*e.g.,* depression, substance use disorders). Clinicians furnishing tele-psychiatry services at Massachusetts General Hospital Department of Psychiatry during the PHE observed several advantages of the virtual format for furnishing psychiatric services, noting that patients with psychiatric pathologies that interfere with their ability to leave home (*e.g.,* immobilizing depression, anxiety, agoraphobia, and/or time-consuming obsessive-compulsive rituals) were able to access care more consistently since eliminating the need to travel to a psychiatry clinic can increase privacy and therefore decrease stigma-related barriers to treatment, potentially bringing care to many more patients in need, as well as enhanced ease of scheduling, decreased rate of no-shows, increased understanding of family and home dynamics, and protection for patients and practitioners with underlying health conditions.[110]

These findings are consistent with our analysis of Medicare claims data that indicate that interactive communications technology for mental health care is likely to continue to be in broad use beyond the circumstances of the pandemic. According to our analysis of Medicare Part B claims data for services furnished via Medicare telehealth during the PHE, use of telehealth for many professional services spiked in utilization around April 2020 and diminished over time. In contrast, Medicare claims data suggest that for mental health services added to the Medicare Telehealth list both permanently and temporarily, subsequent to April 2020, the trend is toward maintaining a steady state of usage over time. Given this information, broad acceptance in the public and medical community, and the relatively stable Medicare utilization of mental health services during the COVID–19 pandemic, we believe use of interactive communication technology in furnishing mental health care is becoming an established part of medical practice, very likely to persist after the COVID–19 pandemic, and available across the country under the Medicare statute for the range of professionals furnishing mental health care and paid under the PFS.

In many cases, hospitals provide hospital outpatient mental health services (including behavioral health), education, and training services that are furnished by hospital-employed counselors or other licensed professionals. Examples of these services include psychoanalysis, psychotherapy, diabetes self-management training, and medical nutrition therapy. With few exceptions, the Medicare statute does not have a benefit category that would allow these types of professionals (for example, mental health counselors and registered nurses) to bill Medicare directly for their services. These services can, in many cases, be billed by providers such as hospitals under the OPPS or by physicians and other practitioners as services incident to their professional services under the PFS. We also note that while partial hospitalization services are paid under the OPPS, section 1861(ff)(3)(A) of the Act explicitly prohibits partial hospitalization services from being furnished in an individual's home or residential setting.

As we explained in the interim final rule with comment period published on May 8, 2020 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'' (the May 8th COVID–19 IFC) (85 FR 27550, 27563), outpatient mental health services, education, and training services require communication and interaction. We stated that facility staff can effectively furnish these services using telecommunication technology and, unlike many hospital services, the clinical staff and patient are not required to be in the same location to furnish them. We further explained that blanket waivers in effect during the COVID–19 PHE allow the hospital to consider the beneficiary's home, and any other temporary expansion location operated by the hospital during the COVID–19 PHE, to be a provider-based department (PBD) of the hospital, so long as the hospital can ensure the locations meet all of the conditions of participation, to the extent not waived. In light of the need for infection control and a desire for continuity of behavioral health care and treatment services, we recognized the ability of the hospital's clinical staff to continue to deliver these services even when they are not physically located in the hospital. Therefore, in the May 8th COVID–19 IFC (85 FR 27564), we made clear that when a hospital's clinical staff are furnishing hospital outpatient mental health services, education, and training services to a patient in the hospital (which can include the patient's home so long as it is provider-based to the hospital), and the patient is registered as an outpatient of the hospital, we will consider the requirements of the regulations at § 410.27(a)(1) to be met. We reminded readers that the physician supervision level for the vast majority of hospital outpatient therapeutic services is currently general supervision under § 410.27. This means a service must be furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service.

In the May 8th COVID–19 IFC we emphasized that all services furnished by the hospital still require an order by a physician or qualified NPP and must be supervised by a physician or other NPP appropriate for supervising the service given their hospital admitting privileges, state licensing, and scope of practice, consistent with the requirements in § 410.27 (85 FR 27563). We noted that hospitals may bill for these services as if they were furnished in the hospital and consistent with any specific requirements for billing Medicare in general, including any relevant modifications in effect during the COVID–19 PHE. We also noted that when these services are provided by clinical staff of the physician or other practitioner and furnished incident to their professional services, and are not provided by staff of the hospital, the hospital would not bill for the services. We stated that in those circumstances, the physician or other practitioner should bill for such services incident to their own services and would be paid under the PFS.

Given that the widespread use of communications technology to furnish services during the PHE has illustrated acceptance within the medical community and among Medicare beneficiaries of the possibility of furnishing and receiving care through the use of that technology, we are interested in information on the role of hospital staff in providing care to beneficiaries remotely in their homes. During the PHE, hospital staff have had the flexibility to provide these kinds of services to beneficiaries in their homes through communications technology; however, this flexibility is tied to

States (see section 1862(a)(4) of the Act). This payment exclusion was not changed by the CAA.

[109] *https://www.commonwealthfund.org/blog/2020/using-telehealth-meet-mental-health-needs-during-covid-19-crisis.*

[110] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7347331/.*

waivers and other temporary policies that expire at the end of the PHE. In instances where a beneficiary may be receiving mental health services from a hospital clinical staff member who cannot bill Medicare independently for their professional service, the beneficiary would then need to physically travel to the hospital to continue receiving the services post-PHE. We are concerned that this could have a negative impact on access to care in areas where beneficiaries may only be able to access mental health services provided by hospital staff and, during the PHE, have become accustomed to receiving these services in their homes. We also note that the ability to receive mental health services in their homes may help expand access to care for beneficiaries who prefer additional privacy for the treatment of their condition.

We are concerned that, during the PHE, practice patterns may have shifted to support expanded virtual services. During the PHE, we have not required any claims-based modifier identifying specifically when a service is furnished by clinical staff of the hospital to a beneficiary in their home through communications technology, and therefore we are not able to gauge the magnitude of these practice pattern shifts. Therefore, we are seeking comment on the extent to which hospitals have been billing for mental health services provided to beneficiaries in their homes through communications technology during the PHE, and whether they would anticipate continuing demand for this model of care following the conclusion of the PHE. As described in preceding paragraphs, billing for Medicare telehealth services has increased dramatically during the PHE, particularly for mental health services. We are seeking comment on whether hospitals have experienced a similar increase during the PHE in utilization of mental health services provided by hospital staff to beneficiaries in their homes through communications technology. We are also seeking comment on whether there are changes commenters believe CMS should make to account for shifting patterns of practice that rely on communication technology to provide mental health services to beneficiaries in their homes.

2. Direct Supervision by Interactive Communications Technology

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 § 400.200, the presence of the physician for purposes of the direct supervision requirement for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation 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 practitioner. 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 end of the PHE as defined in § 400.200 or December 31, 2021, whichever is later (85 FR 86113). We noted that the public comments we received, along with feedback we have received since the implementation of the policy in the April 6th COVID–19 IFC allowing for direct supervision through virtual presence (85 FR 19246) have convinced us that we need more information on the issues involved with direct supervision through virtual presence before implementing this policy permanently. We acknowledge that the additional time between the issuance of the CY 2021 OPPS/ASC final rule with comment period and the issuance of this proposed rule may have allowed providers to collection more information that could inform CMS' decision making and are therefore seeking additional comment on whether this policy should be adopted on a permanent basis. While we are not proposing to maintain this flexibility after the later of the end of the PHE or December 31, 2021, we are seeking comment on whether and to what extent hospitals have relied upon this flexibility during the PHE and whether providers expect this flexibility would be beneficial outside of the PHE. We are seeking comment on whether we should continue to allow direct supervision for these services to include presence of the supervising practitioner via two-way, audio/video communication technology permanently, or for some period of time after the conclusion of the PHE or beyond December 31, 2021, to facilitate a gradual sunset of the policy. We are also seeking comment on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE. Finally, if this policy is made permanent, we are seeking comment on whether a service-level modifier should be required to identify when the requirements for direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services were met using audio/video real-time communications technology.

3. Payment for COVID–19 Specimen Collection in Hospital Outpatient Departments

Also in the May 8th COVID–19 IFC, 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 COVID–19 IFC, we did not identify a code that explicitly described the exact services of symptom assessment and specimen collection that HOPDs were undertaking to facilitate widespread testing for COVID–19. As stated in the May 8th COVID–19 IFC, 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 27605).

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 $24.67 for CY 2021. HCPCS code C9803 was also assigned a status indicator of ''Q1.'' The Q1 status indicator indicates that the OPPS 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 will make separate payment for the service under the OPPS. The OPPS 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 OPPS.

We are soliciting public comments on whether we should keep HCPCS code C9803 active beyond the conclusion of the COVID–19 PHE and whether we should extend or make permanent the OPPS payment associated with specimen collection for COVID–19 tests after the COVID–19 PHE ends, including why commenters believe it would be necessary to continue to provide OPPS payment for this service, as well as how long commenters believe payment should be extended for this code.

E. Use of CY 2019 Claims Data for CY 2022 OPPS and ASC Payment System Ratesetting Due to the PHE

As described in section I.A. of this proposed rule with comment period, section 1833(t) of the Social Security Act requires the Secretary 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 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) 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.

In updating the OPPS payment rates and system for each rulemaking cycle we primarily use two sources of information: The outpatient Medicare claims data and 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 OPPS ratesetting process, our goal is to use the best available data for ratesetting so that we can accurately estimate the costs associated with furnishing outpatient services, and thus set appropriate payment rates. Ordinarily, the best available claims data is the set of data from 2 years prior to the calendar year that is the subject of rulemaking. For CY 2022 OPPS/ASC proposed rule ratesetting, this typically would have been the set of CY 2020 calendar year outpatient claims data processed through December 31, 2020. 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. For example, ordinarily, the best available cost report data used in developing the OPPS relative weights would be from cost reports beginning 3 fiscal years prior to the year that is the subject of the rulemaking. For CY 2022 OPPS ratesetting, under ordinary circumstances, that would be cost report data from HCRIS extracted in December 2020, which would contain many cost reports ending in FY 2020 based on each hospital's cost reporting period.

As discussed in section I.F. of the FY 2022 IPPS/LTCH proposed rule, there are a number of issues related to the use of the standard hospital data we would otherwise use for purposes of CY 2022 ratesetting because data from the applicable time period would include the effects of the COVID–19 PHE (86 FR 25086 through 25090). Even though the specific data elements might be slightly different between the inpatient and outpatient hospital settings, the same questions and challenges exist for hospital data from CY/FY 2020. Some of the issues are focused on the source data and the degree to which the utilization of services and cost patterns found in them are affected by the PHE. Other issues are more prospective in nature and concern whether hospital claims data from this time period might be consistent with our expectations for the prospective year, particularly in a changing environment with regards to COVID–19 vaccinations and treatment.

In the FY 2022 IPPS proposed rule, we proposed to use FY 2019 data for FY 2022 IPPS ratesetting based on our determination that the FY 2019 data would be more representative of FY 2022 inpatient hospital experience than the FY 2020 data (86 FR 25089). We note that there are a number of policies that apply and interact across the IPPS and OPPS, in part because they both concern services furnished in the hospital setting. We have noted in annual rulemaking in regards to adopting the fiscal year IPPS wage index into the OPPS, the ''inseparable, subordinate status of the HOPD within the hospital overall'' (85 FR 85908). It is in this context where inpatient and outpatient hospital departments are inherently connected to each other, as parts of the broader hospital setting overall, that we have identified many of the same reasons to use 2019 data for 2022 ratesetting as discussed in the FY 2022 IPPS proposed rule.

We note that we observe a number of changes, likely as a result of the PHE, in the CY 2020 OPPS claims data that we would ordinarily use for ratesetting. The most significant difference compared to prior years is the decrease in the overall volume of outpatient hospital claims—with approximately 20 percent fewer claims usable for ratesetting purposes when compared to the prior year. In addition, this decrease in outpatient claims volume applied to a majority of the clinical APCs in the OPPS.

In some cases, we saw broad changes as a result of the PHE, including in the APCs for hospital emergency department and clinic visits. Among those APCs, the decrease in volume was approximately 30 percent—some of which may be related to changing practice patterns during the PHE. For example, we see a significant increase in the use of the HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims, with the approximately 35,000 services billed in the CY 2019 OPPS claims increasing to 1.8 million services in the CY 2020 OPPS claims. This example highlights two types of differences we see in the CY 2020 set of claims when comparing to more typical claims data. One difference is likely due to the degree to which elective procedures/services were not performed as often during the PHE. The other difference is the result of site of service changes due to flexibilities available during the PHE.

In other cases, we saw changes in the claims data that were associated with specific services that were furnished more frequently during the PHE. For example, two notable exceptions to this decrease in claims volume between CY 2019 and CY 2020 are for APC 5731 (Level 1 Minor Procedures) and APC 5801 (Ventilation Initiation and Management). In the case of APC 5731, HCPCS code C9803 was made effective for services furnished on or after March 1, 2020 through the 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'' (85 FR 27602 through 27605) to describe a COVID–19 Specimen collection. In the CY 2020 claims, HCPCS C9803 has 1,023,957 single claims available for cost modeling, representing approximately 93% of claims used to model the APC cost. While in some cases this would be appropriate in establishing the APC cost, we generally would not expect the same volume of the procedure in the CY 2022 OPPS because we anticipate that specimen collection for COVID–19 testing will be significantly lower than it was in CY 2020. Similarly, the estimated increase in the geometric mean cost of APC 5801 based on the CY 2020 claims data may not be predictive of CY 2022 costs for APC 5801 if there is less use of this service in CY 2022 than in CY 2020.

As a result of a number of COVID–19 PHE-related factors, including the

changes in services potentially related to the COVID–19 PHE, the significant decrease in volume suggesting that patients may have been deferring elective care during CY 2020, the changes in APC relative weights for services, and the increasing number of Medicare beneficiaries vaccinated against COVID–19, we believe that CY 2020 data are not the best overall approximation of expected outpatient hospital services in CY 2022. Instead we believe that CY 2019 data, as the most recent complete calendar year of data prior to the COVID–19 PHE, are a better approximation of expected CY 2022 hospital outpatient services.

We analyzed the extent the decision to use CY 2019 or CY 2020 claims data as the basis for ratesetting differentially impacts the CY 2022 OPPS rates. To do this, we estimated the difference in case-mix under the CY 2019-based weights and the CY 2020-based weights if the CY 2022 outpatient experience ended up being the reverse of the assumption made when calculating that set of relative weights. In other words, we compared estimated case-mix calculated under four different scenarios. For the CY 2019-based weights, we calculated the case-mix using claims from the CY 2019-based claims extract as an approximation of the actual CY 2022 experience (Scenario A), and using claims from the CY 2020 based claims extract as an approximation of the actual CY 2022 experience (Scenario B). For the CY 2020-based weights, we calculated the case-mix using claims from the CY 2020 claims based extract as an approximation of the actual CY 2022 outpatient experience (Scenario C), and using claims from the CY 2019 claims based extract as an approximation of the actual CY 2022 experience (Scenario D). The results are shown in the following table 37.

Table 37: Estimated Impact of Claims Based Assumptions for CY 2022 Outpatient Experience

Scenario	Assumed CY 2022 Experience for Relative Weights	Actual CY 2022 Experience	Case-mix	Assumption Matched Experience	Percent change in case-mix if Mismatch between Assumption and Actual Experience
A	CY 2019	CY 2019	4.620	Yes	
B	CY 2019	CY 2020	5.056	No	0.10%
C	CY 2020	CY 2020	5.051	Yes	
D	CY 2020	CY 2019	4.600	No	-0.44%

In Scenario A and Scenario C, there is no differential impact as a result of a less accurate assumption made when the OPPS relative weights were calculated: The CY 2022 outpatient experience matches the assumption made when the OPPS relative weights were calculated. In Scenario B and Scenario D, the actual experience is the reverse of the assumption used when the OPPS relative weights were calculated.

In Scenario B, when the CY 2019-based weights were used, but the CY 2022 outpatient experience turns out to be more similar to CY 2020 claims data, the less accurate assumption slightly affects the calculated case-mix, by 0.1 percent. This can be seen by comparing the modeled case mix under Scenario B (5.056) with the modeled case-mix under Scenario C (5.051). In other words, if we use the CY 2019-based weights and CY 2022 outpatient experience turns out to be more similar to the CY 2020 data, then the modeled case-mix is slightly lower than if we had accurately used the CY 2020-based weights. This suggests that, while there is some impact from using the CY 2019 data if CY 2022 outpatient service utilization ends up being more similar to CY 2020 utilization, that impact would be limited.

In Scenario D, where the CY 2020-based weights were used, but the CY 2022 outpatient experience turns out to be more similar to CY 2019 claims data, this inaccurate assumption has a somewhat more significant effect. In this case, the modeled case-mix is −0.44 percent lower than it would be if we had correctly assumed that CY 2022 outpatient services utilization would be more like CY 2019 than CY 2020. This can be seen by comparing the modeled case-mix under Scenario D (4.600) to the modeled case-mix under Scenario A (4.620). In other words, if we use the CY 2020-based weights and the CY 2022 outpatient experience turns out to be more similar to CY 2019 data, the modeled case-mix is −0.44 percent lower than if we had used the CY 2019-based weights.

In addition to our expectation that CY 2019 is a more likely approximation of the CY 2022 outpatient experience for the reasons discussed earlier, the previous analysis indicates that the differential effect of making an incorrect assumption about which year's data to use to set the CY 2022 OPPS relative weights is more limited if the CY 2019-based weights are used than it is if the CY 2020-based weights are used. While CY 2022 outpatient hospital services data is unlikely to look exactly like either CY 2019 data or CY 2020 data, we believe that it will be more similar to a standard year (not having the effects of the PHE) as pandemic-related issues decline and more of the U.S. population is vaccinated against COVID–19. Since the update provided in the FY 2022 IPPS final rule, continued progress has been made in vaccinating the U.S. population, with approximately 320 million doses administered as of July 1, 2021, as reported to the Centers for Disease Control (CDC) *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html.*

Consistent with the proposal to use CY 2019 claims data in establishing the CY 2022 OPPS rates, we are also proposing to use cost report data from

the same set of cost reports we originally used in final rule 2021 OPPS ratesetting, where we ordinarily would have used the most updated available cost reports available in HCRIS in determining the proposed CY 2022 OPPS APC relative weights (as discussed in greater detail in section II.E. of this proposed rule). As discussed previously, if we were to proceed with the standard ratesetting process of using updated cost reports, we would have used approximately 1,000 cost reports with the fiscal year ending in CY 2020 based on each hospital's cost reporting period. We note that Medicare outpatient claims data and cost report data from the HCRIS file are examples of data sources for which we discuss the proposed use of CY 2019 data for CY 2022 OPPS ratesetting. While we are generally using CY 2019 claims data and the data components related to it in establishing the CY 2022 OPPS, we note in this rule the specific cases where we are using updated information, such as the ASP data used in determining drug packaging status discussed in section V. of this proposed rule with comment period.

We also considered the alternative of continuing with our standard process of using the most updated claims and cost report data available. To facilitate comment on this alternative proposal for CY 2022, we are making available the cost statistics and addenda utilizing the CY 2020 data we would ordinarily have provided in conjunction with this proposed rule. We are providing a file comparing the budget neutrality and certain other ratesetting adjustments calculated under our proposal with those adjustments calculated under this alternative approach. Finally, we are making available other proposed rule supporting data files based on the use of the CY 2020 data that we ordinarily would have provided, including: The OPPS Impact File, cost statistics files, addenda, and budget neutrality factors. We refer the reader to the CMS website for this proposed rule for more information on where these supplemental files may be found.

F. Proposal To Provide Separate Payment in CY 2022 for the Device Category, Drugs, and Biologicals With Transitional Pass-Through Payment Status Expiring Between December 31, 2021 and September 30, 2022

In the CY 2021 OPPS/ASC final rule (85 FR 86012 through 86013), we discussed the public comments we received in response to the comment solicitation we included in the CY 2021 OPPS/ASC proposed rule regarding whether we should utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide separate payment for some period of time after pass-through status ends for devices with expiring pass-through status in order to account for the period of time that utilization for the devices was reduced due to the PHE.[111] Although we only solicited comments on use of our equitable adjustment authority to pay separately for devices with pass-through status during the PHE, we received public comments both suggesting that drugs, biologicals, and biosimilar biological products with pass-through status during the same time period should also be subject to an adjustment to extend the pass-through period for those products, but also pointing out that most of these products continue to be separately paid after their pass-through status expires, and therefore, it would be unnecessary to utilize the equitable adjustment authority to ''extend'' pass-through status for these products.

As discussed elsewhere in section X.E. of this proposed rule and section I.F of the FY 2022 IPPS/LTCH proposed rule (86 FR 25211–25212), our goal is to use the best available data for ratesetting. Ordinarily, the best available claims data is the set of data from 2 years prior to the calendar year that is the subject of rulemaking, and accordingly, we would have used claims data from CY 2020 for calculating proposed rates for this CY 2022 OPPS/ASC proposed rule. As noted in section X.E., however, we are proposing to use CY 2019 claims data in establishing the CY 2022 OPPS rates and to use cost report data from the same set of cost reports originally used in the final rule for 2021 OPPS ratesetting. We recognize that due to the effects of the PHE, the CY 2020 claims data may not be the best available data for ratesetting, including for purposes of ratesetting for devices, drugs, and biologicals for which pass-through status expires between December 31, 2021 and September 30, 2022.

For this reason, and after consideration of the public comments we received in response to the comment solicitation included in the CY 2021 OPPS/ASC proposed rule (85 FR 48862), we propose a one-time equitable adjustment under section 1833(t)(2)(E) to continue separate payment for the remainder of CY 2022 for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022. We have consistently explained that transitional pass-through payment for drugs, biologicals, and devices is intended as an interim measure to allow for adequate payment of certain new technology while we collect the necessary data to incorporate the costs for these items into the procedure APC rate (66 FR 55861). We believe an equitable adjustment to continue separate payment for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022 is necessary to ensure that we have full claims data from CY 2021 with which to set payment rates beginning in CY 2023. We also believe it is necessary to pay separately for these products in CY 2022 in a manner that mimics continued pass-through status, rather than having to set rates and make APC assignments and packaging decisions for these products for CY 2022 based on data from CY 2020, which we do not believe is the best available data for this purpose.

For those drugs, biologicals and the device for which payment would be packaged following expiration of their pass-through status, we believe providing separate payment for up to a full year in CY 2022 is warranted to ensure there is a full year of data for ratesetting, including to ensure appropriate APC assignments for the services with which these products are billed. For drugs and biologicals that would generally remain separately payable after their pass-through status expires, we believe providing separate payment for up to a full year in CY 2022 is necessary to ensure that these drugs and biologicals would, in fact, be separately payable when their pass-through status expires, including to ensure that their payment would be packaged if the drug's cost is below the per-day packaging threshold. Specifically, for threshold packaged drugs and biologicals, CMS requires current, appropriate data to determine whether the drug should be packaged and then to determine the impact of that packaging on the associated service rates. We also believe separate payment in CY 2022 is necessary to ensure we have sufficient data in the event payment for the drug is packaged with payment for a primary C–APC service. Finally, consistent with our goal of ensuring that the equitable adjustment

[111] On January 31, 2020, HHS Secretary Azar determined that a PHE exists retroactive to January 27, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d) in response to COVID–19, and on April 21, 2020 Secretary Azar renewed, effective April 26, 2020, and again effective July 25, 2020, the determination that a PHE exists. On March 13, 2020, the President of the United States declared that the COVID–19 outbreak in the U.S. constitutes a national emergency, retroactive to March 1, 2020.

to provide separate payment for drugs and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022 mimics pass-through payment to the extent possible, we propose that separately payable drugs and biologicals that are eligible for this adjustment would not be paid the proposed reduced amount of ASP minus 22.5 percent when they are acquired under the 340B program, and would generally continue to be paid ASP plus 6 percent for the duration of the time period during which the adjustment applies.

Under our proposal, the device category, drugs, and biologicals that would be affected are as follows. One device category, HCPCS code C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads), would receive adjusted payment equivalent to an additional four quarters of device pass-through status. There are 27 drugs and biologicals whose pass-through payment status expires between December 31, 2021 and September 30, 2022. Based on the CY 2020 data, payment for three of the 27 drugs and biologicals would otherwise be packaged after the expiration of their pass-through status. The remaining 24 drugs and biologicals would be paid separately and would otherwise receive reduced payment at the proposed rate of ASP minus 22.5 percent when they are acquired under the 340B program.

There are currently six drugs and one device category whose pass-through payment status will expire on December 31, 2021, nine drugs and three biologicals whose pass-through status will expire on March 31, 2022, seven drugs whose pass-through status will expire on June 30, 2022, and two drugs whose pass-through payment status will expire on September 30, 2022. Because pass-through status can expire at the end of a quarter, the proposed adjusted payment would be made for between one and four quarters, depending on when the pass-through period expires for the device category, drug, or biological. In particular, separate payment would be made a full year for the device category and 6 drugs for which pass-through status will expire on December 31, 2021, three quarters for the 12 drugs and biologicals for which pass-through status will expire on March 31, 2022, two quarters for the 7 drugs for which pass-through status will expire on June 30, 2022, and one quarter for the 2 drugs for which pass-through status will expire on September 30, 2022.

Table 38 lists pass-through drugs, biologicals and the device category that we propose would receive adjusted separate payment, their pass-through payment period effective dates and end dates, as well as the number of quarters of separate payment equivalent to an extension of pass-through status that we propose each drug or device category would receive.

BILLING CODE 4120–01–P

TABLE 38: DEVICE CATEGORY, DRUGS, AND BIOLOGICALS WITH EXPIRING PASS-THROUGH STATUS THAT WOULD RECEIVE SEPARATE PAYMENT FOR ONE TO FOUR QUARTERS IN CY 2022

HCPCS Code	Long Descriptor	Pass-Through Status Effective Date	Pass-Through Status Expiration Date	Proposed Adjustment Equivalent to an Extension of Pass-through Status (number of quarters)
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads)	01/01/2019	12/31/2021	4
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	01/01/2019	12/31/2021	4
J0222	Injection, Patisiran, 0.1 mg	01/01/2019	12/31/2021	4
J0291	Injection, plazomicin, 5 mg	01/01/2019	12/31/2021	4
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	01/01/2019	12/31/2021	4
J2798	Injection, risperidone, (perseris), 0.5 mg	01/01/2019	12/31/2021	4
J9204	Injection, mogamulizumab-kpkc, 1 mg	01/01/2019	12/31/2021	4
J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	04/01/2019	03/31/2022	3
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	04/01/2019	03/31/2022	3
J0642	Injection, levoleucovorin 0(khapzory), 0.5 mg	01/01/2020	03/31/2022	3
J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	04/01/2019	03/31/2022	3
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)	04/01/2019	03/31/2022	3
J3245	Injection, tildrakizumab, 1 mg	04/01/2019	03/31/2022	3
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	04/01/2019	03/31/2022	3
J9119	Injection, cemiplimab-rwlc, 1 mg	04/01/2019	03/31/2022	3
J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	04/01/2019	03/31/2022	3

HCPCS Code	Long Descriptor	Pass-Through Status Effective Date	Pass-Through Status Expiration Date	Proposed Adjustment Equivalent to an Extension of Pass-through Status (number of quarters)
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	04/01/2019	03/31/2022	3
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	04/01/2019	03/31/2022	3
Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	04/01/2019	03/31/2022	3
C9047	Injection, caplacizumab-yhdp, 1 mg	07/01/2019	06/30/2022	2
J0121	Injection, omadacycline, 1 mg	07/01/2019	06/30/2022	2
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	07/01/2019	06/30/2022	2
J1303	Injection, ravulizumab-cwvz, 10 mg	07/01/2019	06/30/2022	2
J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	07/01/2019	06/30/2022	2
J9210	Injection, emapalumab-lzsg, 1 mg	07/01/2019	06/30/2022	2
J9269	Injection, tagraxofusp-erzs, 10 micrograms	07/01/2019	06/30/2022	2
J3111	Injection, romosozumab-aqqg, 1 mg	10/01/2019	09/30/2022	1
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	10/01/2019	09/30/2022	1

BILLING CODE 4120–01–C

We are soliciting comments on our proposal to utilize our equitable adjustment authority to pay separately for the remainder of CY 2022 for the device category, drugs and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022.

XI. Proposed CY 2022 OPPS Payment Status and Comment Indicators

A. Proposed CY 2022 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system, and also whether particular OPPS policies apply to the code.

For CY 2022, we are not proposing to make any changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2021 OPPS/ASC final rule with comment period available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

We are requesting public comments on the proposed definitions of the OPPS status indicators for CY 2022.

The complete list of the proposed payment status indicators and their definitions that would apply for CY 2022 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/index.html*.

The proposed CY 2022 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 2022 Comment Indicator Definitions

In this proposed rule, we propose to use four comment indicators for the CY 2022 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2021 and we propose to continue their use in CY 2022. The proposed CY 2022 OPPS comment indicators are as follows:

- ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.

• ''NC''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will *not* be accepted on the final APC assignment for the new code.

• ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

• ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPPS comment indicators for CY 2022 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 believe that the existing CY 2021 definitions of the OPPS comment indicators continue to be appropriate for CY 2022. Therefore, we propose to use those definitions without modification for CY 2022.

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 OPPS and ASC payment systems as discussed in its March 2021 report.

A. Proposed OPPS Payment Rates Update

The March 2021 MedPAC ''Report to the Congress: Medicare Payment Policy,'' recommended that Congress update Medicare OPPS payment rates by 2 percent, with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the ''Hospital Value Incentive Program (HVIP).'' We refer readers to the March 2021 report for a complete discussion of these recommendations.[112] We appreciate MedPAC's recommendations, but as MedPAC acknowledged in its March 2021 report, the Congress would need to change current law to enable us to implement its recommendations.

B. Proposed ASC Conversion Factor Update

In the March 2021 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC found that, based on its analysis of indicators of payment adequacy, the number of ASCs had increased, beneficiaries' use of ASCs had increased, and ASC access to capital has been adequate.[113] As a result, for CY 2022, MedPAC stated that payments to ASCs are adequate and recommended that in the absence of cost report data no payment update should be given for CY 2022 (that is, the update factor would be zero percent).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59079), we adopted a policy, which we codified at 42 CFR 416.171(a)(2), to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for complete details regarding our policy to use the productivity-adjusted hospital market basket update for the ASC payment system for CY 2019 through CY 2023. Therefore, consistent with our policy for the ASC payment system, as discussed in section XIII.G. of this proposed rule, we propose to apply a 2.3 percent productivity-adjusted hospital market basket update factor to the CY 2021 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2022 ASC payment amounts.

C. ASC Cost Data

In the March 2021 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers, and that CMS could use ASC cost data to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or an ASC specific market basket should be developed. Further, MedPAC suggested that CMS could limit the scope of the cost reporting system to minimize administrative burden on ASCs and the program but should make cost reporting a condition of ASC participation in the Medicare program.[114]

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 CY 2022 OPPS/ASC proposed rule, we are interested in 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.

The full March 2021 MedPAC Report to Congress can be downloaded from MedPAC's website at: *http://www.medpac.gov*.

XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. 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, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, and 2021 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through

[112] Medicare Payment Advisory Committee. March 2021 Report to the Congress. Chapter 3: Hospital Inpatient and outpatient services, pp.81–82. Available at: *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf?sfvrsn=0*.

[113] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.147. Available at: *http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0*.

[114] Medicare Payment Advisory Committee. March 2021 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.157. Available at: *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf?sfvrsn=0*.

59080; 84 FR 61370 through 61410, and 85 FR 86121 through 86179, respectively).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under §§ 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15.

In previous years, we identified surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS (72 FR 42478).

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at 42 CFR 416.164(b), we make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (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.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests (CRs) to update services paid for under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the American Medical Association (AMA) and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

3. Definition of ASC Covered Surgical Procedures

Since the implementation of the ASC prospective payment system, we have historically defined a ''surgical'' procedure under the 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 42478). We also have included as ''surgical,'' procedures that are described by Level II HCPCS codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range.

As we noted in the August 7, 2007 final rule that implemented the revised ASC payment system, using this definition of surgery would exclude from ASC payment certain invasive, ''surgery-like'' procedures, such as cardiac catheterization or certain radiation treatment services that are assigned codes outside the CPT surgical range (72 FR 42477). We stated in that final rule that we believed continuing to rely on the CPT definition of surgery is administratively straightforward, is logically related to the categorization of services by physician experts who both establish the codes and perform the procedures, and is consistent with a policy to allow ASC payment for all outpatient surgical procedures.

However, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), after consideration of public comments received in response to the CY 2019 OPPS/ASC proposed rule and earlier OPPS/ASC rulemaking cycles, we revised our definition of a surgical procedure under the ASC payment system. In that final rule, 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 CPL. These criteria included that a procedure is not expected to pose a significant risk to beneficiary safety when performed in an ASC, that standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and that the procedure is separately

paid under the OPPS. In CY 2021, we revised the definition of covered surgical procedures to surgical procedures specified by the Secretary that are separately paid under the OPPS, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15 (85 FR 86153).

B. Proposed ASC Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised HCPCS Codes

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. 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 and track drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. We refer to these codes as new and revised in this CY 2022 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we are proposing to solicit public comments in this proposed rule (and respond to those comments in the CY 2022 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2022 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2023 OPPS/ASC final rule with comment period).

2. April 2021 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2021 update, there was one new CPT code and there were 11 new Level II HCPCS codes. In the April 2021 ASC quarterly update (Transmittal 10702, CR 12183, dated April 1, 2021), we added 11 new Level II HCPCS codes to the list of ASC covered surgical procedures and the list of covered ancillary services. Table 39 below lists the new Level II HCPCS codes that were implemented April 1, 2021, along with their proposed payment indicators for CY 2022. 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 proposed ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective April 1, 2021 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. Also, the list of proposed 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.

BILLING CODE 4120–01–P

TABLE 39.—NEW LEVEL II HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 PI
A9592	Copper cu-64, dotatate, diagnostic, 1 millicurie	NP	K2
C9074*	Injection, lumasiran, 0.5 mg	NP	K2
C9776	Intraoperative near-infrared fluorescence imaging of major extra-hepatic bile duct(s) (e.g., cystic duct, common bile duct and common hepatic duct) with intravenous administration of indocyanine green (icg) (list separately in addition to code for primary procedure)	NP	N1
C9777	Esophageal mucosal integrity testing by electrical impedance, transoral (list separately in addition to code for primary procedure)	NP	N1
J1427	Injection, viltolarsen, 10 mg	NP	K2
J1554	Injection, immune globulin (asceniv), 500 mg	NP	K2
J7402	Mometasone furoate sinus implant, (sinuva), 10 micrograms	NP	K2
J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	NP	K2
J9349	Injection, tafasitamab-cxix, 2 mg	NP	K2

*HCPCS code C9074, which was effective April 1, 2021, was deleted June 30, 2021 and replaced with HCPCS code J0224 (Injection, lumasiran, 0.5mg) effective July 1, 2021.

We are inviting public comments on these proposed payment indicators for the new HCPCS codes that were recognized as ASC covered surgical procedures and ancillary services in April 2021 through the quarterly update CRs, as listed in Table 39 above. We are proposing to finalize their payment indicators in the CY 2022 OPPS/ASC final rule with comment period.

3. July 2021 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

In the July 2021 ASC quarterly update (Transmittal 10858, Change Request 12341, dated June 25, 2021), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 40 below lists the new HCPCS codes that are effective July 1, 2021. The proposed payment indicators and payment rates for these codes can be found in Addendum AA and Addendum BB to this proposed rule. The list of proposed ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective July 1, 2021 are assigned 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 those assignments. The list of proposed 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 40.—NEW LEVEL II HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 PI
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	NP	K2
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	NP	K2
C1761	Catheter, transluminal intravascular lithotripsy, coronary	NP	J7
C9075	Injection, casimersen, 10 mg	NP	K2
C9076	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	NP	K2
C9077	Injection, cabotegravir and rilpivirine, 2mg/3mg	NP	K2
C9078	Injection, trilaciclib, 1mg	NP	K2
C9079	Injection, evinacumab-dgnb, 5mg	NP	K2
C9080	Injection, melphalan flufenamide hydrochloride, 1 mg	NP	K2
C9778	Colpopexy, vaginal; minimally invasive extra-peritoneal approach (sacrospinous)	NP	G2
J0224*	Injection, lumasiran, 0.5mg	NP	K2
J1951	Injection, leuprolide acetate for depot suspension (fensolvi), 1 mg	NP	K2
J7168	Prothrombin complex concentrate (human), kcentra, per i.u. of factor ix activity	NP	K2
J9348	Injection, naxitamab-gqgk, 1 mg	NP	K2
J9353	Injection, margetuximab-cmkb, 5 mg	NP	K2
Q4201	Matrion 1 sq cm	NP	N1
Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	NP	K2

*HCPCS code C9074, which was effective April 1, 2021, was deleted June 30, 2021 and replaced with HCPCS code J0224 (Injection, lumasiran, 0.5mg) effective July 1, 2021.

In addition, through the July 2021 quarterly update CR, we added 11 new Category III CPT codes to the list of ASC covered ancillary services, effective July 1, 2021. This code is listed in Table 41 below, along with the proposed comment indicator and payment indicator. The CY 2022 proposed payment rate for these new Category III CPT codes can be found in Addendum BB. As noted above, the lists of proposed payment indicators and comment indicators used under the ASC payment system are included in Addenda DD1 and DD2, respectively, of this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

TABLE 41.—NEW CATEGORY III CPT CODE FOR COVERED ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 PI
0493T	Contact near-infrared spectroscopy studies of lower extremity wounds (eg, for oxyhemoglobin measurement)	CH	N1
0644T	Transcatheter removal or debulking of intracardiac mass (eg, vegetations, thrombus) via suction (eg, vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed	NP	J8
0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report	NP	J8
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	NP	Z2
0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	NP	N1
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report	NP	J8
0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	NP	J8

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 PI
0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple	NP	J8
0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter	NP	J8
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging	NP	G2
0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure)	NP	N1

BILLING CODE 4120–01–C

We are inviting public comments on the proposed comment indicators and payment indicators for the new Level II HCPCS codes newly recognized as ASC covered surgical procedures and covered ancillary services and the new Category III CPT codes for covered ancillary services beginning in July 2021 through the quarterly update CRs, as listed in Tables 39, 40, and 41 above. We are proposing to finalize the proposed payment indicators in the CY 2022 OPPS/ASC final rule with comment period.

4. October 2021 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2022 OPPS/ASC Final Rule With Comment Period

For CY 2022, consistent with our established policy, we are proposing that the Level II HCPCS codes that will be effective October 1, 2021 would be flagged with comment indicator ''NI'' in Addendum B to the CY 2022 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2022. We will invite public comments in the CY 2022 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2023 OPPS/ASC final rule with comment period.

5. January 2022 HCPCS Codes

a. Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2022 OPPS/ASC Final Rule With Comment Period

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 January 2022 ASC Update CR, and included on the CMS HCPCS website and in the CY 2022 OPPS/ASC final rule with comment period.

In addition, for CY 2022, 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, 2022 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 2022 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2023 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For new and revised CPT codes effective January 1, 2022 that were received in time to be included in this proposed rule, we are proposing the appropriate payment indicator assignments, and soliciting public comments on the payment assignments. We will accept comments and finalize the payment indicators in the CY 2022 OPPS/ASC final rule with comment period. For those new/revised CPT codes that are received too late for inclusion in this OPPS/ASC proposed rule, we may either make interim final assignments in the CY 2022 OPPS/ASC final rule with comment period or 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.

For the CY 2022 ASC update, the new and revised Category I and III CPT codes that will be effective on January 1, 2022 can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website). The CPT codes are assigned to comment indicator ''NP'' 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 and that comments will be accepted on the proposed payment indicator. 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 and revised CY 2022 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 2021 OPPS/ASC Proposed Rule 5-Digit Placeholder Code.'' The final CPT code numbers will be included in the CY 2022 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2022 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2022. Because these codes are listed in Addenda AA and Addendum BB with short descriptors only, we are listing them again in Addendum O with the long descriptors. We are also proposing to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2022 OPPS/ASC final rule with comment period. The proposed payment indicator and comment indicator 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. These new CPT codes that will be effective January 1, 2022 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. Also, the list of comment indicators and definitions used under the ASC 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 42 below, 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 42.—COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2021	HCPCS (CPT and Level II codes)	April 1, 2021	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
July 2021	HCPCS (CPT and Level II codes)	July 1, 2021	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
October 2021	HCPCS (CPT and Level II codes)	October 1, 2021	CY 2022 OPPS/ASC final rule with comment period	CY 2023 OPPS/ASC final rule with comment period
January 2022	CPT Codes	January 1, 2022	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2022	CY 2022 OPPS/ASC final rule with comment period	CY 2023 OPPS/ASC final rule with comment period

C. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Covered Surgical Procedures Designated as Office-Based

(1) 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 standard ASC payment 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 non office-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2022 to Covered Surgical Procedures Designated as Office-Based

In developing this CY 2022 OPPS/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), including their potential designation as office-based. Historically, we would also review the most recent claims volume and utilization data (CY 2020 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2020 of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight), as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2'', ''P3'', or ''R2'' in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86131 through 86139). However, as discussed in Section II.A.1.a of this proposed rule, given our concerns with CY 2020 claims data as a result of the PHE, we are not proposing to review the most recent claims volume and utilization data from CY 2020 claims and instead we are proposing not to assign permanent office-based designations for CY 2022 to any covered surgical procedure 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).

Similarly, we are also proposing not to use the most recent claims volume and utilization data and other information for procedures designated as temporarily office-based and temporarily assigned one of the office-based payment indicators, specifically ''P2,'' ''P3'' or ''R2,'' as shown in Table 56 and Table 57 in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86136 through 86137). Instead, we propose to continue to designate these procedures, shown in Table 43, as temporarily office-based for CY 2022. The procedures we propose to designate as temporarily office-based for CY 2022 are identified with an asterisk in Addendum AA to this proposed rule with comment period (which is available via the internet on the CMS website).

BILLING CODE 4120–01–P

TABLE 43: PROPOSED CY 2022 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2021 OPPS/ASC FINAL RULE

CY 2022 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2021 ASC Payment Indicator	Proposed CY 2022 ASC Payment Indicator*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	P3*
65785	Implantation of intrastromal corneal ring segments	P2	P2*
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 (eg, retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (report medication separately)	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	R2*
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	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*
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 are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2022 PFS proposed rates. For a discussion of the PFS rates, we refer readers to the CY 2022 PFS proposed rule.

BILLING CODE 4120–01–C

As discussed in the August 2, 2007 revised ASC payment system 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 would be permanently assigned to the list of office-based

procedures. In the absence of claims data, we stated we would 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.

For CY 2022, we propose to designate two new CY 2022 CPT codes for ASC covered surgical procedures as temporarily office-based. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedures listed in Table 44 would be predominantly performed in physicians' offices. We believe the procedure described by CPT code 42XXX (Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic) is similar to CPT code 31505 (Laryngoscopy, indirect; diagnostic (separate procedure)) which is currently on the list of ASC covered surgical procedures and was assigned a final payment indicator of ''P3''—Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs.—in CY 2021. Additionally, we believe the procedure described by CPT code 53XX4 (Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume) is similar to CPT code 0551T (Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume), which is currently on the list of ASC covered surgical procedures and was assigned a final payment indicator of ''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—for CY 2021. As such, we propose to add CPT codes 42XXX and 53XX4 in Table 44 to the list of ASC covered surgical procedures designated as temporarily office-based for CY 2022.

TABLE 44: PROPOSED CY 2022 PAYMENT INDICATORS FOR NEW CY 2022 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2022 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2022 Long Descriptor	Proposed CY 2022 ASC Payment Indicator**
42XXX	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic	R2**
53XX4	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume	R2**

** Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2022 PFS proposed rates. For a discussion of the PFS rates, we refer readers to the CY 2022 PFS proposed rule.

b. Proposed Device-Intensive ASC Covered Surgical Procedures

(1) 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.

(2) Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2022

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 590401 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. 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 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. For consistency with 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 involving 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 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 Food and Drug Administration (FDA) marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the 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 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).

Based on these criteria, for 2022, we propose to update the ASC CPL to indicate procedures that are eligible for payment according to our device-intensive procedure payment methodology, based on the proposed individual HCPCS code device-offset percentages using the CY 2019 OPPS claims and cost report data available for the CY 2022 OPPS/ASC proposed rule.

The ASC covered surgical procedures that we propose to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2022, are assigned payment indicator ''J8'' and are included in ASC Addendum AA to this proposed rule (which is available via the internet on the CMS website). The CPT code, the CPT code short descriptor, and the proposed CY 2022 ASC payment indicator, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy would apply because the procedure is designated as device-intensive are also included in Addendum AA to the proposed rule (which is available via the internet on the CMS website).

Under current policy, the payment rate under the ASC payment system for device-intensive procedures furnished with an implantable or inserted medical device are calculated by applying the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment based on the standard ratesetting methodology to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We calculate the service portion of the ASC payment for device intensive procedures by applying the uniform ASC conversion factor to the service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the ASC payment system (82 FR 59409).

In past rulemaking (79 FR 66924), we have stated that the device-intensive methodology for ASCs should align with the device-intensive policies under the OPPS. Further, we have stated that we do not believe that procedures are device-intensive in one setting and not in another setting. We have heard concerns from stakeholders that our methodology does not provide device-intensive status to certain procedures even though the procedures' device offset percentages are greater than our 30 percent threshold when calculated under the standard ASC ratesetting methodology. We have also heard concerns from stakeholders that procedures designated as device-intensive under the OPPS are not assigned device-intensive status under the ASC payment system even though the procedure has significant device costs.

The different ratesetting methodologies used under the OPPS and ASC payment system can create conflicts when determining device-intensive status. For example, procedures with device offset percentages greater than 30 percent under the OPPS may not have device offset percentages greater than 30 percent when calculated under the standard ASC ratesetting methodology. Under current policy, procedures must be device-intensive in the OPPS setting to be eligible for device-intensive status under the ASC payment system. However, this methodology has caused confusion among stakeholders and has denied device-intensive status to procedures with significant device costs. While we believe that device-intensive policies under the ASC payment system should align with device-intensive policies under the OPPS, we believe device-intensive status under the ASC payment system should, at a minimum, reflect a procedure's estimated device costs under the ASC standard ratesetting methodology. Therefore, for CY 2022 and subsequent years, we are proposing to assign device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS.

Further, in situations where a procedure is designated as device-intensive under the OPPS but the procedure's device offset percentage is below the device-intensive threshold under the standard ASC ratesetting methodology, we believe that deference should be given to the OPPS designation to address this conflict in status. Since the comprehensive ratesetting methodology under the OPPS packages a greater amount of non-device costs into the primary procedure and is typically able to use a greater number of claims in its ratesetting methodology, we believe that if a device receives OPPS device-intensive status, the device should also be device-intensive in the ASC setting, give that fewer non-device costs are generally packaged into a procedure's cost under the ASC methodology compared to the OPPS methodology. Therefore, for CY 2022 and subsequent years, we are proposing that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent.

We are soliciting comments on our proposed changes related to designating surgical procedures as device-intensive under the ASC payment system.

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 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 would append the HCPCS ''FB'' modifier on the line in the claim with the procedure to implant or insert the device. The contractor would reduce 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.

Effective in CY 2019 (83 FR 59043 through 59044), for partial credit, we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS ''FC'' modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) Submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our ''FB''/''FC'' modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we propose 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. 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 other changes to our policies related to no/cost full credit or partial credit devices.

d. 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 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.

From CY 2008 through CY 2020, under our regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2008 were surgical procedures that met the general standards specified in § 416.166(b) and were not excluded under the general exclusion criteria specified in § 416.166(c). Specifically, under § 416.166(b), the general standards provided that covered surgical procedures were surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that were 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 dictated that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. Section 416.166(c) set 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 provided 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. For a discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86143 through 86145).

In the CY 2021 OPPS/ASC Final Rule, we significantly revised our policy for adding surgical procedures to the ASC CPL. We revised the definition of covered surgical procedures at 42 CFR 416.166(a) and (b) to add new subparagraphs to provide that, for services furnished on or after January 1, 2021, covered surgical procedures for purposes of the ASC CPL 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; and are not: Designated as requiring inpatient care as of December 31, 2020; only able to be reported using a CPT unlisted surgical procedure code; or otherwise excluded under § 411.15.

We added a new paragraph (d) to 42 CFR 416.166 to provide that the general exclusion and general standard criteria that we used to identify covered surgical procedures furnished between January 1, 2008, and December 31, 2020, would, beginning January 1, 2021, be safety factors that physicians consider as to a specific beneficiary when determining whether to perform a covered surgical procedure. We also added a new paragraph (e) to 42 CFR 416.166 to provide that, on or after January 1, 2021, we add surgical procedures to the list of ASC covered surgical procedures either when we identify a surgical procedure that meets the requirements of paragraph (b)(2) or we are notified of a surgical procedure that could meet the requirements of paragraph (b)(2) and we confirm that such procedure meets those requirements. We added 267 surgical procedures to the ASC CPL that met the revised criteria for covered surgical procedures beginning in CY 2021.

As we explained in the CY 2021 OPPS/ASC final rule with comment period, there were a number of reasons that we made changes to our ASC CPL policy, including that ASCs are increasingly able to safely provide services that meet some of the general exclusion criteria. We explained that we believed it was important that we adapt the ASC CPL in light of significant advances in medical practice, surgical techniques, and ASC capabilities (85 FR 86150). We stated that, while many of the procedures we were adding to the ASC CPL were performed on non-Medicare patients who tend to be younger and have fewer comorbidities than the Medicare population, we believed careful patient selection can identify Medicare beneficiaries who are suitable candidates to receive these services in the ASC setting. We also emphasized the importance of ensuring that the healthcare system has as many access points and patient choices for Medicare beneficiaries as possible, which includes enabling physicians and patients to choose the ASC as the site of care when appropriate. Finally, we reiterated the critical role that physicians play in determining the appropriate site of care for their patients, including whether a surgical procedure can be safely performed in the ASC setting for an individual patient.

1. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2022

Since the CY 2021 OPPS/ASC final rule was published, we have reexamined our ASC CPL policy and the public comments we received in response to the CY 2021 OPPS/ASC proposed rule, considered the concerns we received from stakeholders since the final rule was published, and conducted an internal clinical review of the 267 procedures we added to the ASC CPL under our revised policy beginning in CY 2021. After examining our revised policy and the feedback we have received, and reviewing the procedures we added to the ASC CPL under our revised policy, we have reconsidered our policy and believe that the policy may not appropriately assess the safety of performing surgical procedures on a typical Medicare beneficiary in an ASC, and that the 258 surgical procedures we added to the ASC CPL beginning in CY 2021 under our revised policy may not be appropriate to be performed on a typical beneficiary in the ASC setting. We believe that our current policy—to shift 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 from CMS to physicians—needs to be modified to better ensure that surgical procedures added to the ASC CPL under the revised criteria can be performed safely in the ASC setting on the typical Medicare beneficiary. We recognize that appropriate patient selection and physicians' complex medical judgment could help mitigate risks for patient safety. But while we are always striving to balance the goals of increasing physician and patient choice, and expanding site neutral options with patient safety considerations, we nonetheless believe the current policy could be improved with additional patient safety considerations in determining whether a surgical procedure should be added to the ASC CPL.

One issue we identified with our revised policy is that many of the procedures added in CY 2021 would only be appropriate for Medicare beneficiaries who are healthier and have less complex medical conditions than the typical beneficiary. Upon further review, we believe the subset of Medicare beneficiaries who may be suitable candidates to receive these procedures in an ASC setting do not necessarily represent the average Medicare beneficiary. After evaluating the 267 surgery or surgery-like codes

that were added last year, CMS clinicians determined that 258 of these surgical procedures may pose a significant safety risk to a typical Medicare beneficiary when performed in an ASC, and that nearly all would likely require active medical monitoring and care at midnight following the procedure. In the CY 2021 OPPS/ASC Final Rule, we established that physicians would consider certain safety factors as to a specific beneficiary when determining whether to perform a covered surgical procedure in an ASC. However, while a physician can make safety determinations for a specific beneficiary, CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries.

While there could be some appropriately selected patient populations for which some of these procedures could be safely performed in the ASC setting, that may not be the case for the typical Medicare beneficiary, due to comorbidities and other health risks that may require more intensive care and monitoring than provided in an ASC setting among this population. We believe it is appropriate to assess the safety of these procedures in the context of the typical Medicare beneficiary, whose health status is representative of the broader Medicare population. Thus, we believe evaluating procedures for their potential to require additional care and monitoring for the typical beneficiary is an appropriate consideration for CMS to make in determining which procedures can safely be performed in an ASC.

We are concerned that, under our current policy, we do not make an active enough determination about whether a procedure is suitable to perform on a typical Medicare beneficiary in an ASC setting. The policy finalized last year allows individual physicians discretion to perform a number of procedures in the ASC setting that would not necessarily be appropriate for the typical Medicare beneficiary in that setting. Clinicians apply appropriate screening criteria to determine either that the procedure should not be performed in the ASC setting because of the risks to the specific beneficiary, or that the specific beneficiary presents a low enough risk profile that the procedure could be safely performed in the ASC setting.

However, we want to reiterate that, in accordance with section 1833(i)(1)(A) of the Act, the Secretary shall specify those surgical procedures that are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but that also can be performed safely on an ambulatory basis in an ambulatory surgical center. That is, if Medicare allows payment for these services in the ASC setting, it means that Medicare has determined that the procedure is safe to perform on the typical Medicare beneficiary.

Accordingly, the addition of a procedure to the ASC CPL can signal to physicians that the procedure is safe to perform on the typical Medicare beneficiary in the ASC setting, even though the current criteria, adopted in CY 2021, for adding procedures to the ASC CPL do not include safety criteria other than ensuring that the procedure was not on the IPO list as of CY 2020. We recognize that, while there are similarities between the ASC and HOPD settings, there are also significant differences between the two care settings. The HOPD setting has additional capabilities, resources, and certifications that are not required for the ASC setting. For example, hospitals operate 24/7 and are subject to EMTALA requirements, while ASCs are not. Therefore, a procedure that can be furnished in the HOPD setting is not necessarily safe and appropriate to perform in an ASC setting simply because we make payment for the procedure when it is furnished in the HOPD setting.

In light of these concerns, in this CY 2022 OPPS/ASC proposed rule, we propose to revise the criteria and process for adding procedures to the ASC CPL by reinstating the ASC CPL policy and regulation text that were in place in CY 2020. While this approach is a departure from the revised policy we adopted for CY 2021, it is consistent with our policy from CY 2008 through CY 2020 where we gradually expanded the ASC CPL while giving careful consideration to safety concerns and risks to the typical beneficiary. This approach would also continue to support our efforts to maximize patient access to care by, when appropriate, adding procedures to the ASC CPL to further increase the availability of ASCs as an alternative, lower cost site of care. While expanding the ASC CPL offers benefits like preserving the capacity of hospitals to treat more acute patients and promoting site neutrality, it is also essential that any expansion of the ASC CPL be done in a carefully calibrated fashion to ensure that Medicare is appropriately signaling that a procedure is safe to be performed in the ASC setting for a typical Medicare beneficiary.

Accordingly, for CY 2022, we propose to revise the requirements for covered surgical procedures in the regulation at § 416.166 to reinstate the specifications we had established prior to CY 2021. Specifically, we propose that, effective for services furnished on or after January 1, 2022, covered surgical procedures are those procedures that meet the general standards and do not meet the general exclusions. We propose to again provide in paragraph (b) of § 416.166 that, subject to the exclusions we propose to again include in paragraph (c), 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. We propose to revise paragraph (c) to again include the five criteria currently included in paragraph (d) of the regulation as safety factors physicians consider. We propose that revised paragraph (c) would provide that, notwithstanding paragraph (b), 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. We propose to remove the physician considerations at § 416.166(d) and change the notification process at § 416.166(e) to a nomination process, which is discussed further in section (d)(2) below.

We expect that we would continue to expand the ASC CPL in future years under our proposed revised criteria as the practice of medicine and medical technology continue to evolve. We believe that adding appropriate procedures to the ASC CPL, that meet the safety criteria that we are proposing to reinstate, has beneficial effects for Medicare beneficiaries and healthcare professionals, including increased access, better utilization of existing healthcare resources, and expansion of the capacity of the healthcare system.

(1) Comment Solicitation on Procedures That Were Added to the ASC CPL in CY 2021 and Would Not Meet the Proposed Revised CY 2022 Criteria

As stated above, we are proposing to remove 258 procedures from the ASC CPL for CY 2022 that were added to the ASC CPL in CY 2021 that we believe do not meet the proposed revised CY 2022 ASC CPL criteria, listed in Table 45. Based on our internal review of preliminary claims submitted to Medicare, we do not believe that ASCs have been furnishing the majority of the 267 procedures finalized in 2021. Because of this, we believe it is unlikely that ASCs have made practice changes in reliance on the policy we adopted in CY 2021. Therefore, we do not anticipate that ASCs would be significantly affected by the removal of these 258 procedures from the ASC CPL. For the final rule, we seek input from commenters who believe any of the 258 procedures added to the ASC CPL in CY 2021 meet the proposed revised CY 2022 criteria and, if those revised criteria are finalized, should remain on the ASC CPL for CY 2022. We request any clinical evidence or literature to support commenters' views that any of these procedures meet the proposed revised CY 2022 criteria and should remain on the ASC CPL for CY 2022.

Nomination Process Proposal

For CY 2022, we propose to change the current notification process for adding surgical procedures to the ASC CPL to a nomination process. We propose that external parties, for example, medical specialty societies or other members of the public, could nominate procedures to be added to the ASC CPL. CMS anticipates that stakeholders, such as specialty societies that specialize in and have a deep understanding of the complexities involved in providing certain procedures, would be able to provide valuable suggestions as to which additional procedures may reasonably and safely be performed in an ASC. While members of the public may already suggest procedures to be added to the ASC CPL through meetings with CMS or through public comments on the proposed rule, we believe it may be beneficial to enable the public, particularly specialty societies who are very familiar with procedures in their specialty, to formally nominate procedures based on the latest evidence available as well as input from their memberships.

We propose to include the nomination process in a new subparagraph (d)(1) of § 416.166. We propose that the regulation at § 416.166(d)(2) would provide that, if we identify a surgical procedure that meets the requirements at paragraph (a) of this section, including a surgical procedure nominated by an external party under paragraph (d)(1), we will propose to add the surgical procedure to the list of ASC covered surgical procedures in the next available annual rulemaking. Under this proposal, we would propose to add a nominated procedure to the ASC CPL if it meets the proposed general standards for covered surgical procedures at proposed § 416.166(b), and does not meet the general exclusions in proposed § 416.166(c).

Specifically, for the OPPS/ASC rulemaking for a calendar year, we would request stakeholder nominations by March 1 of the year prior to the calendar year for the next applicable rulemaking cycle in order to be included in that rulemaking cycle. For example, stakeholders would need to send in nominations by March 1, 2022, to be considered for the CY 2023 rulemaking cycle and potentially have their nomination effective by January 1, 2023. We would evaluate procedures nominated by stakeholders based on the applicable statutory and regulatory requirements for ASC covered surgical procedures. We propose to address nominated procedures beginning in the CY 2023 rulemaking cycle. We would address in rulemaking nominated procedures for which stakeholders have provided sufficient information for us to evaluate the procedure. We propose to include in the applicable proposed rule, a summary of the justification for proposing to add or not add each nominated procedure, which would allow members of the public to assess and comment on nominated procedures during the public comment period. After reviewing comments provided during the public comment period, we would indicate whether or not we are adding the procedures to ASC CPL in the final rule. In the event that CMS determines that a nominated procedure does not meet the criteria to be added to the ASC CPL, we would provide our rationale in the rulemaking. In certain cases, we may need to defer a proposal regarding a nominated procedure to the next regulatory cycle or future rulemaking in order to have sufficient time to evaluate and make an appropriate proposal about the nominated procedure.

We are also seeking comment on how we might prioritize our review of nominated procedures, in the event we receive an unexpectedly or extraordinarily large volume of nominations for which CMS has insufficient resources to address in the annual rulemaking. For example, if we could not address every nomination in a rulemaking cycle due to a large volume, we may need to prioritize our review such that we would only address in rulemaking those nominations that merit priority. Therefore, we are seeking comments as to how CMS should prioritize nominations. For example, whether we would prioritize the nominations that have codes nominated by multiple organizations or individuals, codes recently removed from the IPO list, codes accompanied by evidence that other payers are paying for the service on an outpatient basis or in an ASC setting, or a variety of other factors. If we were to finalize a prioritization hierarchy for CMS's review of nominated procedures to the ASC CPL, we would indicate in regulation text, likely in proposed § 416.166(d)(2) *Inclusion in Rulemaking:* (1) That CMS would apply a prioritization hierarchy for reviewing nominated procedures if necessary because of an unexpectedly or extraordinarily large volume of nominations; and (2) specify CMS's prioritization hierarchy.

We believe that this nominations proposal allows for the expansion of the ASC CPL in a more gradual fashion, which would better balance the goals of increasing patient choice and expanding site neutral options with patient safety considerations. We believe a nomination process will take time to develop because we want to incorporate stakeholder input on the most effective way to structure this process. We also acknowledge that stakeholders will need time to consider and evaluate potential surgical procedures to nominate. We propose to accept nominations for surgical procedures to be added to the ASC CPL beginning in CY 2023.

BILLING CODE 4120–01–P

TABLE 45: SURGICAL PROCEDURES PROPOSED FOR REMOVAL FROM THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2022

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle	G2
20100	Exploration of penetrating wound (separate procedure); neck	G2
20101	Exploration of penetrating wound (separate procedure); chest	G2
20102	Exploration of penetrating wound (separate procedure); abdomen/flank/back	G2
20660	Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure)	G2
21049	Excision of benign tumor or cyst of maxilla; requiring extra-oral osteotomy and partial maxillectomy (eg, locally aggressive or destructive lesion[s])	G2
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)	G2
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (eg, plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)	G2
21193	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; without bone graft	G2
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation	J8

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
21256	Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (eg, micro-ophthalmia)	G2
21261	Periorbital osteotomies for orbital hypertelorism, with bone grafts; combined intra- and extracranial approach	G2
21263	Periorbital osteotomies for orbital hypertelorism, with bone grafts; with forehead advancement	G2
21346	Open treatment of nasomaxillary complex fracture (lefort ii type); with wiring and/or local fixation	G2
21385	Open treatment of orbital floor blowout fracture; transantral approach (caldwell-luc type operation)	G2
21386	Open treatment of orbital floor blowout fracture; periorbital approach	G2
21387	Open treatment of orbital floor blowout fracture; combined approach	G2
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)	G2
21408	Open treatment of fracture of orbit, except blowout; with bone grafting (includes obtaining graft)	G2
21470	Open treatment of complicated mandibular fracture by multiple surgical approaches including internal fixation, interdental fixation, and/or wiring of dentures or splints	J8
21601	Excision of chest wall tumor including rib(s)	G2
21742	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), without thoracoscopy	G2
21743	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), with thoracoscopy	G2
22100	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; cervical	G2
22101	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; thoracic	G2
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	J8
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	J8
24150	Radical resection of tumor, shaft or distal humerus	G2
24935	Stump elongation, upper extremity	G2
25170	Radical resection of tumor, radius or ulna	G2
25909	Amputation, forearm, through radius and ulna; re-amputation	G2
27006	Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
27027	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle), unilateral	G2
27057	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle) with debridement of nonviable muscle, unilateral	G2
27179	Open treatment of slipped femoral epiphysis; osteoplasty of femoral neck (heyman type procedure)	G2
27235	Percutaneous skeletal fixation of femoral fracture, proximal end, neck	G2
27477	Arrest, epiphyseal, any method (eg, epiphysiodesis); tibia and fibula, proximal	J8
27485	Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (eg, genu varus or valgus)	G2
27722	Repair of nonunion or malunion, tibia; with sliding graft	J8
28360	Reconstruction, cleft foot	G2
28805	Amputation, foot; transmetatarsal	G2
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral	G2
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	G2
31292	Nasal/sinus endoscopy, surgical, with orbital decompression; medial or inferior wall	G2
31293	Nasal/sinus endoscopy, surgical, with orbital decompression; medial and inferior wall	G2
31294	Nasal/sinus endoscopy, surgical, with optic nerve decompression	G2
31584	Laryngoplasty; with open reduction and fixation of (eg, plating) fracture, includes tracheostomy, if performed	G2
31587	Laryngoplasty, cricoid split, without graft placement	G2
31600	Tracheostomy, planned (separate procedure);	G2
31601	Tracheostomy, planned (separate procedure); younger than 2 years	G2
31610	Tracheostomy, fenestration procedure with skin flaps	G2
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	J8
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	J8
31785	Excision of tracheal tumor or carcinoma; cervical	G2
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	G2
32560	Instillation, via chest tube/catheter, agent for pleurodesis (eg, talc for recurrent or persistent pneumothorax)	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
32561	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); initial day	G2
32562	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); subsequent day	G2
32601	Thoracoscopy, diagnostic (separate procedure); lungs, pericardial sac, mediastinal or pleural space, without biopsy	G2
32604	Thoracoscopy, diagnostic (separate procedure); pericardial sac, with biopsy	G2
32606	Thoracoscopy, diagnostic (separate procedure); mediastinal space, with biopsy	G2
32607	Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral	G2
32608	Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral	G2
32609	Thoracoscopy; with biopsy(ies) of pleura	G2
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction	G2
33272	Removal of subcutaneous implantable defibrillator electrode	G2
34101	Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision	G2
34111	Embolectomy or thrombectomy, with or without catheter; radial or ulnar artery, by arm incision	G2
34201	Embolectomy or thrombectomy, with or without catheter; femoropopliteal, aortoiliac artery, by leg incision	G2
34203	Embolectomy or thrombectomy, with or without catheter; popliteal-tibio-peroneal artery, by leg incision	G2
34421	Thrombectomy, direct or with catheter; vena cava, iliac, femoropopliteal vein, by leg incision	G2
34471	Thrombectomy, direct or with catheter; subclavian vein, by neck incision	G2
34501	Valvuloplasty, femoral vein	G2
34510	Venous valve transposition, any vein donor	G2
34520	Cross-over vein graft to venous system	G2
34530	Saphenopopliteal vein anastomosis	G2
35011	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm and associated occlusive disease, axillary-brachial artery, by arm incision	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery	G2
35180	Repair, congenital arteriovenous fistula; head and neck	G2
35184	Repair, congenital arteriovenous fistula; extremities	G2
35190	Repair, acquired or traumatic arteriovenous fistula; extremities	G2
35201	Repair blood vessel, direct; neck	G2
35206	Repair blood vessel, direct; upper extremity	G2
35226	Repair blood vessel, direct; lower extremity	G2
35231	Repair blood vessel with vein graft; neck	G2
35236	Repair blood vessel with vein graft; upper extremity	G2
35256	Repair blood vessel with vein graft; lower extremity	G2
35261	Repair blood vessel with graft other than vein; neck	G2
35266	Repair blood vessel with graft other than vein; upper extremity	G2
35286	Repair blood vessel with graft other than vein; lower extremity	G2
35321	Thromboendarterectomy, including patch graft, if performed; axillary-brachial	G2
35860	Exploration for postoperative hemorrhage, thrombosis or infection; extremity	G2
35879	Revision, lower extremity arterial bypass, without thrombectomy, open; with vein patch angioplasty	G2
35881	Revision, lower extremity arterial bypass, without thrombectomy, open; with segmental vein interposition	G2
35883	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with nonautogenous patch graft (eg, dacron, eptfe, bovine pericardium)	G2
35884	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with autogenous vein patch graft	G2
35903	Excision of infected graft; extremity	G2
36460	Transfusion, intrauterine, fetal	G2
36838	Distal revascularization and interval ligation (dril), upper extremity hemodialysis access (steal syndrome)	G2
37183	Revision of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recannulization/dilatation, stent placement and all associated imaging guidance and documentation)	J8

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
37191	Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	J8
37192	Repositioning of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	J8
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	G2
37195	Thrombolysis, cerebral, by intravenous infusion	G2
37213	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed;	G2
37214	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed; cessation of thrombolysis including removal of catheter and vessel closure by any method	G2
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	J8
37565	Ligation, internal jugular vein	G2
37600	Ligation; external carotid artery	G2
37605	Ligation; internal or common carotid artery	G2
37606	Ligation; internal or common carotid artery, with gradual occlusion, as with selverstone or crutchfield clamp	G2
37615	Ligation, major artery (eg, post-traumatic, rupture); neck	G2
37619	Ligation of inferior vena cava	G2
38120	Laparoscopy, surgical, splenectomy	G2
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor	G2
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor	G2
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, t-cell depletion	G2
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion	G2
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal	G2
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion	G2
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion	G2
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer	G2
38240	Hematopoietic progenitor cell (hpc); allogeneic transplantation per donor	G2
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	G2
38720	Cervical lymphadenectomy (complete)	G2
39401	Mediastinoscopy; includes biopsy(ies) of mediastinal mass (eg, lymphoma), when performed	G2
39402	Mediastinoscopy; with lymph node biopsy(ies) (eg, lung cancer staging)	G2
42842	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; without closure	G2
42844	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with local flap (eg, tongue, buccal)	G2
43020	Esophagotomy, cervical approach, with removal of foreign body	G2
43280	Laparoscopy, surgical, esophagogastric fundoplasty (eg, nissen, toupet procedures)	G2
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	G2
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	G2
43420	Closure of esophagostomy or fistula; cervical approach	G2
43510	Gastrotomy; with esophageal dilation and insertion of permanent intraluminal tube (eg, celestin or mousseaux-barbin)	G2
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum	J8
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum	G2
43651	Laparoscopy, surgical; transection of vagus nerves, truncal	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
43652	Laparoscopy, surgical; transection of vagus nerves, selective or highly selective	G2
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)	J8
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	G2
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	G2
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	G2
43830	Gastrostomy, open; without construction of gastric tube (eg, stamm procedure) (separate procedure)	G2
43831	Gastrostomy, open; neonatal, for feeding	G2
44180	Laparoscopy, surgical, enterolysis (freeing of intestinal adhesion) (separate procedure)	G2
44186	Laparoscopy, surgical; jejunostomy (eg, for decompression or feeding)	G2
44950	Appendectomy;	G2
44955	Appendectomy; when done for indicated purpose at time of other major procedure (not as separate procedure) (list separately in addition to code for primary procedure)	N1
44970	Laparoscopy, surgical, appendectomy	G2
47370	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency	G2
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical	G2
47490	Cholecystostomy, percutaneous, complete procedure, including imaging guidance, catheter placement, cholecystogram when performed, and radiological supervision and interpretation	G2
49185	Sclerotherapy of a fluid collection (eg, lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic study, imaging guidance (eg, ultrasound, fluoroscopy) and radiological supervision and interpretation when performed	G2
49323	Laparoscopy, surgical; with drainage of lymphocele to peritoneal cavity	G2
49405	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
49491	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; reducible	G2
49492	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; incarcerated or strangulated	G2
50020	Drainage of perirenal or renal abscess, open	G2
50541	Laparoscopy, surgical; ablation of renal cysts	G2
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed	G2
50543	Laparoscopy, surgical; partial nephrectomy	G2
50544	Laparoscopy, surgical; pyeloplasty	G2
50945	Laparoscopy, surgical; ureterolithotomy	G2
51060	Transvesical ureterolithotomy	G2
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, stamey, raz, modified pereyra)	G2
51860	Cystorrhaphy, suture of bladder wound, injury or rupture; simple	G2
51990	Laparoscopy, surgical; urethral suspension for stress incontinence	G2
53500	Urethrolysis, transvaginal, secondary, open, including cystourethroscopy (eg, postsurgical obstruction, scarring)	G2
54332	1-stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	G2
54336	1-stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	G2
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	J8
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	J8
54535	Orchiectomy, radical, for tumor; with abdominal exploration	G2
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (eg, fowler-stephens)	G2
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
55970	Intersex surgery; male to female	G2
55980	Intersex surgery; female to male	G2
57106	Vaginectomy, partial removal of vaginal wall;	G2
57107	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy)	G2
57109	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy)	G2
57284	Paravaginal defect repair (including repair of cystocele, if performed); open abdominal approach	G2
57285	Paravaginal defect repair (including repair of cystocele, if performed); vaginal approach	G2
57292	Construction of artificial vagina; with graft	G2
57330	Closure of vesicovaginal fistula; transvesical and vaginal approach	G2
57335	Vaginoplasty for intersex state	G2
57423	Paravaginal defect repair (including repair of cystocele, if performed), laparoscopic approach	G2
57555	Excision of cervical stump, vaginal approach; with anterior and/or posterior repair	G2
58263	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele	G2
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele	G2
58290	Vaginal hysterectomy, for uterus greater than 250 g;	G2
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	G2
58292	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele	G2
58294	Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele	G2
58770	Salpingostomy (salpingoneostomy)	G2
58920	Wedge resection or bisection of ovary, unilateral or bilateral	G2
58925	Ovarian cystectomy, unilateral or bilateral	G2
59030	Fetal scalp blood sampling	G2
59409	Vaginal delivery only (with or without episiotomy and/or forceps);	G2
59612	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps);	G2
60252	Thyroidectomy, total or subtotal for malignancy; with limited neck dissection	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
60260	Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid	G2
60271	Thyroidectomy, including substernal thyroid; cervical approach	G2
60502	Parathyroidectomy or exploration of parathyroid(s); re-exploration	G2
60512	Parathyroid autotransplantation (list separately in addition to code for primary procedure)	N1
60520	Thymectomy, partial or total; transcervical approach (separate procedure)	G2
61623	Endovascular temporary balloon arterial occlusion, head or neck (extracranial/intracranial) including selective catheterization of vessel to be occluded, positioning and inflation of occlusion balloon, concomitant neurological monitoring, and radiologic supervision and interpretation of all angiography required for balloon occlusion and to exclude vascular injury post occlusion	J8
61626	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)	J8
61720	Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus	G2
62000	Elevation of depressed skull fracture; simple, extradural	G2
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy	G2
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; sacral	G2
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (gill type procedure)	G2
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; cervical	G2
63016	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; thoracic	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; lumbar	G2
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (list separately in addition to code for primary procedure)	N1
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical	G2
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (list separately in addition to code for primary procedure)	N1
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (list separately in addition to code for primary procedure)	N1
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (list separately in addition to code for primary procedure)	N1
63064	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; single segment	G2
63066	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; each additional segment (list separately in addition to code for primary procedure)	N1
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace	G2
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (list separately in addition to code for primary procedure)	N1
63741	Creation of shunt, lumbar, subarachnoid-peritoneal, -pleural, or other; percutaneous, not requiring laminectomy	J8
64804	Sympathectomy, cervicothoracic	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
64911	Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve	G2
69725	Decompression facial nerve, intratemporal; including medial to geniculate ganglion	G2
69955	Total facial nerve decompression and/or repair (may include graft)	G2
69960	Decompression internal auditory canal	G2
69970	Removal of tumor, temporal bone	G2
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	J8
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	J8
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	N1
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel	J8
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	N1
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 (eg, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
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 (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	G2
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, tems), including muscularis propria (ie, full thickness)	G2
0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar	G2
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	G2
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (egj), with implantation of pulse generator, includes programming	G2
0453T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; mechano-electrical skin interface	G2
0454T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; subcutaneous electrode	G2
0457T	Removal of permanently implantable aortic counterpulsation ventricular assist system; mechano-electrical skin interface	G2
0458T	Removal of permanently implantable aortic counterpulsation ventricular assist system; subcutaneous electrode	G2
0460T	Repositioning of previously implanted aortic counterpulsation ventricular assist device; subcutaneous electrode	G2
0499T	Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed	G2
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	J8

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])	J8
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	G2
0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; pulse generator component(s) (battery and/or transmitter) only	J8
0518T	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing	G2
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)	J8
0520T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter), including placement of a new electrode	J8

BILLING CODE 4120–01–C

2. Covered Ancillary Services

We are proposing to continue our existing policies relating to covered ancillary services with a proposed revision to the regulation at 42 CFR 416.164(b)(6) regarding our policy related to payment for non-opioid pain management drugs and biologicals.

In the CY 2019 OPPS/ASC final rule (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 CY 2019 OPPS final rule. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services because of changes that are being finalized under the OPPS for CY 2022. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2021, but will be packaged under the CY 2022 OPPS, to maintain consistency with the OPPS, we would also package the ancillary service under the ASC payment system for CY 2022. In the CY 2019 OPPS/ASC final rule, we finalized the policy to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator ''CH'', which is discussed in section XIII.F. of the CY 2021 OPPS/ASC proposed rule, is used in Addendum BB to this CY 2022 OPPS/ASC final rule (which is available via the internet on the CMS website) to indicate covered ancillary services for which we are finalizing a change in the ASC payment indicator to reflect a finalized change in the OPPS treatment of the service for CY 2021.

For CY 2022, as discussed in section II.A.3.b, we propose 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 in proposed new § 416.174.

New CPT and HCPCS codes for covered ancillary services and their proposed payment indicators for CY 2022 can be found in section XIII.B of this CY 2022 OPPS/ASC proposed rule. All ASC covered ancillary services and their proposed payment indicators for CY 2022 are also included in Addendum BB to this CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

D. Proposed Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services

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 retained payment indicator ''A2'' because it is used to identify procedures that are exempted from the application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so only the service portion of the rate is subject to the ASC conversion factor. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86122 through 86179), we updated the CY 2020 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2'', ''G2'', and ''J8'' using CY 2019 data, consistent with the CY 2021 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2021 OPPS device offset percentages calculated under the standard APC ratesetting methodology, as discussed earlier in this section.

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. In the CY 2021 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2021 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 was lower and, therefore, would be the CY 2021 payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There would be 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 continued to provide separate payment since CY 2014 and assigned the current ASC payment indicators associated with these procedures.

b. Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests

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. The reduced coinsurance will be phased-in beginning January 1, 2022. Our proposals to implement this legislation are included in the CY 2022 PFS proposed rule and section X.B., ''Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests'' of this proposed rule.

c. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2022

We propose to update ASC payment rates for CY 2022 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XII.C.1.b. of this CY 2022 OPPS/ASC proposed rule. Because the proposed OPPS relative payment weights are generally based on geometric mean costs, the ASC system would 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, for device-intensive procedures, using our modified definition of device-intensive procedures, as discussed in section XII.C.1.b. of this CY 2022 OPPS/ASC proposed rule. Therefore, we propose to update the payment amount for the service 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 2022 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures would be at the lesser of the proposed CY 2022 MPFS nonfacility PE RVU-based amount or the proposed CY 2022 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2021, for CY 2022 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'') would be assigned the current ASC payment indicators associated with those procedures and would continue to be paid separately under the ASC payment system.

d. Proposed Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b. of this CY 2022 OPPS/ASC proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology. However, for low-volume device-intensive procedures, the proposed relative payment weights are based on median costs, rather than geometric mean costs, as discussed in section IV.B.5. of this CY 2022 OPPS/ASC proposed rule.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61400), we finalized our policy to limit the ASC payment rate for low-volume device-intensive procedures to a payment rate equal to the OPPS payment rate for that

procedure. Under this policy, where the ASC payment rate based on the standard ASC ratesetting methodology for low volume device-intensive procedures would exceed the rate paid under the OPPS for the same procedure, we establish an ASC payment rate for such procedures equal to the OPPS payment rate for the same procedure.

As discussed in Section X of this CY 2022 OPPS/ASC proposed rule, we are proposing a low volume APC policy for CY 2022 and subsequent calendar years. Under our proposal, a clinical APC, brachytherapy APC, or new technology APC with fewer than 100 claims per year would be designated as a low volume APC. For items and services assigned to APCs we propose to designate as low volume APCs, we are proposing to use up to 4 years of claims data to establish a payment rate for each item or service as we currently do for low volume services assigned to New Technology APCs. The payment rate for a low volume APC would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data. Because we are proposing to adopt a low volume APC policy, we are also proposing to eliminate our low volume device-intensive procedure policy and subsume the ratesetting issues associated with HCPCS code 0308T within our broader low volume APC proposal. Consequently, we are proposing to modify our existing regulations at § 416.171(b)(4) to apply our ASC payment rate limitation to services assigned to low volume APCs rather than low volume device-intensive procedures.

We seek comments on our proposal to modify our existing regulations at § 416.171(b)(4) and limit the ASC payment rate for services assigned to low volume APCs to the payment rate for the OPPS.

2. Proposed Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N'', ''Q1'', and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment for procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ''N1'') under the ASC payment system (except for device removal procedures, as discussed in section IV. of this CY 2022 OPPS/ASC proposed rule). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in section XIII.D.3. of this CY 2022 OPPS/ASC proposed rule, for CY 2022, we are proposing 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 proposed new § 416.174. We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount (''Z3''), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include a reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2022

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 2022 OPPS and ASC payment rates and subsequent year payment rates. We also propose to continue to set the CY 2022 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2022 and subsequent year payment rates.

Covered ancillary services and their proposed payment indicators for CY 2022 are listed in Addendum BB of this CY 2022 OPPS/ASC 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 proposed rates under the ASC standard rate setting methodology and the PFS final rates, the proposed payment indicators and rates set forth in the proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2022. For a discussion of the PFS rates, we refer readers to the CY 2022 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. CY 2022 ASC Packaging Policy for Non-Opioid Pain Management Drugs and Biologicals

Please refer to Section II.A.3.b for a discussion of the proposed CY 2022 OPPS/ASC for payment for non-opioid pain management drugs and biologicals.

E. 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 entitled ''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: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.

• We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 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 updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2022

We did not receive any requests for review to establish a new NTIOL class for CY 2022 by March 1, 2021, the due date published in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86173).

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 are not proposing to revise the payment adjustment amount for CY 2022.

F. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 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 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 (which 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 with comment period 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, 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.

2. ASC Payment and Comment Indicators for CY 2022

For 2022, we propose new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Therefore, proposed Category I and III CPT codes that are new and revised for CY 2022 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2022, compared to the CY 2021 descriptors, are included in ASC Addenda AA and BB to this proposed rule and labeled with proposed comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes are open for comment as part of this proposed rule. Proposed comment indicator ''NP'' meant a new code for the next calendar year or an existing code with substantial revision to its code descriptor in the next calendar year, as compared to the current calendar year; and denoted that comments would be accepted on the proposed ASC payment indicator for the new code.

We will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2022 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 of this proposed rule (which are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2022 update. Addenda DD1 and DD2 to this proposed rule (which are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for CY 2022.

G. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 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 OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

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 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2. of this CY

2022 OPPS/ASC proposed rule), 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 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. 18–04 may be obtained at *https://www.whitehouse.gov/wpcontent/uploads/2018/90/Bulletin-18-04.pdf*. We are utilizing the revised delineations as set forth in the April 10, 2018 OMB Bulletin No. 18–03 and the September 14, 2018 OMB Bulletin No. 18–04 to calculate the CY 2021 ASC wage index effective beginning January 1, 2021.

For CY 2022, we noted that the proposed CY 2022 ASC wage indexes fully reflects the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 15–01, 17–01, 18–03, and 18–04). 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 2022, we applied 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 have continued 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 2022 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 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, given our concerns with CY 2020 claims data as a result of the PHE, we are using the CY 2019 claims data to be consistent with the OPPS claims data for this CY 2022 OPPS/ASC proposed rule. Consistent with our established policy, we propose to scale the CY 2022 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 2019, we propose to compare the total payment using the CY 2021 ASC relative payment weights with the total payment using the CY 2022 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2021 and CY 2022. We propose to use the ratio of CY 2021 to CY 2022 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2022. The proposed CY 2022 ASC weight scalar is 0.8591. Consistent with historical practice, we would scale 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.

Scaling would not apply in the case of 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. At the time of this proposed rule, we have available 100 percent of CY 2019 ASC claims data.

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 2022, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2019 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2022 ASC wage indexes. Specifically, holding CY 2019 ASC utilization, service-mix, and the proposed CY 2022 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2021 ASC wage indexes and the total adjusted payment using the proposed CY 2022 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 2021 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2022 ASC wage indexes and applied the resulting ratio of 0.9999 (the proposed CY 2022 ASC wage index budget neutrality adjustment) to the CY 2021 ASC conversion factor to calculate the proposed CY 2022 ASC conversion factor.

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 our proposal 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 will 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. In addition, we finalized our proposal to revise our regulations under § 416.171(a)(2), which address the annual update to the ASC conversion factor. During this 5-year period, we intend to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and could propose a plan to collect such information. We refer readers to that final rule for a detailed discussion of the rationale for these policies.

The proposed hospital market basket update for CY 2022 is projected to be 2.5 percent, as published in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25435), based on IHS Global Inc.'s (IGI's) 2020 fourth quarter forecast with historical data through the third quarter of 2020.

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 2022 is projected to be 0.2 percentage point, as published in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25435) based on IGI's 2020 fourth quarter forecast.

For 2022, we propose to utilize the hospital market basket update of 2.5 percent reduced by the productivity adjustment of 0.2 percentage point, resulting in a productivity-adjusted hospital market basket update factor of 2.3 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to apply a 2.3 percent productivity-adjusted hospital market basket update factor to the CY 2021 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2022 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 CY 2022 OPPS/ASC 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 hospital market basket update of 2.5 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 0.3 percent productivity-adjusted hospital market basket update factor to the CY 2021 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 hospital market basket update or productivity adjustment), we would use such data, if appropriate, to determine the CY 2022 ASC update for the CY 2022 OPPS/ASC final rule with comment period.

For 2022, we propose to adjust the CY 2021 ASC conversion factor ($48.952) by the proposed wage index budget neutrality factor of 0.9993 in addition to the productivity-adjusted hospital market basket update of 2.3 percent discussed above, which results in a proposed CY 2022 ASC conversion factor of $50.043 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we propose to adjust the CY 2021 ASC conversion factor ($48.952) by the proposed wage index budget neutrality factor of 0.9993 in addition to the quality reporting/productivity-adjusted hospital market basket update of 0.3 percent discussed above, which results in a proposed CY 2022 ASC conversion factor of $49.064.

3. Display of Proposed CY 2022 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 2022 for covered surgical procedures and covered ancillary services, respectively. Historically, for those covered surgical procedures and covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard ratesetting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the PFS rates that would be effective January 1, 2022. For a discussion of the PFS rates, we refer readers to the CY 2022 PFS proposed rule that is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The proposed payment rates included in addenda AA and BB to this proposed rule reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the proposed CY 2022 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.

Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2021. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the interim payment indicator for the new code. Display of the comment indicator ''NP'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the ASC payment indicator for the new code.

For 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 2021 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2021. 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 2022 payment rate displayed in the ''Proposed CY 2022 Payment Rate'' column, each ASC payment weight in the ''Proposed CY 2022 Payment Weight'' column was multiplied by the proposed CY 2022 conversion factor of $50.043. 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 2022 ASC conversion factor uses the CY 2022 productivity-adjusted hospital market basket update factor of 2.3 percent (which is equal to the projected hospital market basket update of 2.5 percent reduced by a projected productivity adjustment of 0.2 percentage point).

In Addendum BB, there are no relative payment weights displayed in the ''Proposed CY 2022 Payment Weight'' column for items and services

with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2021 Payment'' column displays the proposed CY 2022 national unadjusted ASC payment rates for all items and services. The proposed CY 2022 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in 2020.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2022.

XIV. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Outpatient Quality Programs—Request for Information

We aim to move fully to digital quality measurement in the Centers for Medicare & Medicaid Services (CMS) quality reporting and value-based purchasing (VBP) programs by 2025. As part of this modernization of our quality measurement enterprise, we are issuing this request for information (RFI). The purpose of this RFI is to gather broad public input solely for planning purposes for our transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future rulemaking, as necessary. This RFI contains five parts:

- Background. This part provides information on our quality measurement programs and our goal to move fully to digital quality measurement by 2025. This part also provides a summary of recent HHS policy developments that are advancing interoperability and could support our move towards full digital quality measurement.
- Definition of Digital Quality Measures (dQMs). This part provides a potential definition for dQMs. Specific requests for input are included in the section.
- Use of Fast Healthcare Interoperability Resources (FHIR®) for Current Electronic Clinical Quality Measures (eCQMs). This part provides information on current activities underway to align CMS eCQMs with the FHIR standard and support quality measurement via application programming interfaces (APIs), and contrasts this approach to current eCQM standards and practice.
- Changes Under Consideration to Advance Digital Quality Measurement: Potential Actions in Four Areas to Transition to dQMs by 2025. This part introduces four possible steps that would enable transformation of CMS' quality measurement enterprise to be fully digital by 2025. Specific requests for input are included in the section.
- Solicitation of Comments. This part lists all requests for input included in the sections of this RFI.

A. Background

As required by law, we implement quality measurement and VBP programs across a broad range of inpatient acute care, outpatient, and post-acute care (PAC) settings consistent with our mission to improve the quality of health care for Americans through measurement, transparency, and increasingly, value-based purchasing. These quality programs are foundational for incentivizing value-based care, contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. In October 2017, we launched the Meaningful Measures Framework. This framework for quality measurement captures our vision to better address health care quality priorities and gaps, including emphasizing digital quality measurement, reducing measurement burden, and promoting patient perspectives, while also focusing on modernization and innovation. The scope of the Meaningful Measures Framework evolves as the health care environment continues to change.[115] Consistent with the Meaningful Measures Framework, we aim to move fully to digital quality measurement by 2025. We acknowledge facilities within the various care and practice settings covered by our quality programs may be at different stages of readiness and, therefore, the timeline for achieving full digital quality measurement across our quality reporting programs may vary.

We also continue to evolve the Medicare Promoting Interoperability Program's focus on the use of certified electronic health record (EHR) technology, from an initial focus on electronic data capture to enhancing information exchange and expanding quality measurement (83 FR 41634). However, reporting data for quality measurement via EHRs remains burdensome, and our current approach to quality measurement does not readily incorporate emerging data sources such as patient-reported outcomes (PRO) and patient-generated health data (PGHD).[116] There is a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

Additionally, advancements in technical standards and associated regulatory initiatives to improve interoperability of healthcare data are creating an opportunity to significantly improve our quality measurement systems. In May 2020, we finalized interoperability requirements in the CMS Interoperability and Patient Access final rule (85 FR 25510) to support beneficiary access to data held by certain payers. At the same time, the Office of the National Coordinator for Health Information Technology (ONC) finalized policies in the ONC 21st Century Cures Act final rule (85 FR 25642) to advance the interoperability of health information technology (IT) as defined in section 4003 of the 21st Century Cures Act, including the ''complete access, exchange, and use of all electronically accessible health information.'' Closely working with ONC, we collaboratively identified Health Level 7 (HL7®) FHIR Release 4.0.1 as the standard to support API policies in both rules. ONC, on behalf of HHS, adopted the HL7 FHIR Release 4.0.1 for APIs and related implementation specifications at 45 CFR 170.215. We believe the FHIR standard has the potential to be a more efficient and modular standard to enable APIs. We also believe this standard enables collaboration and information sharing, which is essential for delivering high-quality care and better outcomes at a lower cost. By aligning technology requirements for payers, health care facilities, and health IT developers HHS can advance an interoperable health IT infrastructure that ensures healthcare facilities and patients have access to health data when and where it is needed.

In the ONC 21st Century Cures Act final rule, ONC adopted a ''Standardized API for Patient and Population Services'' certification criterion for health IT that requires the use of FHIR Release 4 and several implementation specifications. Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third party applications (85 FR 25742).[117] The

[115] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[116] What are patient generated health data: *https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data.*

[117] Application Programming Interfaces (API) Resource Guide, Version 1.0. Available at: *https://www.healthit.gov/sites/default/files/page/2020-11/API-Resource-Guide_v1_0.pdf.*

ONC 21st Century Cures Act final rule also requires health IT developers to update their certified health IT to support the United States Core Data for Interoperability (USCDI) standard.[118] The scope of patient data identified in the USCDI and the data standards that support this data set are expected to evolve over time, starting with data specified in Version 1 of the USCDI. In November 2020, ONC issued an interim final rule with comment period extending the date when health IT developers must make technology meeting updated certification criteria available under the ONC Health IT Certification Program until December 31, 2022 (85 FR 70064).[119]

The CMS Interoperability and Patient Access final rule (85 FR 25510) and program policies build on the ONC 21st Century Cures Act final rule (85 FR 25642). The CMS Interoperability and Patient Access final rule and policies require certain payers (for example, Medicare Advantage organizations, Medicaid and Child Health Insurance Program (CHIP) Fee-for-Service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and issuers of certain Qualified Health Plan (QHP) on the Federally-facilitated Exchanges (FFEs)) to implement and maintain a standards-based Patient Access API using HL7 FHIR Release 4.0.1 to make available claims and encounter data to their enrollees and beneficiaries (called ''patients'' in the CMS interoperability rule) with the intent of ensuring enrollees and beneficiaries have access to their own health care information through third-party software applications.

The CMS Interoperability and Patient Access final rule also established new conditions of participation for Medicare and Medicaid participating hospitals and critical access hospitals (CAHs), requiring them to send electronic notifications to another healthcare facility or community provider or practitioner when a patient is admitted, discharged, or transferred (85 FR 25603).

In the calendar year (CY) 2021 Physician Fee Schedule (PFS) final rule (85 FR 84472), we finalized a policy to align the certified EHR technology required for use in the Promoting Interoperability Programs and the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category with the updates to health IT certification criteria finalized in the ONC 21st Century Cures Act final rule. Under this policy, MIPS eligible clinicians, and eligible hospitals and CAHs participating in the Promoting Interoperability Programs, must use technology meeting the updated certification criteria for performance and reporting periods beginning in 2023 (85 FR 84825).

The use of APIs can also reduce long-standing barriers to quality measurement. Currently, health IT developers are required to implement individual measure specifications within their health IT products. The health IT developer must also accommodate how that product connects with the unique variety of systems within a specific care setting.[120] This may be further complicated by systems that integrate a wide range of data schemas. This process is burdensome and costly, and it is difficult to reliably obtain high quality data across systems. As health IT developers map their health IT data to the FHIR standard and related implementation specifications, APIs can enable these structured data to be easily accessible for quality measurement or other use cases, such as care coordination, clinical decision support, and supporting patient access.

We believe the emerging data standardization and interoperability enabled by APIs will support the transition to full digital quality measurement by 2025, and are committed to exploring and seeking input on potential solutions for the transition to digital quality measurement as described in this RFI.

B. Definition of Digital Quality Measures

In this section we seek to refine the definition of digital quality measures (dQMs) to further operationalize our objective of fully transitioning to dQMs by 2025. We previously noted dQMs use ''sources of health information that are captured and can be transmitted electronically and via interoperable systems'' (85 FR 84845). In this RFI, we seek input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources. We also note that dQMs are intended to improve the patient experience including quality of care, improve the health of populations, and/or reduce costs. We discuss one potential approach to developing dQM software in section XIV.D.2. of the preamble of this proposed rule. In this section, we are seeking comment on the potential definition of dQMs in this RFI.

We also seek feedback on how leveraging advances in technology (for example, FHIR-based APIs) to access and electronically transmit interoperable data for dQMs could reinforce other activities to support quality measurement and improvement (for example, the aggregation of data across multiple data sources, rapid-cycle feedback, and alignment of programmatic requirements).

The transition to dQMs relies on advances in data standardization and interoperability. As providers and payers work to implement the required advances in interoperability over the next several years, we will continue to support reporting of eCQMs through CMS quality reporting programs and through the Promoting Interoperability Programs.[121] These fully digital measures continue to be important drivers of interoperability advancement and learning. As discussed in the next section, we are currently re-specifying and testing these measures to use FHIR rather than the currently adopted Quality Data Model (QDM) in anticipation of the wider use of FHIR standards. CMS intends to apply significant components of the output of this work, such as the re-specified measure logic and the learning done through measure testing with FHIR-based APIs, to define and build future dQMs that take advantage of the expansion of standardized, interoperable data.

C. Use of FHIR for Current eCQMs

Since we adopted eCQMs in our hospital and clinician quality programs, we have heard from stakeholders about the technological challenges, burden, and related costs of reporting eCQM data. The CMS eCQM Strategy Project engaged with stakeholders through site visits and listening sessions with health

[118] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[119] Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the Covid-19 Public Health Emergency. Available at: *https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24376.pdf.*

[120] The Office of the National Coordinator for Health Information Technology, Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, Final Report (Feb. 2020). Available at: *https://www.healthit.gov/sites/default/files/page/2020–02/BurdenReport_0.pdf.*

[121] eCQI Resource Center. Available at: *https://ecqi.healthit.gov/.*

systems and provider organizations to learn about their experiences. This stakeholder feedback identified recommendations to improve processes related to alignment; development; implementation and reporting; certification; and communication, education, and outreach. Over the past 2 years, we have focused on opportunities to streamline and modernize quality data collection and reporting processes, such as exploring FHIR (*http://hl7.org/fhir*) as a framework for measure structure and data submission for quality reporting programs, specifically for eCQMs. FHIR is a free and open source standards framework (in both commercial and government settings) created by HL7 International that establishes a common language and process for all health information technology. FHIR allows systems to communicate and information to be shared seamlessly, with a lower burden for hospitals, providers, clinicians, vendors, and quality measurement stakeholders. Specifically, for quality reporting, FHIR enables representing the data in eCQMs as well as provides a structure for eCQMs and reporting, using FHIR as the standard for all. Whereas today, multiple standards being used to report eCQMs is challenging and burdensome.

We are working to convert current eCQMs to the FHIR standard. We are currently testing the exchange of data elements represented in FHIR to CMS through ongoing HL7 Connectathons and integrated system testing by using and refining implementation guides (IGs). Submitting data through FHIR-based APIs has the potential to improve data exchange by providing consistent security, performance, scalability, and structure to all users. In addition, development of FHIR-based APIs could decrease provider burden by automating more of the measure data collection process. We continue to explore and expand potential applications of the FHIR standard and testing with eCQM use cases, and we are strongly considering a transition to FHIR-based quality reporting with the use of the FHIR standard for eCQMs in quality and value-based reporting programs. As we move to an all-dQM format for quality programs, we are depending on testing results and community readiness to improve interoperability, reduce burden, and facilitate better patient care. We will continue to consider how to leverage the interoperability advantages offered by the FHIR standards and API-based data submission, including digital quality measurement.

D. Changes Under Consideration To Advance Digital Quality Measurement: Potential Actions in Four Areas To Transition to Digital Quality Measures by 2025

Building on the advances in interoperability and learning from testing of FHIR-converted eCQMs, we aim to move fully to dQMs, originating from sources of health information that are captured and can be transmitted electronically via interoperable systems, by 2025.

To enable this transformation, we are considering further modernization of the quality measurement enterprise in four major ways: (1) Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate.

These changes would enable us to collect and utilize more timely, actionable, and standardized data from diverse sources and care settings to improve the scope and quality of data used in quality reporting and payment programs, reduce quality reporting burden, and make results available to stakeholders in a rapid-cycle fashion. Data collection and reporting efforts would become more efficient, supported by advances in interoperability and data standardization. Aggregation of data from multiple sources would allow assessments of costs and outcomes to be measured across multiple care settings for an individual patient or clinical conditions. We believe that aggregating data for measurement can incorporate a more holistic assessment of an individual's health and health care and produce the rich set of data needed to enable patients and caregivers to make informed decisions by combining data from multiple sources (for example, patient reported data, EHR data, and claims data) for measurement.

Perhaps most importantly, these steps would help us deliver on the full promise of quality measurement and drive us toward a learning health system that transforms healthcare quality, safety, and coordination and effectively measures and achieves value-based care. The shift from a static to a learning health system hinges on the interoperability of healthcare data, and the use of standardized data. dQMs would leverage this interoperability to deliver on the promise of a learning health system wherein standards-based data sharing and analysis, rapid-cycle feedback, and quality measurement and incentives are aligned for continuous improvement in patient-centered care. Similarly, standardized, interoperable data used for measurement can also be used for other use cases, such as clinical decision support, care coordination and care decision support, which impacts health care and care quality.

We are requesting comments on four potential future actions that would enable transformation to a fully digital quality measurement enterprise by 2025.

1. Leveraging and Advancing Standards for Digital Data and Obtaining All EHR Data Required for Quality Measures via Provider FHIR-Based APIs

We are considering targeting the data required for our quality measures that utilize EHR data to be data retrieved via FHIR-based APIs based on standardized, interoperable data. Utilizing standardized data for EHR-based measurement (based on FHIR and associated IGs) and aligning where possible with interoperability requirements can eliminate the data collection burden providers currently experience with required chart-abstracted quality measures and reduce the burden of reporting digital quality measure results. We can fully leverage this advance to adapt eCQMs and expand to other dQMs through the adoption of interoperable standards across other digital data sources. We are considering methods and approaches to leverage the interoperability data requirements for APIs in certified health IT set by the ONC 21st Century Cures Act final rule to support modernization of CMS quality measure reporting. As discussed previously, these requirements will be included in certified technology in future years (85 FR 84825) including availability of data included in the USCDI via standards-based APIs, and CMS will require clinicians and hospitals participating in MIPS and the Promoting Interoperability Programs, respectively, to transition to use of certified technology updated consistent with the 2015 Cures Edition Update (85 FR 84825).

Digital data used for measurement could also expand beyond data captured in traditional clinical settings, administrative claims data, and EHRs. Many important data sources are not currently captured digitally, such as survey and PGHD. We intend to work to innovate and broaden the digital data used across the quality measurement enterprise beyond the clinical EHR and administrative claims. Agreed upon

standards for these data, and associated implementation guides will be important for interoperability and quality measurement. We will consider developing clear guidelines and requirements for these digital data that align with interoperability requirements, for example, requirements for expressing data in standards, exposing data via standards-based APIs, and incentivizing technologies that innovate data capture and interoperability.

High quality data are also essential for reliable and valid measurement. Hence, in implementing the shift to collect all clinical EHR data via FHIR-based APIs, we would support efforts to strengthen and test the quality of the data obtained through FHIR-based APIs for quality measurement. We currently conduct audits of eCQM data submitted under our quality programs, including the Hospital Inpatient Quality Reporting (IQR) Program, with functions including checks for data completeness and data accuracy, confirmation of proper data formatting, alignment with standards, and appropriate data cleaning (82 FR 38398 through 38402). These functions would continue and be applied to dQMs and further expanded to automate the manual validation of the data compared to the original data source (for example, the medical record) where possible. Analytic advancements such as natural language processing, big data analytics, and artificial intelligence, can support this evolution. These techniques can be applied to validating observed patterns in data and inferences or conclusions drawn from associations, as data are received, to ensure high quality data are used for measurement.

We are seeking feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach. We are also seeking feedback on the importance of and approaches to supporting inclusion of PGHD and other currently non-standardized data. We also welcome comment on approaches for testing data quality and validity.

2. Redesigning Quality Measures To Be Self-Contained Tools

We are considering approaches for including quality measures that take advantage of standardized data and interoperability requirements that have expanded flexibility and functionality compared to CMS' current eCQMs. We are considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payers, CMS, and others; calculate measure score(s); and produce reports. In general, we believe to optimize the use of standardized and interoperable data, the software solution for dQMs should do the following:

- Have the flexibility to support calculation of single or multiple quality measure(s).
- Perform three functions —
  - ++ Obtain data via automated queries from a broad set of digital data sources (initially from EHRs, and in the future from claims, PRO, and PGHD);
  - ++ Calculate the measure score according to measure logic; and
  - ++ Generate measure score report(s).
- Be compatible with any data source systems that implement standard interoperability requirements.
- Exist separately from digital data source(s) and respect the limitations of the functionality of those data sources.
- Be tested and updated independently of the data source systems.
- Operate in accordance with health information protection requirements under applicable laws and comply with governance functions for health information exchange.
- Have the flexibility to be deployed by individual health systems, health IT vendors, data aggregators, and health plans; and/or run by CMS depending on the program and measure needs and specifications.
- Be designed to enable easy installation for supplemental uses by medical professionals and other non-technical end-users, such as local calculation of quality measure scores or quality improvement.
- Have the flexibility to employ current and evolving advanced analytic approaches such as natural language processing.
- Be designed to support pro-competitive practices for development, maintenance, and implementation as well as diffusion of quality measurement and related quality improvement and clinical tools through, for example, the use of open-source core architecture.

We seek comment on these suggested functionalities and other additional functionalities that quality measure tools should ideally have particularly in the context of the possible expanding availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs).

We are also interested whether and how this more open, agile strategy may facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research.

3. Building a Pathway to Data Aggregation in Support of Quality Measurement

Using multiple sources of collected data to inform measurement would reduce data fragmentation (or, different pieces of data regarding a single patient stored in many different places). Additionally, we are considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. Qualified Clinical Data Registries and Qualified Registries that report quality measures for eligible clinicians in the MIPS program are potential examples [122] at 42 CFR 414.1440(b)(2)(iv) and (v) and (c)(2)(iii) and (iv) and can also support measure reporting. We are considering establishing similar policies for third-party aggregators to maintain the integrity of our measure reporting process and to encourage market innovation.

We seek feedback on aggregation of data from multiple sources to inform measurement and potential policy considerations. We also seek feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers, and how we can best facilitate and enable aggregation.

4. Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

We are committed to using policy levers and working with stakeholders to solve the issue of interoperable data exchange and to transition to full digital quality measurement. We are considering the future potential development and multi-staged implementation of a common portfolio of dQMs across our regulated programs, agencies, and private payers. This common portfolio would require alignment of: (1) Measure concepts and specifications including narrative statements, measure logic, and value sets; and (2) the individual data elements used to build these measure

[122] CY 2021 Physician Fee Schedule Final Rule: Finalized (New and Updated) Qualified Clinical Data Registry (QCDR) and Qualified Registry Policies, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1362/QCDR%20and%20QR%20Updates%202021%20Final%20Rule%20Fact%20Sheet.pdf.*

specifications and calculate the measure logic. Further, the required data elements would be limited to standardized, interoperable data elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and IGs for key data elements. We would coordinate closely with quality measure developers, Federal and state agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across Federal and state agencies and payers to the extent possible.

We intend for this coordination to be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, PROs, disparities, and care coordination), and track with the transformation of data collection, alignment with health IT module updates including capabilities and standards adopted by ONC (for example, standards to enable APIs). This coordination would build on the principles outlined in HHS' National Health Quality Roadmap.[123] It would focus on the quality domains of safety, timeliness, efficiency, effectiveness, equitability, and patient-centeredness. It would leverage several existing Federal and public-private efforts including our Meaningful Measures 2.0 Framework; the Federal Electronic Health Record Modernization (Department of Defense and Veterans Affairs (DoD/VA)); the Agency for Healthcare Research and Quality's (AHRQ) Clinical Decision Support Initiative; the Centers for Disease Control and Prevention's (CDC) Adapting Clinical Guidelines for the Digital Age initiative; Core Quality Measure Collaborative, which convenes stakeholders from America's Health Insurance Plans (AHIP), CMS, National Quality Forum (NQF), provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership (MAP), which recommends measures for use in public payment and reporting programs. We would coordinate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health. Through this coordination, we would identify which existing measures could be used or evolved to be used as dQMs, in recognition of current healthcare practice and priorities.

This multi-stakeholder, joint Federal, state, and industry effort, made possible and enabled by the pending advances towards true interoperability, would yield a significantly improved quality measurement enterprise. The success of the dQM portfolio would be enhanced by the degree to which the measures achieve our programmatic requirements for measures as well as the requirements of other agencies and payers.

We seek feedback on initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools, and data standards). We also seek to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities across sectors.

E. Solicitation of Comments

As noted previously, we seek input on the future development of the following:

• Definition of Digital Quality Measures. We are seeking feedback on the following as described in section XIV.2. of the preamble of this proposed rule:

++ Do you have feedback on the potential future dQM definition?

++ Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcome more specific comments on the attributes or functions to support such an approach of deploying dQMs.

• Use of FHIR for Current eCQMs. We are seeking feedback on the following as described in section XIV.3. of the preamble of this proposed rule:

++ Would a transition to FHIR-based quality reporting reduce burden on health IT vendors and providers? Please explain.

++ Would access to near real-time quality measure scores benefit your practice? How so?

++ What parts of the current CMS Quality Reporting Data Architecture (QRDA) IGs cause the most burden (please explain the primary drivers of burden)?

++ In what ways could CMS FHIR Reporting IG be modified to reduce burden on providers and vendors?

• Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025.

++ We are seeking feedback on the following as described in section XIV.4.a. of the preamble of this proposed rule:

—Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements? What are the strengths and limitations of this approach? Are there specific FHIR IGs suggested for consideration?

—How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data?

—What are possible approaches for testing data quality and validity?

++ We are seeking feedback on the following as described in section XIV.4.b. of the preamble of this proposed rule:

—What functionalities, described in section (4)(b) or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs)?

—How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?

++ We seek feedback on the following as described in section XIV.4.c. of the preamble of this proposed rule:

—What are key policy considerations for aggregation of data from multiple sources being used to inform measurement?

—What role can or should data aggregators play in CMS quality measure reporting in collaboration with providers? How can CMS best facilitate and enable aggregation?

++ We seek feedback on the following as described in section XIV.4.d. of the preamble of this proposed rule:

—What are initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools)?

—We also seek to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities and across sectors.

Commenters should consider provisions in the CMS Interoperability and Patient Access final rule (85 FR

[123] Department of Health and Human Services, National Health Quality Roadmap (May 2020). Available at: *https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.*

25510), CMS CY 2021 PFS final rule (85 FR 84472), and the ONC 21st Century Cures Act final rule (85 FR 25642).

We plan to continue working with other agencies and stakeholders to coordinate and to inform any potential transition to dQMs by 2025. While we will not be responding to specific comments submitted in response to this Request for Information in the CY 2022 OPPS/ASC final rule, we will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

XV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. Consistent with these goals, CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program. The Hospital OQR Program regulations are codified at 42 CFR 419.46. In the CY 2021 OPPS/ASC final rule (85 FR 86179), we finalized to update the regulations to include a reference to the statutory authority for the Hospital OQR Program. Section 1833(t)(17)(A) of the Social Security Act (the Act) states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual Outpatient Department (OPD) fee schedule increase factor. In the CY 2021 OPPS/ASC final rule (85 FR 86179) we codified the Hospital OQR Program's statutory authority at § 419.46(a).

3. Regulatory History of the Hospital OQR Program

We refer readers to the CY 2008 through 2021 OPPS/ASC final rules with comment period for detailed discussions of the regulatory history of the Hospital OQR Program:

- The CY 2008 OPPS/ASC final rule (72 FR 66860 through 66875);
- The CY 2009 OPPS/ASC final rule (73 FR 68758 through 68779);
- The CY 2010 OPPS/ASC final rule (74 FR 60629 through 60656);
- The CY 2011 OPPS/ASC final rule (75 FR 72064 through 72110);
- The CY 2012 OPPS/ASC final rule (76 FR 74451 through 74492);
- The CY 2013 OPPS/ASC final rule (77 FR 68467 through 68492);
- The CY 2014 OPPS/ASC final rule (78 FR 75090 through 75120);
- The CY 2015 OPPS/ASC final rule (79 FR 66940 through 66966);
- The CY 2016 OPPS/ASC final rule (80 FR 70502 through 70526);
- The CY 2017 OPPS/ASC final rule (81 FR 79753 through 79797);
- The CY 2018 OPPS/ASC final rule (82 FR 59424 through 59445);
- The CY 2019 OPPS/ASC final rule (83 FR 59080 through 59110);
- The CY 2020 OPPS/ASC final rule (84 FR 61410 through 61420); and
- The CY 2021 OPPS/ASC final rule (85 FR 86179 through 86187).

We have codified certain requirements under the Hospital OQR Program at 42 CFR 419.46. We refer readers to section XV.E. of this proposed rule for a detailed discussion of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements for the CY 2024 payment determination.

B. Hospital OQR Program Quality Measures

1. Considerations in Selecting Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously finalized and codified at § 419.46(h)(1) a policy to retain measures from a previous year's Hospital OQR Program measure set for subsequent years' measure sets, unless removed (77 FR 68471 and 83 FR 59082). We are not proposing any changes to these policies in this proposed rule.

3. Removal of Quality Measures From the Hospital OQR Program Measure Set

a. Immediate Removal

We previously finalized and codified at § 419.46(i)(2) and (3) a process for removal and suspension of Hospital OQR Program measures, based on evidence that the continued use of the measure as specified raises patient safety concerns (74 FR 60634 through 60635, 77 FR 68472, and 83 FR 59082).[124] We are not proposing any changes to these policies in this proposed rule.

b. Consideration Factors for Removing Measures

We previously finalized and codified at § 419.46(i)(3) policies to use the regular rulemaking process to remove a measure for circumstances for which we do not believe that continued use of a measure raises specific patient safety concerns (74 FR 60635 and 83 FR 59082).[125] We are not proposing any changes to these policies in this proposed rule.

c. Proposed Removals Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination: OP–02 (Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and OP–03 (Median Time To Transfer to Another Facility for Acute Coronary Intervention)

In this proposed rule, we are proposing to remove two chart-abstracted measures under removal Factor 4—the availability of a more broadly applicable (across settings, populations, or conditions) measure for the particular topic:

- Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP–2); and
- Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3).

The OP–2 measure assesses the number of acute myocardial infarction (AMI) patients with: (a) ST-segment elevation on the electrocardiogram closest to arrival time receiving fibrinolytic therapy during the ED visit; and (b) a time from hospital arrival to fibrinolysis of 30 minutes or less. For

[124] We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our reasons for changing the term ''retirement'' to ''removal'' in the Hospital OQR Program.

[125] We initially referred to this process as ''retirement'' of a measure in the 2010 OPPS/ASC proposed rule, but later changed it to ''removal'' during final rulemaking.

more details on this measure, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66865), where this measure was designated as ED–AMI–3, and the CY 2009 OPPS/ASC final rule with comment period (73 FR 68761), where this measure was relabeled OP–2 (for the CY 2010 payment determination and subsequent years). The OP–3 measure assesses the median number of minutes before outpatients with chest pain or possible heart attack who needed specialized care were transferred to another hospital capable of offering such specialized care. For more details on this measure, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66865), where this measure was designated as ED–AMI–5, and the CY 2009 OPPS/ASC final rule with comment period (73 FR 68761), where this measure was relabeled OP–3 (for the CY 2010 payment determination and subsequent years).

In this proposed rule, we are proposing to remove these two measures (Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP–2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3)) beginning with the CY 2023 reporting period/CY 2025 payment determination due to the availability of a more broadly applicable measure. Specifically, in this proposed rule, we are proposing to adopt the ST-Segment Elevation Myocardial Infarction (STEMI) electronic clinical quality measure (eCQM) into the Hospital OQR Program measure set, which would serve as a replacement for these two measures. We refer readers to section XV.B.4.c. of this proposed rule for further discussion of the STEMI eCQM, including the measure overview, data sources, and measure calculation.

OP–2 and OP–3 measure the proportion of eligible STEMI patients who receive timely fibrinolytic therapy and timely transfer from an ED to another facility to receive appropriate care, respectively. The STEMI eCQM is a proposed electronic process measure that includes both the populations of OP–2 and OP–3. It measures the percentage of ED patients diagnosed with STEMI that received timely fibrinolytic therapy (within 30 minutes) or timely transfer to a percutaneous coronary intervention (PCI)-capable facility (within 45 minutes). Additionally, the STEMI eCQM captures transfer and non-transfer patients at a PCI-capable facility who receive PCI (within 90 minutes). Pursuant to removal Factor 4, we believe that the adoption of the STEMI eCQM would capture the OP–2 and OP–3 measure populations and expand beyond these populations to comprehensively measure the timeliness and appropriateness of STEMI care.

Furthermore, the OP–2 and OP–3 measures are chart-abstracted measures, which result in greater provider burden due to manual abstraction. The STEMI eCQM allows for the retrieval of data directly from the electronic health record (EHR) using patient-level data. As a result, we believe the STEMI eCQM is a more broadly applicable measure and transitions the Hospital OQR Program toward the use of EHR data for quality measurement. We note that removal of these measures is contingent on the finalization of the STEMI eCQM. We invite public comment on our proposals to remove these measures.

4. Proposals To Adopt New Measures for the Hospital OQR Program Measure Set

In this proposed rule, we are proposing to adopt three new measures: (1) COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure, beginning with the CY 2022 reporting period; (2) Breast Screening Recall Rates measure, beginning with the CY 2022 reporting period; and (3) STEMI eCQM, beginning as a voluntary measure with the CY 2023 reporting period, and then as a mandatory measure beginning with the CY 2024 reporting period. We refer readers to the following sections for more information.

a. Proposal To Adopt the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination

(1) Background

On January 31, 2020, the Secretary declared a public health emergency (PHE) for the United States (U.S.) in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[126] COVID–19 is a contagious respiratory infection[127] that can cause serious illness and death. Older individuals, some racial and ethnic minorities, and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[128] [129] As of July 2, 2021, the U.S. has reported over 33 million cases of COVID–19 and over 600,000 COVID–19 deaths.[130] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[131] Between December 2, 2020 and January 30, 2021, more than 100,000 Americans with COVID–19 were hospitalized at the same time.[132]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[133] Ongoing research indicates that fully vaccinated people without immunocompromising conditions are able to engage in most activities with very low risk of acquiring or transmitting SARS–CoV–2, and the Centers for Disease Control and Prevention (CDC) issued new guidance for fully vaccinated individuals on May 28, 2021.[134] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[135] Thus, the CDC advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone

[126] 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*.

[127] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[128] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[129] Centers for Disease Control and Prevention. (2020). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html*.

[130] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days*.

[131] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895*. Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html*.

[132] US Currently Hospitalized | The COVID Tracking Project. Accessed January 31, 2021 at: *https://covidtracking.com/data/charts/us-currently-hospitalized*.

[133] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[134] Centers for Disease Control and Prevention. (2021). Interim Public Health Recommendations for Fully Vaccinated People. Accessed on June 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html*.

[135] *Ibid*.

who has COVID–19.[136] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface [137] and that in certain circumstances, infection can occur through airborne transmission.[138] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed COVID–19 infection, regardless of whether the individual has symptoms.[139] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between HCP and patients or from patient to patient given the close contact that may occur during the provision of care.[140] The CDC has emphasized that health care settings, including long-term care (LTC) settings, can be high-risk places for COVID–19 exposure and transmission.[141]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[142] On December 11, 2020, the Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[143] Subsequently, the FDA issued EUAs for additional COVID–19 vaccines.[144] [145]

As part of its national strategy to address COVID–19, the White House stated on March 25, 2021 that it would work with states and the private sector to execute an aggressive vaccination strategy and has outlined a goal of administering 200 million shots in 100 days.[146] On April 21, 2021, it was announced that this goal had been achieved.[147] Although the goal of the U.S. Government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, the Department of Health and Human Services (HHS), the Department of Defense (DoD), and the CDC, recommended that early vaccination efforts focus on those critical to the PHE response, including HCP, and individuals at highest risk for developing severe illness from COVID–19.[148] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in health care settings and the need to preserve health care system capacity.[149] Research suggests most states followed this recommendation,[150] and HCP began receiving the vaccine in mid-December of 2020.[151]

Frontline healthcare workers, such as those employed in hospitals, have been prioritized for vaccination in most locations. There are approximately 18 million healthcare workers in the U.S.[152] A survey of HCP found that 66 percent of hospital HCP and 64 percent of outpatient clinic HCP reported receiving at least one dose of the vaccine.[153] As of July 2, 2021, the CDC reported that over 328 million doses of COVID–19 vaccine had been administered and approximately 155.9 million people were fully vaccinated.[154] The White House indicated on April 6, 2021, that the U.S. retains sufficient vaccine supply, and every adult became eligible to receive the vaccine beginning April 19, 2021.[155]

We believe it is important to require that hospital outpatient departments (HOPDs) report HCP vaccination information for health care facilities to assess whether these facilities are taking steps to limit the spread of COVID–19 among their health care workers and to help sustain the ability of HOPDs to continue serving their communities throughout the PHE and beyond. Therefore, we are proposing to adopt a new measure, COVID–19 Vaccination Coverage Among HCP, beginning with the CY 2024 payment determination. For that payment year, hospitals would be required to report data quarterly on the measure for the January 2022 through December 2022 reporting period. The measure would assess the proportion of a hospital's health care workforce that has been vaccinated against COVID–19.

HCP are at risk of transmitting COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 themselves, and

[136] *Ibid.*

[137] *Ibid.*

[138] Centers for Disease Control and Prevention. (2020). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[139] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html.*

[140] Centers for Disease Control and Prevention. 2021). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19.

[141] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[142] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[143] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144412/download.*

[144] U.S. Food and Drug Administration. (2021). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download.*

[145] U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download.*

[146] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on April 3, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/.*

[147] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 2, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/21/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations-2/.*

[148] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf*; Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[149] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[150] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/.*

[151] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f.*

[152] Centers for Disease Control and Prevention. Healthcare Workers. (2017) Accessed February 18, 2021 at: *https://www.cdc.gov/niosh/topics/healthcare/default.html.*

[153] KFF/The Washington Post Frontline Health Care Workers Survey. (2021). Accessed June 2, 2021 at: *https://www.kff.org/coronavirus-covid-19/poll-finding/kff-washington-post-health-care-workers/.*

[154] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. COVID Data Tracker. COVID–19 Vaccinations in the United States. (2021). Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations.*

[155] The White House. Remarks by President Biden Marking the 150 Millionth COVID–19 Vaccine Shot. Accessed April 8, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/06/remarks-by-president-biden-marking-the-150-millionth-covid-19-vaccine-shot/.*

transmitting it to their families, friends, and the general public. We believe HOPDs should report the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can reduce illness that leads to work absence and limit disruptions to providing care [156] with major reductions in SARS–CoV–2 infections among those receiving two dose COVID–19 vaccine despite a high community infection rate.[157] Data from influenza vaccination demonstrates that provider vaccination is associated with that provider recommending vaccination to patients,[158] and we believe HCP COVID–19 vaccination in HOPDs could similarly increase uptake among that patient population. We also believe that publicly reporting the HCP vaccination rates would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose HOPDs for treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure addresses the quality priority of ''Promote Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure (''COVID–19 HCP vaccination measure'') is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in non-LTC facilities including outpatient hospitals.

(a) Measure Specifications

The denominator for the HCP measure is the number of HCP eligible to work in the hospital for at least 1 day during the self-selected week, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[159]

The numerator for the HCP measure is the cumulative number of HCP eligible to work in at the hospital for at least 1 day during the self-selected week and who received a complete vaccination course against COVID–19 using an FDA-authorized or FDA-approved vaccine for COVID–19 (whether the FDA issued an approval or EUA).[160] A complete vaccination course is defined under the specific FDA authorization and may require multiple doses or regular revaccination.[161] Vaccination coverage for purposes of this measure is defined as the estimated percentage (given the potential for week-to-week variation) of HCP eligible to work at the hospital for at least 1 day who received a COVID–19 vaccine. Acute care facilities would count HCP working in all inpatient or outpatient units that are physically attached to the inpatient acute care facility site and share the same CMS certification number (CCN), regardless of the size or type of unit. Facilities would also count HCP working in inpatient and outpatient departments that are affiliated with the specific acute care facility (such as sharing medical privileges or patients), regardless of distance from the acute care facility and also share the same CCN. The decision to include or exclude HCP from the acute care facility's HCP vaccination counts would be based on whether individuals meet the specified National Healthcare Safety Network (NHSN) criteria and are physically working in a location that is considered any part of the on-site acute care facility that is being monitored.[162] The proposed specifications for the COVID–19 vaccination coverage among HCP measure is available on the NQF website at: *https://www.cdc.gov/nhsn/nqf/index.html*.[163]

(b) Review by the Measure Applications Partnership

The COVID–19 HCP vaccination measure was included on the publicly available ''List of Measures Under Consideration for December 21, 2020,'' [164] a list of measures under consideration for use in various Medicare programs. The Measure Applications Partnership (MAP) hospital workgroup convened on January 11, 2021, and it reviewed the list of Measures Under Consideration (MUC) including the COVID–19 HCP vaccination measure. The MAP hospital workgroup agreed that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it could bring value to the Hospital OQR Program measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[165] The MAP hospital workgroup also stated in its preliminary recommendations that collecting information on COVID–19 vaccination coverage among HCP and providing feedback to hospitals would allow hospitals to benchmark coverage rates and improve coverage in their facility, and that reducing COVID–19 infection rates in HCP may reduce transmission among patients and reduce instances of staff shortages due to illness.[166]

In its preliminary recommendations, the MAP hospital workgroup did not support this measure for rulemaking, subject to the potential for mitigation.[167] To mitigate its concerns, the MAP hospital workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and National Quality Forum (NQF) endorsement prior to implementation.[168] Subsequently, the MAP Coordinating Committee met on January 25, 2021, and reviewed the COVID–19 HCP vaccination measure. In the 2020–2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measure back to MAP once the specifications were further refined. The MAP specifically stated, ''the incomplete specifications require immediate mitigation and further development should continue.'' [169] In its

[156] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm*.

[157] Benenson S, Oster Y, Cohen MJ, Nir-Paz R. BNT162b2 mRNA Covid–19 Vaccine Effectiveness among Health Care Workers. N Engl J Med. 2021. See also: Keehner J, Horton LE, Pfeffer MA, Longhurst CA, Schooley RT, Currier JS, et al. SARS–CoV–2 Infection after Vaccination in Health Care Workers in California. N Engl J Med. 2021.

[158] Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[159] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed March 15, 2021 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications*.

[160] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[161] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[162] Centers for Disease Control and Prevention. CMS Reporting Requirements FAQs. Accessed June 2, 2021 at: *https://www.cdc.gov/nhsn/PDFs/CMS/faq/FAQs-CMS-Reporting-Requirements.pdf*.

[163] *https://www.cdc.gov/nhsn/nqf/index.html*.

[164] The National Quality Forum. (2021) Accessed March 14, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212*.

[165] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[166] *Ibid*.

[167] *Ibid*.

[168] *Ibid*.

[169] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

final report, the MAP noted that the measure would add value by providing visibility into an important intervention to limit COVID–19 infections in HCP and the patients for whom they provide care.[170] The spreadsheet of final recommendations no longer cited concerns regarding evidence, testing, or NQF endorsement.[171] In response to the MAP final recommendation request that CMS bring the measure back to the MAP once the specifications are further refined, CMS and the CDC met with the MAP Coordinating Committee on March 15, 2021. Additional information was provided to address vaccine availability, alignment of the COVID–19 HCP vaccination measure as closely as possible with the data collection for the Influenza HCP vaccination measure (NQF #0431), and clarification related to how HCP are defined. CMS and the CDC also presented preliminary findings from the testing of the numerator of the COVID–19 HCP vaccination measure, which is currently in process. These preliminary findings show numerator data should be feasible to collect and reliable. Testing of the measure numerator (the number of HCP vaccinated) involves a comparison of the data collected through the NHSN and independently reported through the Federal pharmacy partnership program for delivering vaccination to LTC facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination, the number of healthcare workers vaccinated in approximately 1,200 facilities for which data from both systems was available, the number of healthcare personnel vaccinated was highly correlated between the two systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[172] Because of the high correlation across a large number of facilities and high number of HCP within those facilities receiving at least one dose of the COVID–19 vaccine, we believe the measure is feasible and reliable for use in HOPDs. After reviewing this additional information, the MAP retained its final recommendation of conditional support, and expressed support for CMS' efforts to use the measure as part of the solution for the COVID–19 public health crisis.[173]

Section 1890A(a)(4) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the Secretary to take into consideration input from multi-stakeholder groups in selecting certain quality and efficiency measures. While we value input from the MAP, we believe it is important to propose the measure as quickly as possible to address the urgency of the COVID–19 PHE and its impact on high risk populations, including hospitals. CMS continues to engage with the MAP to mitigate concerns and appreciates the MAP's conditional support for the measure.

(c) Measure Endorsement

Under section 1833(t)(17)(C)(i) of the Act, unless the exception of subclause (ii) applies, measures selected for the quality reporting program must have been set forth by the entity with a contract under section 1890(a) of the Act. The NQF currently holds this contract. Under section 1833(t)(17)(C)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, as we have noted in previous rulemaking (for example, 75 FR 72065 and 76 FR 74494 for the Hospital OQR and ASCQR Programs, respectively), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

The proposed COVID–19 HCP vaccination measure is not NQF endorsed and has not been submitted to NQF for endorsement consideration. We will consider the potential for future NQF endorsement as part of its ongoing work with the MAP.

Because this measure is not NQF-endorsed, we considered whether there are other available measures that assess COVID–19 vaccination rates among HCP. We found no other feasible and practical measures on the topic of COVID–19 vaccination among HCP.

(d) Data Collection, Submission, and Reporting

Given the time sensitive nature of this measure considering the current PHE, we are proposing that hospitals would be required to begin reporting data on the proposed COVID–19 HCP vaccination measure beginning January 1, 2022, for the CY 2024 payment determination for the Hospital OQR Program. Thereafter, we propose quarterly reporting periods. While we considered annual reporting periods for the Hospital OQR Program, we are proposing quarterly reporting periods given the immediacy of the PHE and the importance of alignment across quality payment programs proposing this measure.

If our proposal to adopt this measure is finalized, hospitals would report the measure through the CDC's NHSN web-based surveillance system.[174] While the Hospital OQR Program does not currently require use of the NHSN web-based surveillance system, we have previously required use of this system for submitting data. We refer readers to the CY 2014 OPPS/ASC final rule with comment period in which we adopted the Influenza Vaccination Coverage Among Health Care Personnel (NQF #0431) measure (78 FR 75096 through 75099) and section XV.D.5.b.(1). of this proposed rule for additional information on reporting through the NHSN web-based surveillance system under the Hospital OQR Program. Hospitals also have experience reporting acute care hospital measures to the CDC's NHSN under the Hospital IQR Program.

To report this measure, we are proposing that hospitals would collect the numerator and denominator for the COVID–19 HCP vaccination measure for at least one, self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet Hospital OQR Program requirements. While we believe that it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that hospitals would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable snapshot of vaccination levels among a hospital's

[170] *Ibid.*

[171] *Ibid.*

[172] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[173] *Ibid.*

[174] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

HCP while balancing the costs of reporting. 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, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we are proposing that 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 submission periods submitted by the hospital for that quarter. If finalized, CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

Hospitals would submit the number of HCP eligible to have worked at the facility during the self-selected week that the hospital reports data in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week. As previously stated, acute care facilities would count HCP working in all inpatient or outpatient units that share the same CCN, regardless of the size or type of unit.[175]

We invite public comment on our proposal.

b. Proposal To Adopt the Breast Screening Recall Rates Measure Beginning With the CY 2023 Payment Determination

(1) Background

Performing breast imaging in the outpatient setting facilitates early detection of malignancies.[176] However, performing diagnostic mammography or digital breast tomosynthesis (DBT) as a result of a false-positive screening study or other errant data has the potential to expose women to unnecessary follow-up.[177] This could result in increased prevalence of radiation-induced cancers in younger women, including those carrying related gene mutations, such as BRCA–1 and BRCA–2 [178] [179] or additional imaging and biopsies, which could lead to unnecessary procedures for women who do not have breast cancer.[180] [181] In contrast, recalling too few women for follow-up imaging may lead to delayed diagnoses, higher stages at diagnosis, and/or undetected cases of breast cancer.[182] Given the potential negative consequences associated with too many or too few diagnostic mammography and DBT studies performed within the population, evidence from the clinical literature suggests appropriate recall rates should fall between 5 to 12 percent.[183] [184]

To address the health and clinical risks associated with too many or too few breast screening recalls, we are proposing to adopt the Breast Screening Recall Rates measure beginning with the CY 2023 payment determination using a data collection period of July 1, 2020, to June 30, 2021, and then data collection periods from July 1 through June 30 of the following year starting 3 years before the applicable payment calendar year for subsequent years. We intend for this measure to move facilities toward the 5 to 12 percent range of recall rates. Facilities that are above or below the range should consider implementation of internal quality-improvement procedures to ensure they are not missing cases or recalling individuals unnecessarily. This measure would fill the gap in women's health and oncology care that was left in the Hospital OQR Program portfolio following the removal of the Mammography Follow Up Rates measure (OP–9).[185] More specifically, this measure would directly address the reason OP–9 was removed from the Hospital OQR Program by bringing the measure into alignment with current clinical practice and emerging scientific evidence through the addition of screening and diagnostic DBT (83 FR 59096).[186] [187] [188] [189] [190] [191] [192] [193] The Breast Screening Recall Rates measure would be added to a measure set focused on imaging efficiency. While this measure, as currently specified, would not provide data on outcomes (that is, the number of patients who were recalled and subsequently diagnosed with cancer), it would give

[175] *Ibid.*

[176] Coleman, C. (2017). Early detection and screening for breast cancer. Seminars in Oncology Nursing, 33(2), 141–155. *http://dx.doi.org/10.1016/j.soncn.2017.02.009.*

[177] Bernardi D., Li T., Pellegrini M., Macaskill, P., Valentini, M., Fanto, C., Ostillo, L., & Houssami, N. (2018). Effect of integrating digital breast tomosynthesis (3D-mammography) with acquired or synthetic 2D-mammography on radiologists' true positive and false-positive detection in a population screening trial: A descriptive study. European Journal of Radiology, 106, 26–31.

[178] Berrington de Gonzalez, A., Berg, C.D., Visvanathan, K., & Robson, M. (2009). Estimated risk of radiation-induced breast cancer from mammographic screening for young BRCA mutation carriers. Journal of the National Cancer Institute, 101(3), 205–209. *https://doi.org/10.1093/jnci/djn440.*

[179] Miglioretti, D.L., Lange, J., van den Broek, J. J., Lee, C.I., van Ravesteyn, N.T., Ritley, D., Kerlikowske, K., Fenton, J.J., Melnikow, J., de Koning, H.J., & Hubbard, R.A. (2016). Radiation-induced breast cancer incidence and mortality from digital mammography screening: a modeling study. Annals of internal medicine, 164(4), 205–214. *https://doi.org/10.7326/M15-1241.*

[180] Long, H., Brooks, J.M., Harvie, M., Maxwell, A., & French, D.P. (2019). How do women experience a false-positive test result from breast screening? A systematic review and thematic synthesis of qualitative studies. British journal of cancer, 121(4), 351–358. *https://doi.org/10.1038/s41416-019-0524-4.*

[181] Nelson, H.D., Pappas, M., Cantor, A., Griffin, J., Daeges, M., & Humphrey, L. (2016). Harms of breast cancer screening: systematic review to update the 2009 U.S. preventive services task force recommendation. *Annals of internal medicine, 164*(4), 256–267. *https://doi.org/10.7326/M15-0970.*

[182] Nelson, H.D., Tyne, K., Naik, A., Bougatsos, C., Chan, B.K., & Humphrey, L. (2009). Screening for breast cancer: Systematic evidence review update for the U.S. Preventive Services Task Force. *Ann Intern Med,* 151(10):727–W242.

[183] Carney, P.A., Sickles, E. A., Monsees, B.S., Bassett, L.W., Brenner, R.J., Feig, S.A., Smith, R.A., Rosenberg, R.D., Bogart, T.A., Browning, S., Barry, J.W., Kelly, M.M., Tran, K.A., & Miglioretti, D.L. (2010). Identifying minimally acceptable interpretive performance criteria for screening mammography. *Radiology, 255*(2), 354–361. *https://pubmed.ncbi.nlm.nih.gov/20413750/.*

[184] D'Orsi, C.J., Sickles, E.A., Mendelson, E.B., Morris E.A., et al. (2013). ACR BI–RADS® atlas, breast imaging reporting and data system. Reston, VA: American College of Radiology.

[185] CMS finalized OP–9 for removal from the Hospital OQR Program in the CY 2019 Outpatient Payment Prospective System and Ambulatory Surgical Center Payment System final rule (CMS–1695–FC) (83 FR 58818).

[186] Aase, H.S., Holen, A.S., Pedersen, K., Houssami, N., Haldorsen, I.S., Sebuodegard, S., & Hofvind, S. (2019). A randomized controlled trial of digital breast tomosynthesis versus digital mammography in population-based screening in Bergen: Interim analysis of performance indicators from the To-Be trial. 29(3), 1175–1186. doi: 10.1007/s00330–018–5690–x.

[187] Aujero, M.P., Gavenonis, S.C., Benjamin, R., Zhang, Z., & Holt, J.S. (2017). Clinical performance of synthesized two-dimensional mammography combined with tomosynthesis in a large screening population. Radiology, 283(1), 70–76. doi: 10.1148/radiol.2017162674.

[188] Bian, T., Lin, Q., Cui, C., Li, L., Qi, C., Fei, J., & Su, X. (2016). Digital breast tomosynthesis: A new diagnostic method for mass-like lesions in dense breasts. Breast J, 22(5), 535–540. doi: 10.1111/tbj.12622.

[189] Caumo, F., Zorzi, M., Brunelli, S., Romanucci, G., Rella, R., Cugola, L., Bricolo, P., Fedato, C., Montemezzi, S., & Houssami, N. (2018). Digital breast tomosynthesis with synthesized two-dimensional images versus full-field digital mammography for population screening: Outcomes from the Verona screening program. Radiology, 287(1), 37–46. *https://doi.org/10.1148/radiol.2017170745.*

[190] Conant, E.F., Beaber, E.F., Sprague, B.L., Herschorn, S.D., Weaver, D.L., Onega, T., . . . Barlow, W.E. (2016). Breast cancer screening using tomosynthesis in combination with digital mammography compared to digital mammography alone: A cohort study within the PROSPR consortium. Breast Cancer Res Treat, 156(1), 109–116. doi: 10.1007/s10549–016–3695–1.

[191] Pattacini, P., Nitrosi, A., & Giorgi Rossi, P. (2018). Digital mammography versus digital mammography plus tomosynthesis for breast cancer screening: The Reggio Emilia tomosynthesis randomized trial. 288(2), 375–385. doi: 10.1148/radiol.2018172119.

[192] Pozz, A., Corte, A.D., Lakis, M.A., & Jeong, H. (2016). Digital breast tomosynthesis in addition to conventional 2D mammography reduces recall rates and is cost effective. Asian Pac J Cancer Prev, 17(7), 3521–3526.

[193] Skaane, P. (2017). Breast cancer screening with digital breast tomosynthesis. Breast Cancer, 24(1), 32–41. doi: 10.1007/s12282–016–0699–y.

facilities information to use in examining their own imaging practices. Results from the measure could be used to identify opportunities for improving the efficiency and quality of care provided and would be added to a measure set focused on imaging efficiency.

(2) Overview of Measure

This claims-based process measure documents breast screening recall rates at the facility level. The Breast Screening Recall Rates measure would calculate the percentage of Medicare fee-for-service (FFS) beneficiaries for whom a traditional mammography or DBT screening study was performed that was then followed by a diagnostic mammography, DBT, ultrasound of the breast, or magnetic resonance imaging (MRI) of the breast in an outpatient or office setting on the same day or within 45 calendar days of the index image. In assessing this measure based on clinical quality and efficiency, there are potential negative consequences of high and low mammography and DBT recall rates. A middle-range number is the ideal value for this measure. A high cumulative dose of low-energy radiation can be a consequence of too many false-positive mammography and DBT recall studies. Alternatively, inappropriately low recall rates may lead to delayed diagnoses or undetected cases of breast cancer. The inclusion of DBT in evaluating recall care may improve recall rates and positive predictive values compared to metrics that focus solely on mammography.

Although this measure is not based on a specific clinical guidelines, expert clinical consensus and support from publications in the peer-reviewed literature emphasize the importance of appropriate recall rates.[194] [195] The adoption of this measure could potentially fill a gap in breast screening measures for the Hospital OQR Program. This measure would address the Meaningful Measure priority area of ''Making Care Safer.'' The measure addresses this Meaningful Measure area by: (1) Promoting appropriate use of breast cancer screening and diagnostic imaging by encouraging facilities to aim for a performance score within the target recall range; (2) reducing the harms associated with too many recalls, which can lead to unnecessary radiation exposure, anxiety and distress, and increased costs or resource utilization;[196] [197] and (3) addressing the issue of inappropriately low recall rates, which may lead to delayed diagnoses, diagnoses at a later stage, or undetected cases of breast cancer.[198]

The measure was included on the publicly available ''List of Measures Under Consideration for December 21, 2020,'' a list of measures under consideration for use in various Medicare programs.[199] In January 2021, the Breast Screening Recall Rates measure was reviewed by both the MAP's rural health workgroup and hospital workgroup, overseen by the Coordinating Committee (MUC20–0005).[200] Both groups and the Coordinating Committee voted to conditionally support the measure, pending NQF endorsement.[201] Concerns cited during the January 2021 MAP review included: (1) The proposed recall range is not based on clinical practice guidelines, but rather expert consensus and synthesis of findings from the scientific literature; (2) use of a range (as opposed to a targeted high or low value) may be difficult for clinicians, patients, and other stakeholders to interpret; (3) the measure does not address social determinants of health, which may impact the rate of recall at some facilities; and (4) the measure does not provide complementary information about patient outcomes (for example, breast cancer detection rate), which could aid in the interpretation and usefulness of the measure's data.[202] Despite these concerns, some members of the rural health workgroup, hospital workgroup, and Coordinating Committee expressed support of the Breast Screening Recall Rates measure and noted that feedback provided by the MAP did not preclude measure implementation, given its importance to the clinical community and the public.[203] As a part of measure implementation, we would develop a suite of education and outreach materials to aid stakeholders in the interpretation of measure performance data. These materials would explain the measure structure (including use of a range representing ideal performance) to ensure stakeholders understand values within and outside of the target range. Once implemented, the measure would be re-evaluated annually, which would include a consideration of changes to the evidence base and potential integration of social determinants of health (that is, stratification or risk adjustment); updates to the measure specifications would be made iteratively, as appropriate, on an annual basis.

Section 1833(t)(17)(C)(i) of the Act authorizes the Secretary to specify a measure for addition to a program that is not endorsed by the NQF, as long as due consideration is given to other measures that have been endorsed or adopted by a consensus organization (for example, NQF). We have reviewed those NQF-endorsed measures that are related to breast imaging and have not identified any that focus on recall rates specifically. As such, we are proposing to adopt this measure for use in the Hospital OQR Program because of its importance to women's health and its ability to fill a gap in CMS' Meaningful Measure portfolio even though it has not yet been reviewed by NQF. Submission for NQF endorsement would be considered for this measure in the future.

[194] Nelson, H.D., Tyne, K., Naik, A., Bougatsos, C., Chan, B.K., & Humphrey, L. (2009). Screening for breast cancer: Systematic evidence review update for the U.S. Preventive Services Task Force. *Ann Intern Med,* 151(10):727–W242.

[195] D'Orsi, C.J., Sickles, E.A., Mendelson, E.B., Morris EA, et al. (2013). ACR BI–RADS® atlas, breast imaging reporting and data system. Reston, VA: American College of Radiology.

[196] Long, H., Brooks, J.M., Harvie, M., Maxwell, A., & French, D.P. (2019). How do women experience a false-positive test result from breast screening? A systematic review and thematic synthesis of qualitative studies. British journal of cancer, 121(4), 351–358. *https://doi.org/10.1038/s41416-019-0524-4.*

[197] Nelson, H.D., Pappas, M., Cantor, A., Griffin, J., Daeges, M., & Humphrey, L. (2016). Harms of breast cancer screening: Systematic review to update the 2009 U.S. preventive services task force recommendation. *Annals of internal medicine, 164*(4), 256–267. *https://doi.org/10.7326/M15-0970.*

[198] Nelson, H.D., Tyne, K., Naik, A., Bougatsos, C., Chan, B.K., & Humphrey, L. (2009). Screening for breast cancer: Systematic evidence review update for the U.S. Preventive Services Task Force. *Ann Intern Med,* 151(10):727–W242.

[199] The National Quality Forum. ''List of Measures Under Consideration for December 21, 2020''. (2020) Accessed May 14, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212.*

[200] The National Quality Forum. ''List of Measures Under Consideration for December 21, 2020''. (2020) Accessed May 14, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212.*

[201] Measure Applications Partnership. 2020–2021 Measure Applications Partnership. 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Accessed on May 14, 2021 at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

[202] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[203] Measure Applications Partnership. 2020–2021 Measure Applications Partnership. 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Accessed on May 14, 2021 at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

(3) Measure Calculation

This claims-based process measure documents breast screening recall rates at the facility level. The Breast Screening Recall Rates measure would calculate the percentage of Medicare FFS beneficiaries for whom a traditional mammography or DBT screening study was performed that was then followed by a diagnostic mammography, DBT, ultrasound of the breast, or MRI of the breast in an outpatient or office setting on the same day or within 45 days of the index image. Specifically, the measure denominator includes Medicare FFS beneficiaries who received a screening mammography or DBT study at a facility paid under the OPPS. The numerator consists of individuals from the denominator who had a diagnostic mammography study, DBT, ultrasound of the breast, or MRI of the breast following a screening mammography or DBT study on the same day or within 45 days of the screening study. The Breast Screening Recall Rates measure does not have any exclusions. This measure is not risk adjusted. As a process-of-care measure, the decision to image a beneficiary should not be influenced by sociodemographic status factors; rather, risk adjustment for such sociodemographic factors could potentially mask important inequities in care delivery for beneficiaries seen at facilities providing data for this measure. If performance scores for this measure vary across populations, this may be reflective of differences in the quality of care provided to the diverse populations included in the measure's denominator.

Although this measure is not based on a specific clinical guideline, expert clinical consensus and support from the peer-reviewed literature emphasize the importance of appropriate recall rates.[204] We refer readers to the QualityNet website at *http://www.QualityNet.cms.gov* for the full measure specifications.

(4) Data Sources

The Breast Screening Recall Rates measure would be calculated using data from final claims that facilities submit for Medicare beneficiaries enrolled in Medicare FFS. As such, facilities would not have to submit any additional data for this measure. The measurement period for the Breast Screening Recall Rates measure is 12 months. As noted previously, we would use final claims data from July 1, 2020 to June 30, 2021 to calculate the measure for the CY 2023 payment determination and then data collection periods from July 1 through June 30 of the following year starting 3 years before the applicable payment calendar year for subsequent years. Please note that claims for the initial patient population would be identified from July 1 through May 17 of each year, with numerator cases occurring from July 1 through June 30 annually. The data would be calculated only for facilities paid under the OPPS for mammography and DBT screening in the hospital outpatient setting. Data from the hospital outpatient and carrier files would be used to determine beneficiary inclusion (for example, a mammography follow-up study can occur in any location and be eligible for inclusion in the measure's numerator).

We invite public comment on our proposal.

c. Proposal To Adopt the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM Beginning With Voluntary Reporting for the CY 2023 Reporting Period and Mandatory for the CY 2024 Reporting Period/CY 2026 Payment Determination and Subsequent Years

(1) Background

An ST-segment elevation myocardial infarction (STEMI) is a form of heart attack in which there is a complete occlusion of one of the heart arteries.[205] Each year over 250,000 Americans experience a STEMI, approximately 50 percent of whom are Medicare beneficiaries.[206] [207] This is represented on the electrocardiogram as an elevation of the ST segment—the interval between ventricular depolarization and repolarization (which represents the duration of an average ventricular contraction).[208] Time is of the essence in STEMI treatment, and the prompt identification of STEMI and restoration of blood flow to the heart (reperfusion therapy) is a key determinant of health outcomes.[209] [210] [211] Primary percutaneous coronary intervention (PCI), which is the use of balloons and stents to restore blood flow, is the preferred reperfusion modality.[212] The 2013 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) guidelines recommend the initiation of PCI within 120 minutes from first medical contact (FMC).[213] Specifically, if a patient presents to a PCI-capable facility, primary PCI is recommended within 90 minutes of FMC.[214] If a patient presents to a non-PCI-capable facility, the patient should be expeditiously transported to a PCI-capable facility and receive PCI within a total of 120 minutes.[215] However, in care settings where it is not possible for a patient to receive PCI or be transferred and receive primary PCI within the 120-minute timeframe, fibrinolytic therapy (medications to dissolve blood clots and restore flow) should be administered rapidly for reperfusion in the absence of contraindications.[216] The guidelines recommend that eligible patients should receive fibrinolytic therapy within 30 minutes of hospital arrival.

(2) Overview of Measure

The STEMI eCQM measures the percentage of ED patients with a diagnosis of STEMI who received timely delivery of guideline-based reperfusion therapies appropriate for the care setting and delivered in the absence of contraindications. The Meaningful Measures Framework aims to address

[204] Nelson, H.D., Tyne, K., Naik, A., Bougatsos, C., Chan, B.K., & Humphrey, L. (2009). Screening for breast cancer: Systematic evidence review update for the U.S. Preventive Services Task Force. *Ann Intern Med,* 151(10):727–W242.

[205] Anderson JL, Morrow DA. Acute Myocardial Infarction. *New England Journal of Medicine.* 2017;376(21):2053–2064.

[206] Ward et al. Incidence of Emergency Department Visits for ST-Elevation Myocardial Infarction in a Recent 6-Year Period in the United States. Am J Cardiol. 2015 Jan 15; 115(2): 167–170.

[207] Vallabhajosyula S, Kumar V, Sundaragiri PR, et al. Influence of primary payer status on the management and outcomes of ST-segment elevation myocardial infarction in the United States. *PLoS One.* 2020;15(12):e0243810.

[208] Vogel B, Claessen BE, Arnold SV, Chan D, Cohen DJ, Giannitsis E, Gibson CM, Goto S, Katus HA, Kerneis M, Kimura T, Kunadian V, Pinto DS, Shiomi H, Spertus JA, Steg PG, Mehran R. ST-segment elevation myocardial infarction. (2019). Nature Reviews Disease Primers, 5(39). Available at *https://doi.org/10.1038/s41572-019-0090-3.*

[209] Boersma E, Maas AC, Deckers JW, Simoons ML. Early thrombolytic treatment in acute myocardial infarction: reappraisal of the golden hour. *Lancet.* 1996;348(9030):771–775.

[210] Cannon CP, Gibson CM, Lambrew CT, et al. Relationship of symptom-onset-to-balloon time and door-to-balloon time with mortality in patients undergoing angioplasty for acute myocardial infarction. *Jama.* 2000;283(22):2941–2947.

[211] McNamara RL, Wang Y, Herrin J, et al. Effect of door-to-balloon time on mortality in patients with ST-segment elevation myocardial infarction. *J Am Coll Cardiol.* 2006;47(11):2180–2186.

[212] Anderson JL, Morrow DA. Acute Myocardial Infarction. *New England Journal of Medicine.* 2017;376(21):2053–2064.

[213] O'Gara P, Kushner F, Ascheim D, Casey D, Chung M, de Lemos J, Ettinger S, Fang J, Fesmire F, Franklin B, Granger C, Krumholz H, Linderbaum J, Morrow D, Newby L, Ornato J, Ou N, Radford M, Tamis-Holland J, Tommaso C, Tracy C, Woo Y, Zhao D, Anderson J, Jacobs A, Halperin J, Albert N, Brindis R, Creager M, DeMets D, Guyton R, Hochman J, Kovacs R, Kushner F, Ohman E, Stevenson W, Yancy C. (2013). 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 127(4): e362–425. Available at *https://www.ncbi.nlm.nih.gov/pubmed/23247304.*

[214] *Ibid.*

[215] *Ibid.*

[216] *Ibid.*

issues that are most vital to delivering quality, value-based care to improve patient outcomes.[217] In alignment with the Meaningful Measures quality priority of promoting effective prevention and treatment of chronic disease, we believe this STEMI eCQM encourages timely, effective and appropriate treatment using clinical data available in certified electronic health record technology (CEHRT) and that this measure has the potential to reduce adverse health outcomes.

The measure was included on the publicly available ''List of Measures Under Consideration for December 21, 2020,'' a list of measures under consideration for use in various Medicare programs.[218] In January 2021, the STEMI eCQM was reviewed by the MAP's rural health workgroup, hospital workgroup, and Coordinating Committee (MUC20–0004).[219] The MAP rural health workgroup conducted discussion regarding the appropriate treatment time for STEMI and how this may be impacted in rural settings due to proximity and transportation issues, especially with getting someone to a PCI-capable facility, and supported the STEMI eCQM for rural providers in the Hospital OQR Program.[220] The MAP voted to conditionally support the measure, pending NQF endorsement.[221] We note that on-site facilities can perform a PCI (if they have the capability to do so), use fibrinolysis, or they can transfer a patient to a facility that provides PCI. These three treatment scenarios are all captured by the measure, including relative treatment times (non-transfer patients receiving PCI at a PCI-capable facility within 90 minutes of arrival and patients transferred from a non-PCI-capable to a PCI-capable facility within 45 minutes).

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 building entities (for example, NQF). We also note that section 1833(t)(17) of the Act does not require that each measure we adopt for the Hospital OQR Program be endorsed by a national consensus building entity. We have reviewed and identified two related NQF-endorsed chart-abstracted measures—OP–2 (Fibrinolytic Therapy Received within 30 Minutes of ED Arrival) and OP–3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention).

In section XV.B.3.c. of this proposed rule, we are proposing to remove these two related chart-abstracted measures—OP–2 (Fibrinolytic Therapy Received within 30 Minutes of ED Arrival) and OP–3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention)—and replace them with this eCQM. The use of the STEMI eCQM measure, in lieu of the OP–2 and OP–3 measures, would eliminate the need for manual chart-abstraction. It would also broaden the group of measured STEMI patients including patients who present to and receive primary PCI at a PCI-capable facility, which is the vast majority of STEMI patients, instead of only including patients presenting to non-PCI-capable facilities and receiving either fibrinolytics or being transferred to a PCI-capable facility. The STEMI eCQM better supports compliance with the full group of STEMI patients covered in the 2013 ACCF and AHA guidelines for the management of STEMI by measuring timeliness and appropriateness of care for STEMI patients in the ED.[222] We believe that the STEMI eCQM would efficiently and comprehensively measure timeliness of STEMI care by reducing the burden on facilities currently reporting these two chart-abstracted measures, broadening the STEMI population for which performance scores could be publicly reported, and incorporating contraindications to enhance the clinical applicability of the measure. We refer readers to section XV.B.3.c. of this proposed rule for further discussion on our proposal to remove the OP–2 and OP–3 measures from the Hospital OQR Program.

As such, we are proposing to adopt the STEMI eCQM for use in the Hospital OQR Program because of its importance in measuring timely delivery of guideline-based reperfusion therapies appropriate for the care of ED patients with a diagnosis of STEMI and its ability to fill a gap in CMS' Meaningful Measure portfolio. The measure was submitted to NQF in January 2021 and is under review.

(3) Measure Calculation

The STEMI eCQM is a process measure that assesses the percentage of ED patients aged 18 years or older with a diagnosis of STEMI who received appropriate treatment. The denominator includes all ED patients 18 years or older diagnosed with STEMI who do not have contraindications to fibrinolytic, antithrombotic, and anticoagulation therapies.

The numerator includes:

- ED-based STEMI patients whose time from ED arrival to fibrinolytic therapy is 30 minutes or fewer; or
- Non-transfer ED-based STEMI patients who received PCI at a PCI-capable hospital within 90 minutes of arrival; or
- ED-based STEMI patients who were transferred to a PCI-capable hospital within 45 minutes of ED arrival at a non-PCI-capable hospital.

For more information on the STEMI eCQM, we refer readers to the full measure specifications available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website, available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-oqr-ecqms*.

(4) Data Sources

The proposed measure is an eCQM that uses data routinely collected through the EHR and is designed to be calculated by the hospitals' CEHRT using patient-level data and submitted to CMS. In 2020, using data from 2018, the STEMI eCQM was tested at two hospital systems (20 EDs in total) with two different EHR platforms for feasibility, validity, and reliability testing, based on the endorsement criteria outlined by NQF.[223] The

[217] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization*.

[218] The National Quality Forum. (2021). List of Measures under Consideration for December 21, 2020. Accessed March 14, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212*.

[219] The National Quality Forum. (2021). Meeting Summary Measure Applications Partnership Rural Health Workgroup Virtual Review Meeting. Accessed on May 17, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94656*.

[220] The National Quality Forum. (2021). Measure Applications Partnership 2020–2021. Considerations for Implementing Measures in Federal Programs: Clinician, Hospital & PAC/LTC. Accessed on May 17, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94893*.

[221] *Ibid.*

[222] O'Gara P, Kushner F, Ascheim D, Casey D, Chung M, de Lemos J, Ettinger S, Fang J, Fesmire F, Franklin B, Granger C, Krumholz H, Linderbaum J, Morrow D, Newby L, Ornato J, Ou N, Radford M, Tamis-Holland J, Tommaso C, Tracy C, Woo Y, Zhao D, Anderson J, Jacobs A, Halperin J, Albert N, Brindis R, Creager M, DeMets D, Guyton R, Hochman J, Kovacs R, Kushner F, Ohman E, Stevenson W, Yancy C. (2013). 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 127(4): e362–425. Available at *https://www.ncbi.nlm.nih.gov/pubmed/23247304*.

[223] National Quality Forum. What NQF Endorsement Means. Available at: *http://https://*

Continued

feasibility testing showed that the measure is feasible and the key features of the eCQM, such as the code sets and measure logic, were readily interpreted by both sites as assessed by the feasibility scorecard and exit interviews conducted at the two sites. The validity testing results showed a wide range of agreement among data elements between the electronic and manual data extracts. Some data elements were collected but not fully interoperable within providers' EHRs. However, as hospitals and EHR vendors meet ONC requirements for interoperability under the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) and map data elements for interoperability via the FHIR-based API required by December 31, 2022 (85 FR 70075), these data elements would be accessible without special effort.

(5) Implementation

We propose to start with voluntary reporting beginning with the CY 2023 reporting period and then with mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. We believe that taking an incremental approach to implementing this measure would allow hospitals time to implement workflow changes as necessary to better prepare for submitting data and to increase familiarity with data submission with the introduction of an eCQM into the Hospital OQR Program. We refer readers to section XV.D.6. of this proposed rule for additional proposals related to eCQM data submission and reporting requirements under the Hospital OQR Program.

We invite public comment on our proposal.

5. Modifications to Previously Adopted Measures

a. Proposal To Require OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With Voluntary Reporting for the CY 2023 Reporting Period and Mandatory Reporting Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination and for Subsequent Years

We previously adopted the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) measures to assess patient experience with care following a procedure or surgery in a HOPD. These survey-based measures rate patient experience as a means for empowering patients and improving the quality of their care (82 FR 59432). For further details on these measures, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79771 through 79784), in which we adopted these measures beginning with the CY 2020 payment determination.

Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433), we delayed implementation of OP–37a–e for the Hospital OQR Program beginning with the CY 2020 payment determination due to lack of sufficient operational and implementation data. At that time, we believed that our ongoing National OAS CAHPS voluntary reporting program for the survey measures, which began in January 2016 [224] and is unrelated to either the Hospital OQR Program or ASCQR Program, would provide valuable information moving forward. Specifically, we wanted to use the information from the National OAS CAHPS voluntary reporting program to: (1) Ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; (2) reaffirm the reliability of national implementation of OAS CAHPS Survey data; and (3) appropriately account for the burden associated with administering the survey in the outpatient setting of care.

In this proposed rule, we are proposing to restart the OP–37a–e measure by requiring the measure in the Hospital OQR Program beginning with the CY 2024 reporting period/CY 2026 payment determination. Specifically, for the Hospital OQR Program, we are proposing voluntary data collection and reporting beginning with the CY 2023 reporting period, followed by mandatory data collection and reporting beginning with the CY 2024 reporting period/CY 2026 payment determination. As noted previously, the National OAS CAHPS voluntary reporting program is independent of the Hospital OQR Program and the ASCQR Program. This proposal is intended to make the distinction that HOPDs that voluntarily report the OAS CAHPS survey-based measures during the CY 2023 reporting period would do so as part of the Hospital OQR Program until mandatory reporting begins, if these proposals are finalized. The reporting process for HOPDs to submit OAS CAHPS data would remain unchanged for HOPDs (that is, they would not duplicate submissions to the program and National OAS CAHPS voluntary reporting program). We refer readers to section XV.D.4.b. of the preamble of this proposed rule for our related proposals regarding the form, manner, and timing for reporting the OP–37a–e survey-based measures.

Having had the opportunity during the delayed implementation to investigate the concerns about patient response rates and data reliability, we believe that patients are able to respond to OAS CAHPS survey questions, and that those responses are reliable based on our prior experiences collecting voluntary data for public reporting since CY 2016 (available at *https://data.cms.gov/provider-data/*). We reaffirm that the OAS CAHPS survey-based measures assess important aspects of care where the patient is the best or only source of information (81 FR 79771). Furthermore, in section XV.D.4.b.(1)., we are proposing additional collection modes using a web-based module (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents) for administering the survey, which would be available beginning in CY 2023 under the Hospital OQR Program and for subsequent years.[225] We believe this would address some burden concerns raised during the CY 2017 OPPS/ASC final rule with comment period (81 FR 79777) because the web-based modules would produce similar results but at lower costs of collection.[226] We also continue to believe that the benefits of this measure, such as giving patients the opportunity to compare and assess quality of care in the outpatient setting in a standardized and comparable manner, outweigh the burdens (81 FR 79778). As we stated in the CY 2018 OPPS/ASC final rule with comment period, we continue to believe that implementation of these measures will enable objective and meaningful comparisons between hospital outpatient departments (82 FR 59432)

www.qualityforum.org/Measuring_Performance/ABCs/What_NQF_Endorsement_Means.aspx.

[224] Participation in the program is open to any interested Medicare-certified Hospital Outpatient Departments (HOPDs) and free-standing ambulatory surgery centers (ASCs). More information on the National OAS CAHPS voluntary reporting program is available at: *https://oascahps.org/General-Information/National-Implementation* and *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/OAS-CAHPS.*

[225] We note that the mixed modes will be available as part of the National OAS CAHPS voluntary reporting program beginning in CY 2022.

[226] Bergeson SC, Gray J, Ehrmantraut LA, Laibson T, Hays RD. Comparing Web-based with Mail Survey Administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Clinician and Group Survey. Prim Health Care. 2013;3:1000132. doi:10.4172/2167–1079.1000132.

and rating patient experience still provides important information to hospital outpatient departments and patients and enables objective and meaningful comparisons between hospital outpatient departments (82 FR 59432).

We refer readers to section XV.D.4.b. for our related proposals regarding form, manner, and timing for reporting the OP–37a–e survey-based measures. We invite public comment on our proposal.

We also refer readers to section XVI.B.4.c. of this proposed rule where we are also proposing modifications to this measure in the ASCQR Program.

b. Proposal To Require OP–31: Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536) Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75102 through 75104) we finalized the adoption of the OP–31: Cataracts: Improvement in Patient's Visual Function with 90 Days Following Cataract Surgery [227] measure beginning with the 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 achieved within 90 days following the cataract surgery (78 FR 75102). The measure data consists of pre-operative and post-operative visual function surveys. The implementation of this measure has been the subject of a number of changes as discussed in this section for the proposed rule.

During the CY 2014 OPPS/ASC proposed rule, some commenters expressed concern about the burden of collecting pre-operative and post-operative visual function surveys (78 FR 75103). In response to those comments, we modified and finalized our implementation strategy in a manner that we believed would significantly minimize collection and reporting burden (78 FR 75103). Specifically, we applied a sampling scheme and a low case threshold exemption to address commenters' concerns regarding burden (78 FR 75114). With those changes, we intended to decrease burden and facilitate data reporting by allowing random sampling of cases when volume is high, instead of collecting information for all eligible patients (78 FR 75114). For further details, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75102 through 75104).

Shortly thereafter, we became concerned about the use of inconsistent surveys to assess visual function. The measure specifications allowed for the use of any validated survey and we were not positive about the impact the use of varying surveys might have. Therefore, we issued guidance stating that we would delay the implementation of OP–31.[228]

Subsequently, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66947 through 66948), we finalized our proposal to exclude OP–31 from the CY 2016 payment determination measure set, and for subsequent years. We proposed to exclude OP–31 for a few reasons. First, we understood it was operationally difficult for hospitals to collect and report on the measure (79 FR 66947). Notably, the results of the survey used to assess the pre-operative and post-operative visual function of the patient were not consistently shared across clinicians, making it difficult for hospitals to have knowledge of the visual function of the patient before and after surgery (79 FR 66947). Second, the concern about use of various versions of the survey persisted. Specifically, we were concerned that if physicians used different surveys to assess visual function, then the measure could produce inconsistent results (79 FR 66947). By excluding OP–31 from the measure set used for the CY 2016 payment determination and subsequent years, hospitals were excused from reporting on it. Hospitals that did not report on OP–31 for the CY 2016 payment determination were not subject to a payment reduction (79 FR 66947). In conjunction with excusing hospitals from reporting on OP–31 for the CY 2016 payment determination and subsequent years, we finalized allowing hospitals to voluntarily report OP–31 data for the CY 2015 reporting period/CY 2017 payment determination and subsequent years (79 FR 66948).

(2) Proposal To Require Hospitals Report on OP–31 Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination and for Subsequent Years

We now believe it is appropriate to require hospitals to report on OP–31. Our earlier concerns have been ameliorated. At this point, hospitals have had several years to familiarize themselves with OP–31, prepare to operationalize it, and opportunity to practice reporting the measure since the CY 2015 reporting period/CY 2017 payment determination. We note that a small number of facilities have consistently reported data for this measure and these data have been made publicly available. As to our second concern, research indicates that using different surveys will not result in inconsistencies, as the allowable surveys are scientifically validated.[229] Research has demonstrated that of 16 different cataract surgery outcome questionnaires, all were able to detect clinically important change.[230]

Therefore, in this proposed rule, we are proposing to require reporting of the OP–31 measure beginning with the CY 2023 reporting period/CY 2025 payment determination and for subsequent years. As we stated in the CY 2014 OPPS/ASC final rule with comment period, as well as the CY 2015 OPPS/ASC final rule with comment period, and consistent with the MAP recommendation, we continue to maintain that this measure ''addresses a high-impact condition'' that is not otherwise adequately addressed in our current measure set (78 FR 75103 and 79 FR 66947, respectively). Moreover, OP–31 serves to improve patient-centered care by representing an important patient reported outcome (78 FR 75103). This measure provides opportunities for care coordination as well as direct patient feedback.

We refer readers to section XV.D.5.a. of this proposed rule for information about submitting data via a CMS web-based tool.

We invite public comment on our proposal.

[227] We note that this measure was endorsed by the NQF under NQF #1536 at the time of adoption but has subsequently had its endorsement removed.

[228] The implementation was first delayed by 3 months—from January 1, 2014 to April 1, 2014, for the CY 2016 payment determination, via guidance issued December 31, 2013. Available at: *https://qualitynet.cms.gov/outpatient/notifications8772854917*. Because of continuing concerns, on April 2, 2014, we issued additional guidance stating that we would further delay the implementation of the measure from April 1, 2014 to January 1, 2015 for the CY 2016 payment determination. Available at: *https://qualitynet.cms.gov/outpatient/notifications*.

[229] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

[230] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

6. Summary of Previously Finalized and Proposed Hospital OQR Program Measure Sets

a. Summary of Previously Finalized and Proposed Hospital OQR Program Measure Set for the CY 2023 Payment Determination

We refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86180 through 86181) for a summary of the previously adopted Hospital OQR Program measure set for the CY 2023 payment determination and subsequent years. If finalized as proposed in this proposed rule, the CY 2023 payment determination and subsequent years would also include the Breast Screening Recall Rates measure.

Table 46 summarizes the previously finalized and newly proposed Hospital OQR Program measure set for the CY 2023 payment determination:

TABLE 46: Hospital OQR Program Measure Set for the CY 2023 Payment Determination

NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: 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	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	Breast Screening Recall Rates**

† We note that NQF endorsement for this measure was removed.
* OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947). In this proposed rule, we are proposing mandatory reporting of this measure beginning with the CY 2023 reporting period/CY 2025 payment determination and for subsequent years.
** We note that, if adoption finalized, an OP/measure number will be assigned for this measure in the final rule.

b. Summary of Previously Finalized and Proposed Hospital OQR Program Measure Set for the CY 2024 Payment Determination

Table 47 summarizes the previously finalized and newly proposed Hospital OQR Program measure set for the CY 2024 payment determination, which includes the proposed COVID–19 Vaccination Coverage Among HCP measure:

TABLE 47: Hospital OQR Program Measure Set for the CY 2024 Payment Determination

NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: 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	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	Breast Screening Recall Rates**
None	COVID-19 Vaccination Coverage Among Health Care Personnel**

† We note that NQF endorsement for this measure was removed.
* OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947). In this proposed rule, we are proposing mandatory reporting of this measure beginning with the CY 2023 reporting period/CY 2025 payment determination and for subsequent years.
** We note that, if adoption finalized, an OP/measure number will be assigned for this measure in the final rule.

c. Summary of Previously Finalized and Proposed Hospital OQR Program Measure Set for the CY 2025 Payment Determination

Table 48 summarizes the previously finalized and newly proposed Hospital OQR Program measure set for the CY 2025 payment determination, which includes the proposed OP–39: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM and proposed removals of the OP–2 and OP–3 measures:

TABLE 48: Hospital OQR Program Measure Set for the CY 2025 Payment Determination

NQF #	Measure Name
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: 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	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff*
None	OP-37b: OAS CAHPS – Communication About Procedure*
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery*
None	OP-37d: OAS CAHPS – Overall Rating of Facility*
None	OP-37e: OAS CAHPS – Recommendation of Facility*
None	Breast Screening Recall Rates**
None	COVID-19 Vaccination Coverage Among Health Care Personnel**
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM***

† We note that NQF endorsement for this measure was removed.
* OP-37a-e measures reporting delayed beginning with CY 2018 reporting and for subsequent years as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433). In this proposed rule, we are proposing voluntary reporting beginning with the CY 2023 reporting period/CY 2025 payment determination; and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.
** We note that, if finalized, an OP/measure number will be assigned for this measure in the final rule.
*** The STEMI eCQM is being proposed in this proposed rule, beginning with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and for mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. We refer readers to section XV.B.4.c. of the preamble of this proposed rule for more detail.

d. Summary of Previously Finalized and Proposed Hospital OQR Program Measure Set for the CY 2026 Payment Determination and Subsequent Years

Table 49 summarizes the previously finalized and newly proposed Hospital OQR Program measure set for the CY 2026 payment determination and subsequent years, which includes the proposed mandatory reporting of the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM and the proposed requirement of the OAS CAHPS measures (OP–37a–e):

TABLE 49: Hospital OQR Program Measure Set for the CY 2026 Payment Determination and Subsequent Years

NQF #	Measure Name
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: 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	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff
None	OP-37b: OAS CAHPS – Communication About Procedure
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery
None	OP-37d: OAS CAHPS – Overall Rating of Facility
None	OP-37e: OAS CAHPS – Recommendation of Facility
None	Breast Screening Recall Rates*
None	COVID-19 Vaccination Coverage Among Health Care Personnel*
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM*

† We note that NQF endorsement for this measure was removed.
* We note that, if finalized, an OP/measure number will be assigned for this measure in the final rule.

7. Hospital OQR Program Measures and Topics for Future Considerations

a. Request for Comment on Potential Adoption of Future Measures for the Hospital OQR Program

We seek to adopt a comprehensive set of quality measures for widespread use to inform decision-making regarding care and for quality improvement efforts in the hospital outpatient setting. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083 through 86110), under the OPPS we finalized the elimination of the Inpatient Only (IPO) list over a 3-year transitional period, beginning with the removal of approximately 300 primarily musculoskeletal-related services, with the list to be completely phased out by CY 2024.[231] As discussed in section IX. of this rule, we have continued to receive stakeholder requests to reconsider the elimination of the IPO list, to reevaluate services removed from the IPO list due to safety and quality concerns, and to, at a minimum, extend the timeframe for eliminating the list. After further consideration and review of the additional feedback from stakeholders, we believe that the timeframe we adopted for removing services from the IPO list does not give us a sufficient opportunity to carefully assess whether a procedure can be removed from the IPO list while still ensuring beneficiary safety. For CY 2022, we are proposing to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021, we propose to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022.

However, as technology and surgical techniques advance, services will continue to transition off of the IPO list, becoming payable in the outpatient setting. We recognize that there may be a need for more measures that inform decision-making regarding care and for quality improvement efforts, particularly focused on the behaviors of services that become newly eligible for payment in the outpatient setting. In light of this, we seek comment on potential future adoption of measures that would allow better tracking of the quality of care for services that transition from the IPO list and become eligible for payment in the outpatient setting.

Therefore, we invite public comment on the potential future adoption of measures for our consideration that address care quality in the hospital outpatient setting given the transition of procedures from inpatient settings to outpatient settings of care.

b. Request for Comment on Potential Future Adoption and Inclusion of a Hospital-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)

As described in section XV.B.7.a., we are seeking comment on priorities for quality measurement in outpatient settings due to changes to the IPO procedure list (82 FR 59385 and 84 FR 61355) and the ASC covered procedures list (CPL) (84 FR 61388 and 85 FR 86146) announced in the CY 2021 OPPS/ASC final rule with comment period.

We are also requesting comment on the potential future adoption of a respecified version of a patient-reported outcome-based performance measure

[231] Centers for Medicare & Medicaid Services. (2020, December 2). CY 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS–1736–FC). Retrieved from *www.cms.gov/newsroom*: *https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0.*

(PRO–PM) for two such procedures—elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA), which were removed from the IPO list effective with CY 2020 and CY 2018, respectively. We recently solicited public comment on the potential future inclusion of a hospital-level Risk-Standardized Patient-Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (Hospital-level THA/TKA PRO–PM (NQF #3559)) in the FY 2022 IPPS/LTCH PPS proposed rule for the inpatient hospital setting (86 FR 25589). This measure reports the hospital-level risk-standardized improvement rate (RSIR) in patient-reported outcomes (PROs) following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older. 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; and (2) the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients. Improvement is measured from the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk adjusted to account for differences in patient case mix. Potential non-response bias in measure scores due to the voluntary nature of PROs is incorporated in the measure calculation with stabilized inverse probability weighting based on likelihood of response.

Currently, the volume of THA and TKA procedures performed is lower among HOPDs than in the inpatient setting. Given the relatively recent removal of TKA and THA from the IPO list, we expect that the volume of THA and TKA procedures will continue to increase in HOPDs, and that significant numbers of Medicare beneficiaries 65 and older will potentially undergo these procedures in the outpatient setting in future years.

We recognize that potential future adoption and implementation of a respecified version of the THA/TKA PRO–PM in the Hospital OQR Program would require sufficient numbers of procedures for each measured HOPD to ensure a reliable measure score. Additionally, implementing a THA/TKA PRO–PM would require providers to successfully collect pre- and post-operative PRO data for each procedure. Specifically, the inpatient THA/TKA PRO–PM discussed in the FY 2022 IPPS/LTCH PPS proposed rule proposes to require a minimum of 25 cases with completed pre- and post-operative PRO data per hospital to ensure a reliable measure score. For more details on the inpatient THA/TKA PRO–PM, we refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25589) and the PROs Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure — Measure Methodology Report, available on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

We will continue to monitor the number of THA and TKA procedures in the outpatient setting and when we believe there is a sufficient number of such procedures performed in these settings to reliably measure a meaningful number of facilities, we may consider expanding the PRO–PM to these settings. We also note that, as finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79764 through 79771), the Hospital OQR Program currently includes a Hospital Visits after Hospital Outpatient Surgery (OP–36) measure using claims data, which provides facilities with important information on patient outcomes for Medicare FFS beneficiaries following surgery at HOPDs and is publicly reported on CMS' *Care Compare* website (*https://www.medicare.gov/care-compare/*). The measure calculates a facility-specific risk-standardized hospital visit ratio within 7 days of hospital outpatient surgery, and has as outcomes of interest unplanned hospital admissions, ED visits, and observation stays thereby providing valuable quality information as these procedures are increasingly conducted as outpatient surgeries.

As described in our Meaningful Measures 2.0 Framework, we aim to promote better collection and integration of patients' voices by developing PRO measures as an additional tool for measuring and improving quality. Given the unique challenges and opportunities for PRO–PMs for THA and TKA procedures in the outpatient setting, we invite public comment on the potential future adoption of a respecified version of PRO measures for elective THA/TKA PRO–PM for the Hospital OQR Program. Specifically, we invite public comment on the following:

- Input on the mechanism of PRO data collection and submission, including anticipated barriers and solutions to data collection and submission.
- Usefulness of having an aligned set of PRO–PMs across settings where elective THA/TKA are performed, that is, hospital inpatient setting, hospital outpatient departments, and ASCs for patients, providers, and other stakeholders. Specifically, usefulness and considerations for a hospital that performs both inpatient and outpatient elective THA/TKAs.
- Considerations unique to THA/TKAs performed in the hospital outpatient setting such as the volume of procedures performed or the measure cohort, outcome, or risk adjustment approach.

c. Request for Comment on Potential Future Efforts To Address Health Equity in the Hospital OQR Program

(1) Introduction and Expansion of the CMS Disparity Methods to Hospital OQR Program Setting

Significant and persistent inequities in health care outcomes exist in the U.S.[232] Belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; and being near or below the poverty level, are often associated with worse health outcomes.[233 234 235 236 237 238 239 240] Such disparities in health outcomes are the

[232] United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*.

[233] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[234] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346.

[235] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308.

[236] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[237] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf*.

[238] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf*.

[239] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm*.

[240] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv*. 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

result of number of factors, including social, economic, and environmental factors, but importantly for CMS programs, although not the sole determinant, negative experiences, poor access, and provision of lower quality health care can contribute to health inequities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[241] [242] [243] [244] [245] [246] Readmission rates for common conditions in the Hospital Readmissions Reduction Program (HRRP) are higher for Black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with congestive heart failure and acute myocardial infarction.[247] [248] [249] [250] [251] Studies have also shown that African Americans are significantly more likely than White Americans to die prematurely from heart disease and stroke.[252] The COVID–19 pandemic has further highlighted many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among Black, Latino, and Indigenous and Native American persons relative to White persons.[253] [254] As noted by the CDC, ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID–19.'' [255] One important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across our programs and policies.

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care inequities.[256] For the purposes of this proposed rule, we are using a definition of equity established in Executive Order 13985, issued on January 25, 2021, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; LGBTQ+ persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [257] We note that this definition was recently established and provides a useful, common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Network Quality Improvement Organizations (QIN–QIOs); Federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity.[258]

We refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070) which summarizes our existing initiatives aimed at closing the equity gap in outcomes for Medicare beneficiaries, including the CMS Disparity Methods. The methods were finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42496 through 42500), and results are currently reported confidentially across six quality measures in the HRRP stratified by dual eligibility status. As described in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070), we are considering further expanding the confidential reporting to include measurement of racial and ethnic disparities for one measure in the Hospital IQR Program, the Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789).

We have developed two complementary disparity methods to report stratified measure results for outcome measures. The first method (the Within-Hospital Disparity Method) promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method also allows for a comparison of the magnitude of disparity across hospitals at a given point in time, so hospitals could assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital Disparity Method) is complementary to the first method and assesses hospitals' outcome rates for patients with a given risk factor, across facilities, allowing for a comparison among hospitals on their performance caring for their patients with social risk

[241] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[242] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[243] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[244] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[245] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[246] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[247] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[248] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[249] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[250] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[251] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[252] HHS. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[253] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[254] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[255] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[256] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[257] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[258] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

factors. These methods were first confidentially reported for the inpatient setting in 2019 for the Pneumonia Readmission (NQF #0506) and Pneumonia Mortality (NQF #0468) measures, stratified dual eligibility for Medicare and Medicaid, and confidential reporting for hospitals has since expanded to include additional measures. For additional information on the two disparity methods, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the 2020 Disparity Methods Updates and Specifications Report.[259] As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41599) and the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070), the two disparity methods do not place any additional collection or reporting burden on hospitals because social risk factor data are readily available in claims data.

In this proposed rule, we are seeking comment on expanding our efforts to provide results of the disparity methods to promote health equity and improve healthcare quality. Specifically, we are seeking comment on the idea of stratifying the performance results in the hospital outpatient setting. We have identified six priority measures included in the Hospital OQR Program as candidate measures for disparities reporting stratified by dual eligibility:

- MRI Lumbar Spine for Low Back Pain (OP–8);
- Abdomen CT—Use of Contract Material (OP–10);
- Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (OP–13);
- Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (OP–32);
- Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP–35); and
- Hospital Visits after Hospital Outpatient Surgery (OP–36).

To identify these measures, we considered evidence of existing disparities, procedure volume, and statistical reliability. For more information about these measures, we refer readers to the Hospital Outpatient Quality Reporting Specifications Manual available on the QualityNet website.[260] We are seeking public comment on potential future confidential reporting of the six aforementioned measures, as well as other potential measures described in section XV.B.4., stratified by dual eligibility status, if technically feasible, adequately representative, and statistically reliable.

(2) Additional Social Risk Factors

We are committed to advancing health equity by improving data collection to better measure and analyze disparities across programs and policies.[261] As we described earlier, we have been considering, among other things, expanding our efforts to stratify data by additional social risk factors and demographic variables, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity. Following potential confidential reporting using dual eligibility as an indicator of social risk, we are exploring the possibility of further expanding stratified reporting to include race and ethnicity.

We refer readers to the ''Closing the Health Equity Gap in CMS Hospital Quality Programs'' section of the FY 2022 IPPS/LTCH PPS proposed rule which summarizes the existing challenges in accurately determining race and ethnicity in our administrative data, and the need for using advanced statistical methods for enhancing the accuracy of race and ethnicity disparity estimates (86 FR 25554).

As we stated in the ''Closing the Health Equity Gap in CMS Hospital Quality Programs'' section of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25554), because development of sustainable and consistent programs to collect demographic information related to health disparities, such as race and ethnicity, can be considerable undertakings, we recognize that another method to identify more accurate race and ethnicity disparities is needed in the short term. In working with our contractors, two algorithms have been developed to indirectly estimate the race and ethnicity of Medicare beneficiaries (as described further in the next section). We believe that using indirect estimation can help to overcome some of the current limitations of demographic information and enable timelier reporting of equity results until longer term collaborations to improve demographic data quality across the health care sector materialize. The use of indirectly estimated race and ethnicity for conducting stratified reporting does not place any additional collection or reporting burdens on facilities as these data are derived using existing administrative and census-linked data.

Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily available. Indirectly estimated data are most commonly used at the population level (such as the hospital or health plan-level) where aggregated results form a more accurate description of the population than existing, imperfect data sets. For missing race and ethnicity information, these methods use a combination of other data sources which estimate self-identified race and ethnicity, such as language preference, information about race and ethnicity in our administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood. Indirect estimation has been used in other settings to support population-based equity measurement when self-identified data are not available.[262]

As described previously, we have previously supported the development of two such methods of indirect estimation of race and ethnicity of Medicare beneficiaries. One indirect estimation approach developed by our contractor uses Medicare administrative data, first name and surname matching, derived from the U.S. Census and other sources, with beneficiary language preference, state of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or Asian/Pacific Islander (API).[263] In recent years, we have also worked with another contractor to develop a new approach, the Medicare Bayesian Improved Surname Geocoding (MBISG), which combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census data,

[259] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.*

[260] *https://qualitynet.cms.gov/outpatient/specifications-manuals.*

[261] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[262] Institute of Medicine. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press. Available at: *https://www.ahrq.gov/sites/default/files/publications/files/iomracereport.pdf.*

[263] Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

applying both Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of the six racial/ethnic groups.[264]

The MBISG model is currently used to conduct the national, contract-level, stratified reporting of Medicare Part C & D performance data for Medicare Advantage Plans by race and ethnicity.[265] Validation testing reveals concordances between 0.88–0.95 between indirectly estimated and self-reported race and ethnicity among those who identify as White, Black, Hispanic, and API for the MBISG version 2.0 and concordances with self-reported race and ethnicity of 0.96–0.99 for these same groups for MBISG version 2.1.[266] [267] The algorithms under consideration are considerably less accurate for individuals who self-identify as American Indian/Alaskan Native or multiracial.[268] Indirect estimation is a statistically reliable approach for calculating aggregate results for groups of individuals (such as the facility-level) and is not intended, nor being considered, as an approach for predicting the race and ethnicity of individuals.

Despite the high degree of accuracy of the indirect estimation algorithms under consideration there remains the small risk of introducing measurement bias. For example, if the indirect estimation is not as accurate in correctly estimating race and ethnicity in certain geographies or populations it could lead to some bias in the method results. Such bias might result in slight overestimation or underestimation of the quality of care received by a given group. We believe this risk of bias is considerably less than would be expected if stratified reporting were conducted using the race and ethnicity currently contained in our administrative data. Indirect estimation of race and ethnicity is envisioned as an intermediate step, filling the pressing need for more accurate demographic information for the purposes of exploring inequities in service delivery, while allowing newer approaches, as described in the next section, for improving demographic data collection to progress. We are interested in learning more about, and soliciting comments about, the potential benefits and challenges associated with measuring facility equity using indirect estimation to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

(a) Improving Demographic Data Collection

Stratified facility-level reporting using indirectly estimated race and ethnicity would represent an important advance in our ability to provide accurate equity reports to facilities. However, self-reported race and ethnicity data remain the gold standard for classifying an individual according to race or ethnicity. The CMS Quality Strategy outlines our commitment to strengthening infrastructure and data systems by ensuring that standardized demographic information is collected to identify disparities in health care delivery outcomes.[269] Collection and sharing of a standardized set of social, psychological, and behavioral data by hospitals, including race and ethnicity, using electronic data definitions which permit nationwide, interoperable health information exchange, can significantly enhance the accuracy and robustness of our equity reporting.[270] This could potentially include expansion of stratified reporting to additional social risk factors, such as language preference and disability status, where accuracy of administrative data is currently limited. We are mindful that additional resources, including data collection and staff training may be necessary to ensure that conditions are created whereby all patients are comfortable answering demographic questions, and that individual preferences for non-response are maintained.

We note that facilities participating in the Medicare Promoting Interoperability Program must use CEHRT that has been certified to the 2015 Edition of health IT certification criteria as defined at 45 CFR 170.102. As noted earlier, the certification criterion for Demographics under the 2015 Edition (45 CFR 170.315(a)(5)) supports collection of data using both the OMB standards for collecting data on race and ethnicity as well as the more granular ''Race & Ethnicity—CDC'' standard. In the 2020 ONC 21st Century Cures Act final rule, ONC also adopted a new framework for the core data set which certified health IT products must exchange, called the USCDI (85 FR 25669). The USCDI incorporates the demographic data and associated code sets finalized for the 2015 Edition certification criteria.

As noted previously, ONC also finalized a certification criterion in the 2015 Edition which supports a certified health IT product's ability to collect social, psychological, and behavioral data (45 FR 170.315(a)(15)). However, this functionality is not included as part of the CEHRT required by the Medicare Promoting Interoperability Program. While the technical functionality exists to achieve the gold standard of data collection, we understand challenges and barriers exist in using the technologies with these capabilities.

We are interested in learning about and soliciting comments on current data collection practices by facilities to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), primary language, and disability status). Further, we are interested in potential challenges facing facility collection, on the day of service, of a minimum set of demographic data elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act [271]) and standards for interoperable exchange (such as the USCDI incorporated into certified health IT products as part of the 2015 Edition of health IT certification criteria [272]). Advancing data interoperability through collection of a minimum set of demographic data collection, and incorporation into quality measure specifications, has the potential for improving the robustness of the disparity method results, potentially permitting reporting using more accurate, self-reported information, such as race and ethnicity, and expanding reporting to additional dimensions of equity, including stratified reporting by disability status.

[264] Haas, A, Elliott, MN, Dembosky, JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res. 2019; 54: 13–23. *https://doi.org/10.1111/1475-6773.13099.*

[265] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[266] The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage, The Centers for Medicare and Medicaid Services, (pg vii). *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[267] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[268] Haas, A, Elliott, MN, Dembosky, JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res. 2019; 54: 13– 23. *https://doi.org/10.1111/1475-6773.13099.*

[269] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[270] The Office of the National Coordinator for Health Information Technology. United State Core Data for Interoperability Draft Version 2. 2021. Available at: *https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf.*

[271] *https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf.*

[272] *https://www.healthit.gov/sites/default/files/2020-08/2015EdCures_Update_CCG_USCDI.pdf.*

(b) Solicitation of Public Comments

We are currently seeking comment on the possibility of expanding our current disparities methods to include reporting by race and ethnicity using indirect estimation. We are also seeking comment on the possibility of facility collection of standardized demographic information for the purposes of potential future quality reporting and measure stratification to permit more robust equity measurement. Additionally, we are seeking comment on the design of a Facility Equity Score for presenting combined results across multiple social risk factors and measures, including race/ethnicity and disability. Any data pertaining to these areas that are recommended for collection for measure reporting for a CMS program and potential public disclosure on *Care Compare* or successor website would be addressed through a separate and future notice-and-comment rulemaking. We plan to continue working with the Office of the Assistant Secretary for Planning and Evaluation, facilities, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

Specifically, we are inviting public comment on the following:

- The potential future application to the Hospital OQR Program measures of the two disparity methods currently used to confidentially report stratified measures in HRRP.
- The possibility of reporting stratified results confidentially in Facility-Specific Reports (FSRs) using dual eligibility as a proxy for social risk.
- The possibility of reporting stratified results using dual eligibility as the proxy for social risk publicly on *Care Compare* in future years.
- The potential future application of an algorithm to indirectly estimate race and ethnicity to permit stratification of measures (in addition to dual-eligibility) for facility-level disparity reporting until more accurate forms of self-identified demographic information are available.
- The possibility of facility collection, on the day of service, of a minimum set of demographic data using standardized and interoperable electronic health record standards.

8. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we modify the Hospital OQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet website at: *https://qualitynet.cms.gov/outpatient/specifications-manuals*. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59104 through 59105), where we changed the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019 and subsequent years, such that we will release a manual once every 12 months and release addenda as necessary. We are not proposing any changes to these policies in this proposed rule.

In section XV.B.4. of this proposed rule, we are proposing the adoption of eCQMs into the Hospital OQR Program measure set beginning with the CY 2023 reporting period. Therefore, we are also proposing the manner to update the technical specifications for eCQMs. We propose that the technical specifications for eCQMs used in the Hospital OQR Program would be contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). The Annual Update and implementation guidance documents are available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/*. For eCQMs, we would generally update the measure specifications on an annual basis through the Annual Update which includes code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and EHR vendors to use in order to collect and submit data on eCQMs from hospital EHRs.

Hospitals would be required to register and submit quality data through the Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal). 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 invite public comment on our proposal.

We also refer readers to section XIV. of this proposed rule where we request 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 FHIR standard (as described in that section).

9. Public Display of Quality Measures

a. Background

We refer readers to the CY 2009, CY 2014, and CY 2017 OPPS/ASC final rules with comment period (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 are not proposing any changes to these policies in this proposed rule.

b. Overall Hospital Quality Star Rating

In the CY 2021 OPPS/ASC final rule (85 FR 86182), we finalized a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Rating). We refer readers to section XVI. (''Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years'') of the CY 2021 OPPS/ASC final rule with comment period for details. We are not proposing any changes to this policy in this proposed rule.

C. Administrative Requirements

1. QualityNet Account and Security Administrator/Security Official

a. Background

The previously finalized QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109). We codified these procedural requirements at § 419.46(b) in that final rule with comment period. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86182), we finalized to use the term ''security official'' instead of ''security administrator'' to denote the exercise of authority invested in the role. The term ''security official'' would refer to ''the individual(s)'' who have responsibilities for security and account management requirements for a hospital's QualityNet account. This update in terminology did not change the individual's responsibilities or add burden. We are not proposing any changes to this policy.

b. Active Security Official Account and Maintenance Requirements for Data Submission

The previously finalized QualityNet security administrator (now referred to as a security official) requirements, including those for setting up a QualityNet account and the associated timelines, are described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479), we indicated that hospitals would be required to maintain a current QualityNet security administrator (now referred to as a security official) for as long as the hospital participates in the Program. In this proposed rule, we are clarifying that failing to maintain an active QualityNet security official once a hospital has successfully registered to participate in the Hospital OQR Program will not result in a finding that the hospital did not successfully participate in the Hospital OQR Program. Again, we refer readers to requirements at § 419.46(b).

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519), and the CY 2019 OPPS/ASC final rule with comment period (83 FR 59103 through 59104) for requirements for participation and withdrawal from the Hospital OQR Program. We codified these requirements at § 419.46(b) and (c). We are not proposing any changes to these policies in this proposed rule.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Submission Deadlines

We refer readers to the CYs 2014, 2016, and 2018 OPPS/ASC final rules with comment period (78 FR 75110 through 75111; 80 FR 70519 through 70520; and 82 FR 59439, respectively) where we finalized our policies for clinical data submission deadlines. We codified these submission requirements at § 419.46(d). The clinical data submission deadlines for the CY 2024 payment determination are illustrated in Table 50.

TABLE 50: CY 2024 Payment Determination*

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.

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 for the CY 2024 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of chart-abstracted measures for the CY 2014 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

The following previously finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2023 payment determination and subsequent years:

- OP–2: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496);[273]
- OP–3: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496);[274]
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496); and
- OP–23: Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival (NQF #0661).

3. Claims-Based Measure Data Requirements for the CY 2024 Payment Determination and Subsequent Years

Currently, in addition to the proposed Breast Screening Recall Rates measure, the following previously finalized Hospital OQR Program claims-based measures are required for the CY 2023 payment determination and subsequent years:

- OP–8: MRI Lumbar Spine for Low Back Pain (NQF #0514);
- OP–10: Abdomen CT—Use of Contrast Material;
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery (NQF #0669);
- OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539);
- OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy;
- OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687); and
- Breast Screening Recall Rates.[275]

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59106 through 59107), where we established a 3-year reporting period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination and for subsequent years. In that final rule with comment period (83 FR 59136 through 59138), we established a similar policy under the ASCQR Program. We are not proposing any changes to these policies in this proposed rule. We refer readers to section XV.B.4.b. of this proposed rule where we are also proposing a 3-year reporting period for the Breast Screening Recall Rates measure.

[273] In this year's proposed rule we are proposing to remove OP–2 beginning with the CY 2023 reporting period/CY 2025 payment determination.

[274] In this year's proposed rule we are proposing to remove OP–3 beginning with the CY 2023 reporting period/CY 2025 payment determination.

[275] We note that, if finalized, an OP/measure number will be assigned for this measure in the final rule.

4. Data Submission Requirements for the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2024 Reporting Period/CY 2026 Payment Determination and Subsequent Years

a. Background

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79792 through 79794) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures. In addition, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433), where we finalized a policy to delay implementation of the OP–37a–e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 reporting period) until further action in future rulemaking.

b. Proposed Form, Manner, and Timing for OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

As discussed in section XV.B.5.a. of this proposed rule, we are proposing to begin data collection of five survey-based measures derived from the OAS CAHPS Survey beginning with voluntary data collection and reporting for the CY 2023 reporting period/CY 2025 payment determination,[276] followed by mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. The OAS CAHPS survey contains three OAS CAHPS composite survey-based measures and two global survey-based measures. In this section, we are proposing requirements related to survey administration, vendors, and oversight activities.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79792 through 79794), we previously discussed the form, manner, and timing of this survey. In this proposed rule, we are reaffirming our approach to the form, manner, and timing which OAS CAHPS information will be submitted and we are now proposing to add two additional data collection modes (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents),[277] beginning with voluntary data collection for the CY 2023 reporting period/CY 2025 payment determination and continuing for mandatory reporting for subsequent years. For more information about the modes of administration, we refer readers to the OAS CAHPS website: *https://oascahps.org*. We reiterate our clarification from when we adopted these measures in the CY 2017 OPPS/ASC final rule with comment period that, when implemented, hospital outpatient departments that anticipate receiving more than 300 surveys would be required to either: (1) Randomly sample their eligible patient population; or (2) survey their entire OAS CAHPS eligible patient population (81 FR 79773). We also refer readers to section XVI.D.1.d. of the preamble of this proposed rule where we are proposing similar policies for the ASCQR Program.

(1) Survey Requirements

The data collection modes as currently specified for the survey include three administration modes: (1) Mail-only; (2) telephone-only; and (3) mixed mode (mail with telephone follow-up of non-respondents). We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (*https://oascahps.org/Survey-Materials*) for materials for each mode of survey administration. In the 2018 OPPS/ASC final rule with comment period, we expressed interest in investigating the feasibility of offering the OAS CAHPS Survey using a web-based format (82 FR 59433). As a result, we designed a mode experiment to assess the impact of adding web-based survey administration. This mode experiment tested five administration modes with patients who receive outpatient surgical care: (1) Mail-only; (2) telephone-only; (3) web-only; (4) web with mail follow-up; and (5) web with a telephone follow-up. Data collection was completed in the fall of 2019. Response rates by mode in the experiment were: 35 percent (mail-only); 19 percent (telephone-only); 29 percent (web-only); 39 percent (web with mail follow-up); and 35 percent (web with telephone follow-up).

Based on these results, in addition to the three previously established modes, in this proposed rule we are proposing to incorporate two more administration methods: (1) Mixed mode web with mail follow-up of non-respondents, and (2) mixed mode web with telephone follow-up of non-respondents. This would allow a total of five methods of survey administration for reporting beginning with voluntary data collection and reporting as part of the Hospital OQR Program for the CY 2023 reporting period/CY 2025 payment determination[278] and mandatory reporting for the CY 2024 reporting period/CY 2026 payment determination—the first year the survey would be required if our proposal in section XV.B.5.a. is finalized as proposed. We are not proposing a purely web-based format at this time because the use of a web-based mode is included in the two mixed modes options being proposed and the purely web-based format would create response bias since not all patients have the ability to respond by web.

For all five proposed modes of administration as part of the Hospital OQR Program, we are proposing that data collection must be initiated no later than 21 calendar days after the month in which a patient has a surgery or procedure at a hospital and completed within 6 weeks (42 days) after initial contact of eligible patient begins, beginning with voluntary reporting in the CY 2023 reporting period/CY 2025 payment determination and subsequent years. Under this proposal, hospitals, via their CMS-approved vendors (discussed in section XV.D.4.b.(2) of this proposed rule.), must make multiple attempts to contact eligible patients unless the patient refuses or the vendor learns that the patient is ineligible to participate in the survey. In addition, we are proposing that hospitals, via their CMS-approved survey vendor, collect survey data for eligible patients using the established quarterly deadlines to report data to CMS for each data collection period unless the hospital has been exempted from the OAS CAHPS Survey requirements under the low volume exemption. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79774) where we previously established the low volume exemption, which

[276] As stated in section XV.B.5.a., we note that National OAS CAHPS voluntary reporting program is independent of the Hospital OQR Program, but the submission process will otherwise remain unchanged. This proposal is intended to clarify that voluntary reporting of OAS CAHPS would begin as part of the Hospital OQR Program in the CY 2023 reporting period until mandatory reporting would begin in the CY 2024 reporting period/CY 2026 payment determination and for subsequent years, if both proposals are finalized.

[277] The two additional modes will be available as part of National OAS CAHPS voluntary reporting program in 2022.

[278] As stated in section XV.B.5.a., we note that the two modes (web with mail follow-up of non-respondents; and web with telephone follow-up of non-respondents) will be available beginning in CY 2022 for National OAS CAHPS voluntary reporting, and then if finalized, available as part of OQR Program's reporting beginning in the CY 2023 reporting period and subsequent years.

exempts hospital outpatient departments with fewer than 60 survey-eligible patients during the ''eligibility period,'' (which is the calendar year before the data collection period), that submit the participation exemption request form, which would be made available on the OAS CAHPS Survey website (*https://oascahps.org*) on or before May 15 of the data collection year. As finalized previously, all exemption requests would be reviewed and evaluated by CMS (81 FR 79774). For hospitals that do not have an exemption, the submission deadlines would be posted on the OAS CAHPS Survey website (*https://oascahps.org*). Late submissions would not be accepted.

As discussed in more detail in this section of the proposed rule, compliance with the OAS CAHPS Survey protocols and guidelines, including this monthly data collection requirement as part of each quarterly data submission, would be overseen by CMS or its contractor who would receive approved vendors' monthly submissions, review the data, and analyze the results. We previously finalized (81 FR 79774) all data collection and submission for the OAS CAHPS Survey measures would be reported at the Medicare participating hospital level, as identified by its CCN. If data collection and reporting becomes mandatory beginning with the CY 2024 reporting period as proposed, under this proposal, all locations that offer outpatient services, of each eligible Medicare participating hospital, would be required to participate in the OAS CAHPS Survey (81 FR 79793), except for those that meet and receive an exception for having fewer than 60 survey-eligible patients during the year preceding the data collection period (81 FR 79773). Therefore, the survey data reported using a Medicare participating hospital's CCN must include all eligible patients from all outpatient locations (whether the hospital outpatient department is on campus or off campus) of an eligible Medicare participating hospital; or if more than 300 completed surveys are anticipated, a hospital can choose to randomly sample their eligible patient population (81 FR 79784).

In this proposed rule, we also propose that survey vendors acting on behalf of hospitals must submit data by the specified data submission deadlines, which generally would be posted on the OAS CAHPS Survey website located at *https://oascahps.org/Data-Submission/Data-Submission-Deadlines*. If a hospital's data are submitted after the data submission deadline, it would not fulfill the OAS CAHPS quality reporting requirements. Therefore, in regard to any OAS CAHPS reporting, we would strongly encourage hospitals to be fully apprised of the methods and actions of their survey vendors—especially the vendors' full compliance with OAS CAHPS Survey administration protocols—and to carefully inspect all data warehouse reports in a timely manner.

We reiterate that the use of predictive or auto dialers in telephonic survey administration is governed by the Telephone Consumer Protection Act (TCPA) (47 U.S.C. 227) and subsequent regulations promulgated by the Federal Communications Commission (FCC) (47 CFR 64.1200) and Federal Trade Commission. We refer readers to the FCC's declaratory ruling released on July 10, 2015 further clarifying the definition of an auto dialer, available at: *https://apps.fcc.gov/edocs_public/attachmatch/FCC-15-72A1.pdf*. In the telephone-only and mixed mode survey administration methods involving telephone, hospitals and vendors must comply with the regulations and any other applicable regulations. To the extent that any existing CMS technical guidance conflicts with the TCPA or its implementing regulations regarding the use of predictive or auto dialers, or any other applicable law, CMS would expect vendors to comply with applicable law.

We invite comments on our proposals as discussed previously.

(2) Vendor Requirements

We are not proposing new vendor requirements, but reiterate the vendor requirements finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79793 through 79794) to ensure that patients respond to the survey in a way that reflects their actual experiences with outpatient care, and is not influenced by the hospital. We finalized that hospitals must contract with a CMS-approved OAS CAHPS Survey vendor to conduct or administer the survey. We believe that a neutral third-party should administer the survey for hospitals, and it is our belief that an experienced survey vendor would be best able to ensure reliable results. CAHPS Survey-approved vendors are also already used or required in the following CMS quality programs: The Hospital IQR Program (71 FR 68203 through 68204); the Hospital VBP Program (76 FR 26497, 26502 through 26503, and 26510); the End Stage Renal Disease Quality Improvement Program (76 FR 70269 through 70270); the Home Health QRP (80 FR 68709 through 68710); and the Hospice QRP (80 FR 47141 through 47207).

Information about the list of approved survey vendors and how to authorize a vendor to collect data on a hospital's behalf is available through the OAS CAHPS Survey website at: *https://oascahps.org*. The web portal has both public and secure (restricted access) sections to ensure the security and privacy of selected interactions. As mentioned previously, requirements for survey vendors were previously finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79793 through 79794) and codified at § 419.46(h)(2). Hospitals will need to register on the OAS CAHPS Survey website (*https://oascahps.org*) in order to authorize the CMS-approved vendor to administer the survey and submit data on their behalf. Each hospital must then administer (via its vendor) the survey to all eligible patients (or for those anticipating more than 300 completed surveys, randomly sample their eligible patient population) treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (*https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website.

5. Data Submission Requirements for Measures Submitted via a Web-Based Tool for the CY 2023 Payment Determination and Subsequent Years

a. Data Submission Requirements for Measures Submitted via a CMS Web-Based Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521), and 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. We are not proposing any changes to these policies.

The following previously adopted quality measures require data to be submitted via a CMS web-based tool for the CY 2022 reporting period/CY 2024 payment determination and subsequent years:

- OP–22: Left Without Being Seen (NQF #0499); and
- OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up

Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658).

(1) Proposed Form, Manner, and Timing for Reporting OP–31: Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536)

The following measure that is being proposed for modification in this proposed rule would require data to be submitted via a CMS web-based tool for the CY 2023 reporting period/CY 2025 payment determination and subsequent years:

- OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

We propose that this measure would be submitted according to our existing policies for data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal). As noted earlier, we are not proposing changes to those policies. We invite public comment on our proposal.

b. Data Submission Requirements for Measures Submitted via the CDC NHSN Website

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the previously finalized requirements for measure data submitted via the CDC NHSN website. While we are not proposing any changes to those policies in this proposed rule, we are proposing policies specific to the proposed COVID–19 Vaccination Coverage Among HCP measure, which would be submitted via the CDC NHSN website.

(1) Proposed Form, Manner, and Timing for the COVID–19 Vaccination Coverage Among HCP Measure Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination and Subsequent Years

For the COVID–19 Vaccination Coverage Among HCP measure, we are proposing to require reporting data on the number of HCP who have received the completed vaccination course of a COVID–19 vaccine by each individual facility's CCN.

For the COVID–19 Vaccination Coverage Among HCP measure, we are proposing that facilities would report COVID–19 vaccination data to the NHSN for at least one week each month, beginning with the January 1, 2022 through December 31, 2022 reporting period affecting the CY 2024 payment determination and continuing with quarterly reporting deadlines for subsequent years. If facilities report more than one week of data in a month, the most recent week's data would be used for measure calculation purposes. We propose that hospitals would report the measure through the NHSN web-based surveillance system.[279] Specifically, hospitals would use the COVID–19 vaccination data reporting modules in the NHSN Healthcare Personnel Safety (HPS) Component to report the number of HCP eligible to have worked at the facility that week (denominator) and the number of those HCP who have received COVID–19 vaccination (numerator). Specific details on data submission for this measure can be found in the CDC's Overview of the Healthcare Safety Component, available at *https://www.cdc.gov/nhsn/PDFs/slides/NHSN-Overview-HPS_Aug2012.pdf*. We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75097 through 75100) for details about requirements for measure data submitted via the NHSN. Each quarter, the CDC would calculate a summary measure of COVID–19 vaccination coverage from the reporting periods for the quarter in four-quarter increments, when four quarters of data are available.

With respect to public reporting of this measure, for each CCN, a percentage of the HCP who received a complete course of the COVID–19 vaccine would be calculated and publicly reported on the *Care Compare* website, so that the public would know what percentage of the HCP have been vaccinated in each hospital. Once four quarters are available, data would be refreshed on a quarterly basis with the most recent four quarters. This quarterly average COVID–19 vaccination coverage would be publicly reported. We invite public comment on our proposals.

6. Proposed eCQM Reporting and Submission Requirements

a. Background

We believe that collection and reporting of data through health information technology would greatly simplify and streamline reporting for many CMS quality reporting programs. Through electronic reporting, hospitals will be able to leverage EHRs to capture, calculate, and electronically submit quality data to CMS for the Hospital OQR Program.

We believe that automated electronic extraction and reporting of clinical quality data would significantly reduce the administrative burden on hospitals for the Hospital OQR Program. We believe that the use of CEHRT can effectively and efficiently help providers improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of eCQMs. In previous rules, we stated our intent and assessment of the inclusion of eCQMs into the Hospital OQR Program, and we have sought public comment on the addition of such measures into the measure set. We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75106 through 75107), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66956 through 66961), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70516 through 70518), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79785 through 79790), and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59435 through 59438) for more details on previous discussion regarding future measure concepts related to eCQMs and electronic reporting of data for the Hospital OQR Program, including stakeholder support for the introduction of eCQMs into the Program. Measure stewards and developers have worked to advance eCQMs that would be reported in the outpatient setting and we believe the introduction of eCQMs in the Hospital OQR Program is timely. We also believe this is important in aligning the Hospital OQR Program with the Medicare Promoting Interoperability Program and the Hospital IQR Program.

b. Proposed eCQM Reporting and Data Submission Requirements Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination

In section XV.B.4.c. of the preamble of this proposed rule, we discuss the proposed adoption of the STEMI eCQM. In this proposed rule, we are proposing a progressive increase in the number of quarters for which hospitals report eCQM data. Increasing the number of reported quarters to be reported has several benefits. Primarily, a single quarter of data is not enough to capture trends in performance over time. Evaluating multiple quarters of data would provide a more reliable and accurate picture of overall performance. Further, reporting multiple quarters of data would provide hospitals with a more continuous information stream to monitor their levels of performance. Ongoing, timely data analysis can better identify a change in performance that may necessitate investigation and potentially corrective action.

However, we believe that starting with limited voluntary reporting would

[279] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

give hospitals more time to gain experience with reporting data (including time to implement the eCQM and provide training to support eCQM reporting, if necessary). Similar to what was established for the Hospital IQR Program (82 FR 38355), we believe that increasing the number of quarters for which hospitals report eCQM data would produce more comprehensive and reliable quality measure data for patients and providers. In section XV.B.4.c. of this proposed rule, we are proposing to adopt the STEMI eCQM with voluntary reporting beginning with the CY 2023 reporting period. For the CY 2023 reporting period, we propose that hospitals that submit STEMI eCQM data during this reporting period voluntarily submit any quarter(s) of data. Hospitals that chose to submit voluntarily must submit in compliance with the eCQM certification requirements proposed in sections XV.D.6.c., XV.D.6.d, and XV.D.6.e. of this proposed rule.

For the CY 2024 reporting period/CY 2026 payment determination, we propose that hospitals report one self-selected calendar quarter of data for the STEMI eCQM. We note that in section XV.B.4.c. of this proposed rule, we are proposing that the STEMI eCQM is required beginning with the CY 2024 reporting period/CY 2026 payment determination.

For the CY 2025 reporting period/CY 2027 payment determination, we propose to increase the amount of data required. We are proposing that hospitals report two self-selected calendar quarters of data for the required STEMI eCQM.

For the CY 2026 reporting period/CY 2028 payment determination, we propose to further increase the amount of data required for the STEMI eCQM. Specifically, in this proposed rule, we are proposing to require that hospitals report three self-selected calendar quarters of data for the CY 2026 reporting period/CY 2028 payment determination for the required STEMI eCQM. Beginning with the CY 2027 reporting period/CY 2029 payment determination, we propose to require that hospitals report all four calendar quarters (one calendar year) of data for the required STEMI eCQM.

We also refer readers to Table 51 for a summary of the proposed quarterly data increase in eCQM reporting beginning with the CY 2023 reporting period.

TABLE 51: Proposed Progressive Increase in eCQM Reporting Beginning with the CY 2023 Reporting Period/CY 2025 Payment Determination and for Subsequent Years

Calendar Year Period	Calendar Quarters of Reporting	Reporting
CY 2023 Reporting Period/CY 2025 Payment Determination	Any quarter(s)	Voluntary
CY 2024 Reporting Period/CY 2026 Payment Determination	One self-selected quarter	Mandatory
CY 2025 Reporting Period/CY 2027 Payment Determination	Two self-selected quarters	Mandatory
CY 2026 Reporting Period/CY 2028 Payment Determination	Three self-selected quarters	Mandatory
CY 2027 Reporting Period/CY 2029 Payment Determination and Subsequent Years	Four quarters (one calendar year)	Mandatory

We invite public comment on our proposals.

c. Proposed Electronic Quality Measure Certification Requirements for eCQM Reporting

(1) Proposal To Require Use of 2015 Edition Cures Update Certified Technology Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination

In May 2020, the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) finalized updates to the 2015 Edition of health IT certification criteria (hereto referred to as the ''2015 Edition Cures Update''). These updates included revisions to the clinical quality measurement certification criterion at 45 CFR 170.315(c)(3) to refer to CMS Quality Reporting Data Architecture (QRDA) IGs and remove the Health Level 7 (HL7®) QRDA standard from the relevant health IT certification criteria (85 FR 25645). The ONC 21st Century Cures Act final rule provided health IT developers up to 24 months from May 1, 2020 to make technology certified to the updated and/or new criteria available to their customers (85 FR 25670). In November 2020, ONC issued an interim final rule with comment (85 FR 70064) which extended the compliance deadline for the update to the Clinical Quality Measures-Report criterion until December 31, 2022 (85 FR 70075). These updates were finalized to reduce burden on health IT developers under the ONC Health IT certification program (85 FR 25686) and have no impact on providers' existing reporting practices for CMS programs.

For the Hospital OQR Program, we propose to require hospitals to utilize certified technology updated consistent with the 2015 Edition Cures Update for the CY 2023 reporting period/CY 2025 payment determination and subsequent years, which includes both the voluntary period and required submissions. We note that this proposal is in alignment with the Hospital IQR Program proposal in the FY 2022 IPPS/LTCH PPS proposed rule that requires use of technology updated consistent with 2015 Edition Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination (86 FR 25595). We invite public comment on our proposal.

d. File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

(1) File Format for EHR Data

Data can be collected in EHRs and health information technology systems using standardized formats to promote consistent representation and interpretation, as well as to allow for systems to compute data without needing human interpretation. As described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49701), these standards are referred to as content exchange standards because the standard details how data should be represented and the relationships between data elements. This allows the data to be exchanged across EHRs and health IT systems while retaining their meaning. Commonly used content exchange standards include the QRDA. The QRDA standard provides a document format and standard structure to electronically report quality measure data. We believe electronically reporting data elements formatted according to the QRDA standard would promote consistent representation and more efficient calculation of eCQM measure results.

Therefore, in alignment with the Hospital IQR Program file format requirements (85 FR 58940), we are proposing the requirements beginning with the CY 2023 reporting period/CY 2025 payment determination. Specifically, we are proposing that hospitals: (1) Must submit eCQM data via the QRDA Category I (QRDA I) file format; [280] (2) may use third parties to submit QRDA I files on their behalf; and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I. Hospitals could meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemptions. We discuss the zero denominator declaration and case threshold exemptions in the subsequent sections. We also refer readers to section XV.B.8. where we outline the maintenance of technical specifications including those for eCQMs.

Under this proposal, we expect QRDA I files to reflect data for one patient per file per quarter with five key elements necessary to identify the file:

- CMS Certification Number (CCN);
- CMS Program Name;
- EHR Patient ID;
- Reporting period specified in the Reporting Parameters Section; and
- EHR Submitter ID.

We invite public comment on our proposal.

(2) Zero Denominator Declarations

We understand there may be situations in which a hospital does not have data to report on a particular eCQM. Therefore, we propose if the hospital's EHR is certified to an eCQM, but the hospital does not have patients that meet the denominator criteria of that eCQM, the hospital can submit a zero in the denominator for that eCQM. Submission of a zero in the denominator for an eCQM counts as a successful submission for that eCQM for the Hospital OQR Program. For example, if the hospital within the previously mentioned health system does not provide fibrinolytic therapy, but one of the eCQMs the health system's EHR is certified to is a fibrinolytic therapy measure, that hospital's EHR may render a zero in the denominator for that eCQM. The hospital would therefore report a zero denominator for that fibrinolytic therapy eCQM, and this would count toward the required eCQMs for the Hospital OQR Program. Hospitals within that health system for which that fibrinolytic therapy eCQM does apply would provide data on that measure. We invite public comment on our proposal.

(3) Case Threshold Exemptions

We understand that in some cases, a hospital may not meet the case threshold of discharges for a particular eCQM. We propose to align with the case threshold exemption from the Medicare Promoting Interoperability Program (77 FR 54080) and the Hospital IQR Program (79 FR 50324). As stated for the Hospital IQR Program, the case threshold exemption means that for each quality measure for which hospitals do not have a minimum number of patients that meet the patient population denominator criteria for the relevant reporting period, hospitals would have the ability to declare a ''case threshold exemption'' if they have five or fewer applicable discharges. Specifically, for the Hospital OQR Program we propose that beginning with the CY 2023 reporting period/CY 2025 payment determination, if a hospital's EHR system is certified to report an eCQM and the hospital experiences 5 or fewer outpatient discharges per quarter or 20 or fewer outpatient discharges per year (Medicare and non-Medicare combined), as defined by an electronic clinical quality measure's denominator population, that hospital could be exempt from reporting on that electronic clinical quality measure. Case threshold exemptions are entered on the Denominator Declaration screen within the HQR System (formerly referred to as the QualityNet Secure Portal) available during the submission period.[281] The exemption would not have to be used; hospitals could report those individual cases if they would like to. We invite public comment on our proposal.

e. Submission Deadlines for eCQM Data

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), the Hospital IQR Program aligned their eCQM submission deadline with that of the Medicare Promoting Interoperability Program. The eCQM submission deadline for those two programs is the end of two months following the close of the CY (beginning with the CY 2017 reporting period/FY 2019 payment determination and for subsequent years).

In this proposed rule, for the Hospital OQR Program, we are also proposing to require eCQM data submission by the end of 2 months following the close of the calendar year for the CY 2023 reporting period/CY 2025 payment determination and for subsequent years. We believe that by aligning with the Hospital IQR and Promoting Interoperability Programs' deadlines, we would not add unnecessary burden. For example, for the CY 2023 reporting period/CY 2025 payment determination, hospitals that choose to voluntarily report that calendar year would be required to submit eCQM data by February 29, 2024, which is the end of 2 months following the close of the calendar year (December 31, 2023).

In crafting this proposal, we also considered proposing a submission deadline of May 15 to align with the submission deadline for Hospital OQR web-based measures. Under the Hospital OQR Program, the data submission period for web-based measures (for example, OP–29 and OP–31) extends through May 15 (we note the submission deadline may be moved to the next business day if it falls on a weekend or Federal holiday). However, we ultimately proposed instead to align eCQM data submission deadlines across quality reporting programs, because we believe that it would be less burdensome for hospitals.

We invite public comment on our proposal.

7. Population and Sampling Data Requirements for the CY 2022 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our population and sampling requirements. We are not proposing any changes to these policies in this proposed rule. We note that we are not proposing any population and sampling data policies related to eCQM reporting, because we would expect data for all patients who meet the patient population denominator criteria to be reported, if our eCQM-related proposals are finalized as proposed.

8. 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 with comment period (79 FR 66964 and 67014) where

[280] QRDA I is an individual patient-level quality report that contains quality data for one patient for one or more eCQMs. QRDA creates a standard method to report quality measure results in a structured, consistent format and can be used to exchange eCQM data between systems. For further detail on QRDA I, the most recently available QRDA I specifications and Implementation Guides (IGs) can be found at: *https://ecqi.healthit.gov/qrda.*

[281] CMS Adds New Features to Denominator Declaration Screen for eCQM Reporting, available at: *https://qualitynet.cms.gov/news/5fa161829314190021d3c262.*

we formalized 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

In the CY 2021 OPPS/ASC final rule (85 FR 86184), we finalized and codified to expand our review and corrections policy to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

c. Electronic Clinical Quality Measures (eCQMs)

In this proposed rule, we are proposing that hospitals would have a review and corrections period for eCQM data submitted to the Hospital OQR Program. We propose a review and corrections period for eCQM data which would run concurrently with the data submission period. The review and corrections period is from the time the submission period opens to the submission deadline. In the HQR System (formerly referred to as the QualityNet Secure Portal), providers can submit QRDA Category I test and production data files and can correct QRDA Category I test and production data files before production data is submitted for final reporting. We encourage early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in eCQM reporting. The HQR System does not allow data to be submitted or corrected after the annual deadline. We refer readers to the HQR System website (available at: *https://hqr.cms.gov/hqrng/login*) and the eCQI Resource Center (available at: *https://ecqi.healthit.gov/*) for more resources on eCQM reporting.

We invite public comment on our proposal.

d. OAS CAHPS Measures

Each hospital administers (via its vendor) the survey for all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (*https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website as stated in section XV.D.4.b.(2). of this proposed rule. As finalized in the CY 2017 OPPS/ASC final rule with comment period, data cannot be altered after the data submission deadline but can be reviewed prior to the submission deadline (81 FR 79793).

9. Hospital OQR Program Validation Requirements

a. Background

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105 through 72106), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), and 42 CFR 419.46(f) for our policies regarding validation.

b. Proposal To Use Electronic File Submissions for Chart-Abstracted Measure Medical Records Requests Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination and Subsequent Years

Currently, hospitals may choose to submit paper copies of medical records for chart-abstracted measure validation, or they may submit copies of medical records for validation by securely transmitting electronic versions of medical information (79 FR 66965 through 66966). Submission of electronic versions can either entail downloading or copying the digital image of the medical record onto Compact Disc (CD), Digital Video Disc (DVD), or flash drive, or submission of Portable Document Format (PDF) using a secure file transmission process after logging into the HQR System (formerly referred to as the QualityNet Secure Portal) (79 FR 66966). We reimburse hospitals at $3.00 per chart (FY 2016 IPPS/LTCH PPS final rule (80 FR 49763)).

We strive to provide the public with accurate quality data while maintaining alignment with hospital recordkeeping practices. We appreciate that hospitals have rapidly adopted EHR systems as their primary source of information about patient care, which can facilitate the process of producing electronic copies of medical records. Additionally, we monitor the medical records submissions to the CMS Clinical Data Abstraction Center (CDAC) contractor and have found that almost two-thirds of hospitals already use the option to submit PDF copies of medical records as electronic files. In our assessment based on this monitoring, we believe requiring electronic file submissions can be a more effective and efficient process for hospitals selected for validation.

Therefore, in this proposed rule, we are proposing to discontinue the option for hospitals to send paper copies of, or CDs, DVDs, or flash drives containing medical records for validation affecting the CY 2024 payment determination (that is, beginning with data submission for Q1 of CY 2022). We are proposing to require hospitals to instead submit only electronic files when submitting copies of medical records for validation of chart-abstracted measures, beginning with validation affecting the CY 2024 payment determination (that is, Q1 of CY 2022) and for subsequent years. Under this proposal, hospitals would be required to submit PDF copies of medical records using direct electronic file submission via a CMS-approved secure file transmission process as directed by CDAC. We would continue to reimburse hospitals at $3.00 per chart, consistent with the current reimbursement amount for electronic submissions of charts. We note that this process would align with that for the Hospital IQR Program (FY 2016 IPPS/LTCH PPS final rule (85 FR 58949)).

Requiring electronic file submissions reduces the burden of not only coordinating numerous paper-based pages of medical records, but also of having to then ship the papers or physical digital media storage to the CDAC. Therefore, we believe it is appropriate to require that hospitals use electronic file submissions via a CMS-approved secure file transmission process. We invite public comment on our proposal.

c. Proposal To Change the Time Period for Chart-Abstracted Measure Data Validation for Validations Affecting the CY 2024 Payment Determination and Subsequent Years

We refer readers to the chart-abstracted validation requirements and methods we adopted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75117 through 75118) and codified at 42 CFR 419.46(f)(1) for the CY 2024 payment determination and subsequent years. In previous years, charts were requested by the CMS CDAC contractor and hospitals were given 45 calendar days from the date of the request to submit the requested records. If any record(s) were not received by the 45-day requirement, the CMS CDAC contractor assigned a ''zero'' validation score to each measure in a missing record. Using data from the CDAC, we have found that a large majority of hospitals that have participated in Hospital OQR Program data validation efforts have submitted their records prior to 30 calendar days in the current process. Furthermore,

outpatient records typically contain significantly fewer pages than the inpatient records that hospitals have been submitting to the Hospital IQR Program for several years, which suggests that outpatient records could be gathered in less time and use less resources.

Therefore, in this proposed rule, we are proposing to revise § 419.46(f)(1) to change the time period given to hospitals to submit medical records to the CDAC contractor from 45 calendar days to 30 calendar days, beginning with medical record submissions for encounters in Q1 of CY 2022/ validations affecting the CY 2024 payment determination and for subsequent years. We are proposing this deadline modification to reduce the time needed to complete validation, provide hospitals with feedback on their abstraction accuracy in a timelier manner, and to further align with the Hospital IQR Program's validation policy (76 FR 51645). We invite public comment on our proposal.

d. Targeting Criteria

(1) Background

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), 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. We finalized a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68485 through 68486), that for the CY 2014 payment determination and subsequent years, 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. We also refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487) for a discussion of finalized policies regarding our medical record validation procedure requirements. We codified at § 419.46(f)(3) that we select a random sample of 450 hospitals for validation purposes, and select an additional 50 hospitals for validation purposes based on the following criteria:

- The hospital fails the validation requirement that applies to the previous year's payment determination; or
- The hospital has an outlier value for a measure based on the data it submits. An ''outlier value'' is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals and indicates a poor score.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441), we clarified that an ''outlier value'' for purposes of this targeting is defined as a measure value that appears to deviate markedly from the measure values for other hospitals.

(2) Proposal To Add Targeting Criteria

Beginning with validations affecting the CY 2022 reporting period/CY 2024 payment determination and subsequent years, we are proposing to add to the two established targeting criteria used to select the 50 additional hospitals. Specifically, we are proposing to revise § 419.46(f)(3) to add the following criteria for targeting the additional 50 hospitals:

- Any hospital that has not been randomly selected for validation in any of the previous 3 years.
- Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent.

We believe these proposals would allow more hospitals the opportunity for validation. First, by adding targeting criteria for any hospital that has not been randomly selected for validation in any of the previous 3 years, we can ensure that hospitals are eligible to be validated on a regular basis even if they are not selected under the randomly selected sample. Second, the option to selectively review hospitals that have a confidence interval that includes 75 percent is important because hospitals whose confidence interval includes 75 percent indicates a higher level of uncertainty as to the reliability of data for that particular hospital. By adding the targeting criteria for hospitals with two-tailed confidence interval that includes 75 percent, we can target those hospitals that are in the statistical margin of error for their accuracy (which includes hospitals that both pass and fail on this level). These proposals also align Hospital OQR Program validation with additional aspects of Hospital IQR Program validation (77 FR 53553). We believe that these proposed additional criteria would improve data quality by increased targeting of hospitals with possible or confirmed past data quality issues. Additionally, this proposal would respond to concerns that CMS does not have a methodology to address hospitals for which both passing and falling levels of accuracy were included for the statistical margin of error.[282] We invite public comment on our proposals.

[282] Government Accountability Office. ''Hospital Quality Data. CMS needs more rigorous methods to ensure reliability of publicly released data''. GAO–06–54, January 2006.

e. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86185), where we finalized and codified a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction.

We are not proposing any changes to these policies in this proposed rule.

10. Extraordinary Circumstances Exception (ECE) Process for the CY 2022 Payment Determination and Subsequent Years

a. Background

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59444), and 42 CFR 419.46(e) for a complete discussion of our extraordinary circumstances exception (ECE) process under the Hospital OQR Program.

b. Proposal To Expand the Extraordinary Circumstances Exemption to eCQMs

As part of our proposed policies in support of the introduction of eCQMs into the Hospital OQR Program, beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years, we are proposing to expand our established Extraordinary Circumstances Exceptions policy to allow hospitals to request an exception from the Hospital OQR Program's eCQM reporting requirements based on hardships preventing hospitals from electronically reporting. We note that our proposal aligns with the Hospital IQR Program's Extraordinary Circumstances Exceptions policy for eCQMs (80 FR 49695, 42 CFR 412.140(c)(2)).

Under this proposal, applicable hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as

vendor issues outside of the hospital's control (including a vendor product losing certification). In addition, under the Hospital OQR Program, we may consider being a newly participating hospital as undergoing hardship such that newly participating hospitals can apply for an exemption for the applicable program year. Newly participating hospitals are required to begin data submission under the Hospital OQR Program procedural requirements at § 419.46(d)(1), which describes submission and validation of Hospital OQR Program data.

We also propose that a hospital participating in the Hospital OQR Program that wishes to request an exception must submit its request to CMS by April 1 following the end of the reporting calendar year in which the extraordinary circumstances occurred. For example, if an extraordinary circumstance occurred on or by December 31, 2024, the ECE request must be submitted by April 1, 2025. Specific requirements for submission of a request for an exception would be available on the QualityNet website available at: *https://qualitynet.cms.gov/*.

We invite public comment on our proposals.

11. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2022 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), the CY 2021 OPPS/ASC final rule with comment period (85 FR 68185), and 42 CFR 419.46(g) for our reconsideration and appeals procedures. We are not proposing any changes to these policies in this proposed rule.

E. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2022 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 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 this proposed rule.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2022

We propose to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2022 annual payment update factor. For this CY 2022 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which when multiplied by the proposed full conversion factor of $84.457 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 $82.810. 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 assignment of ''S'' and ''T''). We propose to continue to exclude services paid under New Technology APCs. We propose to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also propose to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we propose to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we also propose to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For CY 2022, the proposed reporting ratio is 0.9805, which when multiplied by the final full conversion factor of 84.457 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 82.810.

XVI. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIV.A.1. of the CY 2020 OPPS/ASC final rule with comment period (84 FR 61410) for a general overview of our quality reporting programs and to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58820 through 58822) where we previously discussed our Meaningful Measures Framework.

2. Statutory History of the ASCQR Program

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to the CY 2014 through 2021 OPPS/ASC final rules with comment period for an overview of the regulatory history of the ASCQR Program:

- CY 2014 OPPS/ASC final rule (78 FR 75122);
- CY 2015 OPPS/ASC final rule (79 FR 66966 through 66987);
- CY 2016 OPPS/ASC final rule (80 FR 70526 through 70538);
- CY 2017 OPPS/ASC final rule (81 FR 79797 through 79826);
- CY 2018 OPPS/ASC final rule (82 FR 59445 through 59476);
- CY 2019 OPPS/ASC final rule (83 FR 59110 through 59139);
- CY 2020 OPPS/ASC final rule (84 FR 61420 through 61434); and
- CY 2021 OPPS/ASC final rule (85 FR 86187 through 86193).

We have codified requirements under the ASCQR Program at 42 CFR, part 16, subpart H (42 CFR 416.300 through 416.330).

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 with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for the ASCQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Retention and Removal of Quality Measures From the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously finalized a policy that quality measures adopted for an ASCQR Program measure set for a previous payment determination year be retained in the ASCQR Program for measure sets for subsequent payment determination years, except when such measures are removed, suspended, or replaced as indicated (76 FR 74494 and 74504; 77 FR 68494 through 68495; 78 FR 75122; and 79 FR 66967 through 66969). We are not proposing any changes to this policy in this proposed rule.

b. Removal Factors for ASCQR Program Measures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59111 through 59115), we clarified, finalized, and codified at § 416.320 an updated set of factors [283] and the process for removing measures from the ASCQR Program. We are not proposing any changes to the measure removal factors in this proposed rule.

3. Proposal To Adopt a New Measure for the ASCQR Program Measure Set

In this proposed rule, we are proposing to adopt one new measure: COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure beginning with the CY 2022 reporting period/2024 payment determination.

a. Proposal To Adopt the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination

(1) Background

On January 31, 2020, the Secretary declared a public health emergency (PHE) for the United States (U.S.) in response to the global outbreak of SARS–CoV–2, a novel coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[284] COVID–19 is a contagious respiratory infection [285] that can cause serious illness and death. Older individuals, some racial and ethnic minorities, and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[286] [287] As of July 2, 2021, the U.S. has reported over 33 million cases of COVID–19 and over 600,000 COVID–19 deaths.[288] Hospitals and health systems significant surges of COVID–19 patients as community infection levels increased.[289] From December 2, 2020 through January 30, 2021, more than 100,000 Americans with COVID–19 were hospitalized at the same time.[290]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[291] Ongoing research indicates that fully vaccinated people without immunocompromising conditions are able to engage in most activities with very low risk of acquiring or transmitting SARS–CoV–2, and the Centers for Disease Control and Prevention (CDC) issued new guidance for fully vaccinated individuals on May 28, 2021.[292] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[293] Thus, the CDC advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone who has COVID–19.[294] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface [295] and that in certain circumstances, infection can occur through airborne transmission.[296] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed COVID–19 infection, regardless of whether the individual has symptoms.[297] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between HCP and patients or from patient to patient given the close contact that may occur during the provision of care.[298] The CDC has emphasized that health care settings can be high-risk places for COVID–19 exposure and transmission.[299]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[300] On December 11, 2020, the Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[301] Subsequently, the FDA issued EUAs for additional COVID–19 vaccines.[302] [303]

As part of its national strategy to address COVID–19, the White House stated on March 25, 2021 that it would work with states and the private sector to execute an aggressive vaccination strategy and outlined a goal of

[283] We note that we previously referred to these factors as ''criteria'' (for example, 79 FR 66967 through 66969); we now use the term ''factors'' to align the ASCQR Program terminology with the terminology we use in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

[284] 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.*

[285] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[286] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[287] Centers for Disease Control and Prevention. (2020). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[288] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[289] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895.* Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html.*

[290] US Currently Hospitalized | The COVID Tracking Project. Accessed January 31, 2021 at: *https://covidtracking.com/data/charts/us-currently-hospitalized.*

[291] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[292] Centers for Disease Control and Prevention. (2021). Interim Public Health Recommendations for Fully Vaccinated People. Accessed on June 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.*

[293] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[294] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[295] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[296] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[297] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html.*

[298] Centers for Disease Control and Prevention. (2021). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission.*

[299] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[300] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[301] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144412/download.*

[302] U.S. Food and Drug Administration. (2021). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download.*

[303] U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download.*

administering 200 million shots in 100 days [304] On April 21, 2021, it was announced that this goal had been achieved.[305] Although the goal of the U.S. Government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, the Department of Health and Human Services, the Department of Defense, and the CDC, recommended that early vaccination efforts focus on those critical to the PHE response, including HCP, and individuals at highest risk for developing severe illness from COVID–19.[306] The CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in health care settings and the need to preserve health care system capacity.[307] Reportedly most states followed this recommendation,[308] and HCP began receiving the vaccine in mid-December of 2020.[309]

Frontline healthcare workers, such as those employed in ASCs, have been prioritized for vaccination in most locations. There are approximately 18 million healthcare workers in the U.S.[310] A survey of HCP found that 66 percent of hospital HCP and 64 percent of outpatient clinic HCP reported receiving at least one dose of the vaccine.[311] As of July 2, 2021, the CDC reported that over 328 million doses of COVID–19 vaccine had been administered and approximately 155.9 million people had received full doses.[312] The White House indicated on April 6, 2021 that the U.S. retains sufficient vaccine supply, and every adult became eligible to receive the vaccine beginning April 19, 2021.[313]

We believe it is important to require that ASCs report HCP vaccination information for health care facilities to assess whether these facilities are taking steps to limit the spread of COVID–19 among their health care workers and to help sustain the ability of ASCs to continue serving their communities throughout the PHE and beyond. Therefore, we are proposing to adopt a new measure, COVID–19 Vaccination Coverage Among HCP, beginning with the CY 2024 payment determination. For that payment year, ASCs would be required to report data quarterly on the measure for the January 2022 through December 2022 reporting period. The measure would assess the proportion of an ASC's health care workforce that has been vaccinated against COVID–19.

HCP are at risk of transmitting COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 infection themselves, and transmitting it to their families, friends, and the general public. We believe ASCs should report the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can reduce illness that leads to work absence and limit disruptions to providing care [314] with major reductions in SARS–CoV–2 infections among those receiving a two dose COVID–19 vaccine despite a high community infection rate.[315] Data from influenza vaccination demonstrate that provider vaccination is associated with that provider recommending vaccination to patients [316] and we believe HCP COVID–19 vaccination in ASCs could similarly increase vaccination among that patient population. We also believe that publishing the HCP vaccination rates will be helpful to many patients, particularly those who are at high-risk for developing serious complications from COVID–19, as they choose among ASCs for treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure addresses the quality priority of ''Promote Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure (''COVID–19 HCP vaccination measure'') is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in non-LTC facilities including ASCs.

(a) Measure Specifications

The denominator for the HCP measure is the number of HCP eligible to work in the ASC for at least 1 day during the reporting period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[317]

The numerator for the HCP measure is the cumulative number of HCP eligible to work in at the ASC for at least 1 day during the reporting period and who received a complete vaccination course against COVID–19 using an FDA-authorized or FDA-approved vaccine for COVID–19 (whether the FDA issued an

[304] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on April 3, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/*.

[305] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 2, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/21/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations-2/*.

[306] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf*; Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[307] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[308] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/*.

[309] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f*.

[310] Centers for Disease Control and Prevention. Healthcare Workers. (2017) Accessed February 18, 2021 at: *https://www.cdc.gov/niosh/topics/healthcare/default.html*.

[311] KFF/The Washington Post Frontline Health Care Workers Survey. (2021). Accessed June 2, 2021 at: *https://www.kff.org/coronavirus-covid-19/poll-finding/kff-washington-post-health-care-workers/*.

[312] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. COVID Data Tracker. COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations*.

[313] The White House. Remarks by President Biden Marking the 150 Millionth COVID–19 Vaccine Shot. Accessed April 8, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/06/remarks-by-president-biden-marking-the-150-millionth-covid-19-vaccine-shot/*.

[314] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm*.

[315] Benenson S, Oster Y, Cohen MJ, Nir-Paz R. BNT162b2 mRNA Covid–19 Vaccine Effectiveness among Health Care Workers. N Engl J Med. 2021. See also: Keehner J, Horton LE, Pfeffer MA, Longhurst CA, Schooley RT, Currier JS, et al. SARS–CoV–2 Infection after Vaccination in Health Care Workers in California. N Engl J Med. 2021.

[316] Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[317] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed March 15, 2021 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications*.

approval or EUA).[318] A complete vaccination course is defined under the specific FDA authorization and may require multiple doses or regular revaccination.[319] Vaccination coverage for purposes of this measure is defined as the estimated percentage (given the potential for week-to-week variation) of HCP eligible to work at the ASC for at least 1 day who received a COVID–19 vaccine. For reporting, facilities would count HCP working in all facilities that share the same CMS certification number (CCN).[320] The proposed specifications for the COVID–19 HCP vaccination measure are available on the NQF website at: *https://www.cdc.gov/nhsn/nqf/index.html*.[321]

(b) Review by the Measure Applications Partnership

The COVID–19 HCP vaccination measure was included on the publicly available ''List of Measures Under Consideration for December 21, 2020,'' [322] a list of measures under consideration for use in various Medicare programs. The Measure Applications Partnership (MAP) hospital workgroup convened on January 11, 2021 and reviewed the Measures Under Consideration (MUC) List including the COVID–19 HCP vaccination measure. The MAP hospital workgroup agreed that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it could bring value to the ASCQR Program measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[323] The MAP hospital workgroup also stated in its recommendations that collecting information on COVID–19 vaccination coverage among HCP and providing feedback to facilities will allow facilities to benchmark coverage rates and improve coverage in their facility, and that reducing COVID–19 infection rates in HCP may reduce transmission among patients and reduce instances of staff shortages due to illness.[324]

In its preliminary recommendations, the MAP hospital workgroup did not support this measure for rulemaking, subject to potential for mitigation.[325] To mitigate its concerns, the MAP hospital workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and National Quality Forum (NQF) endorsement prior to implementation.[326] Subsequently, the MAP Coordinating Committee met on January 25, 2021 and reviewed the COVID–19 HCP vaccination measure. In the 2020 and 2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measures back to MAP once the specifications are further refined.[327] The MAP stated, ''the incomplete specifications require immediate mitigation and further development should continue.'' [328] In its final report, the MAP noted that the measure would add value by providing visibility into an important intervention to limit COVID–19 infections in HCP and the patients for whom they provide care.[329] The spreadsheet of final recommendations no longer cited concerns regarding evidence, testing, or NQF endorsement.[330] In response to the MAP final recommendation request that CMS bring the measure back to the MAP once the specifications are further refined, CMS and the CDC met with the MAP Coordinating Committee on March 15, 2021. CMS and CDC provided additional information to address vaccine availability, alignment of the COVID–19 HCP vaccination measure as being as closely as possible with the data collection for the Influenza HCP vaccination measure (NQF #0431), and provided clarification on how HCP are defined. CMS and the CDC also presented preliminary findings from the testing of the numerator of the COVID–19 HCP vaccination measure, which is currently in process. These preliminary findings show numerator data should be feasible to collect and reliable. Testing of the measure numerator (the number of HCP vaccinated) involves a comparison of the data collected through the National Healthcare Safety Network (NHSN) and independently reported through the Federal pharmacy partnership program for delivering vaccination to LTC facilities. These are two independent data collection systems. In initial analyses of the first month of vaccination, the number of healthcare workers vaccinated in approximately 1,200 facilities for which data from both systems were available, the number of healthcare personnel vaccinated was highly correlated between the two systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[331] Because of the high correlation across a large number of facilities and high number of HCP within those facilities receiving at least one dose of the COVID–19 vaccine, we believe the measure is feasible and reliable for use in ASCs. After reviewing this additional information, the MAP retained its final recommendation of conditional support, and expressed support for CMS' efforts to use the measure as part of the solution for the COVID–19 public health crisis.[332]

Section 1890A(a)(4) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the Secretary to take into consideration input from multi-stakeholder groups in selecting certain quality and efficiency measures. While we value input from the MAP, we believe it is important to propose the measure as quickly as possible to address the urgency of the COVID–19 PHE and its impact on vulnerable populations. CMS continues to engage with the MAP to mitigate concerns and appreciates the MAP's conditional support for the measure.

(c) Measure Endorsement

Section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act shall apply with respect to ASC services in a similar manner in which it applies to hospitals for the Hospital OQR Program, except as the Secretary may otherwise provide. The requirements at section 1833(t)(17)(C)(i) of the Act state that measures developed shall ''be appropriate for the measurement of the quality of care (including medication

[318] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[319] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[320] Centers for Disease Control and Prevention. CMS Reporting Requirements FAQs. Accessed June 2, 2021 at: *https://www.cdc.gov/nhsn/PDFs/CMS/faq/FAQs-CMS-Reporting-Requirements.pdf*.

[321] *https://www.cdc.gov/nhsn/nqf/index.html*.

[322] *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212*.

[323] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[324] *Ibid.*

[325] *Ibid.*

[326] *Ibid.*

[327] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 3, 2021 at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*.

[328] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[329] *Ibid.*

[330] *Ibid.*

[331] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[332] *Ibid.*

errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.''

In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, as we have noted in previous rulemaking (for example, 75 FR 72065 and 76 FR 74494 for the Hospital OQR and ASCQR Programs, respectively), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

The proposed COVID–19 HCP vaccination measure is not NQF endorsed and has not been submitted to NQF for endorsement consideration. However, at this time, we find no other feasible and practicable measures on the topic of COVID–19 vaccination among HCP. CMS will consider the potential for future NQF endorsement as part of its ongoing work with the MAP. Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practicable measure has not been endorsed by the entity with a contract under section 1890(a) (currently the NQF), 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. Therefore, with the above considerations, we believe there is sufficient basis to propose adoption of this measure at this time.

(d) Data Collection, Submission, and Reporting

Given the time sensitive nature of this measure considering the current PHE, we are proposing that ASCs would be required to begin reporting data on the proposed COVID–19 HCP vaccination measure beginning January 1, 2022, for the CY 2024 payment determination for the ASCQR Program. Thereafter, we propose quarterly reporting periods. While we considered annual reporting periods for the ASCQR Program, we are proposing quarterly reporting periods given the immediacy of the PHE and the importance of alignment across quality payment programs proposing this measure.

If our proposal to adopt this measure is finalized, ASCs would report the measure through the CDC NHSN web-based surveillance system.[333] While the ASCQR Program does not currently require use of the NHSN web-based surveillance system, we have previously required use of this system for submitting program data. We refer readers to the CY 2014 OPPS/ASC final rule with comment period in which we adopted the Influenza Vaccination Coverage Among HCP (NQF #0431) measure (78 FR 75110 through 75117) and section XVI.D.1.c.(2). of this proposed rule for additional information on reporting through the NHSN web-based surveillance system under the ASCQR Program. The Influenza Vaccination Coverage Among HCP (NQF #0431) measure was removed from the ASCQR Program in the CY 2019 OPPS/ASC final rule as CMS observed that reporting measure data through the NHSN could be more burdensome for ASCs compared to the relative burden for hospitals participating in the Hospital IQR Program and the HAC Reduction Program and especially for freestanding ASCs (83 FR 59115 through 59117). However, the COVID–19 pandemic and associated PHE have had a more significant effect on most aspects of society than influenza, including availability of the healthcare system. With respect to reporting for the COVID–19 HCP vaccination measure, CDC guidance for entering data requires submission of HCP count at the facility level [334] and the measure requires reporting consistent with that guidance. We believe that the public health benefits to having these data available outweigh the burden of reporting for systems with multiple facilities or locations. While we recognize that there may be some elements of the measure specifications that increase burden for some ASCs, given the impact that the COVID–19 PHE has had on society and the healthcare system, we believe that the benefits outweigh this reporting burden. For more information on the associated burden of this measure, we refer readers to XXV.C.5.b. of the proposed rule.

To report this measure, we are proposing that ASCs would collect the numerator and denominator for the COVID–19 HCP vaccination measure for at least one, self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet ASCQR Program requirements. While we believe that it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that ASCs would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable estimate of vaccination levels among an ASC's HCP while balancing the costs of reporting. 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, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we are proposing that 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 submission periods submitted by the ASC for that quarter. If finalized, CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

ASCs would submit the number of HCP eligible to have worked at the facility during the self-selected week that the ASC reports data in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week. As previously stated, facilities would count HCP working in all facilities that share the same CCN.[335]

We invite public comment on our proposal.

4. Proposed Changes to Previously Adopted Measures in the ASCQR Program Measure Set

We previously adopted the following measures into the ASCQR measure set: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC–4: All-Cause Hospital Transfer/Admission; ASC–11: Cataracts—Improvement in Patient's Visual Function with 90 Days Following Cataract Surgery; and ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems. For various reasons discussed in sections XVI.B.4.a., XVI.B.4.b., and XVI.B.4.c., these measures were either paused or suspended from the ASCQR Program.

[333] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.* on February 10, 2021.

[334] COVID–19 Vaccination Non-LTC Healthcare Personnel TOI (*cdc.gov*).

[335] *Ibid.*

We now believe that previous concerns related to the data submission method previously utilized for these measures can be addressed and we are now proposing to return to requiring data submission for these measures.

a. Proposal To Require Previously Suspended ASC–1, ASC–2, ASC–3, and ASC–4 Measures Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination and Subsequent Years

(1) Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74497 through 74498) where we adopted ASC–1: Patient Burn beginning with the CY 2014 payment determination. This outcome measure assesses the percentage of ASC admissions experiencing a burn prior to discharge. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498) where we adopted ASC–2: Patient Fall beginning with the CY 2014 payment determination (NQF #0266). This measure assesses the percentage of ASC admissions experiencing a fall at the ASC. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498 through 74499) where we adopted ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant beginning with the CY 2014 payment determination (NQF #0267). This outcome measure assesses the percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74499) where we adopted ASC–4: All-Cause Hospital Transfer/Admission beginning with the CY 2014 payment determination (NQF #0265). This outcome measure assesses the rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC.

In the CY 2019 OPPS/ASC proposed rule, we proposed to remove ASC–1, ASC–2, ASC–3, and ASC–4 under measure removal Factor 1—measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made—for the CY 2021 payment determination and subsequent years (83 FR 37198 through 37199). We noted that the ASCQR Program had previously finalized two criteria for determining when a measure is ''topped-out,'' including: (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10.[336] We presented data demonstrating that each of these four measures met the criteria for topped-out status and stated that we believed their removal from the ASCQR Program measure set was appropriate as there was little room for improvement. In addition, we stated that removal would alleviate the maintenance costs and administrative burden to ASCs associated with retaining the measures. As such, we believed the burden associated with reporting these measures outweighed the benefits of keeping them in the program (83 FR 37198 through 37199).

However, in the CY 2019 OPPS/ASC final rule with comment period, we stated that we had re-evaluated the data due to public comments and reviewed many studies demonstrating the importance of measuring and reporting the data for these measures (83 FR 59118). It became clear to us that these measures are more valuable to stakeholders than we had initially perceived. We agreed that it was important to continue to monitor these types of events, considering the potential negative impacts to patients' morbidity and mortality, in order to continue to prevent their occurrence and ensure that they remain rare. We acknowledged that these measures provided critical data to beneficiaries and were valuable to the ASC community. We also acknowledged that having measures that apply to all ASCs provides beneficiaries with the most comprehensive patient safety data to use when making decisions about a site of care. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we did not finalize our proposals to remove ASC–1, ASC–2, ASC–3, and ASC–4 (83 FR 59118). We believed it was more prudent to keep them in the measure set in order to continue to detect and prevent these events.

[336] In the CY 2019 OPPS/ASC proposed rule, we also clarified how we calculated the TCOV for ASC–1, ASC–2, ASC–3, and ASC–4, which assess the rate of rare, undesired events for which a lower rate is preferred. Typically, for measures for which a higher rate is preferred, we determine the TCOV by calculating the truncated standard deviation (SD) in performance divided by the truncated mean of performance (the mean of positive events). For these four measures, we employed an alternate methodology utilizing the mean of *non-adverse* events in our calculation of the TCOV. This substitution resulted in a TCOV that was comparable to that calculated for other measures and allowed us to assess rare event measures by still generally using our previously finalized topped-out criteria. For more information, see 83 FR 37196 through 37197.

However, we also stated in the CY 2019 OPPS/ASC final rule with comment period that we were concerned about some of the data submitted for these measures (83 FR 59119). We explained that the data submission method for these measures, which involved adding specific QDCs onto eligible claims, may impact the completeness and accuracy of the data. Specifically, we were concerned that ASCs lacked the ability to correct the QDC codes that are used to calculate these measures from Medicare FFS claims (83 FR 59119) if the claim had been submitted and processed for payment. We stated that we believed that revising the data submission method for the measures, such as via QualityNet, would address this issue and allow facilities to correct any data submissions errors, resulting in more complete and accurate data (83 FR 59119).

Therefore, we suspended the data collection of ASC–1, ASC–2, ASC–3, and ASC–4 beginning with the CY 2019 reporting period/CY 2021 payment determination (83 FR 59119). Starting with the CY 2021 payment determination, facilities were not required to submit data for these four measures as part of ASCQR Program requirements, even though the measures remained in the ASCQR Program measure set. We stated that as we developed future revisions for the data collected for these measures, we would take into consideration other data submission methods that may allow for the reporting of adverse events across payers and would consider commenters' feedback toward the future updates to the measures (83 FR 59119).

(2) Proposal To Require ASC–1, ASC–2, ASC–3, and ASC–4 Measures Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination and Subsequent Years

In this proposed rule, we are proposing to again require and resume data collection for ASC–1, ASC–2, ASC–3, and ASC–4 beginning with the CY 2023 reporting period/CY 2025 payment determination and subsequent years. Under our proposal, providers would submit data via the HQR System (formerly referred to as the QualityNet Secure Portal). We believe that web-based submission will make reporting easier and more efficient for facilities and will allow facilities to review and correct submitted data until the data submission deadline; our review and corrections policy is discussed in more detail at section XVI.D.1.f.

We stated that we believed that revising the data submission method for

the measures, such as via QualityNet (now known as the HQR System) would address this issue and allow facilities to correct any data submissions errors, resulting in more complete and accurate data (83 FR 59119). Facilities would be able to review and correct their data submissions up to the data submission deadline. As we stated above, we also believe that while these measures have been ''topped-out'', the public continues to believe that it is important to monitor these types of events, considering the potential negative impacts to patients' morbidity and mortality, to continue to prevent their occurrence and ensure that they remain rare.

We refer readers to section XVI.D.1.c.(1). of this proposed rule, where we discuss the data submission process for web-based measures, for more detail on how ASCs would be expected to submit data.

We invite public comment on our proposals.

b. Proposal To Require ASC–11: Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536) Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75129) we finalized the adoption of the ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure.[337] This measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery (78 FR 75129). The measure data consists of pre-operative and post-operative visual function surveys. The implementation of this measure underwent a number of changes aimed to address concerns regarding burden and survey instrument usage that we believe are resolved so that this measure can now be proposed as mandatory.

During the CY 2014 OPPS/ASC rule cycle, some commenters expressed concern about the burden of collecting pre-operative and post-operative visual function surveys (78 FR 75129 and 75138). In response to those comments, we modified our implementation strategy in a manner that we believed would significantly minimize collection and reporting burden (78 FR 75129). Specifically, we applied a sampling scheme and a low case threshold exemption to address commenters' concerns regarding burden (78 FR 75138 through 75139). With those changes, we intended to decrease burden and facilitate data reporting by allowing random sampling of cases when volume is high, instead of collecting information for all eligible patients (78 FR 75138 through 75139). For further details, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75129; 75138 through 75139).

Shortly thereafter, we became concerned about the use of what we believed at the time were inconsistent surveys to assess visual function. The measure specifications allowed for the use of any validated survey and we were unclear about the impact the use of varying surveys might have. Therefore, we issued guidance stating that we would delay the implementation of ASC–11.[338]

Subsequently, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985), we finalized our proposal to exclude ASC–11 from the CY 2016 payment determination measure set, and for subsequent years. We proposed to exclude ASC–11 for a few reasons. First, we understood it was operationally difficult for ASCs to collect and report on the measure (79 FR 66984). Notably, the results of the survey used to assess the pre-operative and post-operative visual function of the patient were not consistently shared across clinicians, making it difficult for ASCs to have knowledge of the visual function of the patient before and after surgery (79 FR 66984). Second, the concern about use of various versions of the survey persisted. Specifically, we were concerned that if physicians used different surveys to assess visual function, then the measure could produce inconsistent results (79 FR 66984).

By excluding ASC–11 from the measure set used for the CY 2016 payment determination and subsequent years, ASCs were excused from reporting on it (79 FR 66984). ASCs that did not report on ASC–11 for the CY 2016 payment determination were not subject to a payment reduction (79 FR 66984). In conjunction with excusing ASCs from reporting on ASC–11 for the CY 2016 payment determination and subsequent years, we finalized allowing ASCs to voluntarily report ASC–11 data for the CY 2015 reporting period/CY 2017 payment determination and subsequent years (79 FR 66984).

(2) Proposal To Require the ASC–11 Measure Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination and for Subsequent Years

We now believe it is appropriate to require that ASCs report on ASC–11 as our earlier concerns have been allayed. At this point, ASCs have had several years to familiarize themselves with ASC–11, prepare to operationalize it, and opportunity to practice reporting the measure since the CY 2015 reporting period/CY 2017 payment determination. We note that a small number of facilities have consistently reported data for this measure and these data have been made publicly available. Furthermore, research indicates that using different surveys will not result in inconsistencies, as the allowable surveys are scientifically validated.[339] Research has demonstrated that of 16 different cataract surgery outcome questionnaires, all were able to detect clinically important change.[340]

Therefore, we are proposing to require reporting for the NQF-endorsed ASC–11 measure beginning with the CY 2023 reporting period/CY 2025 payment determination and subsequent years. As we stated in the CY 2014 OPPS/ASC final rule with comment period, as well as the CY 2015 OPPS/ASC final rule with comment period, and consistent with the MAP recommendation, we continue to believe that this measure ''addresses a high-impact condition'' that is not otherwise adequately addressed in our current measure set (78 FR 75129 and 79 FR 66984, respectively). Moreover, ASC–11 serves to drive coordination of care (78 FR 75129 and 79 FR 66984) in multiple ways, including the operational requisites for conducting—and sharing the results of—the surveys. This measure provides opportunities for care

[337] We note that this measure was endorsed by the NQF under NQF #1536 at the time of adoption but has subsequently had its endorsement removed.

[338] The implementation was first delayed by 3 months—from January 1, 2014 to April 1, 2014, for the CY 2016 payment determination, via guidance issued December 31, 2013. Available at: *https://qualitynet.cms.gov/asc/notifications*. Because of continuing concerns, on April 2, 2014, we issued additional guidance stating that we would further delay the implementation of the measure from April 1, 2014 to January 1, 2015 for the CY 2016 payment determination. Available at: *https://qualitynet.cms.gov/asc/notifications*.

[339] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

[340] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

coordination as well as direct patient feedback.

We refer readers to section XVI.D.1.c.(1). for information about submitting data via a CMS web-based tool. We invite public comment on our proposal.

c. Proposal To Require ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With Voluntary Reporting in CY 2023 Reporting Period and Mandatory Reporting Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination and for Subsequent Years

(1) Background

We previously adopted the ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey-based measures to assess patient experience with care following a procedure or surgery in an ASC. These survey-based measures rate patient experience as a means for empowering patients and improving the quality of their care (82 FR 59450). For further details on this measure, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79803 through 79817), in which we adopted these measures beginning with the CY 2020 payment determination.

Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 49450 through 49451), we delayed implementation of ASC–15a–e for the ASCQR Program beginning with the CY 2020 payment determination due to lack of sufficient operational and implementation data. At that time, we believed that our ongoing National OAS CAHPS voluntary reporting program for the survey, which began in January 2016 [341] and is unrelated to either the Hospital OQR Program or ASCQR Program, would provide valuable information moving forward. Specifically, we wanted to use the information from the National OAS CAHPS voluntary reporting program to: (1) Ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; (2) reaffirm the reliability of national implementation of OAS CAHPS Survey data; and (3) appropriately account for the burden associated with administering the survey in the outpatient care setting.

Having had the opportunity during the delayed implementation to investigate the concerns about patient response rates and data reliability, we believe that patients are able to respond to OAS CAHPS questions, and that those responses are reliable based on prior experience collecting voluntary data for public reporting since CY 2016 (available at *https://www.medicare.gov/care-compare/*). We reaffirm that the OAS CAHPS survey-based measures assess important aspects of care where the patient is the best or only source of information (81 FR 79803). Regarding the burden associated with the survey, we believe that rating patient experience still provides important information to ASCs and patients, especially for assessing the quality of care provided at an ASC (82 FR 59450). Furthermore, in section XVI.D.1.d.(2)., we are proposing additional collection modes using a web-based module (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents) for administering the survey, which would be available beginning in CY 2023 under the ASCQR Program and for subsequent years.[342] We believe this would further address some burden concerns raised during the CY 2017 OPPS/ASC final rule with comment period (81 FR 59450) because the web-based modules may produce similar results but at lower costs of collection.[343] As we stated in the CY 2018 OPPS/ASC final rule with comment period, we continue to believe that implementation of these measures will enable objective and meaningful comparisons between ASCs (82 FR 59450) and that patient experience of care data is valuable in assessing the quality of care provided at an ASC and assisting patients in selecting a provider for their care (82 FR 59450).

In this proposed rule, we are proposing to restart the ASC–15a–e measures by proposing to link reporting of measure data with payment determinations as part of the ASCQR Program beginning with the CY 2024 reporting period/CY 2026 payment determination. Specifically, for the ASCQR Program, we are proposing voluntary data collection and reporting beginning with the CY 2023 reporting period, followed by mandatory data collection and reporting beginning with the CY 2024 reporting period/CY 2026 payment determination. As noted above, the National OAS CAHPS voluntary reporting program is independent of the ASCQR Program and the Hospital OQR Program. This proposal is intended to make the distinction that ASCs that voluntarily report the OAS CAHPS survey-based measures during the CY 2023 reporting period would do so as part of the ASCQR Program until mandatory reporting begins, if these proposals are finalized. The reporting process for ASCs to submit OAS CAHPS data would remain unchanged for ASCs (that is, they would not duplicate submissions to the program and National OAS CAHPS voluntary reporting program) and we refer readers to section XVI.D.1.d. for our related proposals regarding the form, manner, and timing for reporting the ASC–15a–e survey-based measures.

We initially considered a 2-year voluntary period, that is, the CY 2023 and CY 2024 reporting periods, because we believed that ASCs may require additional preparation time for OAS CAHPS implementation including contracting with OAS CAHPS vendors. We also considered the challenges that many ASCs may have experienced during the COVID–19 pandemic and the additional operational constraints that they may still be experiencing. However, since voluntary reporting, including the two new modes of data collection we are proposing in section XVI.D.1.d.(2)., will be available in 2022 as part of the National OAS CAHPS voluntary reporting program, and we are proposing one year of voluntary reporting as part of the ASCQR Program for the CY 2023 reporting period, we believe that ASCs will have sufficient time to familiarize themselves with OAS CAHPS measures and OAS CAHPS vendors prior to mandatory reporting in the CY 2024 reporting period/CY 2026 payment determination and for subsequent years.

We refer readers to section XVI.D.1.d. for our related proposals regarding the form, manner, and timing for reporting the ASC–15a–e survey-based measures.

We invite public comment on our proposal. We also refer readers to section XV.B.5.a. of this proposed rule where we are also proposing to restart this measure in the Hospital OQR Program.

[341] Participation in the program is open to any interested Medicare-certified Hospital Outpatient Departments (HOPDs) and free-standing ambulatory surgery centers (ASCs). More information on the National OAS CAHPS voluntary reporting program is available at: *https://oascahps.org/General-Information/National-Implementation* and *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/OAS-CAHPS.*

[342] We note that the mixed modes will be available as part of the National OAS CAHPS voluntary reporting program beginning in CY 2022.

[343] Bergeson SC, Gray J, Ehrmantraut LA, Hays RD. Comparing Web-based with Mail Survey Administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Clinician and Group Survey. Prim Health Care. 2013 Sept; doi: 10.4172/2167–1079.1000132. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3783026/.*

5. Summary of Previously Finalized and Proposed ASCQR Program Quality Measure Set

a. Summary of Previously Finalized and Proposed ASCQR Program Quality Measure Set for the CY 2022 Reporting Period/CY 2024 Payment Determination

Table 52 summarizes the previously finalized and proposed ASCQR Program measure set for the CY 2022 reporting period/CY 2024 payment determination.

TABLE 52: Previously Finalized and Proposed ASCQR Program Measure Set for the CY 2022 Reporting Period/CY 2024 Payment Determination

ASC #	NQF #	Measure Name
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	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-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
	None	COVID-19 Vaccination Coverage Among Health Care Personnel**

† NQF endorsement was removed.
* The ASC-11 measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).
** We note that, if adoption finalized, an ASC/measure number will be assigned for this measure in the final rule.

b. Summary of Previously Finalized and Proposed ASCQR Program Quality Measure Set for the CY 2023 Reporting Period/CY 2025 Payment Determination

Table 53 summarizes the previously finalized and proposed ASCQR Program measure set for the CY 2023 reporting period/CY 2025 payment determination.

TABLE 53: Previously Finalized and Proposed ASCQR Program Measure Set for the CY 2023 Reporting Period/CY 2025 Payment Determination

ASC #	NQF #	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: 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-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
	None	COVID-19 Vaccination Coverage Among Health Care Personnel*

† NQF endorsement was removed.

* We note that, if adoption finalized, an ASC/measure number will be assigned for this measure in the final rule.

c. Summary of Previously Finalized and Proposed ASCQR Program Quality Measure Set for the CY 2024 Reporting Period/CY 2026 Payment Determination and Subsequent Years

Table 54 summarizes the previously finalized and proposed ASCQR Program measure set for the CY 2024 reporting period/CY 2026 payment determination and subsequent years.

TABLE 54: Previously Finalized and Proposed ASCQR Program Measure Set for the CY 2024 Reporting Period/CY 2026 Payment Determination and Subsequent Years

ASC #	NQF #	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: 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	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
	None	COVID-19 Vaccination Coverage Among Health Care Personnel*

† NQF endorsement was removed.

* We note that, if finalized, an ASC/measure number will be assigned for this measure in the final rule.

6. ASCQR Program Measures and Topics for Future Consideration

a. Request for Comment on Potential Adoption of Future Measures for the ASCQR Program

We seek to adopt a comprehensive set of quality measures for widespread use to inform decision-making regarding care and for quality improvement efforts in the ASC setting. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083 through 86110), under the OPPS we finalized the elimination of the Inpatient Only (IPO) list over a 3-year transitional period, beginning with the removal of approximately 300 primarily musculoskeletal-related services, with the list to be completely phased out by CY 2024.[344] As discussed in section IX. of this rule, we have continued to receive stakeholder requests to reconsider the elimination of the IPO list, to reevaluate services removed from the IPO list due to safety and quality concerns, and to, at a minimum, extend the timeframe for eliminating the list. After further consideration and review of the additional feedback from stakeholders, we believe that the timeframe we adopted for removing services from the IPO list does not give us a sufficient opportunity to carefully assess whether a procedure can be removed from the IPO list while still ensuring beneficiary safety. For CY 2022, we are proposing to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021, we propose to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022.

We are also proposing to reinstate the CY 2020 criteria used to add procedures to the ASC Covered Procedures List (CPL) and remove 258 of the additional 267 surgical procedures that were added to the ASC CPL beginning in CY 2021, under the CY 2021 revised criteria[345] with additional procedures being proposed for addition for CY 2022.

However, as technology and surgical techniques advance, services will continue to transition off of the IPO list, becoming payable in the outpatient hospital setting and being eligible for addition to the ASC covered procedures list in subsequent years. We recognize that there may be a need for more measures that inform decision-making regarding care and for quality improvement efforts, particularly focused on the behaviors of services that become newly eligible for payment in the ASC setting. In light of this, we seek comment on potential future adoption of measures that would allow better tracking of the quality of care for services that transition from the IPO list and may subsequently become eligible for addition to the ASC CPL.

Therefore, we invite public comment on the potential future adoption of measures for our consideration that address care quality in the ASC setting given the transition of procedures from inpatient settings to outpatient settings of care.

b. Request for Comment on Potential Future Adoption and Inclusion of an ASC-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)

As described in section XVI.B.6.a. above, we are seeking comment on priorities for quality measurement in outpatient settings due to changes to the IPO procedure list (82 FR 59385 and 84

[344] Centers for Medicare & Medicaid Services. (2020, December 2). CY 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System final rule (CMS–1736–FC). Retrieved from *www.cms.gov/newsroom*: *https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0.*

FR 61355) and the ASC CPL (84 FR 61388 and 85 FR 86146).

We are also requesting comment on the potential future adoption of a re-specified version of a patient-reported outcome-based performance measure (PRO–PM) for two such procedures, elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA), which were removed from the IPO list effective for CY 2020 and CY 2018, respectively, and added to the ASC CPL effective for CY 2021 and CY 2020, respectively. We recently solicited public comment on the potential future inclusion of a Hospital-level THA/TKA PRO–PM (NQF #3559) in the FY 2022 IPPS/LTCH PPS proposed rule for the inpatient hospital setting (86 FR 25589). This measure reports the hospital-level risk-standardized improvement rate (RSIR) in patient-reported outcomes (PROs) following elective primary THA/TKA for Medicare fee-for-service (FFS) beneficiaries aged 65 years and older. 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; and (2) the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients. Improvement is measured from the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk adjusted to account for differences in patient case mix. Potential non-response bias in measure scores due to the voluntary nature of PROs is incorporated in the measure calculation with stabilized inverse probability weighting based on likelihood of response.

Given the recent changes in the ASC CPL, we expect that THA and TKA procedures will increasingly be performed in ASCs and that the volume of these procedures on Medicare beneficiaries 65 and older will also increase in ASCs in future years.

We recognize that potential future adoption and implementation of a re-specified version of the THA/TKA PRO–PM in the ASCQR Program would require sufficient numbers of procedures for each measured ASC to ensure a reliable measure score. Only a subset of ASCs perform orthopedic procedures, so the measure would likely apply to a minority of ASCs. Additionally, implementing a THA/TKA PRO–PM would require providers to successfully collect pre- and post-operative PRO data for each procedure. Specifically, the inpatient THA/TKA PRO–PM discussed in the FY 2022 IPPS/LTCH PPS proposed rule requires a minimum of 25 cases with completed pre- and post-operative PRO data per hospital to ensure a reliable facility-level score. For more details on the inpatient THA/TKA PRO–PM, we refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25589) and the PROs Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

We will continue to monitor the number of THA and TKA procedures in ASCs and when we believe there is a sufficient number of such procedures performed in ASCs to reliably measure a meaningful number of facilities, we may consider expanding the PRO–PM to this setting. We also note that, as finalized in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59455 through 59463), the ASCQR Program currently includes a Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures (ASC–17) measure using claims data which provides facilities with important information on patient outcomes for Medicare FFS beneficiaries following orthopedic surgery at ASCs and this measure includes THA and TKA procedures. The ASC–17 measure calculates a facility-specific risk-standardized hospital visit ratio within 7 days of an orthopedic procedure performed at an ASC and has as outcomes of interest unplanned hospital admissions, emergency department (ED) visits, and observation stays, thereby, providing valuable quality information for these procedures as they expand into the ASC setting.

As described in our Meaningful Measures 2.0 Framework, we aim to promote better collection and integration of patients' voices by developing PRO measures as an additional tool for measuring and improving quality. Given the unique challenges and opportunities for PRO–PMs for THA and TKA procedures in the ASC setting, we invite public comment on the potential future adoption of a re-specified version of PRO measures for elective THA/TKA PRO–PM for the ASCQR Program. Specifically, we invite public comment on the following:

- Input on the mechanism of PRO data collection and submission, including anticipated barriers and solutions to data collection and submission.
- Usefulness of having an aligned set of PRO–PMs across settings where elective THA/TKA are performed, that is, hospital inpatient setting, hospital outpatient departments, and ASCs for patients, providers, and other stakeholders. Specifically, usefulness and considerations for a healthcare system that performs inpatient and/or outpatient and ASC elective THA/TKAs.
- Considerations unique to THA/TKAs performed in the ASC setting such as the volume of procedures performed or the measure cohort, outcome, or risk adjustment approach.

We invite public comment on the adoption of a re-specified version of a PRO–PM measure for elective primary THA and TKA and future inclusion of such in the ASCQR Program measure set.

c. Request for Comment on Potential Future Efforts To Address Health Equity in the ASCQR Program

(1) Background

Significant and persistent inequities in health care outcomes exist in the U.S. Belonging to racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; and being near or below the poverty level, are often associated with worse health outcomes.[346] [347] [348] [349] [350] [351] [352] [353] Such

[346] Joynt K.E., Orav E., Jha A.K. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[347] Lindenauer P.K., Lagu T., Rothberg M.B., et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346.

[348] Trivedi A.N., Nsa W., Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308.

[349] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[350] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018. Available at: *https://www.ruralhealthresearch.org/assets/2200–8536/rural-communities-age-income-health-status-recap.pdf*.

[351] U.S. Department of Health and Human Services Office of Minority Health. 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities, FY 2020. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf*.

[352] Heslin K.C., Hall J.E. Sexual Orientation Disparities in Risk Factors for Adverse COVID–19-Related Outcomes, by Race/Ethnicity—Behavioral

Continued

disparities in health outcomes are the result of number of factors, but importantly for CMS programs, although not the sole determinant, negative experiences, poor access, and provision of lower quality health care contribute to health disparities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[354 355 356 357 358 359] Readmission rates for common conditions in the Hospital Readmissions Reduction Program (HRRP) are higher for Black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with Congestive Heart Failure and Acute Myocardial Infarction.[360 361 362 363 364] Studies have also shown that African Americans are significantly more likely than White Americans to die prematurely from heart disease and stroke.[365] The COVID–19 pandemic has further highlighted many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among Black, Latino, and Indigenous and Native American persons relative to White persons.[366 367] As noted by the CDC, ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID–19.'' [368] One important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across our programs and policies.

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[369] For the purposes of this proposed rule, we are using a definition of equity established in Executive Order 13985, issued on January 25, 2021, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; LGBTQ+ persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [370] We note that this definition was recently established and provides a useful, common definition for equity across different areas of government, though numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Network Quality Improvement Organizations (QIN–QIOs); Federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity.[371]

We refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070) which summarizes our existing initiatives aimed at closing the equity gap in outcomes for Medicare beneficiaries. We also refer readers to the section XV.B.7.c.(1). of this proposed rule which describes the policy and statute which have informed the creation of the CMS Disparity Methods to provide confidential stratified results for measures in the hospital inpatient setting using dual eligibility as a proxy for social risk. Our efforts to stratify outcome measures by dual eligibility are supported by national recommendations from the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine, which identified dual eligibility, as an indicator of social risk, as a powerful predictor of poor health outcomes among the social risk factors that were tested.[372 373]

Risk Factor Surveillance System, United States, 2017–2019. MMWR Morb Mortal Wkly Rep 2021;70:149–154. DOI: *http://dx.doi.org/10.15585/mmwr.mm7005a1*. Available at: *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm*.

[353] Poteat T.C., Reisner S.L., Miller M., Wirtz A.L. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv*. 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[354] Martino, S.C., Elliott, M.N., Dembosky, J.W., Hambarsoomian, K., Burkhart, Q., Klein, D.J., Gildner, J., and Haviland, A.M. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[355] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf*.

[356] Singh J.A., Lu X., Rosenthal G.E., Ibrahim S., Cram P. Racial disparities in knee and hip total joint arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[357] Rivera-Hernandez M., Rahman M., Mor V., Trivedi A.N. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[358] Joynt K.E., Orav E., Jha A.K. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[359] Tsai T.C., Orav E.J., Joynt K.E. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[360] Rodriguez F., Joynt K.E., Lopez L., Saldana F., Jha A.K. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[361] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[362] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf*.

[363] Prieto-Centurion V., Gussin H.A., Rolle A.J., Krishnan J.A. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[364] Joynt K.E., Orav E., Jha A.K. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[365] HHS. Heart disease and African Americans.. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19*.

[366] CMS. Preliminary Medicare COVID–19 Data Snapshot. (April 16, 2021). Available at: *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf*.

[367] Ochieng N., Cubanski J., Neuman T., Artiga S., and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/*.

[368] CDC. Health Equity Considerations & Racial & Ethnic Minority Groups. (April 19, 2021). Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html*.

[369] CMS. CMS Quality Strategy. (2016). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf*.

[370] Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. 86 FR 7009 (Jan. 20, 2021). Available at: *https://www.federalregister.gov/documents/2021/01/25/2021–01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*.

[371] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf*.

[372] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicaresvalue*-based-purchasing-programs.

[373] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

To date, we have not expanded disparities reporting to the ASC setting. Internally testing the two disparities methods (Within- and Across-Hospital Disparity Methods) on ASCQR Program quality measures calculated using Medicare FFS claims revealed several unique challenges to measuring disparities for dually eligible individuals in the ASC setting, principally, relatively low volumes of dual eligible patients in many facilities, and large diversity in the types and patient mix between ASCs as these facilities tend to specialize. In our initial analysis, few facilities met the minimum sample size required to yield technically feasible, adequately representative, and statistically reliable disparity results. We are considering social risk factors, including neighborhood-level social determinants of health, such as the poverty, education, and housing quality, which can adversely influence health outcomes, contributing to health inequities, in order to report more information regarding equity gaps in the care provided in the ASC setting. There are several different approaches for quantifying the health impacts of adverse neighborhood level socioeconomic factors. One approach is the Agency for Healthcare Research and Quality (AHRQ) neighborhood Socioeconomic Status (SES) Index, which uses information from the U.S. Census at the census block-group level to estimate the range of socioeconomic status in the beneficiary's neighborhood.[374] In this proposed rule, we are seeking comment on and are interested in learning more about the potential for measuring disparities in care provided in this setting.

(2) Solicitation of Public Comments

We are seeking comment on the possibility of providing equity reporting in the ASCQR Program in a way that maximally supports facilities in improving the quality of care for all Medicare beneficiaries, regardless of their socioeconomic status or other risk factors. We are particularly interested in learning about measurement approaches or social risk factors which may permit illuminating social-based disparities in facilities which have relatively few individuals who possess social risk factors. Specifically, we are inviting public comment on the following:

- Ways to address the unique challenges of measuring disparities in the ASC setting, such as small sample sizes, ASC specialization, and the relatively smaller proportion of patients with social risk factors.
- The utility of neighborhood-level socioeconomic factors toward measuring disparities in quality-of-care outcomes for ASCs.
- Ways social risk factors influence the access to care, quality of care and outcomes for ASC patients in general or for specific ASC services.

d. Request for Comment on the Future Development and Inclusion of a Pain Management Measure

Chronic pain is linked to a number of adverse physical and mental conditions[375] [376] [377] [378] and contributes to increased health care costs.[379] An estimated 20.4 percent (50 million) of U.S. adults have chronic pain.[380] As patients with acute and chronic pain continue to face challenges in obtaining adequate care,[381] Congress has advanced policies to improve the treatment of pain and substance use disorders. The Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114–198), the 21st Century Cures Act (Pub. L. 114–225), and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271) outline evidence-based national strategies and prevention toward reducing opioid dependence. In conjunction with the opioid epidemic efforts, the SUPPORT Act also provides guidelines for providers to be prepared to discuss pain management risks and options with patients, including providing referrals to a pain management specialist.[382] As a result of the opioid epidemic and as pain management procedures become more advanced, pain management practices and surgery centers have become increasingly viewed as feasible for the initial treatment of pain as well as for the expansion of non-opioid treatments for pain management.[383] Based on a growing body of evidence on the risks of opioid misuse, we have developed a strategy to impact the national opioid misuse epidemic by combating nonmedical use of prescription opioids, opioid use disorder, and overdose through the promotion of safe and appropriate opioid utilization, improved access to treatment for opioid use disorders, and evidence-based practices for acute and chronic pain management.[384]

With advances in techniques and growing recognition by providers that pain is a treatable condition, pain management services have seen rapid growth as a form of early intervention[385] and more such procedures are being performed in ASCs.[386] ASCs specializing in pain management services are also growing

[374] Bonito A.J., Bann C., Eicheldinger C., Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

[375] Institute of Medicine (US) Committee on Pain, Disability, and Chronic Illness Behavior; Osterweis M, Kleinman A, Mechanic D, editors. Washington (DC): National Academies Press (US); 1987. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK219250/.*

[376] Hooten W.M. Chrnoic Pain and mental Health Disorders: Shared Neural Mechanisms, Epidemiology, and Treatment. (2016). May Clinic Proceedings. Available at: *https://www.mayoclinicproceedings.org/article/S0025-6196(16)30182-3/fulltext.*

[377] De Heer E.W., Gerrits MMJG., Beekman ATF., Dekker J., van Marwijk HWJ., de Waal MWM., Spinhoven P., Penninx BWJH., van der Feltz-Cornelis C.M. (2014). The Association of Depression and Anxiety with Pain: A Study for NESDA. PLOS ONE 9(12): e115077. *https://doi.org/10.1371/journal.pone.0115077.*

[378] Rayner L., Hotopf M., Petkova H., Matcham F., Simpson A., and McCracken L.M. (2016). Depression in patients with chronic pain attending a specialised pain treatment centre: Prevalence and impact on health care costs. Pain; 157(7): 1472–1479. doi: 10.1097/j.pain.0000000000000542.

[379] Gaskin D.J. and Richard P. (2012). The Economic Costs of Pain in the United States. The Journal of Pain; 13(8): 715–724. Available at: *https://www.jpain.org/article/S1526-5900(12)00559-7/pdf#:~:text=The%20additional%20health%20care%20costs,from%20%24299%20to%20%24335%20billion.*

[380] Dahlhamer J., Lucas J., Zelaya, C., et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults—United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:1001–1006. DOI: *http://dx.doi.org/10.15585/mmwr.mm6736a2.*

[381] *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

[382] H.R.6—SUPPORT for Patients and Communities Act. Available at: *https://www.congress.gov/bill/115th-congress/house-bill/6/text.*

[383] MedPac. Report to the Congress: Medicare Payment Policy, Chapter 16: Opioids and alternatives in hospital settings—Payments, incentives, and Medicare data. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch16_sec.pdf?sfvrsn=0.*

[384] CMS Opioid Misuse Strategy 2016. Available at: *https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Prescription-DrugInformation-for-Partners-Items/CMS-OpioidMisuse-Strategy-2016.html.*

[385] Manchikanti, L., Parr A., Singh V., Fellows B. Ambulatory Surgery Centers and Interventional Techniques: A Look at Long-Term Survival. Pain Physician 2011; 14: E177–215. Available at: *https://www.painphysicianjournal.com/current/pdf?article=MTQ1MQ%3D%3D&journal=60.*

[386] Manchikanti, L., Parr A., Singh V., Fellows B. Ambulatory Surgery Centers and Interventional Techniques: A Look at Long-Term Survival. Pain Physician 2011; 14: E177–215. Available at: *https://www.painphysicianjournal.com/current/pdf?article=MTQ1MQ%3D%3D&journal=60.*

as a share of overall ASCs.[387] The most common multispecialty ASCs that focused on two specialties in 2017 were those specializing in pain management and either neurology or orthopedic services.[388]

We internally analyzed CY 2019 and CY 2020 Medicare FFS claims data using the methodology previously adopted for the ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures measure (76 FR 74507 through 74509), which identifies procedure categories for the top 100 current procedural terminology (CPT®) codes reimbursed (we refer readers to Table 55). In our analyses of the Medicare FFS claims data from CY 2019 and CY 2020, we found that overall, the number of procedures declined 22 percent, likely reflecting conditions imposed by the COVID–19 PHE. The rank ordering of the types of procedures performed remained constant for the most part with pain management procedures (contained in the Nervous System category) being the third most commonly performed procedure category with 22.3 percent and 22.6 percent in CY 2019 and CY 2020, respectively.

TABLE 55. ASC Procedures from Medicare FFS Claims for CY 2019 and CY 2020 Based on CPT Codes

CY 2019				CY 2020				% Decline CY 2019 to CY 2020
Procedure Category	# of CPTs	# of Procedures	% of Total Procedures	Procedure Category	# of CPTs	# of Procedures	% of Total Procedures	
Gastrointestinal	15	1,895,911	32.9%	Gastrointestinal	15	1,479,220	32.5%	22.0%
Eye	19	1,864,585	32.3%	Eye	19	1,469,128	32.2%	21.2%
Nervous System	22	1,287,131	22.3%	Nervous System	22	996,813	21.9%	22.6%
Musculoskeletal	14	265,967	4.6%	Musculoskeletal	15	233,791	5.1%	12.1%
Genitourinary	8	169,470	2.9%	Genitourinary	8	143,894	3.2%	15.1%
Skin	8	119,329	2.1%	Skin	9	95,001	2.1%	20.4%
Imaging	7	89,075	1.5%	Imaging	6	66,939	1.5%	24.9%
Dialysis-related	3	51,102	0.9%	Dialysis-related	3	54,749	1.2%	-7.1%
Respiratory	3	20,330	0.4%	Respiratory	2	11,562	0.3%	43.1%
Anesthesia	1	6,635	0.1%	Anesthesia	1	6,062	0.1%	NA
Total	100	5,769,535	100.0%		100	4,557,159	100.0%	22.0%

Thus, we see pain management surgical procedures as a significant portion of procedures performed in the ASC setting and that an applicable measure would provide important quality of care information for a specialty not included in the current ASCQR Program measure set.

We invite public comment on the development and future inclusion of a measure to assess pain management surgical procedures performed in ASCs.

7. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CYs 2012, 2013, 2014, 2015, and 2016 OPPS/ASC final rules with comment period (76 FR 74513 through 74514; 77 FR 68496 through 68497; 78 FR 75131; 79 FR 66981; and 80 FR 70531, respectively) for detailed discussion of our policies regarding the maintenance of technical specifications for the ASCQR Program which are codified at 42 CFR 416.325. We are not proposing any changes to these policies in this proposed rule.

We also refer readers to section XIV. of this proposed rule where we request 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 (as described in that section).

8. Public Reporting of ASCQR Program Data

We refer readers to the CYs 2012, 2016, 2017, and 2018 OPPS/ASC final rules with comment period (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 at 42 CFR 416.315 (80 FR 70533). We are not proposing any changes to these policies in this proposed rule.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133) for a detailed discussion of the QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533), we codified the administrative requirements regarding the maintenance of a QualityNet account and security administrator for the ASCQR Program at § 416.310(c)(1)(i). In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86189), we finalized the use of the term ''security official'' instead of ''security administrator'' to denote the

[387] MedPac. Report to the Congress: Medicare Payment Policy, Chapter 5: Ambulatory Surgical Center Services. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0.*

[388] Report to the Congress: Medicare Payment Policy, Ambulatory Surgical Center Services. March 2019. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0.*

exercise of authority invested in the role. The term ''security official'' refers to ''the individual(s)'' who have responsibilities for security and account management requirements for a facility's QualityNet account. We are not proposing any changes to this policy in this proposed rule.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533 through 70534), we codified these requirements regarding participation status for the ASCQR Program at § 416.305. We are not proposing any changes to these policies in this proposed rule.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Data Collection and Submission

a. Background

We previously codified our existing policies regarding data collection and submission under the ASCQR Program 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 with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program 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 requirements 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 with comment period (82 FR 59472) (and the previous rulemakings cited therein), as well as 42 CFR 416.310(a)(3) and 42 CFR 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. As noted in section XVI.D.1.b., our policies for minimum threshold, minimum case volume, and data completeness 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.

(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 with comment period (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 at § 416.310(b). We note that these requirements for non-QDC based, claims-based measures apply to the following previously adopted measures:

- ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; and
- ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357).

We are not proposing any changes to these requirements 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 with comment period (82 FR 59473) (and the previous rulemakings cited therein) and 42 CFR 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) to host our CMS online data submission tool, available at: *https://qualitynet.cms.gov/*. We note that in the CY 2018 OPPS/ASC final rule with comment period (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). We are not proposing any changes to these policies for data submitted via a CMS online data submission tool in this proposed rule.

The following previously finalized measures require data to be submitted via a CMS online data submission tool for the CY 2021 payment determination and subsequent years:

- ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients;
- ASC–11: Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery;
- ASC–13: Normothermia Outcome; and
- ASC–14: Unplanned Anterior Vitrectomy.

As discussed in section XVI.B.4.a.(2). of this proposed rule, we are proposing to require and resume data collection beginning with the CY 2023 reporting period/CY 2025 payment determination and subsequent years for the following four measures:

- ASC–1: Patient Burn;
- ASC–2: Patient Fall;
- ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- ASC–4: All-Cause Hospital Transfer/Admission.

Measure data for these measures would be submitted via the HQR System (formerly referred to as the QualityNet Secure Portal).

(2) Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS online data submission tool (specifically, the CDC NHSN website). 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 at § 416.310(c)(2). While we are not proposing any changes to those policies in this proposed rule, we are proposing policies specific to the proposed COVID–19 Vaccination Coverage Among HCP measure, for which data would be submitted via the CDC NHSN website.

(a) Proposed Form, Manner, and Timing for the COVID–19 Vaccination Coverage Among HCP Measure Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination and Subsequent Years

For the COVID–19 Vaccination Coverage Among HCP measure, we are proposing to require reporting data on the number of HCP who have received the completed vaccination course of a COVID–19 vaccine by each individual facility's CMS CCN.

We propose that ASCs would report the measure through the NHSN web-based surveillance system.[389] Specifically, ASCs would use the COVID–19 vaccination data reporting modules in the NHSN HPS Component to report the number of HCP eligible to have worked at the ASC that week (denominator) and the number of those HCP who have received COVID–19 vaccination (numerator). Specific details on data submission for this measure can be found in the CDC's Overview of the Healthcare Safety Component, available at: *https://www.cdc.gov/nhsn/PDFs/slides/NHSN-Overview-HPS_Aug2012.pdf*.

For the COVID–19 Vaccination Among HCP measure, we are proposing that ASCs would report the measure to the NHSN for at least one week each month, beginning with the January 1, 2022, through December 31, 2022, reporting period affecting CY 2024 payment determination and continuing with quarterly reporting deadlines for subsequent years. If ASCs report more than one week of data in a month, the most recent week's data would be used for measure calculation purposes. Each quarter, the CDC would calculate a summary measure of COVID–19 vaccination coverage from the reporting periods for the quarter.

With respect to public reporting, this quarterly average COVID–19 vaccination coverage would be publicly reported on the *Care Compare* website in four-quarter increments, when four quarters of data are available. Once four quarters are available, data will be refreshed on a quarterly basis with the most recent four quarters publicly displayed. For each CMS CCN, a percentage of the HCP who received a complete course of the COVID–19 vaccine would be calculated and publicly reported. We invite public comment on our proposal.

[389] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

d. Proposed Form, Manner, and Timing for Reporting the ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures

(1) Background

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79822 through 79824) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures. In addition, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451), where we finalized a policy to delay implementation of the ASC–15a–e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 reporting period) until further action in future rulemaking.

(2) Proposal To Add Data Collection Survey Modes of OAS CAHPS Measures Collection to Existing Three Modes

As discussed in section XVI.B.4.c. of this proposed rule, we are proposing to begin data collection of five survey-based measures derived from the OAS CAHPS Survey for the ASCQR Program beginning with voluntary reporting for the CY 2023 reporting periods/CY 2025 payment determination,[390] followed by mandatory data collection and reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. The OAS CAHPS survey contains three OAS CAHPS composite survey-based measures and two global survey-based measures. In this section, we are proposing requirements related to survey administration, vendors, and oversight activities.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79822 through 79825), we previously discussed the time, form, and manner which OAS CAHPS information will be submitted. We are now proposing two additional data collection modes (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents)[391] beginning with voluntary data collection and reporting for the CY 2023 reporting/CY 2025 payment determination and continuing for mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years, if finalized in section XVI.B.4.c. For more information about the modes of administration, we refer readers to the OAS CAHPS website: *https://oascahps.org*. We reiterate our clarification from when we adopted these measures in the CY 2017 OPPS/ASC final rule that, when implemented, ASCs that anticipate receiving more than 300 surveys would be required to either: (1) Randomly sample their eligible patient population; or (2) survey their entire OAS CAHPS eligible patient population (81 FR 79809). We also refer readers to section XV.D.4.b of this proposed rule where we describe our similar policy for the Hospital OQR Program.

[390] As stated in section XVI.B.4.c., we note that National OAS CAHPS voluntary reporting is independent of the ASCQR Program, but the submission process will otherwise remain unchanged. This proposal is intended to clarify that voluntary reporting of OAS CAHPS would begin as part of the ASCQR program in the CY 2023 reporting period until mandatory reporting would begin in the CY 2024 reporting period, if both proposals are finalized.

(a) Survey Requirements

The data collection for the survey currently has three administration methods: (1) Mail-only; (2) telephone-only; and (3) mixed mode (mail with telephone follow-up of non-respondents). We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (*https://oascahps.org/Survey-Materials*) for materials for each mode of survey administration. In the 2018 OPPS/ASC final rule with comment period, we expressed interest in investigating the feasibility of offering the OAS CAHPS Survey using a web-based format (82 FR 59451). As a result, we designed a mode experiment to assess the impact of adding web-based survey administration. This mode experiment tested five administration modes with patients who receive outpatient surgical care: (1) Mail-only; (2) telephone-only; (3) web-only; (4) web with mail follow-up; and (5) web with a telephone follow-up. Data collection was completed in the fall of 2019. Response rates by mode in the experiment were: 35 percent (mail-only); 19 percent (telephone-only); 29 percent (web-only); 39 percent (web with mail follow-up); and 35 percent (web with telephone follow-up).

Based on these results, in addition to the three previously established modes, in this proposed rule we are proposing to incorporate two additional administration methods: (1) Web with mail follow-up of non-respondents; and

[391] The two additional modes will be available as part of National OAS CAHPS voluntary reporting in 2022.

(2) web with telephone follow-up of non-respondents. This would allow a total of five modes of survey administration for reporting beginning with voluntary data collection and reporting as part of the ASCQR Program for the CY 2023 reporting period [392] and continuing for mandatory data collection and reporting for the CY 2024 reporting period/CY 2026 payment determination—the first year the survey would be required if our proposal in section XVI.B.4.c. is finalized as proposed—and thereafter. We are not proposing a purely web-based format at this time because the use of a web-based mode is included in the two mixed modes options being proposed and the purely web-based format would create response bias since not all patients have the ability to respond by web.

For all five proposed modes of administration as part of the ASCQR Program, we are proposing that data collection must be initiated no later than 21 calendar days after the month in which a patient has a surgery or procedure at an ASC and completed within 6 weeks (42 days) after initial contact of eligible patients begins, beginning with voluntary data collection and reporting in the CY 2023 reporting period/CY 2025 payment determination and subsequent years. Under this proposal, ASCs, via their CMS-approved survey vendors, must make multiple attempts to contact eligible patients unless the patient refuses or the ASC/vendor learns that the patient is ineligible to participate in the survey. In addition, we are proposing that ASCs, via their CMS-approved survey vendor, collect survey data for eligible patients using the established quarterly deadlines to report data to CMS for each data collection period, unless the ASC has been exempted from the OAS CAHPS Survey requirements under our minimum case volume for program participation [393] or our OAS CAHPS low-volume exemption policy, which exempts ACS that treat fewer than 60 survey-eligible patients during the ''eligibility period,'' (which is the calendar year before the data collection period (81 FR 79806)), that submit the participation exemption request form, which will be made available on the OAS CAHPS Survey website (*https://oascahps.org*) on or before May 15 of the data collection year. As finalized previously, all exemption requests would be reviewed and evaluated by CMS (81 FR 79806). For ASCs with minimum case volumes, but without a low-volume exemption, these submission deadlines would be posted on the OAS CAHPS Survey website (*https://oascahps.org*). Late submissions would not be accepted.

As discussed in more detail below, compliance with the OAS CAHPS Survey protocols and guidelines, including this monthly data collection requirement as part of each quarterly data submission, would be overseen by CMS or its contractor who would receive approved vendors' monthly submissions, review the data, and analyze the results. As stated previously (81 FR 79805), all data collection and submission for the OAS CAHPS Survey measures would be reported at the CCN level, and if data collection and reporting becomes mandatory in CY 2024 reporting period/CY 2026 payment determination as proposed, under this proposal, all eligible ASCs in a CCN would be required to participate in the OAS CAHPS Survey, except for those that meet and receive an exception for having fewer than 60 survey-eligible patients during the year preceding the data collection period (81 FR 79806). Therefore, the survey data reported for a CCN must include eligible patients from all eligible ASCs covered by the CCN; or if more than 300 completed surveys are anticipated, an ASC can choose to randomly sample their eligible patient population (81 FR 79817).

In this proposed rule, we also propose that survey vendors acting on behalf of ASCs must submit data by the specified data submission deadlines, which generally would be posted on the Outpatient and Ambulatory Surgery CAHPS Survey website located at *https://oascahps.org/Data-Submission/Data-Submission-Deadlines*. If an ASC's data are submitted after the data submission deadline, it would not fulfill the OAS CAHPS quality reporting requirements. Therefore, in regard to any OAS CAHPS reporting, we would strongly encourage ASCs to be fully appraised of the methods and actions of their survey vendors, especially the vendors' full compliance with OAS CAHPS Survey administration protocols, and to carefully inspect all data warehouse reports in a timely manner.

We reiterate that the use of predictive or auto dialers in telephonic survey administration is governed by the Telephone Consumer Protection Act (TCPA) (47 U.S.C. 227) and subsequent regulations promulgated by the Federal Communications Commission (FCC) (47 CFR 64.1200) and Federal Trade Commission. We refer readers to the FCC's declaratory ruling released on July 10, 2015 further clarifying the definition of an auto dialer, available at: *https://apps.fcc.gov/edocs_public/attachmatch/FCC–15–72A1.pdf*. In the telephone-only and mixed mode survey administration methods involving telephone, ASCs and vendors must comply with the regulations discussed above, and any other applicable regulations. To the extent that any existing CMS technical guidance conflicts with the TCPA or its implementing regulations regarding the use of predictive or auto dialers, or any other applicable law, CMS would expect vendors to comply with applicable law.

We invite comments on our proposals discussed previously.

(b) Vendor Requirements

We are not proposing new vendor requirements, but reiterate the vendor requirements finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79823 through 79824) to ensure that patients respond to the survey in a way that reflects their actual experiences with outpatient care, and is not influenced by the ASC. We finalized that ASCs must contract with a CMS-approved OAS CAHPS Survey vendor to conduct or administer the survey. We believe that a neutral third-party should administer the survey for ASCs, and it is our belief that an experienced survey vendor will be best able to ensure reliable results. CAHPS Survey-approved vendors are also already used or required in the following CMS quality programs: The Hospital Inpatient Quality Reporting Program (71 FR 68203 through 68204); the Hospital Value-Based Purchasing (VBP) Program (76 FR 26497, 26502 through 26503, and 26510); the End Stage Renal Disease Quality Improvement Program (76 FR 70269 through 70270); the Home Health QRP (80 FR 68709 through 68710); and the Hospice QRP (80 FR 47141 through 47207).

Information about the list of approved survey vendors and how to authorize a vendor to collect data on an ASC's behalf is available through the OAS CAHPS Survey website, available at: *https://oascahps.org*. The web portal has both public and secure (restricted access) sections to ensure the security and privacy of selected interactions. As

[392] As stated in section XVI.B.4.c., we note that the two modes (web with mail follow-up of non-respondents; and web with telephone follow-up of non-respondents) will be available beginning in CY 2022 for National OAS CAHPS voluntary reporting, and then if finalized, available as part of ASCQR Program beginning in the CY 2023 reporting period and subsequent years.

[393] ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) per year during an annual reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent annual reporting period for that subsequent payment determination year. See 42 CFR 416.305.

mentioned earlier, requirements for survey vendors were previously finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79793 through 79794) and codified at § 416.310(e)(2). ASCs will need to register on the OAS CAHPS Survey website (*https://oascahps.org*) in order to authorize the CMS-approved vendor to administer the survey and submit data on their behalf. Each ASC must then administer (via its vendor) the survey to eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (*https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website.

e. ASCQR Program Data Submission Deadlines

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86191) we finalized that all program deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Act, 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days.'' Specifically, the Act indicates that 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, shall 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 (42 U.S.C. 416(j)). We codified this policy 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

(1) Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool

Under the ASCQR Program, for measures submitted via a CMS online data submission tool, ASCs submit measure data to CMS from January 1 through May 15 during the calendar year subsequent to the current data collection period (84 FR 61432).[394] For example, ASCs collect measure data from January 1, 2020 through December 31, 2020 and submit these data to CMS from January 1, 2021 through May 15, 2021. ASCs may begin submitting data to CMS as early as January 1. ASCs are encouraged, but not required, to submit data early in the submission period so that they can identify errors and resubmit data before the established submission deadline.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86191 through 86192), we finalized the formalization of that process and established a review and corrections period similar to what was finalized for the Hospital OQR Program in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86184) for data submitted via the CMS web-based tool. For the ASCQR Program, we finalized the implementation of a review and corrections period which runs concurrently with the data submission period beginning with the effective date of this rule. During this review and corrections period, ASCs may enter, review, and correct data submitted directly to CMS. However, after the submission deadline, ASCs are not allowed to change these data. We codified this review and corrections period at § 416.310(c)(1)(iii). We are not proposing any changes to this policy in this proposed rule.

(2) Review and Corrections Period for the OAS CAHPS Measures

Each ASC administers (via its vendor) the survey to all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (available at: *https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website as stated above in section XVI.D.1.d.(2).(b). Data cannot be altered after the data submission deadline but can be reviewed prior to the submission deadline (81 FR 79822 through 79823).

g. ASCQR Program Reconsideration Procedures

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (82 FR 59475) (and the previous rulemakings cited therein) and 42 CFR 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 for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475) (and the previous rulemakings cited therein) and 42 CFR 416.310(d) for the ASCQR Program's policies for extraordinary circumstance exceptions (ECE) requests. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475), we: (1) Changed the name of this policy from ''extraordinary circumstances extensions or exemption'' to ''extraordinary circumstances exceptions'' for the ASCQR Program, beginning January 1, 2018; and (2) revised § 416.310(d) of our regulations to reflect this change. We will strive to complete our review of each request within 90 days of receipt. We are not proposing any changes to this policy in this proposed rule.

E. Proposed Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499) 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 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

[394] ASCQR Program Data Submission Deadlines. Available at: *https://qualitynet.cms.gov/asc/data-submission#tab2*.

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 our proposal that we would calculate two conversion factors: A full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the 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. We finalized our proposal 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, 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 believe 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 that 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 2021 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 CY 2022.

XVII. Request for Information on Rural Emergency Hospitals

A. Background

Americans who live in rural areas of the nation make up about 20 percent of the United States population, and they often experience shorter life expectancy, higher all-cause mortality, higher rates of poverty, fewer local doctors, and greater distances to travel to see healthcare providers, than do their urban and suburban counterparts.[395]

The healthcare inequities that many rural Americans face raise serious concerns that the trend for poor healthcare access and worse outcomes overall in rural areas will continue unless the potential causes of such healthcare inequities are addressed.

In addition, one in five rural residents identifies as Black, Hispanic, American Indian/Alaska Native (AI/AN), Asian American/Pacific Islander (AA/PI), or a combination of ethnic backgrounds. Compared to the non-Hispanic White rural population, these minority groups often and regularly experience several disadvantageous social determinants of health.[396]

Rural hospitals are essential to providing health care to their communities and the closure of these hospitals limits access to care for the communities they once served and reduces employment opportunities, further impacting local economies. Barriers to accessing health services can

[395] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[396] Rural Health Research Gateway. (2020). Rural Ethnic/Racial Disparities: Adverse Health Outcomes. *https://www.ruralhealthresearch.org/assets/3973-16600/rural-ethnic-racial-disparities-health-recap.pdf.*

lead to unmet health needs, delays in receiving appropriate care, inability to get preventive services, financial burdens, and preventable hospitalizations.[397] Healthcare workforce shortages can also significantly impact healthcare access in rural communities.[398] As of March 2021, 61.47 percent of Primary Medical Health Professional Shortage Areas (HPSAs) were located in rural areas.[399]

The Consolidated Appropriations Act (CAA), 2021, was signed into law in December 2020. In this legislation, Congress established a new Medicare provider type: Rural Emergency Hospitals (REHs). Section 125 of the CAA, 2021, Division CC, defines an REH as a facility that: Is enrolled in the Medicare program on or after January 1, 2023; does 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 (SNF)); has a transfer agreement in effect with a level I or level II trauma center; meets certain licensure requirements; meets requirements to be a staffed emergency department; meets staff training and certification requirements established by the Secretary; and meets certain conditions of participation (CoPs) applicable to hospital emergency departments and critical access hospitals (CAHs) with respect to emergency services. CAHs and small rural hospitals that convert to REHs may furnish rural emergency hospital services for Medicare payment beginning in 2023.

The Secretary is required to establish quality measurement reporting requirements for REHs, which may include claims-based measures and/or patient experience surveys. An REH is required to submit quality measure data to the Secretary, and the Secretary shall establish procedures to make the data available to the public on the CMS website.

The Quality Improvement Organization requirements established at section 1156(a) of the Social Security Act (the Act) shall apply to REHs in the same manner that they apply to hospitals and CAHs, in accordance with section 125(b)(1) of the CAA. In addition, the requirements established at section 1864 of the Act for hospitals and CAHs to be surveyed for compliance with the CoPs shall apply to REHs in the same manner as other hospitals and CAHs, in accordance with section 125(d)(2) of the CAA.

Additionally, section 125 of the CAA, 2021, requires that REHs provide emergency department services and observation services, and, at the election of the REH, other medical and health services furnished on an outpatient basis, as specified by the Secretary. The REH must also have a staffed emergency department 24 hours a day, 7 days a week, with staffing requirements similar to those for CAHs.[400]

In order to become an REH, a provider must, on the date of enactment of the CAA, 2021 (December 27, 2020), either already be a CAH or a rural subsection (d) hospital with not more than 50 beds. In addition, the REH must meet certain other requirements, including, but not limited to the following:

- An annual per patient average of 24 hours or less in the REH;
- staff training and certification requirements established by the Secretary;
- emergency services CoPs applicable to CAHs;
- hospital emergency department CoPs determined applicable by the Secretary;
- the applicable SNF requirements (if the REH includes a distinct part SNF);
- a transfer agreement with a level I or level II trauma center; and
- any other requirements the Secretary finds necessary in the interest of the health and safety of individuals who are furnished REH services.

Starting on January 1, 2023, an REH that provides rural emergency hospital services (as defined in section 1861(kkk)(1) of the Act) will receive a Medicare payment for those services pursuant to section 1843(x)(1) of the Act that reflects a 5 percent increase over the payment rate the provider would otherwise receive through the OPPS. Any co-payments for these services will be calculated based on the standard OPPS rate for the service excluding the 5 percent payment increase.

REHs also will receive an additional facility payment pursuant to section 1834(x)(2) of the Act. The annual payment amount will be determined based on the excess (if any) of the total amount that was paid to all CAHs in 2019 over the estimated total amount that would have been paid to CAHs in 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during such year. This excess amount is divided by the total number of CAHs in 2019. After the initial Medicare subsidy amount is calculated for CY 2023, the additional facility payments in subsequent years will increase by the hospital market basket percentage increase. REHs will receive these additional facility payments in twelve monthly installments. REHs also will be required to maintain detailed information as to how they have used these payments.

B. Solicitation of Public Comments

Under the statute, in addition to the applicable mandatory CAH requirements (42 CFR part 485, subpart F), hospital emergency services requirements (42 CFR 482.55) and SNF requirements (42 CFR part 483, subpart B), the Secretary has discretion to determine what, if any, additional health and safety requirements should apply to REHs. We are soliciting stakeholder input as we consider the health and safety standards that, in accordance with the statute, should apply to REHs in order for them to be certified to participate in the Medicare program. We are also seeking broad input on the concerns of rural providers that should be taken into consideration by CMS in establishing additional CoPs for REHs. Specifically, we are asking for stakeholder input on the following questions:

Type and Scope of Services Offered

1. What are the barriers and challenges to delivering emergency department services customarily provided by hospitals and CAHs in rural and underserved communities that may require different or additional CoPs for REHs (for example, staffing shortages, transportation, and sufficient resources)?

2. An REH must provide emergency and observation services and may elect to provide additional services as determined appropriate by the Secretary. What other outpatient medical and health services, including behavioral health services, should the Secretary consider as additional eligible services? In particular, what other services may otherwise have a lack of access for Medicare beneficiaries if an REH does not provide them?

[397] Healthy People 2020 (n.d.) Access to Health Services. *https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services.*

[398] Hempel S., Gibbons M.M., Ulloa J.G., et al. Rural Healthcare Workforce: A Systematic Review [Internet]. Washington (DC): Department of Veterans Affairs (U.S.); 2015 Dec. INTRODUCTION. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK409502/.*

[399] Health Resources and Services Administration. (2021). HRSA Data Warehouse: Designated Health Professional Shortage Areas Statistics. *https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport.*

[400] *Congress.gov.* (2020). H.R.133—Consolidated Appropriations Act, 2021. *https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf.*

3. What, if any, virtual or telehealth services would be appropriate for REHs to provide, and what role could virtual care play in REHs??

4. Should REHs include Opioid Treatment Programs, clinics for buprenorphine induction, or clinics for treating stimulant addiction in their scope of services? Please discuss the barriers that could prevent inclusion of each of these types of services.

5. What, if any, maternal health services would be appropriate for REHs to provide and how can REHs address the maternal health needs in rural communities? What unique challenges or concerns will the providing of care to the maternal health population present for an REH?

Health and Safety Standards, Including Licensure and Conditions of Participation

6. The statute requires that REHs meet the requirements for emergency services (set forth at § 485.618) that apply to CAHs. Which hospital emergency department requirements (set forth at § 482.55) should or should not be mandated for REHs and why or why not? Are there additional health and safety standards that should be considered? What are they, why are they important, and are there data that speak to the need for a particular standard?

7. The REH must meet staff training and certification requirements established by the Secretary. Should these be the same as, or similar to, CAH requirements (*Personnel qualifications,* § 485.604 and *Staffing and staff responsibilities,* § 485.631)? Are there additional or different staff training and certification requirements that should be considered for REHs and why? Are there any staffing concerns that the existing CAH requirements would not address?

8. What additional considerations should CMS be aware of as it evaluates the establishment of CoPs for REHs? Are there data and/or research of which we should particularly be aware?

9. What, if any, lessons have been learned as they relate to rural emergency services during the COVID–19 pandemic that might be pertinent to consider for policy implementation after the Public Health Emergency?

10. Are there state licensure concerns for hospitals and CAHs that wish to become REHs? What issues with respect to existing or potential state licensure requirements should CMS consider when developing the CoPs for this new provider type? What supports and timelines should be in place for States to establish licensing rules?

Health Equity

On January 20 and 21, 2021, President Biden issued three executive orders related to issues of health equity: Executive Order 13985 ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'';[401] Executive Order 13988, ''Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation'';[402] and Executive Order 13995 ''Ensuring an Equitable Pandemic Response and Recovery''.[403]

Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'' requires the Federal Government to pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality by recognizing and working to redress inequities in its policies and programs that serve as barriers to equal opportunity. In accordance with this Executive order, persons who live in rural areas are identified as belonging to underserved communities that have been adversely affected by inequality.

Executive Order 13988, ''Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation'' requires the Federal Government to prevent and combat discrimination, including when accessing healthcare, on the basis of gender identity or sexual orientation, and to fully enforce Title VII of the Civil Rights Act. This Executive order also requires the Federal Government to fully enforce other laws that prohibit discrimination on the basis of gender identity or sexual orientation, all of which impact all persons, including those in rural communities.

In accordance with Executive Order 13995, ''Ensuring an Equitable Pandemic Response and Recovery,'' the Federal Government must identify and eliminate health and social inequities resulting in disproportionately higher rates of exposure, illness, and death related to COVID–19 and take swift action to prevent and remedy differences in COVID–19 care and outcomes within communities of color and other underserved populations. The Executive order highlights the observed inequities in rural and Tribal communities, territories, and other geographically isolated communities which would have an impact on REHs given the rural communities they will serve.

Consistent with these Executive orders, we are committed to advancing equity for all, including racial and ethnic minorities, members of the lesbian, gay, bisexual, transgendered, and queer/questioning (LGBTQ) community, people with limited English proficiency, people with disabilities, rural populations, and people otherwise adversely affected by persistent poverty or inequality. We are, therefore, asking for public comments on the following health equity focused issues:

11. How can REHs address the social needs arising in rural areas from challenging social determinants of health, which are the conditions in which people are born, live, learn, work, play, worship, and age, and which can have a profound impact on patients' health, ensuring that REHs are held accountable for health equity?

12. With respect to questions 1 through 11 above, are there additional factors we should consider for specific populations including, but not limited to, elderly and pediatric patients; homeless persons; racial, ethnic, sexual, or gender minorities; veterans; and persons with physical, behavioral (for example, mental health conditions and substance use disorders), and/or intellectual and developmental disabilities?

13. How can the CoPs ensure that an REH's executive leadership (that is, its governance, or persons legally responsible for the REH) is fully invested in and held accountable for implementing policies that will reduce health disparities within the facility and the community that it serves? In addition, with regards to governance and leadership, how can the CoPs:

- Encourage a REH's executive leadership to utilize diversity and inclusion strategies to establish a diverse workforce that is reflective of the community that it serves;

[401] The White House. (2021). Briefing Room: Executive Order ON Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[402] The White House. (2021). Briefing Room: Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-preventing-and-combating-discrimination-on-basis-of-gender-identity-or-sexual-orientation/.*

[403] The White House. (2021). Briefing Room: Executive Order on Ensuring an Equitable Pandemic Response and Recovery. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-ensuring-an-equitable-pandemic-response-and-recovery/.*

• Ensure that health equity is embedded into a facility's strategic planning and quality improvement efforts; and

• Ensure that executive leadership is held accountable for reducing health disparities?

14. An important first step in addressing health disparities and improving health outcomes is to begin considering a patient's post-discharge needs and social determinants of health prior to discharge from a facility. How can health equity be advanced through the care planning and discharge planning process? How can the CoPs address the need for REHs to partner with community-based organizations in order to improve a patient's care and outcomes after discharge?

15. In order to ensure that health care workers understand and incorporate health equity concepts as they provide culturally competent care to patients, and in order to mitigate potential implicit and explicit bias that may exist in healthcare, what types of staff training or other efforts would be helpful?

16. Finally, how can the CoPs ensure that providers offer fully accessible services for their patients in terms of physical, communication, and language access with the resources they have available to them?

Collaboration and Care Coordination

17. How can CMS and other Federal agencies best encourage and incentivize collaboration and coordination between an REH and the healthcare providers, entities, or organizations with which an REH routinely works (for example, requirements related to the Emergency Medical Treatment and Active Labor Act, transfer agreements, and participation in EMS protocols), to help the REH successfully fulfill its role in its community? Healthcare providers, entities, and organizations with which an REH might typically work and interact might include, for example, federally qualified health centers, rural health clinics, state and local public health departments, Veterans Administration and Indian Health Service facilities, primary care and oral health providers, transportation, education, employment and housing providers, faith-based entities, and others.

Quality Measurement

The CAA also contains provisions regarding the establishment of quality measurement requirements for REHs, including quality reporting requirements, specification of quality measures, and public availability of quality reporting data. As a result, we are also seeking broad input on the concerns of rural providers that should be taken into consideration by CMS in establishing quality measures and quality reporting requirements for REHs. Specifically, we are asking for stakeholder input on the following questions:

18. What existing quality measures that reflect the care provided in rural emergency department settings can be recommended? What existing quality measures from other quality reporting programs, such as the Hospital Inpatient Quality Reporting and Hospital Outpatient Quality Reporting Programs, are relevant to the services that are likely to be furnished in REHs and should be considered for adoption in the REH context? What measures, specific to REHs, should be developed?

19. Based on experiences in quality reporting by small rural hospitals and CAHs, what barriers and challenges to quality reporting are REHs likely to encounter? What quality reporting strategies should CMS consider to mitigate those barriers?

20. For CAHs, what are the barriers and challenges to electronic submission of quality measures, and will those barriers likely apply to REHs? What similar barriers and challenges could CAHs and REHs experience for chart abstracted measures?

21. What factors should be considered for the baseline measure set and how should CMS assess expanding quality measures for REHs? How could quality measures support survey and certification for REHs?

22. What additional incentives and disincentives for quality reporting unrelated to payment would be appropriate for REHs? Are there limitations or lower limits based on case volume/mix or geographic distance that would be appropriate for CMS to consider when assessing the quality performance of REHs?

23. The inclusion of CAHs within the Overall Hospital Quality Star Ratings provides patients with greater transparency on the performance of CAHs that provide acute inpatient and outpatient care in their area. What factors should CMS consider in determining how to publicly report REH quality measure data?

Payment Provisions

We are also soliciting stakeholder input regarding the payment provisions established for rural emergency hospitals and that will go into effect for items and services furnished on or after January 1, 2023. Specifically, we are asking for stakeholder input on the following items:

24. Under the law, only existing critical access hospital or subsection (d) hospitals with not more than 50 beds that are located in a rural area are eligible to convert to an REH. While REHs will receive the applicable OPPS rate that would otherwise apply under section 1833(t)(1) of the Act and with an increase of 5 percent under section 1834(x)(1) of the Act as well as an additional facility payment to be made on a monthly basis under section 1834(x)(2) of the Act, we note that rural sole community hospitals (SCHs) currently receive an additional 7.1 percent payment for all services paid through the OPPS. We are seeking comment on the likelihood of rural SCHs deciding to seek to become REHs.

25. In order to calculate the additional annual facility payment for rural emergency hospitals required by section 1834(x)(2) of the Act, CMS will need to compare all CY 2019 payments to CAHs with an estimate of the total amount of payment that would have been made to CAHs in CY 2019 if CAHs were paid through the inpatient, outpatient, and skilled nursing facility prospective payment systems, rather than receiving Medicare payment at 101 percent of the reasonable costs of these services. Are there any claims or other payment reporting issues that CMS should consider when calculating the hypothetical estimated payment under the prospective payment systems for services furnished by CAHs in CY 2019?

26. We also are seeking comment on whether the claims forms used by CAHs to report inpatient hospital services, outpatient hospital services, and skilled nursing services contain all of the necessary information in order that the claims could be processed by the applicable CMS prospective payment systems. We are seeking this information because section 1834(x)(2)(C) of the Act requires as a part of the calculation to determine the additional facility payment for CY 2023 for CMS to estimate what CAHs would have received for payment of inpatient hospital services, outpatient hospital services, and skilled nursing facility services if those services were paid through their respective prospective payment systems. We want to know what barriers, if any, we may face when attempting to use CAH claims to perform this calculation. If the CAH claims are missing information that would be required to process the claims through a prospective payment system, what challenges could CAHs face in collecting the missing information and submitting it to CMS for processing?

27. The statute requires that a facility seeking to enroll as an REH must provide information regarding how the facility intends to use the additional facility payment provided under section 1834(x)(2) of the Act, including a detailed description of the services that the additional facility payment would be supporting, such as furnishing of telehealth and ambulance services, including operating the facility and maintaining the emergency department to provide covered services. What challenges will providers face to maintain and submit what will likely be similar detailed information about how their facility has spent the additional facility payment for rural emergency hospitals as required by section 1834(x)(2)(D) of the Act? What assistance or guidance should HHS consider providing to facilities to meet this reporting requirement?

Enrollment Process

28. The statute requires that an eligible facility must submit an application to enroll as an REH in a form determined by the Secretary. In accordance with the requirements of the CAA, the application for enrollment must include an action plan for initiating REH services, including a detailed transition plan that lists the specific services that the facility will retain, modify, add and discontinue. What suggestions do facilities who are considering enrolling as REHs want us to take into account in developing the enrollment requirements?

29. What considerations should be taken into account regarding the steps and timing for conversion to an REH?

CMS appreciates comments and feedback as we work towards developing new health and safety standards for REHs and establishing payment rules to implement the statutory payment methodology. In accordance with the statute, CMS intends to engage in rulemaking to implement these provisions. We intend to consider the comments received in response to this request for information to inform the development of a proposed rule that will solicit comments on the implementation of this new provider type. In accordance with the statute, we will propose and finalize provisions establishing and governing REHs in time for the statutorily required effective date of January 1, 2023.

XVIII. Radiation Oncology Model

A. Introduction

On September 29, 2020, the Centers for Medicare & Medicaid Services (CMS) published in the **Federal Register** the final rule entitled ''Specialty Care Models to Improve Quality of Care and Reduce Expenditures,'' hereafter referred to as the Specialty Care Models Rule (85 FR 61114) and codified policies at 42 CFR part 512. The Radiation Oncology (RO) Model is designed to test whether prospective episode-based payments for radiotherapy (RT) services (also referred to as radiation therapy services) will reduce Medicare program expenditures and preserve or enhance quality of care for beneficiaries. As radiation oncology is highly technical and furnished in well-defined episodes, and because patient comorbidities generally do not influence treatment delivery decisions, we believe that radiation oncology is well-suited for testing a prospective episode payment model. Under the RO Model, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare fee-for service (FFS) beneficiaries diagnosed with certain cancer types. The RO Model will include 30 percent of all eligible RO episodes (these occur in 204 eligible Core-Based Statistical Areas (CBSAs) in 48 states and the District of Columbia). We finalized that the base payment amounts for RT services included in the RO Model would be the same for hospital outpatient departments (HOPDs) and freestanding radiation therapy centers. We finalized that the model performance period [404] for the RO Model would be five performance years (PYs), beginning January 1, 2021, and ending December 31, 2025, with final data submission of clinical data elements and quality measures in 2026 to account for episodes ending in 2025.

To ensure that participation in the RO Model during the public health emergency (PHE) for the Coronavirus disease 2019 (COVID–19) pandemic did not further strain RO participants' capacity, CMS revised the RO Model's model performance period to begin on July 1, 2021, and end December 31, 2025, in the Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs final rule with comment period (CMS–1736–IFC) (85 FR 85866) (hereinafter referred to as ''CY 2021 OPPS/ASC final rule''). In the CY 2021 OPPS/ASC final rule, we changed the duration of the model performance period from 5 years to 4.5 years, changed the timelines for the submission of clinical data elements, quality measures and Certified Electronic Health Record Technology (CEHRT) requirements, and modified the eligibility dates of the RO Model as an Advanced Alternative Payment Model (APM) and Merit-based Incentive Payment System (MIPS) APM (85 FR 85866).

Section 133 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260), enacted on December 27, 2020, included a provision that prohibits implementation of the RO Model before January 1, 2022. This Congressional action supersedes the RO Model delayed start date established in the CY 2021 OPPS/ASC final rule. In this proposed rule, we are proposing provisions related to the additional delayed implementation due to the CAA, 2021, as well as modifications to certain RO Model policies not related to the delay. We are proposing to modify §§ 512.205, 512.210, 512.217, 512.220, 512.230, 512.240, 512.245, 512.250, 512.255, 512.275, 512.280, and 512.285 and add §§ 512.292 and 512.294.

B. Background

We are committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries while reducing costs. Accordingly, as part of that effort, we have in recent years undertaken a number of initiatives to improve cancer treatment, most notably with our Oncology Care Model (OCM). We believe that a model in radiation oncology will further these efforts to improve cancer care for Medicare beneficiaries and reduce Medicare expenditures.

Radiotherapy is a common treatment, received by nearly two thirds of all patients undergoing cancer treatment, and it is typically furnished by a radiation oncologist.[405] [406] As described in the 2017 REPORT TO CONGRESS: Episodic Alternative Payment Model for Radiation Therapy Services and the Specialty Care Models (Proposed Rule), CMS–5527–P (84 FR 34490), because there are differences in the underlying methodologies used for rate setting in the OPPS and Physician Fee Schedule (PFS), there often are differences in the payment rate for the same RT service depending on whether the service is furnished in a freestanding radiation

[404] CMS has made a stylistic change to this term. CMS changed ''Model performance period'' to ''model performance period'' to be consistent with other CMMI Models.

[405] Physician Characteristics and Distribution in the U.5., 2010 Edition, 2004 IMV Medical Information Division, 2003 SROA Benchmarking Survey.

[406] 2012/13 Radiation Therapy Benchmark Report, IMV Medical Information Division, Inc. (2013).

therapy center paid under the PFS, or an HOPD paid under the OPPS. This is called the site-of-service payment differential, and stakeholders from freestanding radiation therapy centers have asserted that such differentials between HOPDs and freestanding radiation therapy centers are unwarranted because the actual treatment and care received by patients for a given modality is the same in each setting.

For these reasons, the RO Model is designed to test whether making site-neutral, prospective episode-based payments to HOPDs, physician group practices (PGPs), and freestanding radiation therapy centers for RT episodes of care preserves or enhances the quality of care furnished to Medicare beneficiaries while reducing or maintaining Medicare program spending.

C. RO Model Proposed Regulations

1. Proposed Model Performance Period

In the Specialty Care Models Rule, we specified at § 512.205 that the model performance period would last five performance years, beginning January 1, 2021, and ending December 31, 2025 (85 FR 61367). We finalized that each PY is the 12-month period beginning on January 1 and ending on December 31 of each CY during the model performance period, and no new RO episodes may begin after October 3, 2025, in order for all RO episodes to end by December 31, 2025.

In the CY 2021 OPPS/ASC final rule, we amended the definition of model performance period, specifying that it would begin July 1, 2021 and end on December 31, 2025, and we amended the definition of PY to mean the 6-month period beginning on July 1, 2021, and ending on December 31, 2021, and the 12-month period beginning on January 1 and ending on December 31 of each subsequent year (2022 through 2025) during the model performance period.

Section 133 of the CAA 2021 prohibits implementation of the RO Model prior to January 1, 2022. We are proposing to begin the RO Model as soon as we are permitted to do so by law, on January 1, 2022, as we continue to believe that a prospective episode payment model is needed and well suited to be tested in the radiation oncology space. We are proposing to modify the model performance period to begin on January 1, 2022, and end December 31, 2026 as described in detail in the proposed definitions in section XVIII.C.2. No new RO episodes may begin after October 3, 2026, in order for all RO episodes to end by December 31, 2026. We are also proposing that each PY will be a 12-month period beginning on January 1 and ending on December 31 of each year during the model performance period, unless the initial model performance period starts mid-year, in which case PY1 will begin on that date and end on December 31 of that year.

We invite public comments on these proposals related to the dates associated with the model performance period.

2. Proposed Definitions

We codified at § 512.205 definitions for the RO Model. We are proposing to modify some of these definitions in this proposed rule and add a definition for baseline period, as described in more detail later in this section of the preamble. We are also proposing to add a definition for ''EUC'' (extreme and uncontrollable circumstances) to correspond with the proposed EUC policy described in more detail in section XVIII.C.10 of this proposed rule. To describe how changes in CMS Certification Numbers (CCNs) and Tax Identification Numbers (TINs) are treated under the RO Model, which is described in more detail in section XVIII.C.5.g of this proposed rule, we are also proposing to add definitions for ''legacy CCN'' and ''legacy TIN''. And, to clarify how RO Model requirements align with the Quality Payment Program (QPP), we are proposing to add definitions for ''Track One'' and ''Track Two'' as described in section XVIII.C.7 of this proposed rule.

We are proposing to add a definition for ''baseline period'', specifying which episodes (dependent on the model performance period) are used in the pricing methodology. We propose to define ''baseline period'' to mean the three calendar year (CY) period that begins on January 1 no fewer than 5 years but no more than 6 years prior to the start of the model performance period during which episodes must initiate in order to be used in the calculation of the national base rates, participant-specific professional and technical historical experience adjustments for the model performance period, and the participant-specific professional and technical case mix adjustments for PY1. The baseline period would be January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in CY 2022, in which case the baseline period would be adjusted according to the new model performance period (that is, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

We propose to modify the definition of the ''model performance period'' to mean the five PYs during which RO episodes must initiate and terminate. The model performance period would begin on January 1, 2022 and end on December 31, 2026, unless the RO Model is prohibited by law from starting on January 1, 2022, in which case the model performance period would begin on the earliest date permitted by law that is January 1, April 1, or July 1.

We propose to modify the definition of ''PY'' (performance year) to mean each 12-month period beginning on January 1 and ending on December 31 during the model performance period, unless the model performance period begins on a date other than January 1, in which case, the first performance year (PY1) would begin on that date and end on December 31 of the same year.

We propose to modify the definition of ''stop-loss reconciliation amount'' to mean the amount set forth in § 512.285(f) owed by CMS for the loss incurred under the Model to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation.

We invite public comments on these proposed definitions.

3. Proposed RO Model Participant Exclusions

At § 512.210(b), we exclude from the RO Model any PGP, freestanding radiation therapy center, or HOPD that furnishes RT only in Maryland; furnishes RT only in Vermont; furnishes RT only in United States (U.S.) Territories; is classified as an ambulatory surgical center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or participates in or is identified by CMS as eligible to participate in the Pennsylvania Rural Health Model (PARHM).

a. Pennsylvania Rural Health Model (PARHM)

We are proposing to modify § 512.210(b)(5) to exclude from the RO Model only the HOPDs that are participating in PARHM, rather than excluding both HOPDs that are participating in PARHM and those that have been identified by CMS as eligible to participate in PARHM. We continue to believe that HOPDs that are participating in PARHM should be excluded from the RO Model because these hospitals receive global budgets,

and these global budgets would include payments for RT services and as such would overlap with the RO Model payment. In the Specialty Care Models final rule, we also excluded HOPDs that are eligible to participate in the PARHM from the RO Model on the grounds that additional hospitals and CAHs may join PARHM in the future or may be included in the evaluation comparison group for that model (see 85 FR 61144).

However, after further consideration, we believe that including in the RO Model those HOPDs that have been identified as eligible to participate in PARHM, but that are not actually participating in PARHM because they are not currently a party to a PARHM participation agreement with CMS, would not affect the PARHM evaluation. First, such HOPDs do not receive global budgets under PARHM, so including these hospitals in the RO Model would not result in an overlap between PARHM payments and RO Model payments. Second, while we initially explored the potential for HOPDs that are eligible to participate in PARHM being included in that model's evaluation comparison group, we now expect that the PARHM comparison group will consist only of hospitals located outside of Pennsylvania because of selection constraints. Thus, it is now our expectation that HOPDs that have been identified as eligible to participate in PARHM—all of which are located within the Commonwealth of Pennsylvania—would not be selected for the comparison group for the PARHM evaluation. Accordingly, we do not expect that including in the RO Model those HOPDs that have been identified as eligible to participate, but not actually participating in, PARHM would affect the ability to detect the impact of PARHM on the cost and quality of care.

In addition, while it remains the case that hospitals and CAHs may join PARHM on an ongoing basis, hospitals and CAHs generally join PARHM at the start of a given CY. Because the RO Model's PYs would align with CYs, we have concluded it would be possible to update the RO Model exclusions for a given PY if an HOPD leaves or joins PARHM. For instance, if a rural hospital identified as eligible to participate in PARHM later initiates its participation in PARHM by signing a PARHM participation agreement with CMS, then the HOPDs participating in PARHM as part of that participating rural hospital would be excluded from participation in the RO Model as of the start of the next CY quarter that follows the date that the HOPD begins participating in PARHM. Similarly, if an HOPD no longer participates in PARHM as part of a participating rural hospital, and the HOPD otherwise meets the definition of an RO participant, then the HOPD would be required to participate in the RO Model as of the start of the next CY quarter.

We would continue to use the list on the PARHM website at *https://innovation.cms.gov/initiatives/pa-rural-health-model/*, which is updated quarterly, to identify the hospitals that are participating in PARHM, and therefore identify the specific HOPDs excluded from participation in the RO Model. We therefore are proposing that HOPDs that are identified as eligible to participate in PARHM, but that are not current PARHM participants, should be included in the RO Model if they are located in a CBSA selected for participation in the RO Model and that this exclusion of HOPDs associated with hospitals that participate in PARHM from the RO Model would apply only during the period of such participation.

We invite public comments on the inclusion of HOPDs eligible to participate in PARHM, but that are not current PARHM participants in the RO Model.

b. Community Health Access and Rural Transformation Model

We are also proposing to modify the exclusions from the RO Model at § 512.210(b)(6) so that the HOPD of any participating hospital in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model is excluded from the RO Model. Specifically, for any CHART Community Transformation Track performance period during which a hospital is participating in the CHART Model, the HOPD would be excluded from the RO Model. We are proposing to exclude these ''CHART HOPDs'' because these hospitals will receive prospective capitated payments, including HOPD-based RT services, that are not retrospectively reconciled based on experience during the CHART performance year, rather future payments are adjusted based on changes in population and proportion of services that participating HOPDs provide. We are proposing to exclude CHART HOPDs to avoid double payment for the same services. The participating hospitals will be listed and updated on the CHART Model website at *https://innovation.cms.gov/innovation-models/chart-model*. For the CHART ACO Transformation Track, we will follow the same policy for overlap between the RO Model and the Medicare Shared Savings Program ACOs, which was finalized at 85 FR 61260.

We invite public comments on the exclusion of HOPDs the HOPD of any participating hospital in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model from the RO Model.

c. Low Volume Opt-Out

We codified at § 512.210(c) that a PGP, freestanding radiation therapy center, or HOPD, which would otherwise be required to participate in the RO Model may choose to opt out of the RO Model for a given PY if it has fewer than 20 episodes of RT services across all CBSAs selected for participation in the most recent year with claims data available prior to the applicable PY. In the CY 2021 OPPS/ASC final rule (85 FR 86261), we amended this policy at § 512.210(c) to clarify the type of episodes used to determine eligibility for the low volume opt-out in each performance year, where episodes, as defined at § 512.205, are used to determine eligibility in PY1 and PY2 and RO episodes, as defined at § 512.205 and described at § 512.245(a), are used to determine eligibility in PY4 and PY5, and both episodes and RO episodes are used to determine eligibility in PY3. Specifically, for PY3, eligibility for the low volume opt-out is determined by counting episodes from January 1, 2021 through June 30, 2021 and RO episodes from July 1, 2021 through December 31, 2021.

Because section 133 of the CAA 2021 prohibits implementation of the RO Model prior to January 1, 2022, in this proposed rule, we are again clarifying the dates of the data used to determine eligibility for the low volume opt-out. A PGP, freestanding radiation therapy center, or HOPD, which would otherwise be required to participate in the RO Model may choose to opt-out of the RO Model for a given PY if it has fewer than 20 episodes or RO episodes, as applicable, depending on the PY, across all CBSAs selected for participation in the most recent year with claims data available, which is 2 years prior to the applicable PY. At least 30 days prior to the start of each PY, CMS will notify RO participants eligible for the low volume opt-out for the upcoming PY. If the RO participant wishes to opt out, it must attest that it intends to do so prior to the start of the upcoming PY. We are further clarifying that episodes furnished prior to the start of the model performance period in CBSAs selected for participation will be used to determine the eligibility of the low volume opt-out for PY1 and PY2. If PY1 begins on January 1, RO episodes will be used to determine the eligibility of the low volume opt-out for PY3. If

PY1 begins on any date other than January 1, both RO episodes of PY1 and episodes occurring in the CY of PY1 (but occurring prior to the start of PY1 in that year) in CBSAs selected for participation will be used to determine the eligibility of the low volume opt-out for PY3. RO episodes of PY2 and PY3 will be used to determine the eligibility of the low volume opt-out for PY4 through PY5, respectively.

We are proposing to codify at § 512.210(c)(7) that during the model performance period, an entity would not be eligible for the low volume opt-out if its legacy TIN or legacy CCN was used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services in the 2 years prior to the applicable PY across all CBSAs selected for participation across all CBSAs selected for participation.

If finalized as proposed, CMS would include episodes and RO episodes, as applicable, associated with the RO participant's current CCN or TIN and episodes and RO episodes, as applicable, attributed to the RO participant's legacy CCN(s) or legacy TIN(s). We propose that a legacy CCN means a CCN that an RO participant that is a hospital outpatient department, or its predecessor(s), previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services. We propose that a legacy TIN means a TIN that an RO participant that is a PGP, or a freestanding radiation therapy center, or its predecessor(s), previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services.

We are proposing this change to remove any incentive for RO participants to change their TIN or CCN in an effort to become eligible for the low volume opt-out.

We invite public comments on the proposed definitions of legacy TIN and legacy CCN, as well as the proposal for how to address low volume opt-out eligibility in the case of an entity that has a change in TIN or CCN.

4. Certain Changes to RO Model Episodes

a. Criteria for Determining Included Cancer Types

The criteria for cancer types to be included in the RO Model are set forth at § 512.230(a). To be included in the RO Model, a cancer type must be commonly treated with radiation and associated with current International Classification of Diseases (ICD)–10 codes that have demonstrated pricing stability. We also established the criteria for removal of cancer types from the RO Model are set forth at § 512.230(b). CMS will remove a cancer type from the RO Model if it determines that RT is no longer appropriate to treat that cancer type per nationally recognized, evidence-based clinical treatment guidelines; CMS discovers a >10 percent error in established national base rates; or the Secretary determines that the cancer type is not suitable for inclusion in the RO Model.

Upon further review, we believe that reorganization of § 512.230(a) and (b) would improve the clarity and internal consistency of the regulatory text. We are therefore proposing to amend § 512.230(a) and (b) such that to be included in the RO Model, a cancer type must be commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines; associated with current ICD–10 codes that have demonstrated pricing stability, which is determined by analyzing the interquartile ranges of the episode prices across cancer types as described in the Specialty Care Models final rule at 85 FR 61155; and the Secretary must not have determined that the cancer type is not suitable for inclusion in the RO Model. We propose that CMS will remove from the RO Model a cancer type that does not meet all three of these criteria or for which CMS discovers a >10 percent error in established national base rates.

We invite public comments on the reorganization of § 512.230(a) and (b).

b. Removal of Liver Cancer From Included Cancer Types

We finalized 16 cancer types (Anal Cancer, Bladder Cancer, Bone Metastases, Brain Metastases, Breast Cancer, Cervical Cancer, Central Nervous System (CNS) Tumors, Colorectal Cancer, Head and Neck Cancer, Liver Cancer, Lung Cancer, Lymphoma, Pancreatic Cancer, Prostate Cancer, Upper Gastrointestinal (GI) Cancer, and Uterine Cancer) for inclusion in the RO Model because they meet the criteria set forth in § 512.230(a) (85 FR 61157). These cancers are commonly treated with RT and are associated with current ICD–10 codes that have demonstrated pricing stability. They can be accurately priced for prospective episode payments in that episode prices across these included diagnosis codes the RO Model have been stable.

The treatment of liver cancer with RT services continues to develop, with limited guidance for first-line use of radiotherapy.[407] While RT may represent a promising treatment for certain types of liver cancers, there are few prospective, randomized controlled trials.[408] Some guidelines do not include radiotherapy as a first-line therapy for the treatment of the most common type of liver cancer, hepatocellular carcinoma.[409] After continued conversations with radiation oncologists consulting on the RO Model and additional reviews of the latest literature, we now believe that the inclusion of liver cancer does not meet the inclusion criteria at § 512.230(a)(1) because liver cancer is not commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines.

We believe that liver cancer meets the current criteria for exclusion and that it would meet the criteria for exclusion under our proposal to reorganize the regulatory language in § 512.230(a) and (b) as described earlier in more detail. Therefore, if the reorganization is finalized as proposed, or if the current regulatory text is not changed, we will remove liver cancer from the RO Model as an included cancer type. We will remove the liver cancer ICD–10 diagnosis code(s) from the list on the RO Model website no later than 30 days prior to the start of the model performance period in accordance with § 512.230(c).

c. Proposal To Remove Brachytherapy From Included RT Services

We codified at § 512.240 the modalities that are included under the RO Model: 3-dimensional conformal radiotherapy (3DCRT), intensity-modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), proton beam therapy (PBT), image-guided radiation therapy (IGRT), and brachytherapy. We finalized the inclusion of all of these modalities because they are commonly used to treat

[407] Marrero, J.A., Kulik, L.M., Sirlin, C.B., Zhu, A.X., Finn, R.S., Abecassis, M.M., Roberts, L.R., & Heimbach, J.K. (2018). Diagnosis, Staging, and Management of Hepatocellular Carcinoma: 2018 Practice Guidance by the American Association for the Study of Liver Diseases. *Hepatology (Baltimore, Md.), 68*(2), 723–750. *https://doi.org/10.1002/hep.29913.*

[408] Chen C.P. (2019). Role of Radiotherapy in the Treatment of Hepatocellular Carcinoma. *Journal of clinical and translational hepatology, 7*(2), 183–190. *https://doi.org/10.14218/JCTH.2018.00060.*

[409] Marrero, J.A., Kulik, L.M., Sirlin, C.B., Zhu, A.X., Finn, R.S., Abecassis, M.M., Roberts, L.R., & Heimbach, J.K. (2018). Diagnosis, Staging, and Management of Hepatocellular Carcinoma: 2018 Practice Guidance by the American Association for the Study of Liver Diseases. *Hepatology (Baltimore, Md.), 68*(2), 723–750. *https://doi.org/10.1002/hep.29913.*

the cancer types included in the RO Model and because including these modalities would allow us to test a modality-agnostic approach.

In response to the publication of the Specialty Care Models proposed rule and final rule, we received stakeholder feedback encouraging CMS to reconsider how multimodality episodes—which are episodes involving two or more types of RT treatment—are handled in the RO Model, especially in the cases of cervical cancer and prostate cancer, where standard clinical practice is concordant treatment with external beam radiation therapy (EBRT) and brachytherapy. Stakeholders expressed concern that the RO episode-based payment does not account for multimodality care. Stakeholders were particularly concerned about cases where the RO participant furnishing the external beam radiation therapy is different from the RO participant providing brachytherapy. Stakeholders suggested creating a separate bundled payment for brachytherapy or removing it from the RO Model. We have also heard continued concern from some stakeholders about the inclusion of the brachytherapy sources, particularly fast-acting radioisotopes, in the bundled payments, because they are more like medical devices used in conjunction with medical procedures than other modalities. Brachytherapy sources are also typically paid for separately.

Some stakeholders suggested that inclusion of brachytherapy in the bundled payments could lead to reduced utilization of brachytherapy in situations where a combination of brachytherapy and EBRT is clinically indicated (particularly for cervical and prostate cancers). Stakeholders expressed concern that in the case of multimodality treatment including brachytherapy, there may be a disincentive to refer patients to other radiation oncologists for treatment when the RO participant cannot deliver brachytherapy services themselves.

CMS seeks to neither incentivize nor discourage the use of one modality over another, but rather to encourage providers to choose RT services that are the most clinically appropriate for beneficiaries under their care. The exclusion of a modality from the RO Model is not meant to imply anything about the value of such modality. Published clinical evidence suggests brachytherapy is a high-value RT service, which could warrant its inclusion in the RO Model. However, we acknowledge the concerns stakeholders have about possible unintended consequences for beneficiaries' access to care.

We are proposing to amend § 512.240 to remove brachytherapy as an included modality in the RO Model. If finalized as proposed, we would continue to monitor utilization of brachytherapy, both as a single modality and multimodality among RO participants compared to non-participants, and consider whether there is opportunity to adjust pricing for multimodality episodes, without disrupting the RO Model design, and potentially add brachytherapy to the RO Model in the future. We would also make conforming edits to the list of included RT services previously set forth in the Specialty Care Models Rule at 85 FR 61166 to account for the proposed removal of brachytherapy. The proposed list of included RT services as identified by HCPCS codes are in Table 56 of this proposed rule.

We invite public comments on the removal of brachytherapy.

BILLING CODE 4120–01–P

TABLE 56: List of RO Model Bundle HCPCS

HCPCS	HCPCS Description	Category
77014	Computed tomography guidance for placement of	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77021	Magnetic resonance guidance for needle placem	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77261	Radiation therapy planning	Treatment Planning
77262	Radiation therapy planning	Treatment Planning
77263	Radiation therapy planning	Treatment Planning
77280	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77285	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77290	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77293	Respirator motion mgmt simul	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77295	3-d radiotherapy plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77299	Radiation therapy planning	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77300	Radiation therapy dose plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77301	Radiotherapy dose plan imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77306	Telethx isodose plan simple	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77307	Telethx isodose plan cplx	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77321	Special teletx port plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77331	Special radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77332	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77333	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77334	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77336	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77338	Design mlc device for imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77370	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77371	Srs multisource	Radiation Treatment Delivery
77372	Srs linear based	Radiation Treatment Delivery
77373	Sbrt delivery	Radiation Treatment Delivery
77385	Ntsty modul rad tx dlvr smpl	Radiation Treatment Delivery
77386	Ntsty modul rad tx dlvr cplx	Radiation Treatment Delivery

77399	External radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77402	Radiation treatment delivery	Radiation Treatment Delivery
77407	Radiation treatment delivery	Radiation Treatment Delivery
77412	Radiation treatment delivery	Radiation Treatment Delivery
77417	Radiology port images(s)	Radiation Treatment Delivery (Guidance)
77427	Radiation tx management x5	Treatment Management
77431	Radiation therapy management	Treatment Management
77432	Stereotactic radiation trmt	Treatment Management
77435	Sbrt management	Treatment Management
77470	Special radiation treatment	Treatment Management
77499	Radiation therapy management	Treatment Management
77520	Proton trmt simple w/o comp	Radiation Treatment Delivery
77522	Proton trmt simple w/comp	Radiation Treatment Delivery
77523	Proton trmt intermediate	Radiation Treatment Delivery
77525	Proton treatment complex	Radiation Treatment Delivery
G0339	Robot lin-radsurg com, first	Radiation Treatment Delivery
G0340	Robt lin-radsurg fractx 2-5	Radiation Treatment Delivery
G6001	Echo guidance radiotherapy	Radiation Treatment Delivery (Guidance)
G6002	Stereoscopic x-ray guidance	Radiation Treatment Delivery (Guidance)
G6003	Radiation treatment delivery	Radiation Treatment Delivery
G6004	Radiation treatment delivery	Radiation Treatment Delivery
G6005	Radiation treatment delivery	Radiation Treatment Delivery
G6006	Radiation treatment delivery	Radiation Treatment Delivery
G6007	Radiation treatment delivery	Radiation Treatment Delivery
G6008	Radiation treatment delivery	Radiation Treatment Delivery
G6009	Radiation treatment delivery	Radiation Treatment Delivery
G6010	Radiation treatment delivery	Radiation Treatment Delivery
G6011	Radiation treatment delivery	Radiation Treatment Delivery
G6012	Radiation treatment delivery	Radiation Treatment Delivery
G6013	Radiation treatment delivery	Radiation Treatment Delivery
G6014	Radiation treatment delivery	Radiation Treatment Delivery
G6015	Radiation tx delivery imrt	Radiation Treatment Delivery
G6016	Delivery comp imrt	Radiation Treatment Delivery
G6017	Intrafraction track motion	Radiation Treatment Delivery (Guidance)

BILLING CODE 4120–01–C

Our proposal to remove brachytherapy from the RO Model, if finalized, would render our waiver of section 1833(t)(2)(H) of the Act (as discussed in the Specialty Care Models Rule at 85 CFR 61242 and codified at § 512.280(f)(4) moot, and therefore we are proposing to withdraw this waiver if our proposal to remove brachytherapy is finalized as proposed. We finalized this waiver under the authority of section 1115A(d)(1) of the Act, because it was necessary for the purposes of testing the RO Model when we were including brachytherapy as part of the RO Model. Because we are proposing to remove brachytherapy from the RO Model, we believe that the waiver under section 1833(t)(2)(H) of the Act would no longer be necessary solely for the purposes of testing the RO Model and therefore are proposing to withdraw this waiver.

We invite public comments on the removal of the 1833(t)(2)(H) waiver.

If we remove brachytherapy from the RO Model, we are requesting information on how payments for multi-modality care might be handled in the future. For example, we request information on how RO participants should be paid under the RO Model in cases where brachytherapy is furnished in conjunction with one or more other modalities during an RO episode. CMS does not intend to respond to these comments in the CY 2022 OPPS/ASC final rule; instead, we intend to use these comments to inform potential changes to the RO Model that could be proposed in future notice and comment rulemaking.

d. Exclusion of Intraoperative Radiotherapy (IORT)

We finalized that Intraoperative Radiotherapy (IORT)—a technique that involves precise delivery of a large dose of ionizing radiation to the tumor or tumor bed during surgery—would not be included in the RO Model in the Specialty Care Models Rule (85 FR 61175). We have received comments from stakeholders requesting that we re-evaluate this decision and include IORT in the RO Model for certain cancer types, particularly early stage breast cancer.

At this time, episode payment rates are modality-agnostic. They include all Medicare FFS claims paid during the baseline period as well as claims that are included under an episode where the initial treatment planning service occurred during the baseline period so long as the RT service furnished is not of a modality excluded from the RO Model. We do not have separate national base rates per included cancer type based on a specific modality. Given that the evidence base for IORT is limited to certain cancer types, it does not meet the qualifications for inclusion in this Model. As we have reconsidered IORT's inclusion, we also note that it is a modality that is not site neutral, meaning that the TC of IORT is primarily delivered in HOPDs (during surgery) instead of freestanding radiation therapy centers. One of the primary goals of the RO Model is to test site neutral payments, where care delivered in HOPDs or freestanding radiation therapy centers are paid the same bundled payment. Given that this modality is only provided in one of those locations, it is not site neutral, and therefore does not meet the goals of the RO Model. Modalities that are not included in the RO Model, including IORT, would continue to be paid under Medicare FFS.

We are soliciting comments on whether and how we might include IORT in our pricing methodology in future years of the RO Model, for example whether CMS should include cancer-specific modalities in the RO Model. CMS does not intend to respond to these comments in this CY 2022 OPPS/ASC final rule. We intend to use these comments to inform potential changes to the RO Model that could be proposed in future notice and comment rulemaking.

5. Pricing Methodology

a. Assignment of Cancer Types to an Episode

We finalized at 85 FR 61179 our process for assigning a cancer type to an episode as follows: First, we identify ICD–10 diagnosis codes during an episode from: (1) Medicare PFS claims for evaluation and management (E&M) services with an included cancer diagnosis code with a date of service during the 30 days before the episode start date, on the episode start date, or during the 29 days after the episode start date; and (2) Medicare PFS claims for treatment planning and delivery services with an included cancer diagnosis code (See Table 57), or Medicare OPPS claims for treatment delivery services with an included cancer diagnosis code on the claim header, with a date of service on the episode start date or during the 29 days after the episode start date. The cancer diagnosis code from OPPS claims must be the principal diagnosis to count toward cancer type assignment, and treatment delivery services that concern image guidance do not count toward cancer type assignment as we determined that image guidance was not an important indicator of cancer type. Then, we analyze and count these ICD–10 diagnosis codes across the claim lines to determine the episode's cancer type assignment according to the algorithm described in (1) through (3):

(1) If two or more claim lines fall within brain metastases or bone metastases or secondary malignancies (per the mapping of ICD–10 diagnosis code to cancer type described in Table 57 of Identified Cancer Types and Corresponding ICD–10 Codes), we set the episode cancer type to the type (either brain metastases or bone metastases) with the highest count. If the count is tied, we assign the episode in the following order of precedence: Brain metastases; bone metastases; other secondary malignancies.

(2) If there are fewer than two claim lines for brain metastases, bone metastases or other secondary malignancies, we assign the episode the cancer type with the highest claim line count among all other cancer types. We exclude the episode if the cancer type with the highest claims line count among other cancer types is not an included cancer type.

(3) If there are no claim lines with a cancer diagnosis meeting the previously discussed criteria, then no cancer type is assigned to that episode and therefore, that episode is excluded from the national base rate calculations.

Since the publication of the Specialty Care Models Rule, a stakeholder has asked for clarification on how to identify when there are fewer than two claim lines for brain metastases, bone metastases or other secondary malignancies. In response to the stakeholder's request, in this proposed rule, we would like to clarify paragraph (2). Specifically, if there are not at least two claim lines for brain metastases or at least two claim lines for bone metastases or at least two claim lines for any other secondary malignancy, then we assign the episode the cancer type with the highest line count among all other cancer types. For example, one bone metastases claim line and one secondary metastases claim line would not qualify as two or more claim lines that fall within brain metastases or bone metastases or secondary malignancies. Instead, the episode would be assigned whatever cancer type had the highest line count among all other cancers.

We would also like to clarify that we use a broad list of cancer diagnoses (those included in the RO Model and those not included) to assign cancer type to episodes in the baseline period. This broad list of cancer diagnoses will be posted on the RO Model website at *https://innovation.cms.gov/innovation-models/radiation-oncology-model*. We identify ICD–10 diagnosis codes for cancer during an episode from E&M services, and treatment planning and delivery services that have a cancer diagnosis code from that broad cancer diagnosis list. We assign a cancer type to the episode as described in the Specialty Care Models Rule at 85 FR 61179. We then exclude those episodes that are not assigned an included cancer type. We do not exclude claims of excluded cancer types prior to episode construction, as this could lead to an episode being included in the RO Model where most of the RT services were related to treating an excluded cancer type.

BILLING CODE 4120–01–P

TABLE 57: Identified Cancer Types and Corresponding ICD-10 Codes

Cancer Type	ICD-10 Codes
Anal Cancer	C21.xx
Bladder Cancer	C67.xx
Bone Metastases	C79.51
Brain Metastases	C79.3x
Breast Cancer	C50.xx, D05.xx
Cervical Cancer	C53.xx
CNS Tumors	C70.xx, C71.xx, C72.xx
Colorectal Cancer	C18.xx, C19.xx, C20.xx
Head and Neck Cancer	C00.xx, C01.xx, C02.xx, C03.xx, C04.xx, C05.xx, C06.xx, C07.xx, C08.xx, C09.xx, C10.xx, C11.xx, C12.xx, C13.xx, C14.xx, C30.xx, C31.xx, C32.xx, C76.0x
Lung Cancer	C33.xx, C34.xx, C39.xx, C45.xx
Lymphoma	C81.xx, C82.xx, C83.xx, C84.xx, C85.xx, C86.xx, C88.xx, C91.4x
Pancreatic Cancer	C25.xx
Prostate Cancer	C61.xx
Upper GI Cancer	C15.xx, C16.xx, C17.xx
Uterine Cancer	C54.xx, C55.xx

b. Proposal To Construct Episodes Using Medicare FFS Claims and Calculation of Episode Payment

We finalized at 85 FR 61181 that we construct episodes based on dates of service for Medicare FFS claims paid during the baseline period (CYs 2016 through 2018) as well as claims that are included under an episode where the initial treatment planning service occurred during the baseline period. In the construction of episodes, we also weigh the most recent observations more heavily than those that occurred in earlier years, weighting episodes that initiated in 2016 at 20 percent, episodes that initiated in 2017 at 30 percent, and episodes that initiated in 2018 at 50 percent.

We are proposing to update how we describe this approach. Although we are removing references to specific CYs from the definition of baseline period, we still construct episodes based on dates of service for Medicare FFS claims paid during the baseline period as well as claims that are included under an episode where the initial treatment planning service occurred during the baseline period. Furthermore, although we are removing references to specific CYs, we will continue to weigh the most recent observations more heavily than those that occurred in earlier years, as previously finalized. We would continue to weigh episodes that initiated in the first year of the baseline period at 20 percent, episodes that initiated in second year of the baseline period at 30 percent, and episodes that initiated in the third year of the baseline period at 50 percent.

We invite public comment on this proposal to weigh the most recent episodes more heavily than those that occurred in earlier years in the baseline period.

We codified at § 512.255(c)(13) that for sequestration, we deduct 2 percent from each episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, discount, withholds, and coinsurance to the national base rate. At times, the requirements for sequestrations are modified by legislation or regulation. For example, section 3709(a) of division A of the Coronavirus Aid, Relief and Economic Security (CARES) Act (Pub. L.

116–136) included a temporary moratorium on sequestration for all Medicare programs beginning on May 1, 2020 and ending on December 31, 2020, while section 102(a) of division N of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), extended the suspension period to March 31, 2021. An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes (Pub. L. 117–7), signed into law on April 14, 2021, extends the suspension period to December 31, 2021. Thus, we are proposing to amend § 512.255(c)(13) by removing the percentage amount and indicating that sequestration will be applied in accordance with applicable law.

We invite public comments on the application of sequestration.

c. Proposed National Base Rates

We codified at § 512.250(b) the criteria for excluding episodes, as more fully described in 85 FR 61183 through 61184. We finalized that we would exclude episodes in the baseline (currently proposed to be formally defined as ''baseline period'') that are not attributed to an RT provider or RT supplier. These episodes are exceedingly rare. There were fewer than 15 episodes out of more than 518,000 episodes in the 2016 to 2018 baseline period where the only RT delivery services in the episode were classified as professional services. There are a few brachytherapy surgery services that are categorized as professional services. We also finalized that episodes would be excluded if either the PC or TC is attributed to an RT provider or RT supplier with a U.S. Territory service location or to a PPS-exempt entity, but that services within an episode provided in a U.S. Territory or provided by a PPS-exempt entity would be included in the episode pricing. We finalized that episodes would be excluded if they include any RT service furnished by a CAH. Finally, we finalized that we would exclude all Maryland and Vermont claims before episodes are constructed and attributed to an RT provider or RT supplier, and we would similarly exclude inpatient and ASC claims from episode construction and attribution.

We finalized a policy that excluded claims before episodes were constructed in certain cases, while in other cases, we excluded entire episodes after construction if they included claims that were to be excluded. To simplify episode construction, attribution, and pricing, we propose to exclude all Maryland, Vermont, and U.S. Territory claims and all CAH, inpatient, ASC, and PPS-exempt claims in the same manner: Before episodes are constructed and attributed to an RT provider or RT supplier. Furthermore, to mirror the participant exclusion policy proposed in section XVIII.C.3 of this proposed rule, we are proposing to exclude all claims of an HOPD participating in PARHM (during the time period of their participation in PARHM) before episodes are constructed and attributed to an RT provider or RT supplier. We are also clarifying that we will exclude episodes from the RO Model's pricing methodology that are attributed to an RT provider or RT supplier that is located in a ZIP Code not assigned to a CBSA, not assigned an included cancer type, or that do not have more than $0 in total allowed amount for professional or technical services from Model pricing. We propose to amend § 512.250(b) accordingly.

We invite public comments on the proposal to exclude all Maryland, Vermont, and U.S. Territory claims and all CAH, inpatient, ASC, and PPS-exempt claims before episodes are constructed and attributed to an RT provider or RT supplier. We also invite public comments on the proposal to exclude all claims of an HOPD participating in PARHM (during the time period of their participation in PARHM) before episodes are constructed and attributed to an RT provider or RT supplier.

We finalized our policy in the Specialty Care Models Rule at 85 FR 61185 to change the baseline from 2015 to 2017 to 2016 to 2018 and finalized our national base rates for the model performance period based on the criteria set forth for cancer type inclusion are summarized in Table 3 of that final rule. As proposed in section XVIII.C.2. of this proposed rule, the baseline period would be updated to be the 3-year period within which episodes must initiate in order to be used in the calculation of the national base rates, participant-specific professional and technical historical experience adjustments, and participant-specific professional and technical case mix adjustments for PY1. The baseline period is January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in CY 2022, in which case the baseline period will be adjusted according to the new model performance period (that is, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

In conjunction with the publication of this proposed rule, we will provide a summary level, de-identified file titled the ''RO Episode File (2017 to 2019),'' on the RO Model website at *https://innovation.cms.gov/innovation-models/radiation-oncology-model* to further facilitate understanding of the RO Model's pricing methodology. We would like to clarify that the number of national base rates will vary based on how many cancer types are included in the RO Model.

Further, we are clarifying that Part B expenditures during the baseline period would be used to establish separate PC and TC national base rates for each of the included cancer types, the participant-specific historical experience adjustments for the model performance period, and the participant-specific case mix adjustments for PY1. The case mix adjustments for subsequent PYs (PY2 to PY5) would be calculated using the case mix model from the baseline period with the inputs coming from the beneficiary characteristics in episodes attributed to the participant in the most recent 3-year period that ends 3 years prior to the start of the CY to which the participant-specific case mix adjustment would apply. Our proposed national base rates for the model performance period are based on the criteria set forth for cancer type inclusion and are summarized in Table 58 of this proposed rule.

TABLE 58: National Base Rates

RO Model-Specific Codes	Professional or Technical	Included Cancer Type	National Base Rate
M1072	Professional	Anal Cancer	$3,104.11
M1073	Technical	Anal Cancer	$16,800.83
M1074	Professional	Bladder Cancer	$2,787.24
M1075	Technical	Bladder Cancer	$13,556.06
M1076	Professional	Bone Metastases	$1,446.41
M1077	Technical	Bone Metastases	$6,194.22
M1078	Professional	Brain Metastases	$1,651.56
M1079	Technical	Brain Metastases	$9,879.40
M1080	Professional	Breast Cancer	$2,059.59
M1081	Technical	Breast Cancer	$10,001.84
M1082	Professional	CNS Tumor	$2,558.46
M1083	Technical	CNS Tumor	$14,762.37
M1084	Professional	Cervical Cancer	$3,037.12
M1085	Technical	Cervical Cancer	$13,560.15
M1086	Professional	Colorectal Cancer	$2,508.30
M1087	Technical	Colorectal Cancer	$12,200.62
M1088	Professional	Head and Neck Cancer	$3,107.95
M1089	Technical	Head and Neck Cancer	$17,497.16
M1094	Professional	Lung Cancer	$2,231.40
M1095	Technical	Lung Cancer	$12,142.39
M1096	Professional	Lymphoma	$1,724.07
M1097	Technical	Lymphoma	$7,951.09
M1098	Professional	Pancreatic Cancer	$2,480.83
M1099	Technical	Pancreatic Cancer	$13,636.95
M1100	Professional	Prostate Cancer	$3,378.09
M1101	Technical	Prostate Cancer	$20,415.97
M1102	Professional	Upper GI Cancer	$2,666.79
M1103	Technical	Upper GI Cancer	$14,622.66
M1104	Professional	Uterine Cancer	$2,737.11
M1105	Technical	Uterine Cancer	$14,156.20

BILLING CODE 4120–01–C

d. Proposed Trend Factors

We codified our policy at § 512.255(c)(1) to apply a trend factor (an adjustment applied to the national base rates that updates those rates to reflect current trends in the OPPS and PFS rates for RT services) to each of the national base rates. For each PY, we will calculate separate trend factors for the PC and TC of each cancer type using data from HOPDs and freestanding radiation therapy centers not participating in the RO Model. Each of the separate trend factors will be updated and applied to the national base rates prior to the start of each PY (for which they would apply) so as to account for trends in payment rates and volume for RT services outside of the RO Model under OPPS and PFS. As finalized in the Specialty Care Models Rule, for the PC of each included cancer type and the TC of each included cancer type, we would calculate a trend factor as the ratio of: (a) Volume-weighted FFS payment rates for RT services included in that component for that cancer type in the upcoming PY (that is, the numerator) to (b) volume-weighted FFS payment rates for RT services included in that component for that cancer type in the most recent baseline year (that is, the denominator), which will be FFS rates from 2018. To calculate the

numerator, we finalized that we would multiply: (a) The average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished for the most recent CY with complete data by (b) the corresponding FFS payment rate (as paid under OPPS or PFS) for the upcoming performance year.

To calculate the denominator, we finalized that we would multiply: (a) The average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished in 2018 (the most recent year used to calculate the national base rates) by (b) the corresponding FFS payment rate in 2018. The volume of HCPCS codes determining the numerator and denominator would be derived from non-participant episodes that would be otherwise eligible for Model pricing.

We would like to clarify that the number of separate trend factors will vary depending on the number of cancer types included in the RO Model. Further, given the delay in the model performance period and proposal to update the baseline period, we are proposing that the numerator of the trend factor be the product of (a) the component's FFS payment rate (as paid under OPPS or PFS) for the CY of the upcoming PY and (b) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished 3 years prior to the CY used to determine the FFS payment rates.

We are proposing the denominator of the trend factor be the product of (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished in the most recent year of the baseline period and (b) the corresponding FFS payment rate for the most recent year of the baseline period. For example, for PY1, we would calculate the trend factor as: 2022 Trend factor = (2019 volume * 2022 corresponding FFS rates as paid under OPPS or PFS)/(2019 volume * 2019 corresponding FFS rates as paid under OPPS or PFS). As another example, for PY3, we would calculate the trend factor as: 2024 Trend factor = (2021 volume * 2024 corresponding FFS rates as paid under OPPS or PFS)/(2019 volume * 2019 corresponding FFS rates as paid under OPPS or PFS).

We would like to clarify that the trended national base rates will be made available on the RO Model website prior to the start of the applicable PY, after CMS issues the annual OPPS and PFS final rules that establish payment rates for the upcoming CY.

We finalized in the Specialty Care Models Rule at 85 FR 61188 the years used in the trend factor's numerator and denominator calculation. For example, the trend factor's numerator calculation for a model performance period that begins in 2021 is the most recent CY with complete data used to determine the average number of times each HCPCS code was furnished. The most recent CY with complete data in that case would have been 2018 for PY1, 2019 for PY2, and so forth. We noted that the corresponding FFS payment rate (as paid under the OPPS and PFS) included in the numerator calculation was still that of the upcoming PY (2021 payment rates for PY1, 2022 payment rates for PY2, and so forth). For a model performance period starting in 2021, the trend factor's denominator calculation would have used data from 2018 to determine: (a) The average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applying) was furnished; and (b) the corresponding FFS payment rate.

Given the delay in the model performance period and proposal to update the baseline period, we are proposing that the denominator of the trend factor be based on the third year of the proposed baseline period, and the numerator of the trend factor would be based on FFS payment rates for the same CY as the upcoming PY combined with utilization from the third year of the baseline period for PY1, the first CY after the baseline period for PY2, the second CY after the baseline period for PY3, and so on. For example, for a model performance period starting in 2022, the trend factor's denominator for PY1 would be based on 2019 FFS payment rates and 2019 utilization, while the numerator would be based on 2022 FFS payment rates and 2019 utilization. The trend factor's denominator would not change and remains based on 2019 FFS payment rates and 2019 utilization over the course of the model performance period. The numerator, however, would change, just as we described in the Specialty Care Models Rule (85 FR 61114). Its volume and utilization would be based on years that roll forward. For instance, for a model performance period starting in 2022, the numerator of the PY3 trend factor would be based on 2024 FFS payment rates and 2021 utilization.

We finalized at 85 FR 61187 through 61188 how RT services that are contractor-priced under Medicare PFS are incorporated into RO Model pricing. Due to the potential differences across jurisdictions, we would calculate the average paid amounts for each year in the baseline period for each of these RT services to determine their average paid amount that would be used in the calculation of the national base rates. We would use the most recent CY with claims data available to determine the average paid amounts for these contractor-priced RT services that would be used in the calculation of the trend factors for the PC and TC of each cancer type.

We would also like to clarify that we will use the allowed charges in the claims data to calculate these average paid amounts for contractor-priced RT services under Medicare PFS.

We invite public comments on the years used in the trend factor's numerator and denominator calculation.

e. Applying the Adjustments

We finalized our policy at 85 FR 61194 that the combined adjustment, that is the adjustment that results when the corresponding participant-specific historical experience and case mix adjustments, and blend are combined, be multiplied by the corresponding trended national base rate from Step 2 for each cancer type. We will repeat this calculation for the corresponding case mix adjustment, historical experience adjustment, and blend for the TC, yielding a total of 32 RO participant-specific episode payments for Dual participants and a total of 16 RO participant-specific episode payments for Professional participants and Technical participants. We are clarifying that the total number of RO participant-specific episode payments for Dual participants and the total number of RO participant-specific episode payments for Professional participants and Technical participants will vary depending on the number of included cancer types. For example, 15 included cancer types would yield a total of 30 RO participant-specific episode payment amounts for Dual participants and a total of 15 RO participant-specific episode payment amounts for Professional participants and Technical participants.

f. Proposal for HOPD or Freestanding Radiation Therapy Center With Fewer Than Sixty Episodes During the Baseline Period

We codified at § 512.255(c)(7)(iv) a stop-loss limit of 20 percent for the RO participants that have fewer than 60 episodes from 2016 through 2018 and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of Specialty Care Models Rule (85 FR

61114). Under this stop-loss limit, CMS would use no-pay claims to determine what these RO participants would have been paid under FFS as compared to the payments they received under the RO Model and CMS would pay these RO participants retrospectively for losses in excess of 20 percent of what they would have been paid under FFS. Payments under the stop-loss policy would be determined at the time of reconciliation.

We propose to modify this stop-loss limit policy such that it applies to RO participants that have fewer than 60 episodes during the proposed baseline period and that were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation and amend § 512.255(c)(7)(iv) accordingly.

We invite public comments on this proposal that the stop-loss limit policy would apply to RO participants that have fewer than 60 episodes during the proposed baseline period and that were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation.

g. Proposal To Apply Adjustments for HOPD or Freestanding Radiation Therapy Center With a Merger, Acquisition, or Other New Business Relationship, With a CCN or TIN Change

We codified at § 512.210(a) those entities that must participate in the RO Model, and as more fully described at 85 FR 61195, an entity must participate in the RO Model if it has a new TIN or CCN that results from a merger, acquisition, or other new clinical or business relationship that occurs prior to October 3, 2025, begins to furnish RT services within a CBSA selected for participation, and meets the RO Model's eligibility requirements. We finalized a requirement for advance notification regarding a new merger, acquisition, or other new clinical or business relationships so that the appropriate adjustments would be made to the new or existing RO participant's participant-specific professional episode payment and participant-specific technical episode payment amounts. We finalized that RO participants must also provide a notification regarding a new clinical relationship that may or may not constitute a change in control, and if there were sufficient historical data from the entities merged, absorbed, or otherwise changed as a result of this new clinical or business relationship, then this data would be used to determine adjustments for the new or existing TIN or CCN. We also note that RO participants are required to report a change in control under § 512.180(c).

We propose to add § 512.255(c)(14) that we would calculate in accordance with § 512.255(c)(3) the RO participant's case mix adjustments based on all episodes and RO episodes, as applicable, attributed to the RO participant's legacy TIN(s) or legacy CCN(s) during the 3-year period that determines the case mix adjustment for each PY and all episodes and RO episodes, as applicable, attributed to the RO participant's current TIN or CCN during the 3-year period that determines the case mix adjustment for each PY. We also propose to calculate the RO participant's historical experience adjustments in accordance with § 512.255(c)(4) based on all episodes attributed to the RO participant's legacy TIN(s) or legacy CCN(s) during the baseline period and all episodes attributed to the RO participant's current TIN or CCN during the baseline period. We propose to eliminate the requirement that RO participants provide a notification regarding all new clinical or business relationship that may or may not constitute a change in control. We continue to believe that some new or altered clinical or business relationships may still pose risks of gaming in the RO Model, regardless of whether a change in control results. However, we believe that requiring RO participants to report changes to TINs or CCNs will capture the types of changes that pose these risks. This would also avoid any ambiguity as to what types of changes RO participants would need to report. We are proposing to add § 512.210(e) requiring an RO participant to furnish to CMS written notice of a change in TIN or CCN in a form and manner specified by CMS at least 90 days before the effective date of any change in TIN or CCN that is used to bill Medicare.

We invite public comments on the proposal of how the case mix adjustments and historical experience adjustments are calculated for an entity that has a change in TIN or CCN. We also invite public comment on the proposal requiring an RO participant to furnish CMS written notice of a change in TIN or CCN.

h. Proposed Discount Factor

We codified at both §§ 512.205 and 512.255(c)(8) that the discount factor for the PC would be 3.75 percent and the discount factor for the TC would be 4.75 percent. We propose to lower the discount factor for the PC to 3.5 percent and the discount factor for the TC to 4.5 percent.

We believe that our proposals to remove brachytherapy from the list of included modalities and liver cancer from the included cancer types, if finalized, will enable us to lower these discounts without increasing the size of the RO Model due to a reduction in pricing variability. Given these proposed modifications to the RO Model, the proposed baseline period, and the current size of the RO Model (approximately 30 percent of eligible episodes), we now expect to be able to detect a savings of 3.2 percent or greater at a significance level of 0.05 and with a power of 0.8. If the proposals to remove brachytherapy and liver cancer are not both finalized, we would not finalize the lowered discounts as proposed.

The definition of discount factor codified at § 512.205 also included the finalized percentages. To simplify the regulation text, we propose to include the discount percentages at § 512.205 and remove the percentages from § 512.255(c)(8).

We invite public comments on these proposals related to the discount factor.

i. Proposed Withholds

We codified at § 512.255(c)(10) that we would apply a 2 percent quality withhold from each professional episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate. In the CY 2021 OPPS/ASC final rule (85 FR 85866), we delayed RO Model quality measures requirements to what would have been PY2 (January 1, 2022 through December 31, 2022) under the model performance period described in that final rule with comment and thus delayed the application of the quality withhold to that PY2. In this proposed rule, we are proposing that RO participants submit quality measure data starting in PY1 (when the model performance period begins) as described in section XVIII.C.6 of this proposed rule, and that beginning in PY1, a 2 percent quality withhold for the PC would be applied to the applicable trended national base rates after the case mix and historical experience adjustments.

We invite public comment on the proposed timing of applying the quality withhold.

j. Proposed Adjustment for Geography

We described in the Specialty Care Models Rule (85 FR 61198) that the geographic adjustment whereby the RO Model-specific relative value unit (RVU) values would be derived from the national base rates which are based on

2016 to 2018 episodes that had the majority of radiation treatment services furnished at an HOPD and that were attributed to an HOPD. We finalized that we would use only 2018 episodes to calculate the implied RVU shares. (See RVUs shares in Table 59).

We propose to modify this provision to align with the proposed model performance period so that the final year of the baseline period would be used to calculate the implied RVU shares. For example, for a baseline period of 2017–2019, 2019 would be used to calculate the implied RVU shares.

We invite public comments on the proposal concerning the calculation of the RVU shares.

TABLE 59: RVU Shares:

RVU Shares					
Professional Component			Technical Component		
WORK	PE	MP	WORK	PE	MP
0.65	0.31	0.04	0	0.99	0.01

k. Example of Participant-Specific Professional Episode Payment and Participant-Specific Technical Episode Payment for an Episode Involving Lung Cancer in PY1

Table 60 and Table 61 are updated versions of Table 8 and Table 9 included in the Specialty Care Model Rule (85 FR 61201 and 85 FR 61202, respectively), that reflect the proposed updated national base rate for lung cancer and proposed discount rate for the respective component represented in each table.

BILLING CODE 4120–01–P

TABLE 60: Example: Participant-Specific Professional Episode Payment for Lung Cancer in PY1 (All numbers are illustrative only.)

	Professional Component	
	Amount	**Formula**
National Base Rate (a)	$2,231.40	
Trend Factor (b)	1.04	
Subtotal (c)	$2,320.66	c = a * b
SPLIT for SOE/EOE payments (d)	$1,160.33	d =c/2
Geographic Adjustment (e)	1.02	
Subtotal1 (f)	$1,183.53	f = d * e
Case Mix Adjustment (g)	0.02	e.g. (102-100) / 100
Historical Experience Adjuster (h)	0.14	e.g. (116-102) / 100
PY1 Blend (i)	0.90	
Adjustments combined (j)	1.15	j = g + (h * i) + 1
Subtotal (k)	$1,356.33	k = j * f
Discount Factor (l)	0.9650	
Subtotal (m)	$1,308.86	m = l * k
Withhold #1 (Incorrect Payment) (n)	0.99	
Withhold #2 (Quality Performance) (o)	0.98	
Total Withhold (p)	0.97	p = 1-((1-n)+(1-o))
Half of Total Episode Payment to RO Participant without sequestration (q)	$1,269.59	q = p * m
Beneficiary Coinsurance for SOE payment Determined (r)	$253.92	r = q * 0.20
SOE Participant Payment	$1,015.67	s = q * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (t) [t = half of the total participant-specific professional episode payment]	$995.36	t = s * 0.98
Episode Payment 1: SOE (u)*	**$995.36**	**u = t**
Episode Payment 2: EOE (v)*	**$995.36**	**v = t**
Total Episode Payment to RO Participant (w)	**$2,498.56**	**w = u+v+2r**

Please note that Table 60, which displays the participant-specific professional episode payment example, does not include any withhold amount that the RO participant would be eligible to receive back or repayment if more money was needed beyond the withhold amount from the RO participant. It also does not include any MIPS adjustment that applies to the RO participant.

TABLE 61: Example: Participant-Specific Technical Episode Payment for Lung Cancer in PY1 (All numbers are illustrative only.)

	Technical Component	
	Amount	**Formula**
National Base Rate (a)	$12,142.39	
Trend Factor (b)	1.04	
Subtotal (c)	$12,628.09	c = a * b
SPLIT for SOE/EOE payments (d)	$6,314.04	d =c/2
Geographic Adjustment (e)	1.02	
Subtotal1 (f)	$6,440.32	f = d * e
Case Mix Adjustment (g)	0.02	e.g. (102-100) / 100
Historical Experience Adjuster (h)	0.11	e.g. (113-102) / 100
PY1 Blend (i)	0.90	
Adjustments combined (j)	1.12	j = g + (h * i) + 1
Subtotal (k)	$7,206.72	k = j * f
Discount Factor (l)	0.9550	
Subtotal (m)	$6,882.42	m = l * k
Withhold #1 (Incorrect Payment) (n)	0.99	
Withhold #2 (Patient Experience) - not applied until PY3 (o)		
Total Withhold (p)	0.99	p = 1-((1-n)+(1-o))
Half of Total Episode Payment to RO Participant without sequestration (q)	$6,813.60	q = p * m
Beneficiary Coinsurance for SOE payment Determined (r)	$1,362.72	r = q * 0.20
SOE Participant Payment	$5,450.88	s = q * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (t) [t = half of the total participant-specific professional episode payment]	$5,341.86	t = s * 0.98
Episode Payment 1: SOE (u)*	**$5,341.86**	**u = t**
Episode Payment 2: EOE (v)*	**$5,341.86**	**v = t**
Total Episode Payment to RO Participant (w)	**$13,409.16**	**w = u+v+2r**

Table 61 details the participant-specific technical episode payment paid by CMS to a single TIN or single CCN for the furnishing of RT technical services to an RO beneficiary for an RO episode of lung cancer. The participant-specific technical episode payment in this example does not include any rural sole community hospital adjustment that the RO participant would be eligible to receive. Also, please note that for the participant-specific technical payment amount, the beneficiary coinsurance cannot exceed the inpatient deductible limit under OPPS.

We are currently analyzing whether the COVID–19 pandemic resulted in a decrease in Medicare FFS claims submissions for RT services during 2020 relative to historical levels. For this reason, under the extreme and uncontrollable policy proposed in section XVIII.C.10 of this proposed rule, pending 12-months of claims run-out for RT services furnished in 2020, we will consider the removal of 2020 data from the calculation of any applicable baseline period or trend factor. We are not considering the exclusion of 2020 from the case mix adjustment at this time, because the case mix episodes are weighted equally (unlike the baseline period, where more recent episodes are given more weight than earlier episodes), and the case mix adjustment does not rely on the volume of RT services furnished.

We solicit comments on this approach to addressing utilization during the 2020 EUC.

We are also providing Table 62, which is an example that summarizes the data sources and time periods used to determine the values of key pricing components for a baseline period of 2017 through 2019 as a result of the proposed modifications to the pricing methodology.

TABLE 62: Data Sources and Time Periods Used to Determine Values of the RO Model's Key Pricing Components for a Baseline Period of 2017 through 2019

Key Components	Data Source	PY 1 (2022)	PY 2 (2023)	PY 3 (2024)	PY 4 (2025)	PY 5 (2026)
National Base Rates	HOPD episodes	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019
Trend factor	Non-participant episodes	(2019 volume * 2022 rates) / (2019 volume * 2019 rates)	(2020 volume * 2023 rates) / (2019 volume * 2019 rates)	(2021 volume * 2024 rates) / (2019 volume * 2019 rates)	(2022 volume * 2025 rates) / (2019 volume * 2019 rates)	(2023 volume * 2026 rates) / (2019 volume * 2019 rates)
Winsorization thresholds	HOPD episodes	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019
Case mix coefficients	HOPD episodes	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019
Case mix values [and whether eligible (>60 episodes) to receive case mix adjustment]	Participant-specific	2017-2019	2018-2020	2019-2021	2020-2022	2021-2023
Historical Experience adjustment [and whether eligible (>60 episodes) to receive historical experience adjustment]	Participant-specific	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019

Key Components	Data Source	PY 1 (2022)	PY 2 (2023)	PY 3 (2024)	PY 4 (2025)	PY 5 (2026)
Blend for RO participant with historical experience adjustment greater than 0.0	N/A	0.90	0.85	0.80	0.75	0.70
Blend for RO participant with historical experience adjustment equal to or less than 0.0	N/A	0.90	0.90	0.90	0.90	0.90
RVU shares used in the PFS geographic adjustment	HOPD episodes	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2019	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2019	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2019	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2019	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2019
Low Volume Opt-Out Eligibility (<20 episodes)	Participant-specific	2020	2021	2022	2023	2024

BILLING CODE 4120–01–C

6. Quality—Proposed Form, Manner, and Timing for Quality Reporting

We finalized that the RO Model quality measure reporting to be based on a CY of data (85 FR 61220 through 61223). In the CY 2021 OPPS/ASC final rule, we delayed RO Model quality measures requirements to PY2 (January 1, 2022 through December 31, 2022). In this proposed rule, we are proposing that Professional participants and Dual participants submit quality measure data starting in PY1 during the proposed model performance period. Under this proposal, if the proposed model performance period starts mid-year, the CY collection period would remain. For example, if the model performance period starts in July, RO participants would collect quality measure data for that CY starting in January. This would allow RO participants to use their MIPS data submission to meet the RO Model requirements. We are proposing this policy because we believe that any segmentation to reflect data from only the portion of the CY in PY1 would be inconsistent with the measure, and add

substantial reporting burden to RO participants.

For PY1, Professional participants and Dual participants would be required to submit data for three pay-for-performance measures: (1) Plan of Care for Pain; (2) Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan. Professional participants and Dual participants would be required to submit data on a fourth measure, Treatment Summary Communication—Radiation Oncology, as a pay-for-reporting measure. All quality measure data is reported using the RO Model secure data portal in the manner consistent with that submission portal and the measure specification.

Data submitted by Professional participants and Dual participants for the Treatment Summary Communication—Radiation Oncology measure will be used to propose a benchmark to re-specify it as a pay-for-performance measure, for PY3.

We are proposing that we may update the specifications for the Treatment Summary Communication—Radiation Oncology measure, should new specifications from the measure's steward meet the RO Model's needs. Any non-substantive updates to the specifications for this measure would be communicated in a form and manner specified by CMS. Any substantive changes to measure specifications would be addressed through notice and comment rulemaking.

We also finalized that we would have a CMS-approved contractor administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Survey for Radiation Therapy, beginning in April 2021 (85 FR 61220). In the CY 2021 OPPS/ASC final rule, we revised this policy so that a CMS-approved contractor would administer the CAHPS® Cancer Care Survey for Radiation Therapy beginning in October 2021. Given the change in model performance period due to the delay under section 133 of the CAA 2021, we are proposing that we amend existing policy such that the CMS-approved contractor will begin administering the CAHPS® Cancer Care Survey for Radiation Therapy on behalf of the RO participants and CMS as soon as there are completed RO episodes, no earlier than the fourth month of the model performance period.

We finalized under the RO Model's clinical data collection policy that Professional participants and Dual participants must collect certain clinical information not available in claims or quality measures, with data collecting starting in PY1 (85 FR 61223 through 61226). In the CY 2021 OPPS/ASC final rule, we revised this policy so that the collection period for clinical data elements (CDEs) would begin on January 1, 2022. In this proposed rule, we are proposing that Professional participants and Dual participants submit CDEs starting in PY1.

We invite public comments on these proposals, including whether there are associated changes to the burden or costs with submitting CDEs.

7. The RO Model as an Advanced Alternative Payment Model (Advanced APM) and a Merit-Based Incentive Payment System APM (MIPS APM)

We finalized in the Specialty Care Models Rule at 85 FR 61238 that we expected the RO Model to meet the criteria to be an Advanced APM and a MIPS APM under the Quality Payment Program beginning in PY1 of the RO Model, on January 1, 2021. In CY 2021 OPPS/ASC final rule (85 FR 86262), we amended this policy to reflect that we anticipated that the RO Model will meet the criteria to be both an Advanced APM and a MIPS APM under the Quality Payment Program starting in PY2 which would begin on January 1, 2022. Despite the delay required by section 133 of the CAA 2021, we expect the RO Model to meet the criteria to be an Advanced APM and a MIPS APM beginning in PY1, beginning January 1, 2022. Final CMS determinations of Advanced APMs and MIPS APMs for the 2022 performance period will be announced via the Quality Payment Program website at *https://qpp.cms.gov/*. We anticipate that the RO Model will meet the Advanced APM criteria, reflected in our regulation at § 414.1415 in PY1 and all subsequent PYs.

The first criterion to be an Advanced APM is set forth at § 414.1415(a), CEHRT use. For the RO Model, this criterion is satisfied by the requirements of § 512.220(b), that participants must use CEHRT; that the RO participant must annually certify its use of CEHRT during the model performance period; and that the RO participant will be required to certify its use of CEHRT within 30 days of the start of each PY.

The second criterion to be an Advanced APM is at § 414.1415(b), Payment based on quality measures. This criterion is satisfied because payment under the RO Model is based on MIPS-comparable quality measures, as specified in regulation at § 414.1415(b). Specifically, the RO participant will have their payment amount adjusted by the 2 percent quality withhold with the chance of earning back some or all of that amount based on their AQS, as codified at § 512.255(c)(10). For further discussion of these requirements, please see 85 FR 61211 through 61231.

The third criterion to be an Advanced APM is set forth at § 414.1415(c), Financial Risk. This criterion is satisfied by the application of the discount factor to RO Model payments, codified at § 512.255(c)(8); the application of the quality withhold to the RO Model payments, codified at § 512.255(c)(10); and the fact that RO participants are responsible for 100 percent of all expenditures in excess of the expected amount of expenditures beyond those covered by the participant-specific professional episode payment or the participant-specific technical episode payment as codified at § 512.265, with the exception of those RO participants that qualify for the stop-loss policy as codified at § 512.285(f). The proposed changes to the stop-loss policy described in section XVIII.C.5.f and the discount amounts described in section XVIII.C.5.h of this proposed rule do not affect the satisfaction of the Financial Risk criterion.

As finalized in the CY 2021 OPPS/ASC final rule at 85 FR 61237, for the subset of RO participants that are limited to the total amount of losses they may incur because they are eligible for the stop-loss policy, that limit is set to 20 percent of expected expenditures for which the RO participants are responsible for under the RO Model. Therefore, even when the RO Model stop-loss policy is applicable, the RO Model still meets the Financial Risk criterion to be an Advanced APM, which is 3 percent of the expected expenditures for which an APM Entity is responsible under the APM, at § 414.1415(c)(3)(i)(B).

The RO Model would also meet the criteria to be a MIPS APM under the definition at § 414.1305 starting January 1, 2022. Any MIPS eligible clinician who is included on the individual practitioner list as described at § 512.217 may report and be scored for MIPS as part of an APM Entity, and through the APM Performance Pathway described at § 414.1367.

The MIPS APM criteria at § 414.1367(b) specify that APM entities in a MIPS APM must participate in the APM under an agreement with CMS or through a law or regulation, and the APM must base payment on quality measures and cost/utilization. Professional participants and Dual participants are required to report quality measures, as codified at § 512.275(c), and the RO Model meets the quality measure and cost/utilization requirement through the application of the quality withhold, codified at § 512.255(c)(10), and the use of the

Aggregate Quality Score (AQS) and its application to the quality withhold, as finalized at 85 FR 61226 through 61231. Pursuant to §§ 414.1317 and 414.1367, MIPS eligible clinicians who are identified on a participation list of an APM Entity participating in a MIPS APM during the performance period have unique reporting options under MIPS.

We are clarifying that Professional participants and Dual participants who meet the RO Model requirements codified at § 512.220, including use of CEHRT, and who are eligible clinicians on a Participation List as those terms are defined at § 414.1305, will fall into a category called ''Track One'' of the RO Model. We propose to define ''Track One'' to mean an Advanced APM and MIPS APM track for Dual participants and Professional participants that use CEHRT. RO Model participants in Track One will be considered to be participating in the Advanced APM track of the RO Model, and we will make Qualifying APM Participant (QP) determinations for the eligible clinicians on the RO Model Participation List for Track One as provided in § 414.1425. If eligible clinicians who are Track One RO Participants do not meet the thresholds to become QPs, they will be considered to be participating in a MIPS APM and can report to MIPS using reporting options applicable to MIPS APM participants as specified at § 414.1367. At the start of a PY, if Professional participants or Dual participants fail to meet any of the RO Model requirements codified at § 512.220, which includes use of CEHRT, they will be moved into a separate category called ''Track Two'' of the RO Model for that PY. We propose to define ''Track Two'' to mean an APM for Dual participants and Professional participants who do not meet the RO Model requirements set forth at § 512.220; and for all Technical participants. RO participants that fall into Track Two will not be participating in an Advanced APM or MIPS APM for the RO Model. As such, we will not make QP determinations for the eligible clinicians on the RO Model Participation List for Track Two. We are proposing to codify definitions for ''Track One'' and ''Track Two'' at § 512.205. If an RO participant meets the CEHRT use requirements pursuant to § 414.1415(a)(1)(i) by the last QP determination snapshot date specified at § 414.1325, they will be moved to Track One of the RO Model and considered at that point to be participating in an Advanced APM, provided the RO participant meets all other RO Model requirements set forth at § 512.220.

We recognize that any failure, however minor, to comply with the RO Model requirements set forth at § 512.220(a)(2) will have an impact on whether an RO Model participant is in Track One versus Track Two. Section 512.220(a)(2) contains a number of requirements, including requirements to discuss goals of care and RO Model cost-sharing responsibilities with each RO beneficiary; adhere to nationally recognized, evidence-based clinical treatment guidelines when appropriate; assess each RO beneficiary's tumor, note, and metastasis cancer stage; and send a treatment summary to each RO beneficiary's referring physician within 3 months of the end of the treatment. Under our proposal, any failure to comply with the requirements of § 512.220(a)(2) will result in Track Two status for the RO participant and would be subject to remedial action under § 512.160. However, we recognize that an RO participant's noncompliance with the terms of § 512.220(a)(2) might not be discovered until after CMS has treated the RO participant as if they were in Track One, including potentially making QP determinations for an RO participant's eligible clinicians and making APM Incentive Payments (or, in years beginning with CY 2026, applying a differentially higher update under the physician fee schedule). In that event, the payments we would make based on the QP status of the RO participant's eligible clinicians pursuant to its Track One status would constitute overpayments. We are concerned that, in the case of minor noncompliance with the requirements of § 512.220(a)(2), such overpayment liability may be too harsh. We considered removing the requirement that RO Model participants must meet all of the requirements codified in § 512.220(a)(2) to remain in Track One, but feel that these requirements are important to quality improvement in radiation oncology. Nevertheless, we are considering whether the final rule should modify some of the requirements in § 512.220(a)(2). For example, instead of requiring certain actions for ''each RO beneficiary,'' we are considering whether to require those actions for a majority of RO beneficiaries or substantially all RO beneficiaries. In addition, we are considering whether the final rule should modify certain requirements to permit payment of some or all of the payments made based on the QP status of the RO participant's eligible clinicians pursuant to its Track One participation, depending on the severity of noncompliance and other factors.

We welcome comments on these considerations, including whether the RO Model can meaningfully improve the quality of care if any of the requirements specified in § 512.220(a)(2) are modified, which requirements would be appropriate for modification, the impact of recoupment, and if there are more effective ways to encourage quality improvement and Track One participation.

a. Technical Participants and the Quality Payment Program

Technical participants that are freestanding radiation therapy centers (as identified by a TIN) that only provide the technical component (TC) are not required to report quality measures under the RO Model and fall into Track Two of the RO Model. Technical participants will not be considered to be participating in Advanced APMs or MIPS APMs under the RO Model. However, Technical participants can attest to their participation in an APM for purposes of MIPS, and may be eligible to receive Improvement Activity credit as specified at § 414.1317(b)(3).

We are also proposing that if the Technical participants that are freestanding radiation therapy centers (as identified by a TIN) begin providing the PC at any point during the model performance period, then they must notify CMS within 30 days, in a form and manner specified by CMS. We propose that they would also be required under the RO Model to report quality measures by the next reporting period, which would be March of a PY for Quality Measures and January and July of a PY for the clinical data elements, as finalized at 85 FR 61211 through 61231. If they meet the requirements to be a Track One RO Model participant at one of the QP determination dates specified in § 414.1425(b), they would be considered to be participating in an Advanced APM and a MIPS APM. Once a Technical participant that is a freestanding radiation therapy center begins providing the professional component, the freestanding radiation therapy center becomes a Dual participant as defined in § 512.205. We will monitor these RO participants for compliance with the requirement to report quality measures if they begin providing the professional component. We are proposing to codify this policy at § 512.275(d).

We invite public comments on these proposals related to Technical

participants that are freestanding radiation therapy centers.

b. Individual Practitioner List

We codified the requirements concerning the review and certification of the individual practitioner list at § 512.217. In CY 2021 OPPS/ASC final rule (85 FR 86262), we amended this regulation so that the individual practitioner list was not to be used for QP determinations or for determining participants in a MIPS APM for purposes of MIPS reporting and scoring rules in PY1, and the individual practitioner list was to only be used for the Quality Payment Program in PY1 to assign an automatic 50 percent score for the Improvement Activity performance category in MIPS for RO participants. This amendment stated that starting in PY2 (January 1, 2022), the individual practitioner list was to be used to identify the relevant eligible clinicians for purposes of making QP determinations and for certain aspects of MIPS under the Quality Payment Program. Section 133 of the CAA 2021 prohibits implementation of the RO Model prior to January 1, 2022. In this proposed rule, we are clarifying that all requirements concerning the review and certification of the individual practitioner list finalized and codified at § 512.217 will remain in effect starting on the first day of the model performance period.

We codified at § 512.217(a) that upon the start of each PY, CMS creates and provides to each Dual participant and Professional participant an individual practitioner list which identifies by NPI each individual practitioner associated with the RO participant.

We are proposing to modify this policy to include that Technical participants that are freestanding radiation therapy centers will also be provided an individual practitioner list. We are also proposing to add to the regulation at § 512.217(b) that in the case of a Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center, which begins participation in the RO Model after the start of a given PY, but at least 30 days prior to the last QP determination snapshot date specified at § 414.1325, of that PY, CMS would create and provide the new Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center with an individual practitioner list. Any new Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center that begins participation in the RO Model after the start of the PY must review and certify their individual practitioner list by the last QP determination snapshot date specified at § 414.1325.

We are proposing to change this policy to be inclusive of new RT providers and RT suppliers that would be required to participate in the RO Model after the start of a PY; we believe this proposal will give all RO participants, including those that begin participation in the RO Model after the start of a PY, more time to review and certify their individual practitioner lists.

We invite public comments on reviewing and certifying individual practitioner lists.

We codified at § 512.217(b) and (c)(1) that the RO participant must review and certify the individual practitioner list within 30 days of receipt of the individual practitioner list. We also codified at § 512.217(d)(1)(i) and (d)(2)(i) that the RO participant must notify CMS within 30 days when there are any additions or removals of eligible clinicians to the individual practitioner list. We are proposing to modify these policies so that RO participants will have the ability to review their individual practitioner list and add or drop the necessary NPIs from the list up until the last QP determination snapshot date specified at § 414.1325. We are proposing to change this policy to give RO participants more time to review and certify their individual practitioner lists by requiring this by the last QP determination snapshot date specified at § 414.1325, instead of within 30 days of receipt of the individual practitioner list.

We invite public comments on this proposal to modify the timeframe for which individual practitioner lists shall be certified.

We codified at § 512.217(c)(3) that if the Dual participant or Professional participant does not verify and certify the individual practitioner list by the deadline specified by CMS, RO participants on the unverified list are not recognized as participants on a participation list of either a MIPS APM or Advanced APM. We are proposing to add § 512.217(c)(3)(iii) that if individual practitioners who participate in the RO Model with Technical participants that are freestanding radiation therapy centers are not included on a verified list they will not be eligible to receive Improvement Activity credit under MIPS.

We invite public comments on this proposal to add § 512.217(c)(3)(iii).

c. RO Model Requirements

We codified at § 512.220(b) that RO participants must use CEHRT, that the RO participant must annually certify its use of CEHRT during the model performance period, and that the RO participant will be required to certify its use of CEHRT within 30 days of the start of each PY. In CY 2021 OPPS/ASC final rule (85 FR 86262), we amended the CEHRT requirement beginning in PY2, on January 1, 2022, and to be required for PY2 through PY5. However, section 133 of the CAA 2021 prohibits implementation of the RO Model prior to January 1, 2022.

Accordingly, we are proposing that the CEHRT requirement would begin in PY1 of the proposed model performance period and that RO participants must certify their use of CEHRT at the start of PY1 and each subsequent PY, as codified at § 512.220(b)(1) and (2). We are proposing to codify at § 512.220(b)(3) that if an RO participant begins participation in the RO Model at any time during an ongoing PY, they must certify their use of CEHRT by the last QP determination snapshot date specified at § 414.1325.

We codified at § 512.220(a)(1) that RO participants must satisfy the requirements set forth at § 512.220 to qualify for the APM Incentive Payment. We propose to amend § 512.220(a)(1) to state that RO participants must satisfy the requirements set forth at § 512.220 to be included in Track One of the RO Model. If RO participants do not meet those requirements in a PY, the participant will be in Track Two for the applicable PY. This proposed change is necessary to align with the Quality Payment Program.

We invite public comments on these proposals related to compliance with the CEHRT requirements and the other requirements as conditions to be included in Track One of the RO Model.

8. Proposed Reconciliation Process

a. Initial Reconciliation

Reconciliation is the process to calculate reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services. We stated in the Specialty Care Models Rule at 85 FR 61243 that we would conduct the initial reconciliation for PY1 as early as August 2022, and the PY2 initial reconciliation as early as August 2023, and so forth. Given the proposed change in model performance period due to the delay under section 133 of the CAA 2021, we expect to conduct the initial reconciliation each August for the preceding PY. For example, for PY1, we would conduct the initial reconciliation as early as August of PY2.

In the CY 2021 OPPS/ASC final rule we amended § 512.285(d) such that the

quality reconciliation payment amount would not be applicable for PY1, because there would not be a quality withhold in PY1. Given the proposed change in model performance period due to the delay under section 133 of the CAA 2021, and our proposal that the application of a quality withhold would begin in PY1 as described in section XVIII.C.5 of this proposed rule, we propose to amend § 512.285(d) such that the quality reconciliation payment amount will apply to all PYs. We invite public comments on our proposal.

b. True-Up Reconciliation

The true-up reconciliation is the process to calculate additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after the initial reconciliation and after a 12-month claims run-out for all RO episodes initiated in the applicable PY. We stated in the Specialty Care Models Rule at 85 FR 61244 that we would conduct the PY1 true-up reconciliation as early as August 2023, and the PY2 true-up reconciliation as early as August 2024, and so forth. Given the proposed change in model performance period due to the delay under section 133 of the CAA 2021, we expect to conduct the true-up reconciliation as early as August of the CY following an initial reconciliation for a PY. For example, for PY1, we would conduct the true-up reconciliation as early as August of PY3.

c. Proposed Reconciliation Amount Calculation

We codified at § 512.285(c)(3) that a subset of incomplete episodes in which (1) the TC is not initiated within 28 days following the PC; (2) the RO beneficiary ceases to have traditional FFS Medicare prior to the date upon which a TC is initiated, even if that date is within 28 days following the PC; or (3) the RO beneficiary switches RT provider or RT supplier before all RT services in the RO episode have been furnished, the RO participant would be owed only what it would have received under FFS for the RT services furnished to that RO beneficiary. CMS would reconcile the episode payment for the PC and TC that was paid to the RO participant with what the FFS payments would have been for those RT services using no-pay claims. Furthermore, we finalized in the case that traditional Medicare ceases to be the primary payer for an RO beneficiary after the TC of the RO episode has been initiated but before all included RT services in the RO episode have been furnished, each RO participant would be paid only the first installment of the episode payment. The RO participant would not be paid the EOE PC or TC for these RO episodes.

We are proposing to modify this policy such that for all incomplete episodes as defined at § 512.205, including when the RO beneficiary ceases to have traditional FFS Medicare before all included RT services in the RO episode have been furnished, CMS would reconcile the episode payment for the PC and TC that was paid to the RO participant(s) with what the FFS payments would have been for those RT services using no-pay claims. After reviewing data for incomplete episodes, including incomplete episodes where an RO beneficiary ceases to have traditional FFS Medicare before the end of an episode, we determined that the data did not support paying RO participants only the first installment of an episode for this type of incomplete episode. Upon further review of this data and stakeholder comments on this policy we propose to amend § 512.285(c)(3) and (4) accordingly.

In light of the proposal to modify payment for incomplete episodes, we are proposing conforming changes to § 512.255(c)(12)(iv) regarding beneficiary coinsurance for incomplete episodes. Specifically, we propose to modify § 512.255(c)(12)(iv) to specify that the coinsurance for all incomplete episodes is 20 percent of the FFS amount applicable to the RT services that were furnished.

We codified at § 512.205 a definition for ''stop-loss reconciliation amount'' to mean the amount owed to RO participants that have fewer than 60 episodes during 2016 through 2018 and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of the Specialty Care Models Rule for the loss incurred under the RO Model as described in § 512.285(f). We propose to modify the definition for ''stop-loss reconciliation amount'' to mean the amount owed to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services before the start of the model performance period in the CBSAs selected for participation for the loss incurred under the RO Model as described in § 512.285(f), in order to make this definition consistent with the updated model performance period.

We invite public comments on these proposals related to the reconciliation amount calculation.

9. Potential Overlap With Other Models Tested Under Section 1115A Authority and CMS Programs

In the Specialty Care Models Rule (85 FR 61258), we stated that we did not envision that the prospective episode payments made under the RO Model would need to be adjusted to reflect payments made under any of the existing models being tested under section 1115A of the Act or the Medicare Shared Savings Program (Shared Savings Program) under section 1899 of the Act. We also stated that if, in the future, we determined that such adjustments are necessary, we would propose overlap policies for the RO Model through notice and comment rulemaking. However, we did not codify this policy in the regulations for the RO Model at that time. The RO Model is not a total cost of care model, and includes only RT services in the episode payment. The RO Model's payments are narrow in scope because they are limited to RT services furnished during a distinct period of time. Because the RO Model makes prospective payments for only RT services provided during an episode, a practice participating in the RO Model would receive the same prospective episode payment for RT services regardless of its participation in other CMS models or programs.

Thus, at this time, we continue to see no need to adjust the prospective episode payments made under the RO Model to reflect payments made under the Shared Savings Program or under any other models tested under section 1115A of the Act. We are proposing to codify this policy on overlaps at § 512.292. The financial methodology and accounting policies under the applicable model tested under section 1115A of the Act or the Shared Savings Program will continue to govern the way in which RO Model payments are factored into reconciliation calculations for that initiative. We believe that other initiatives that use a total cost of care approach could consider taking the necessary steps to update their financial methodologies to adjust for the RO Model payments, but we note that the RO Model payments may only be a small portion of the population's overall payments.

We invite public comments on this proposal to codify our overlap policy.

10. Proposed Extreme and Uncontrollable Circumstances Policy

The nation, its communities, and its health care providers, on certain occasions, are forced to confront extreme and uncontrollable circumstances outside of their control that impact their ability to operate in the ordinary course of business for short-term or sometimes even extended periods. The U.S. is currently responding to an outbreak of respiratory disease caused by a novel coronavirus,

referred to as ''COVID–19'', which has created serious public health threats that have greatly impacted the U.S. health care system, presenting significant challenges for stakeholders across the health care delivery system and supply chain. Other extraordinary events that have a disruptive impact may also occur in the future. These events may include other public health emergencies, large-scale natural disasters (such as, but not limited to, hurricanes, tornadoes, and wildfires), or other types of disasters. Such events may strain health care resources, and CMS understands that RT providers and RT suppliers may have limited capacity to continue normal operations and fulfill RO Model participation requirements under such circumstances.

Therefore, we propose to adopt an extreme and uncontrollable circumstance policy for the RO Model which would allow CMS to revise the model performance period; grant certain exceptions to RO Model requirements to ensure the delivery of safe and efficient health care; and revise the RO Model's payment methodology.

a. Extreme and Uncontrollable Circumstance Affects the Nation, Region, or a Locale

We propose to define an extreme and uncontrollable circumstance (EUC) as a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements, and affects an entire region or locale. We propose that if CMS declares an EUC for a geographic region, CMS may: (1) Amend the model performance period; (2) eliminate or delay certain reporting requirements for RO participants; and (3) amend the RO Model's pricing methodology. Application of the modifications would be based on the severity and types challenges that the circumstance imposes on RO participants. In every circumstance, CMS would seek to minimize impact on the RO participants not affected by the EUC, while supporting those that are affected.

In a national, regional, or local event, we would apply the extreme and uncontrollable circumstance policy only if the magnitude of the event calls for the use of special authority to help providers respond to the emergency and continue providing care. We would not use a bright-line test to assess all types of public health emergencies, disasters, or other extraordinary circumstances; application of the policy would be tailored to the specific circumstance, and to the affected geographic areas. To help identify RO participants that are experiencing an extreme and uncontrollable circumstance, CMS would consider the following factors:

- Whether the RO participants are furnishing services within a geographic area considered to be within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Social Security Act.
- Whether the geographic area within a county, parish, U.S. territory, or tribal government designated under the Stafford Act served as a condition precedent for the Secretary's exercise of the 1135 waiver authority, or the National Emergencies Act.
- Whether a state of emergency has been declared in the relevant geographic area.

In the event that one or more of these conditions are present, CMS would announce that the extreme and uncontrollable circumstances policy applies to one or more RO participants within an affected geographic area. CMS would communicate this decision via the RO Model website and written correspondence to RO participants.

We invite public comment on the definition of EUC.

b. Model Performance Period

In instances where an EUC is nation-wide and impacts RO participants' ability to implement the requirements of the RO Model at the start of the model performance period, we propose that CMS may delay the start date of the model performance period by up to one CY. RO participants would be notified of any changes to the model performance period on the RO Model website no later than 30 days prior to the original start date. In the case where a delay to the RO Model performance period is required because of an EUC, various other aspects of the RO Model may be impacted, including its status as an Advanced APM and the years that would be included in the baseline period. The implications of a model performance period delay on other aspects of the RO Model would also be included in the RO Model website notification no later than 30 days prior to the original start date. In the case of a regional EUC, we propose to not change the model performance period, but instead only to delay or exempt requirements, as discussed in section XVIII.C.10.c for the RO participants in the impacted region.

We invite public comment on this proposal related to when we would amend the model performance period.

c. Reporting Requirements

Quality Measures and Clinical Data Elements: If an EUC impacts RO participants' ability to comply with the RO Model's quality measure or clinical data element reporting requirements, we propose that CMS may delay or exempt the affected RO participants from the reporting requirements, make the requirements optional, and/or extend the time for RO participants to report data to CMS, as applicable. CMS would modify or grant exceptions to the RO Model's reporting requirements if, for example, affected RO participants cannot submit their quality and clinical data reporting due to electricity or internet outages caused by an EUC.

Other Participation Requirements: Because RO participants must focus on direct care, we propose that CMS may waive compliance with or adjust the requirement that RO participants actively engage with an AHRQ-listed patient safety organization (PSO) and provide Peer Review (audit and feedback) on treatment plans.

We invite public comment on these proposals related to reporting requirements during an EUC.

d. Pricing Methodology

Adjusting the Quality Withhold: If CMS decides to remove (not merely extend) quality and clinical data submission requirements for affected RO participants due to a national, regional, or local event, we propose that CMS could choose to repay the quality withhold during the next reconciliation, and award all possible points in the subsequent AQS calculation for affected RO participants, which would potentially increase episode payments during this time.

Trend Factor Adjustments: In situations where RO participants nation-wide experience significant, aggregate-level disruptions to their service utilization, in that the trend factor (specific to a cancer type and component) for the upcoming PY has increased or decreased by more than 10 percent compared to the corresponding trend factor of the previous CY when FFS payment rates are held constant with the previous CY, we propose that CMS may modify the trend factor calculation for the PC and/or TC of an included cancer type.

For example, for PY2, a change in the trend factor calculation for the PC and/or TC of an included cancer type could be warranted if [(2020 volume * 2022 rates)/(2019 volume * 2019 rates)] is more than 10 percent change from [(2019 volume *2022 rates)/(2019 volume * 2019 rates)]. The 10 percent

change threshold aligns with the 10 percent criterion for removing an included cancer type, whereby if CMS discovers a ≥10 percent (≥10%) error in established national base rates, the cancer type will be removed from the RO Model. If CMS were to implement this modification, CMS would ensure that the trend factor calculation is most consistent with the average utilization from the previous CY. We propose to codify the extreme and uncontrollable circumstances policies at § 512.294.

We invite public comments on these proposals related to changes in the pricing methodology due to an EUC.

XIX. 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.

As published in the **Federal Register**, the final rule entitled ''CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals to Make Standard Charges Public'' (84 FR 65524 (November 27, 2019), herein referred to as the CY 2020 Hospital Price Transparency final rule), we implemented these sections by adopting requirements for hospitals to make public their standard charges in two ways: (1) As a comprehensive machine-readable file; and (2) in a consumer-friendly format. We codified these requirements at new 45 CFR part 180.

In the CY 2020 Hospital Price Transparency final rule, we indicated that we believe our policies requiring public release of hospital standard charge information are a necessary and important first step in ensuring transparency in health care prices for consumers, although we also recognized that the release of hospital standard charge information would not be sufficient by itself to achieve the ultimate goals for price transparency. The final regulations were 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. In particular, the regulations sought to address the barriers related to lack of hospital standard charge data by requiring some uniformity in the release of hospital standard charge information. We indicated our belief that more work would need to be done to ensure consumers have access to the information they need to make healthcare decisions. We therefore encouraged hospitals and other health care providers to go further in addressing barriers to price transparency.

2. Summary of Proposals

We are proposing to amend several hospital price transparency policies codified at 45 CFR part 180 in order to encourage compliance. For the reasons explained in this section of the preamble, we are proposing to: (1) Increase the amount of the penalties for noncompliance through the use of a proposed scaling factor based on hospital bed count; (2) deem state forensic hospitals that meet certain requirements to be in compliance with the requirements of 45 CFR part 180, and (3) prohibit certain conduct that we have concluded are barriers to accessing the standard charge information. We believe these proposed modifications are responsive to stakeholders and are necessary to ensure compliance with the hospital price transparency disclosure requirements. We are also clarifying the expected output of hospital online price estimator tools, an issue that occurs with respect to a hospital that chooses to use an online price estimator tool in lieu of posting its standard charges for the required shoppable services in a consumer-friendly format. Finally, we are seeking comment on a variety of issues that we may consider to improve standardization of the data disclosed by hospitals.

B. Proposal To Increase the Civil Monetary Penalty Amounts Using a Scaling Factor

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. In the CY 2020 Hospital Price Transparency final rule (84 FR 65581 through 65590), we established monitoring and enforcement policies at new 45 CFR part 180, subpart C. Specifically, we finalized a process for monitoring hospital compliance with section 2718(e) of the PHS Act, by evaluating complaints made by individuals or entities to the Centers for Medicare & Medicaid Services' (CMS), reviewing individuals' or entities' analysis of noncompliance, and auditing hospitals' websites. Should CMS conclude a hospital is noncompliant with one or more of the requirements to make public standard charges, CMS may take any of the following actions, 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 civil monetary penalty not in excess of $300 per day, 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.

As described in the CY 2020 Hospital Price Transparency final rule (84 FR 65588 and 65589), we noted that commenters tended to be divided between those in favor of lower and higher CMP amounts, which indicated to us that the proposed (and subsequently finalized) $300 per day amount struck an appropriate balance between commenter concerns. We also noted that this $300 maximum daily dollar CMP amount is lower than CMPs imposed under certain other authorities administered by HHS agencies, where an entity's noncompliance poses immediate jeopardy, results in actual harm, or both, and stated our belief that the relatively lower amount for a CMP associated with a hospital's noncompliance with requirements to make public standard charges was reasonable since such noncompliance is less serious than noncompliance that poses or results in harm to the public.

As discussed in the CY 2020 Hospital Price Transparency final rule (84 FR

65589), we considered commenters' concerns that some hospitals may prefer to forgo meeting the requirements of 45 CFR part 180 (for example, to not expend resources on reporting or to protect pricing information they consider sensitive), and, instead, face compliance actions including a $300 maximum daily CMP amount. Although we declined at the time to increase the amount of the CMP based on this concern alone, we indicated that as we gained experience with implementing the policy we intended to monitor for such occurrences, and may revisit the need to adjust the amount of the CMP in future rulemaking.

We also considered the feasibility of implementing a sliding scale CMP approach across institutions that meet the definition of hospital according to § 180.20 (84 FR 65588 and 65589). However, at the time, we believed it would be challenging to find a reliable source of data that provides for a scalable factor across all institutions that meet the definition of hospital. Therefore, we declined the commenters' suggestions to scale the CMP amount based on such factors as hospital bed size, location or patient volume. However, we indicated that we would continue to consider this issue and might revisit use of a CMP scaling methodology in future rulemaking.

Based on our initial months of experience with enforcing the hospital price transparency requirements in 45 CFR part 180, we are concerned by what appears to be a trend towards a high rate of hospital noncompliance identified by CMS through sampling and reviews to date, and the reported initial high rate of hospital noncompliance with 45 CFR part 180 reflected in early studies.[410] [411] [412] [413] [414] [415] One approach we considered to address this trend is to amend the regulations to impose potentially higher CMPs for noncompliance with the hospital price transparency requirements, and to scale the CMP to ensure the penalty amount would be more relevant to the characteristics of the noncompliant hospital. We believe that CMPs are an important component in holding hospitals accountable for their noncompliance with hospital price transparency requirements, and signal the Secretary's continued support for public access to pricing information and enforcement.

Therefore, we considered two general approaches for increasing the CMP amount: (1) Use a flat increase in the amount that would be applied uniformly across all hospitals, for example, increasing the maximum CMP amount from $300 per day per hospital to $1,000 per day per hospital, or (2) establish a minimum penalty amount and apply a scaling factor (such as bed count or hospital revenue) to increase the penalty in a manner uniquely tailored to the noncompliant hospital. After considering these two general approaches, we propose to use a scaling factor to establish the CMP amount for a noncompliant hospital.

Several factors informed our proposal to use a scaling factor to determine the CMP amount for noncompliance with hospital price transparency requirements. First, this would allow us to penalize a hospital on a sliding scale in a manner that generally correlates to the hospital's characteristics, such as using the hospital's number of beds as a proxy for the size of the patient population it serves. Second, in the previous rulemaking, commenters suggested using a scaling factor as an alternative to a uniform CMP amount so as to not overly penalize smaller hospitals, while also providing a sufficient incentive for hospitals to comply. Third, other Federal programs use scaling factors in determining a CMP amount, in particular by taking into consideration the size of the entity subject to the penalty, or calculating the penalty based on the number of enrollees affected.[416] Fourth, since finalization of the CY 2020 Hospital Price Transparency final rule, we have had the opportunity to evaluate and determine a reliable source of data that could be used to establish a CMP amount across most institutions that meet the definition of 'hospital' as defined at § 180.20.

We also considered the potential specific scaling factor or factors that could be used, and an appropriate data source. We considered two options for a scaling factor: Hospital bed count and hospital revenue. We are proposing to use the noncompliant hospital's number of beds, as specified in hospital cost report data submitted to CMS, as the scaling factor to establish CMP amounts. We note that for purposes of this discussion, we consider ''number of beds'' to be synonymous with ''bed count,'' and we use the terms interchangeably.

We believe the hospital cost report data would be an appropriate data source for a scaling factor for the CMP amount because it is routinely submitted by Medicare-enrolled hospitals, is certified by a hospital official, and is reviewed by a Medicare Administrative Contractor (MAC) to determine acceptability. As explained on the *CMS.gov* website, Cost Reports web page, Medicare-certified institutional providers are required to submit an annual cost report to a MAC. The cost report contains provider information such as facility characteristics and financial statement data. CMS maintains the cost report data in the Healthcare Provider Cost Reporting Information System (HCRIS). HCRIS includes subsystems for the Hospital Cost Report (CMS–2552–96 and CMS–2552–10), among others.[417] Cost Report form CMS–2552–10 and related instructions are effective for

[410] Henderson M & Mouslim MC. Low Compliance From Big Hospitals On CMS's Hospital Price Transparency Rule. *Health Affairs.* March 16, 2021. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20210311.899634/full/.*

[411] Kennedy K, et al. The Insanity of U.S. Health Care Pricing: An Early Look at Hospital Price Transparency Data. *Health Care Cost Institute.* April 1, 2021. Available at: *https://healthcostinstitute.org/hcci-research/hospital-price-transparency-1.*

[412] Kurani N, et al. Early results from federal price transparency rule show difficulty in estimating the cost of care. *Peterson-KFF Health System Tracker.* April 9, 2021. Available at: *https://www.healthsystemtracker.org/brief/early-results-from-federal-price-transparency-rule-show-difficultly-in-estimating-the-cost-of-care/.*

[413] Severn C. The state of hospital price transparency, with pictures!. *Turquoise Health.* February 12, 2021. Available at: https://blog.turquoise.health/state-of-hospital-price-transparency-with-pictures/.

[414] Gondi S, et al. Early Hospital Compliance with Federal Requirements for Price Transparency. Research Letter. *JAMA Intern Medicine.* June 14, 2021. Available at: *doi:10.1001/jamainternmed.2021.2531.*

[415] Letter from Representatives Frank Pallone, Jr., Anna G. Eshoo, Cathy McMorris Rodgers & Brett Guthrie, to Secretary Xavier Becerra (April 13, 2021), available at *https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/HHS.2021.04.13.pdf.*

[416] See for example: 42 CFR 3.408(e), specifying factors considered in determining the amount of a civil money penalty include the financial condition of the respondent, including the size of the respondent (among other factors).

45 CFR 160.408(d), specifying factors considered in determining the amount of a civil money penalty include the financial condition of the covered entity or business associate, consideration of which may include but is not limited to the size of the covered entity or business associate (among other factors).

CMS, Civil Money Penalty Calculation Methodology, Revised, June 21, 2019. Available at: *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2019CMPMethodology06212019.pdf* (Pursuant to 42 CFR 422.760(b)(1) and (2), 423.760(b)(1) and (2), 417.500(c), and 460.46, CMS determines if the penalty for a deficiency should be calculated on a per enrollee or per determination basis.).

42 CFR 1003.510 and 45 CFR 102.3, specifying penalty amounts that vary based on number of beds of the hospital; imposing higher penalties for a hospital that has 100 beds or more compared to a hospital that has less than 100 beds.

[417] *CMS.gov*, Cost Reports. Available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports.*

hospitals and hospital health care complexes with cost reporting periods beginning on or after May 1, 2010.[418]

For cost reporting purposes, Medicare requires submission of annual reports covering a 12-month period of operations based upon the provider's accounting year. There are also circumstances under which a provider may file a short period cost report for part of a year.[419] Further, there are several exceptions to full cost reporting, including: If a provider does not furnish any covered services to Medicare beneficiaries during a cost reporting period (42 CFR 413.24(g)); or if the provider has had low utilization of covered services by Medicare beneficiaries (as determined by the MAC) and has received correspondingly low interim payments for the cost reporting period (42 CFR 413.24(h)). If the provider fails to submit the cost report, the MAC imposes a penalty by suspending claims payments until the hospital submits the cost report.[420]

The chief financial officer or administrator of the provider certifies the content of the submitted cost report are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions.[421] The MAC reviews the cost report within 30 days of receipt of the provider's cost report to determine acceptability. If the cost report is considered unacceptable, the MAC returns the cost report with a letter explaining the reasons for the rejection. When a cost report is rejected, it is deemed an unacceptable submission and treated as if a report had never been filed.[422] Further, the MAC enters certain data on the hospital cost report into HCRIS, including the cost report status as either: As submitted; Settled without audit; Settled with audit; Reopened; or Amended.[423]

One of the facility characteristics contained in the cost report is ''number of beds,'' which is the number of beds available for use by patients at the end of the cost reporting period. Specifically, ''[a] bed means an adult bed, pediatric bed, portion of inpatient labor/delivery/postpartum (LDP) room (also referred to as birthing room) bed when used for services other than labor and delivery, or newborn ICU bed (excluding newborn bassinets) maintained in a patient care area for lodging patients in acute, long term, or domiciliary areas of the hospital. Beds in post-anesthesia, post-operative recovery rooms, outpatient areas, emergency rooms, ancillary departments (however, see exception for labor and delivery department), nurses' and other staff residences, and other such areas which are regularly maintained and utilized for only a portion of the stay of patients (primarily for special procedures or not for inpatient lodging) are not termed a bed for these purposes.'' [424]

For Medicare-enrolled hospitals, we propose to determine the CMP amount using the number of beds for the noncompliant hospital, as specified on the most recently available, finalized cost report data. We anticipate this would be the number of beds for the hospital as indicated in HCRIS as either Settled without audit, Settled with audit, Reopened, or Amended.

We propose the following approach to scaling the CMP amount based on the hospital's number of beds, and as summarized in Table 63:

- For a noncompliant hospital with a number of beds equal to or less than 30, the maximum daily dollar CMP amount would be $300, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180.
- For a noncompliant hospital with a number of beds between 31 and 550, the maximum daily dollar CMP amount would be the number of beds times $10, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180.
- For a noncompliant hospital with a number of beds greater than 550, the maximum daily dollar CMP amount would be $5,500, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180.

Therefore, for hospitals with 30 or fewer beds, the CMP amount under the proposed approach would be unchanged compared to the existing policy under § 180.90(c)(2). The proposed use of bed count as a scaling factor would increase the penalty, in some cases significantly, for larger hospitals. The following examples illustrate the proposed approach. A small noncompliant hospital with a bed count of fewer than 30 would be subject to the current CMP amount of $300/day or $109,500/year (that is, 365 days or a full CY of noncompliance). A noncompliant hospital with a bed count of 200 would be assessed a penalty of $2,000/day ($10*200/day) or $730,000/year. A noncompliant hospital with a bed count of 550 beds or more would be assessed a maximum penalty of $5,500/day ($10*550/day) or $2,007,500/year.

[418] CMS, The Provider Reimbursement Manual—Part 2, publication #15–2. Chapter 40, Hospital and Hospital Health Care Complex Cost Report Form CMS–2552–10. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*, Chapter 40–(T16)—Hospital & Hospital Health Care (Form CMS–2552–10) (ZIP), file ''R16P240.pdf'' (herein The Provider Reimbursement Manual—Part 2, Chapter 40). Refer to section 4000, General, 40–7.

[419] CMS, The Provider Reimbursement Manual—Part 2, publication #15–2. Chapter 1, Cost Reporting—General. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*, Chapter 1—Cost Reporting General (ZIP), file ''pr2_100_to_140.doc''. Refer to section 102, Cost Reporting Period, 1–3.

[420] 42 CFR 413.20(e). See also, CMS, Hospital and Hospital Health Care Complex Cost Report, CMS Form CMS–2552–10, dated 2020–11–10. Available at: *https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-2552-10*, CMS–2552–10.zip (ZIP), file ''CMS–2552–10_Supporting_Statement_Part_A.pdf'' (Payment/Gifts to Respondents).

[421] 42 CFR 413.24(f)(4)(iv). See also, Form CMS–2552–10. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*, Chapter 40–(T16)—Hospital & Hospital Health Care (Form CMS–2552–10) (ZIP), file ''R16P240f.pdf'', Part II—Certification.

[422] 42 CFR 413.24(f)(5)(iii).

[423] The Provider Reimbursement Manual—Part 2, Chapter 40. Refer to Worksheet S—HOSPITAL AND HOSPITAL HEALTH CARE COMPLEX COST REPORT CERTIFICATION AND SETTLEMENT SUMMARY, section 4003.1, Part I—Cost Report Status, Line 5, column 1.

[424] The Provider Reimbursement Manual—Part 2, Chapter 40. Refer to Worksheet S–3—HOSPITAL AND HOSPITAL HEALTH CARE COMPLEX STATISTICAL DATA AND HOSPITAL WAGE INDEX INFORMATION, section 4005.1, Part 1—Hospital and Hospital Health Care Complex Statistical Data, Column 2.

TABLE 63: Proposed Application of CMP Daily Amounts for Hospital Noncompliance for CMPs Assessed in CY 2022 and Subsequent Years.

Number of Beds	Penalty Applied Per Day	Total Penalty Amount for full Calendar Year of Noncompliance
30 or less	$300 per hospital	$109,500 per hospital
31 up to 550	$310 - $5,500 per hospital (number of beds times $10)	$113,150 - $2,007,500 per hospital
>550	$5,500 per hospital	$2,007,500 per hospital

Note: In subsequent years, amounts adjusted according to 45 CFR 180.90(c)(3).

We reviewed CMP amounts for other HHS programs that require reporting information and we believe our proposed maximum daily dollar penalty amount on a sliding scale between $300 and $5,500 per day per hospital is commensurate with the level of severity of the potential violation, taking into consideration that nondisclosure of standard charges does not rise to the level of harm to the public as other violations (such as safety and quality issues) for which HHS imposes CMPs and, therefore, should remain at a relatively lower level. For instance, the proposed maximum amount of $5,500/day, totaling $2,007,500/year would generally align with amounts used by other HHS initiatives that impose CMPs, such as HIPAA-related CMPs that, pursuant to statute, cap penalties at $1.5 million annually.[425]

We propose that if the number of beds for the hospital cannot be determined according to the most recently available, finalized Medicare cost report data in HCRIS, CMS would use documentation provided by the hospital to determine the number of beds for purposes of calculating the CMP. This approach would be needed to determine the number of beds for a hospital that is not Medicare-enrolled and therefore does not submit to CMS a hospital cost report. Further, we believe there could be circumstances under which there may be an apparent discrepancy, or obvious error, in the most recently available, finalized cost report data for a hospital within HCRIS, and additional documentation from the hospital would be needed to accurately determine the CMP amount.

In the event that CMS requires additional documentation to determine the CMP amount, we propose to require that the hospital provide CMS with documentation of its number of beds, in a form and manner and by the deadline prescribed by CMS in a written notice provided to the hospital. Should a hospital fail to provide CMS with this documentation, in the prescribed form and manner and by the specified deadline, we propose that we would impose a CMP on the hospital at the highest, maximum daily dollar amount within the proposed sliding scale. For example, under the proposed approach, if CMS cannot determine a noncompliant hospital's number of beds using hospital cost report data in HCRIS, and if the noncompliant hospital fails to provide CMS with documentation of its number of beds, in the form and manner and by the deadline specified by CMS, we would impose a CMP calculated based on a number of beds greater than 550, and therefore we would impose the maximum penalty of $5,500/day ($10*550/day) or $2,007,500/year.

Additionally, we propose that the approach for scaling the CMP amount based on the hospital's number of beds would apply to days the hospital is out of compliance with hospital price transparency requirements beginning with the effective date of the final rule, assuming the rule is finalized as proposed, and which we anticipate would be January 1, 2022. Further, according to § 180.90(c)(3), the amount of the CMP will be adjusted annually using the multiplier determined by OMB for annually adjusting CMP amounts under 45 CFR part 102. As described in the CY 2020 Hospital Price Transparency final rule (84 FR 65586), this multiplier is based on the Consumer Price Index for All Urban Consumers (CPI–U), not seasonally adjusted. Given that the requirements in 45 CFR part 180, as established by the CY 2020 Hospital Price Transparency final rule, were effective January 1, 2021, and because of the proposed effective date of January 1, 2022, for the modifications to the CMP amounts in this proposed rule, we would apply the cost-of-living adjustment multiplier determined by OMB, in calculating CMP amounts for hospital noncompliance with the requirements in 45 CFR part 180, beginning in CY 2023 and subsequent years.

To assist the public in considering the proposals to determine the CMP amount based on the most recently available, finalized number of beds for a hospital indicated in HCRIS, we note that CMS makes public hospital cost report data in several resources. Data files by fiscal year are accessible through the Cost Reports by Fiscal Year web page, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year*. Specifically, refer to data files by fiscal year (through FY 2020, at the time of this proposed rule) for facility type ''HOSPITAL–2010.'' Further, a subset of hospital cost report data for 2014 through 2017 is also made public through the Hospital Cost Report Public Use File web page, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Cost-Report/HospitalCostPUF* (providing access to data as either an Interactive Dataset or a Downloadable Excel file).

We seek comment on the proposal to use a sliding scale approach, based on the hospital's number of beds, to determine the CMP amount. In particular, we seek comment on specifying a minimum penalty amount of $300, consistent with the existing CMP amount, for hospitals with 30 beds or fewer, and whether 30 beds is an appropriate number to delineate for this part of the scale. We seek comment on the proposal to impose a CMP of $10/bed/day on hospitals with 31 beds up to 550 beds, including whether we should specify a higher amount to ensure hospitals' compliance with the requirements to make public standard charges. We seek comment on establishing a maximum daily penalty amount of $5,500 for hospitals with more than 550 beds. We also seek comment on our proposal to use hospital cost report data, as specified in HCRIS, to determine bed count, or if we

[425] *See* section 1176(a)(3) of the Social Security Act; 45 CFR 160.404.

should consider using other validated data sources or files. In particular, we are interested in commenters' input on whether there are any available data sources that would encompass relevant scaling data for all hospitals that are subject to the regulations at 45 CFR part 180, including hospitals that are not Medicare-enrolled.

As an alternative approach, we considered using hospital revenue as a scaling factor, instead of or in addition to hospital bed count, as it could more directly take into account the financial burden that a CMP might impose on a noncompliant hospital. For example, we considered using hospital cost report data to determine the noncompliant hospital's annual ''net patient revenues,'' [426] and to calculate a CMP amount as 0.1 percent of hospital revenue, prorated based on the number of days the hospital is out of compliance. That is, we would multiply the revenue amount by 0.001, and then divide the resulting product by 365 to determine the daily CMP amount. Under this alternative approach to scaling the CMP amount based on hospital revenue, as summarized in Table 64, the minimum penalty applied would remain $300 per day up to a maximum penalty of approximately $5,480 per day, which would continue to generally align with CMPs for issues unrelated to harm to the public. Were we to adopt an approach for using hospital revenue to scale the CMP amount, we would need to address with greater specificity additional factors, including the amount of precision used in the calculations, such as whole dollar amounts, or two decimal place precision.

TABLE 64: Proposed Alternative Application of CMP Daily Amounts for Hospital Noncompliance for CMPs Assessed in CY 2022 and Subsequent Years.

Net Patient Revenues	Penalty Applied Per Day	Total Penalty Amount for full Calendar Year of Noncompliance
$109,500,000 or less	$300 per hospital	$109,500 per hospital
>$109,500,000 up to $2,000,000,000	$300 - $5,479 per hospital (0.1% of revenue prorated by day)	$109,500 - $1,999,835 per hospital
>$2,000,000,000	$5,480 per hospital	$2,000,200 per hospital

Note: In subsequent years, amounts adjusted according to 45 CFR 180.90(c)(3).

However, we are concerned that an approach that uses hospital revenue as a scaling factor for determining the CMP amount may not be as effective as a scaling factor based on bed count in targeting penalties to the size of the hospital. As indicated previously, current evidence suggests that noncompliance is fairly high among larger hospitals.[427] By failing to post the standard charge data, these hospitals are directly hindering consumers' decision-making ability. We believe that the larger the hospital size (as determined by bed count), the more potential patients are impacted, and that hospital bed count can serve as a more reliable proxy for the number of potential patients that the hospital serves than using net patient revenues. Conversely, application of a penalty based on net patient revenues would increase the penalty for better resourced hospitals compared to those that might have fewer resources. Such an approach may be more effective at deterring noncompliance among better resourced hospitals which may choose not to comply with the hospital price transparency requirements when the financial benefit of noncompliance outweighs a relatively low CMP amount.

In addition to bed size and hospital revenue, we also considered whether and how we could use additional scaling factors for assessing CMPs such as:

- Other financial metrics for scaling the CMP amount, such as using gross revenue, inpatient, or outpatient revenue to establish a penalty amount.
- The nature, scope, severity, and duration of the noncompliance. For example, taking into account the nature and number of deficiencies found upon review, in addition to applying penalties based on the number of days out of compliance.
- The hospital's reason for noncompliance. For example, applying a greater penalty for intentional noncompliance, such as if a hospital states its willful noncompliance on its website or in response to a compliance action from CMS, or application of a lesser penalty that takes into account extreme and uncontrollable circumstances.

While using multiple scaling factors might have advantages, such as being able to tailor the amount of the CMP to account for unique hospital circumstances and the potential to assess a greater CMP for egregious noncompliance, we are not proposing it at this time because we would need additional time and input to ensure that such scaling factors could be applied in a consistent manner across all hospitals that are subject to these regulations. However, we believe such refinements could improve our application of CMPs to promote hospital compliance and therefore seek comment on the following:

- What additional factors would be feasible for scaling a CMP amount?
- What data sources for the criteria could be used to ensure consistency in application of the criteria across all hospitals subject to these regulations? For example, if hospital revenue was used to scale penalties, what data source to determine revenue should be used? For example, are gross income, net income, net patient revenues, or some other metric appropriate for determining burden imposed by a CMP?
- How should nature, scope, and severity of noncompliance be

[426] The Provider Reimbursement Manual—Part 2, Chapter 40. Refer to section 4040.4, Worksheet G–3—Statement of Revenues and Expenses, describing calculation of Net Patient Revenues (subtract Less: Allowance and Discounts on Patient's Accounts from Total Patient Revenue).

[427] Henderson M & Mouslim MC. Low Compliance From Big Hospitals On CMS's Hospital Price Transparency Rule. *Health Affairs*. March 16, 2021. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20210311.899634/full/*.

determined and applied for purposes of assessing CMPs?

• How should a hospital's reason for noncompliance be determined? What factors should be considered when evaluating reason for noncompliance? Are there bases for imposing lower CMPs, such as resource limitations or extreme or unusual circumstances? If yes, how could resource limitations or circumstances contributing to noncompliance be demonstrated and should that be treated differently than documented statements of intent to not comply with the requirements?

• If multiple factors are used to scale the CMP amount, should there be a priority applied to specific factors? Should some factors be weighted more when determining the CMP amount? If yes, which one(s)?

We propose to revise the regulations at 45 CFR 180.90(c)(2) to specify an amended approach for determining the daily dollar amount for a CMP CMS may impose upon a hospital for noncompliance with the requirements in 45 CFR part 180. As conforming changes, we propose to specify in the regulations at § 180.90(c)(2)(i), the existing approach to determining the CMP amount, as not to exceed $300 per day, with introductory text specifying the provision is applicable for CY 2021. We propose to specify in the regulations at § 180.90(c)(2)(ii), provisions for determining the CMP amount for each day a hospital is determined by CMS to be out of compliance beginning January 1, 2022. The CMP amount would be based on the hospitals' number of beds: (A) A maximum daily dollar CMP amount of $300 for hospitals with a number of beds equal to or less than 30; (B) a maximum daily dollar CMP amount calculated as number of beds times $10 for hospitals with a number of beds between 31 and 550; and (C) a maximum daily dollar CMP amount of $5,500 for hospitals with a number of beds greater than 550. We also propose to specify within § 180.90(c)(2)(ii)(D)(*1*) that CMS would determine the number of beds for a Medicare-enrolled hospital using the most recently available, finalized Medicare hospital cost report. We also propose to specify within § 180.90(c)(2)(ii)(D)(*2*) the process by which CMS would determine the hospital's number of beds if such information could not be determined using Medicare hospital cost report data. We specify the conditions for CMS' receipt of documentation from the hospital to determine its number of beds, and specify that if the hospital does not provide CMS with such documentation (in the prescribed form and manner, and by the specified deadline), CMS would impose a CMP on the hospital at the highest, maximum daily dollar amount ($5,500 per day). We welcome comments on these proposals, and the alternatives we considered.

C. Proposal To Deem Certain State Forensic Hospitals as Having Met Requirements

Section 180.30(b) of our regulations states that the hospital price transparency requirements at 45 CFR part 180 are not applicable to federally-owned or operated hospitals, including hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act, and federally owned hospital facilities such as facilities operated by the U.S. Department of Veterans Affairs and Military Treatment Facilities (MTFs) operated by the U.S. Department of Defense. As we explained in the CY 2020 Hospital Price Transparency final rule, we concluded that these exceptions were appropriate because, with the exception of some emergency services, these facilities do not provide services to the general public and their established payment rates for services are not subject to negotiation. Instead, each of these facility types is authorized to provide services to specific populations that meet specific eligibility criteria (84 FR 65532). In addition, federally-owned or operated hospitals such as Indian Health Service and Tribal facilities [428] impose no cost-sharing, or, in the case of VA hospitals [429] and Department of Defense MTFs,[430] little cost-sharing. With respect to such facilities where there is cost-sharing, the charges are publicized through the **Federal Register**, Federal websites, or direct communication and therefore known to the populations served by such facilities in advance of receiving health care services. Only emergency services, which would not be shoppable services under our definition because they cannot be scheduled in advance, are available to otherwise non-eligible individuals at federally-owned or operated facilities. Because these hospitals do not treat the general public and their rates are not subject to negotiation, we concluded that it was appropriate to establish different requirements that apply to these hospitals.

Following publication of the final rule, we became aware that some state psychiatric facilities, specifically, state forensic hospitals, may be similarly situated to the types of facilities to which the exception in § 180.30(b) applies and should therefore also be deemed to be in compliance with 45 CFR part 180. Some state forensic facilities are public psychiatric hospitals that exclusively treat patients who are in the custody of penal authorities and who are not responsible for payment for the cost of their care in such facilities which are wholly funded through state general funds.[431] We believe it is reasonable to consider deeming such hospitals as having met the requirements of 45 CFR part 180 for similar reasons that we articulated in the CY 2020 Hospital Price Transparency final rule for deeming federally owned or operated facilities as having met these requirements. Specifically, such state forensic hospitals have specialized patient populations, are not open to the general public, and the rates for such hospital services are not negotiated. Therefore we are proposing to adopt this exception by modifying the introductory language in § 180.30(b) and adding new § 180.30(b)(3) to include state forensic hospitals. For purposes of application of this exception, we propose to add a definition to § 180.20 to define a ''state forensic hospital'' as a public psychiatric hospital that provides treatment for individuals who are in the custody of penal authorities.[432] Such forensic patients typically include: (1) Offenders incompetent to stand trial, (2) offenders with mental health disorders, (3) mentally ill prisoners transferred from prison, (4) offenders found not guilty by reason of insanity, or (5) post incarcerated civilly committed individuals.[433] In order to be deemed as having met requirements, the state forensic hospital must provide treatment exclusively for individuals who are in the custody of penal authorities (for example, a state

[428] Section 1680r(b) of the Indian Health Care Improvement Act (25 U.S.C. 1680r).

[429] VA cost-sharing information available at: *https://www.va.gov/HEALTHBENEFITS/cost/copays.asp.*

[430] MTF cost-sharing information available at: *https://tricare.mil/Costs/Compare* and *https://comptroller.defense.gov/Portals/45/documents/rates/fy2019/2019_ia.pdf.*

[431] Substance Abuse and Mental Health Services Administration, Controlled Expenditures and Revenues for Mental Health Services, State Fiscal Year 2009. Available at: *https://store.samhsa.gov/sites/default/files/d7/priv/sma14-4843.pdf.*

[432] CMS.gov, Psychiatric Hospitals, available at: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Certificationand Complianc/PsychHospitals.*

[433] National Association of State Mental Health Program Directors. Forensic Patients in State Psychiatric Hospitals: 1999–2016. August 2017. Available at: *https://nasmhpd.org/sites/default/files/TACPaper.10.Forensic-Patients-in-State-Hospitals_508C_v2.pdf.*

psychiatric hospital with a forensic wing would not meet criteria necessary to be deemed to be in compliance). We estimate there are approximately 111 such institutions that could meet the definition of hospital at § 180.20.[434] We propose to add this exception to § 180.30(b). We welcome comments on this proposal.

D. Proposals Prohibiting Additional Barriers To Accessing the Machine-Readable File

Section 2718(e) of the PHS Act requires hospitals to ''make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services.''

In the CY 2020 OPPS/ASC final rule (84 FR 65556), we explained that we reviewed how hospitals were implementing earlier guidelines for making public hospital chargemasters, which took effect on January 1, 2019, and we expressed concern that some charge information made public by hospitals may be difficult for the public to locate. For example, information may be difficult to locate if the public is required to click down several levels in order to find the information. We also expressed our concern about barriers that could inhibit the public's ability to access the information once located. For example, we indicated that we were aware that some hospitals require consumers to set up a username and password, or require consumers to submit various types of other information, including, but not limited to, their email address, in order to access the data. We expressed concern that these requirements might deter the public from accessing hospital charge information.

Accordingly, we proposed and finalized regulations that a hospital would have discretion to choose the internet location it uses to post its file containing the list of standard charges so long as the comprehensive machine-readable file is displayed on a publicly-available web page, it is displayed prominently and clearly identifies the hospital location with which the standard charges information is associated, and the standard charge data are easily accessible, without barriers, and the data can be digitally searched (84 FR 65561).

Specifically, § 180.50 requires a hospital to make public its standard charges in a single machine-readable file. Section 180.50(d)(1) of our regulations gives a hospital discretion to choose a website for purposes of making its standard charge information available to the public in the machine-readable file. Section 180.50(d)(2) through (5) set forth our accessibility requirements for this information, including that the standard charge information must be displayed prominently and clearly identify the hospital location with which it is associated; easily accessible, without barriers, including but not limited to being free of charge, without having to establish a user account or password, and without having to submit personal identifying information (PII); and contained in a digital file, within which the standard charge information is digitally searchable. For purposes of these requirements: (1) ''displayed prominently'' means that the value and purpose of the web page and its content is clearly communicated, there is no reliance on breadcrumbs to help with navigation, and the link to the standard charge file is visually distinguished on the web page; (2) ''easily accessible'' means that standard charge data are presented in a single machine-readable file that is searchable and that the standard charges file posted on a website can be accessed with the fewest number of clicks; and (3) ''without barriers'' means that the data can be accessed free of charge, users do not have to input information (such as their name, email address, or other PII) or register to access or use the standard charge data file. Additionally, both the machine-readable file and its contents must be digitally searchable.

As discussed in the CY 2020 Hospital Price Transparency final rule, we believe there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare and lower healthcare coverage costs (84 FR 65526). For purposes of displaying all standard charges for all items and services in a comprehensive machine-readable file, we proposed and finalized requirements for the file format, the content of the data in the file, and how to ensure the public could easily access and find the file. We acknowledged that the machine-readable file would contain a large amount of data; however, we indicated that we believe that a single data file would be highly useable by the public because all the data would be in one place. By ensuring accessibility to all hospital standard charge data for all items and services, we stated these data would 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.

In our experience, many publicly available web pages that are selected by hospitals to host the machine-readable file (or a link to the machine-readable file) are discoverable using simple 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. Because of the flexibility we allowed to hospitals to choose the internet location, we recognize and expect that there will be some variability in how hospitals choose to publicly display their machine-readable file and how quickly the file can be found by the public. However, as noted earlier, this flexibility afforded under the regulation so long as the hospital ensures that the machine-readable file is accessible ''without barriers,'' including that the file and its contents would be digitally searchable (84 FR 65561).

In some cases, it appears that hospitals have made standard charge data available online but embedded it in websites without any ability for users to easily or directly download a ''single machine-readable file.'' In other cases, hospitals have posted a link to a single machine-readable file but have, either intentionally or unintentionally, placed barriers that make it more challenging for the public find and access the file and its contents. Examples of such activities and practices include:

- Employing common methods that hinder the findability[435] of a web page that contains a link to the machine-readable file, such as through the use anti-automation tools such as form submission, or other technological devices that place a ''locked door'' in front of the content thereby making it difficult or impossible for search engines to identify the data. There have also been reports of hospitals using ''blocking codes'' such as use of NOINDEX and ''rel canonical'' tagging or disallow statements or removing the URL from the search index through the use of the webmaster tools URL removal service. These techniques prevent

[434] National Mental Health Services Survey (N–MHSS): 2019, Data On Mental Health Treatment Facilities. Substance Abuse and Mental Health Services Administration. 2020. Available at: *https://www.samhsa.gov/data/report/national-mental-health-services-survey-n-mhss-2019-data-mental-health-treatment-facilities. See Table 3.6.a.*

[435] Fishkin R. 12 Ways to Keep Your Content Hidden from the Search Engines. *Moz.* January 15, 2008. Available at: *https://moz.com/blog/12-ways-to-keep-your-content-hidden-from-the-search-engines.*

commonly used web search engines from caching web pages on which the link to machine-readable files reside.[436] These examples of tools and codes present barriers because they limit the public's ability to easily search for and find the web page that hosts a link to the machine-readable file.

• Employing common methods that prevent direct access to the file and its contents. For example, some hospitals implement anti-automation tools such as requiring users to pass tests proving they are human users prior to accessing the file, for example, the implementation of CAPTCHA and reCAPTCHA in web applications. CAPTCHA stands for ''Completely Automated Public Turing test to Tell Computers and Humans Apart.'' Common CAPTCHA and reCAPTCHA mechanisms may include distorted text inside images, where the user has to type the text or nine or sixteen square images, where the user has to identify the images that contain certain objects, such as vehicles, trees, or street signs. In other instances, some hospitals require the user to take additional actions upon clicking the link to the machine-readable file, prior to download. For example, pop-up windows that require the user to agree all terms and conditions in a legal disclaimer prior to permitting the machine-readable file and its contents to be downloaded. Such pop-up windows do not permit direct access to the file and its contents, and present a barrier.

• Developing file constructs and web forms that obscure access to the data in a single machine-readable file through the use of Application Programming Interfaces (APIs). For example, we have found APIs that use calls for data that will not return a complete data file, that do not provide supporting documentation on the use of the API to retrieve the file, and that do not allow a single query to return all data in a single machine-readable file. These APIs control access to the data in a way that prevents or conceals access to the entire data file. As such, these types of APIs present barriers to direct access to a 'single machine-readable file' and are therefore not permissible forms of APIs for use by a hospital.

Given this additional experience, we are proposing to amend the regulations by adding paragraph (d)(3)(iv) to § 180.50 to specify that the hospital must ensure that the standard charge information is easily accessible, without barriers, including, but not limited to, ensuring the information is accessible to automated searches and direct file downloads through a link posted on a publicly available website. We believe this additional requirement will ensure greater accessibility to the machine-readable file and its contents and would prohibit practices we have encountered in our compliance reviews, such as lack of a link for downloading a single machine-readable file, using ''blocking codes'' or CAPTCHA, and requiring the user to agreement to terms and conditions or submit other information prior to access.

We seek comment on whether stakeholders have identified additional barriers that we should prohibit. We note that the list of examples of barriers we have encountered in our reviews of hospital websites is not intended to be exhaustive, and that should we identify additional barriers that prevent automated searches or direct download of the machine-readable file, we may prohibit them via, as appropriate, guidance or future rulemaking.

Finally, we seek comment on whether there are specific criteria we should consider when evaluating whether a hospital has displayed the machine-readable file in a ''prominent manner.'' Files that are posted in a prominent manner can reduce public burden for searching and finding the files and ensure the public can easily find the machine-readable file and the information contained within it. When files are posted prominently, we can also more easily monitor and assess hospital compliance with the CY 2020 Hospital Price Transparency final rule. For example, we are considering establishing a more standardized approach for how hospitals would be required to make public the machine-readable file, in order to relieve the burden on the public and ensure files are found easily. One such method would be to require hospitals to post their machine-readable files using a CMS-specified URL, in addition to the CMS-specified naming convention. Another approach could be to require a standardized location for hospitals to post a link to the file from the hospital's homepage, thus limiting the public's search for such files to the homepage of the hospital and relieving burden on the public to spend time searching for the file. We seek comment on these methods for ensuring that the machine-readable files posted are prominently displayed and easily accessible.

E. Clarifications and Requests for Comment

1. Clarification of the Price Estimator Tool Option and Request for Comment on Considerations for Future Price Estimator Tool Policies

In the CY 2020 Hospital Price Transparency final rule, we finalized requirements for hospitals to make public payer-specific negotiated charges, discounted cash prices, the de-identified minimum negotiated charge, and the de-identified maximum negotiated charge for 300 ''shoppable'' services that are displayed and packaged in a consumer-friendly manner. 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).

We therefore finalized a policy at § 180.60(a)(2) that a hospital may voluntarily offer an internet-based price estimator tool and thereby be deemed to have met our requirements to make public its standard charges for selected shoppable services in a consumer-friendly manner, so long as such a price estimator tool:

• Provides estimates for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.

• Allows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service.

• Is prominently displayed on the hospital's website and be accessible without charge and without having to register or establish a user account or password.

To satisfy our requirement at § 180.60(a)(2)(ii), a price estimator tool ''[a]llows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service''. Moreover, such a price estimator tool must be ''tailored to individuals' circumstances (whether an individual is paying out of pocket or using insurance) and provide real-time individualized out of pocket estimates

[436] McGinty T, et al. Hospitals Hide Pricing Data from Search Results. *The Wall Street Journal.* March 22, 2021. Available at: *https://www.wsj.com/articles/hospitals-hide-pricing-data-from-search-results-11616405402.*

that combines hospital standard charge information with the individual's benefit information directly from the insurer, or provide the self-pay amount.'' (84 FR 65578) We emphasize this because our reviews of hospital compliance have identified that some hospital price estimator tools do not tailor a single estimated amount based on the individual's circumstance, but, instead, provide estimated average amounts or ranges for the price of a shoppable service that appear to be generated based on a broad population of patients, including outliers. Others do not appear to combine hospital standard charges with the individual's benefit information directly from the insurer to create the estimate, but instead, appear to use information from prior reimbursements or require the user to input benefit information. Still others appear tailored to the individual, but indicate that the price is not what the hospital anticipates that the individual would be obligated to pay, even in the absence of unusual or unforeseeable circumstances. Hence they fail to satisfy our requirements at § 180.60(a)(2).

We note that under the CY 2020 Hospital Price Transparency final rule, hospitals are not required to offer online price estimator tools. However, when a hospital chooses to offer an online price estimator tool as an alternative to presenting their standard charge information in a consumer friendly format, we believe it is important for the hospital to select and offer a price estimator tool that provides a single dollar amount that is tailored to the individual seeking the estimate, taking the individual's circumstances into consideration when developing the estimate. Moreover, the estimate must reflect the amount the hospital anticipates will be paid by the individual for the shoppable service, absent unusual or unforeseeable circumstances. We also emphasize that nothing in this rule precludes a hospital from providing additional information that may be helpful to the consumer, such as a range of prices paid by a defined population of consumers for the item or service in the past, or informing the inquirer what circumstances could change the personalized estimate.

Beyond these current minimum requirements, we are considering whether we should add requirements for the use of an online price estimator tool as an alternative to making public the standard charges for shoppable services in a consumer-friendly format. We seek stakeholder input for future consideration related to the price estimator tool policies, including identifying best practices, common features, and solutions to overcoming common technical barriers, and specifically, seek input on:

- What best practices should online price estimator tools be expected to incorporate?
- Are there common data elements that should be included in the online price estimator tool to improve functionality and consumer-friendliness?
- What technical barriers exist to providing patients with accurate real-time out-of-pocket estimates using an online price estimator tool? How could such technical barriers be addressed?

2. Request for Comment on the Definition of 'Plain Language'

In the CY 2020 Hospital Price Transparency final rule, we finalized requirements for displaying shoppable services in a consumer-friendly manner (§ 180.60). At § 180.60(b), we finalized certain required data elements a hospital must include when displaying its standard charges for its list of shoppable services, the first of which is a 'plain-language' description of each shoppable service. We recommended, but did not require, that hospitals review and use the Federal plain language guidelines,[437] which have been developed to assist Federal agencies to write clearly so that users can find what they need and understand and use what they find. The Federal plain language guidelines inform readers how to write to focus an audience on what it wants to know and guide it through the information, and how to organize information and carefully choose words to avoid jargon and minimize abbreviations.

In our reviews of hospital compliance, we have noticed that not all hospitals appear to be using what could reasonably be considered 'plain language' to describe shoppable services. For example, some hospitals have used internal code descriptions from the comprehensive machine-readable file rather than translating those descriptions into terminology that consumers may readily understand. In our effort to ensure hospital compliance with the use of 'plain language,' we seek public comment on whether we should require specific plain language standards, and, if so, what those plain language standards should be.

3. Request for Comment on Identifying and Highlighting Hospital Exemplars

We are aware that some hospitals are not only fully complying with the hospital price transparency requirements we have adopted, but are also embracing and exemplifying the spirit of consumer price transparency. Moreover, identification of such hospitals may draw attention to developing best practices that other hospitals may choose to adopt, or that could be used to establish criteria for assessing hospital compliance in the future. We therefore seek public comment on potential ways that we could highlight such hospital practices, and are considering approaches that include:

- Opportunities to highlight hospitals that are in compliance with various aspects of the Hospital Price Transparency regulations through education and outreach materials.
- Opportunities to highlight exemplar hospitals on existing CMS websites, for example, the Hospital Price Transparency website, Care Compare, or other CMS websites.
- Publicizing the results of comprehensive compliance reviews on our website.
- Opportunities to collaborate with consumer organizations, health policy organizations, hospital accrediting organizations or others to develop a price transparency certification. Depending on how such a certification process would be structured, we might consider proposing future regulatory action to deem certified hospitals as being in compliance with our regulations.
- Opportunities for integrating price transparency questions into patient experience of care assessments and surveys or other methods for integrating into hospital quality measurement and value-based purchasing initiatives.

In considering ways we could hold out hospitals as exemplars for patient-centered price transparency, we are also seeking public input on the following:

- Should hospitals be recognized for patient-centered price transparency efforts? If yes, how should such hospitals be identified and by whom? What criteria should be used for assessing patient-centered price transparency efforts?
- What method or methods for highlighting exemplar hospitals would be most beneficial to consumers?
- Of the methods described above, what are the relative advantages or disadvantages of each?

4. Request for Comment on Improving Standardization of the Machine-Readable File

In the CY 2020 Hospital Price Transparency final rule, we expressed our concern that lack of uniformity in

[437] See Federal plain language guidelines, available at: *https://plainlanguage.gov/guidelines/*.

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 agreed with commenters that standardization in some form would be important to ensure high utility for users of the hospital standard charge information, and we therefore finalized certain requirements, such as the data elements and file formats, that would be standardized across hospitals.

We codified these requirements at new § 180.50(b) and indicated that we believed that the finalized data elements (which included, as applicable, the hospital's standard charges, a description of the item or service, and common billing and accounting code) would be necessary to ensure that the public can compare standard charges for similar or the same items and services provided by different hospitals.

Commenters provided many additional suggestions for how to standardize the standard charge information displayed by hospitals. At the time we declined to be more prescriptive in our approach, but we noted that we may revisit these requirements in future rulemaking should we find it is necessary to make improvements in the display and accessibility of hospital standard charge information for the public.

Since implementation of the final rule, early feedback from stakeholders, particularly from IT specialists, researchers, and others who seek to use the standard charge information that hospitals are now required to make public, have indicated that more standardization of the machine-readable file may be necessary to meet the goal of permitting comparisons of standard charges from one hospital to the next. We are therefore seeking comment on the following issues:

- What is the best practice for formatting data such as hospital standard charge data? Is there a specific data format that should be required to be used across all hospitals? Are there any barriers to requiring a specific format to be used by all hospitals when displaying standard charge information?
- Are there additional data elements that should be required for inclusion in the future in order to ensure standard charge data is comparable across hospitals? What one(s)? Is such data readily found in hospital systems? In what ways would inclusion of such data impact hospital burden?
- Are there any specific examples of hospital disclosures that represent best practice for meeting the requirements and goals of the CY 2020 Hospital Price Transparency final rule? We invite submissions of links to machine-readable files that the public would consider to represent a best practice.
- What other policies or incentives should CMS consider to improve standardization and comparability of these disclosures?
- What other policies should CMS consider to ensure the data posted by hospitals is accurate and complete, for example, ensuring that hospitals post all payer-specific negotiated charges for all payers and plans with which the hospital has a contract, as required by the regulations?

XX. Additional Hospital Inpatient Quality Reporting (IQR) Program Policies

A. Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) and eCQM Reporting Requirements in the Hospital IQR Program—Request for Information

1. Hospital IQR Program Background

We refer readers to the following final rules for detailed discussions of the history of the Hospital IQR Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set:

- The FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861);
- The FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181);
- The FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 61653);
- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328, 38348);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509); and
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959).

We note this is not an exhaustive list of all prior rulemaking for the Hospital IQR Program. We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations, as well as the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25561 through 25601) for currently proposed program changes for the Hospital IQR Program.

In this request for information (RFI), we seek input regarding the Safe Use of Opioids—Concurrent Prescribing electronic clinical quality measure (eCQM) (NQF # 3316e) (hereinafter referred to as the ''Safe Use of Opioids eCQM'') as well as our previously finalized policy of requiring hospitals to report on the Safe Use of Opioids eCQM beginning with the CY 2022 reporting period/FY 2024 payment determination (84 FR 42503 through 42505). We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42459) where we adopted the Safe Use of Opioids eCQM into the Hospital IQR Program beginning with the CY 2021 reporting period/FY 2023 payment determination. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42503 through 42505) in which we finalized our policy requiring hospitals to report on the Safe Use of Opioids eCQM beginning in the CY 2022 reporting period. We also refer readers to the FY 2021 IPPS/LTCH PPS final rule in which we finalized reporting of the Safe Use of Opioids eCQM as one of the four required eCQMs beginning with the CY 2022 reporting period/FY 2024 payment determination (85 FR 58933 through 58939). Specifically, for the CY 2022 reporting period/FY 2024 payment determination, hospitals will be required to report three self-selected calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQMs. For the CY 2023 reporting period/FY 2025 payment determination and subsequent years hospitals will be required to report four calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQMs. The Safe Use of Opioids eCQM is scheduled to be submitted to the National Quality Forum (NQF) in 2022 for re-endorsement consideration as part of the measure maintenance process. The purpose of this RFI is to gather public input for potential measure updates as we prepare for NQF re-endorsement of the endorsed Safe Use of Opioids—Concurrent Prescribing eCQM and to potentially inform any future rulemaking regarding this measure. We provide more detail on both the Safe Use of Opioids eCQM and the eCQM reporting requirements below.

2. Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e)

a. Overview

The Safe Use of Opioids eCQM seeks to reduce preventable mortality and the costs of adverse events associated with opioid use by encouraging providers to identify patients who have concurrent prescriptions for opioids, or opioids and

benzodiazepines, and discouraging providers from prescribing these drugs concurrently, unless medically necessary or appropriate. This measure is intended to support a patient-centric approach to help identify and monitor patients at risk, and ultimately reduce the risk of harm to patients across the continuum of care. Specifically, the measure encourages providers to identify patients on medication combinations that could lead to adverse drug events at discharge and motivates providers to consider whether reevaluation of the current medication regimen is warranted. This measure ultimately seeks to help combat the opioid crisis, which has been declared a public health emergency and is recognized as a priority focus area for measurement by CMS and HHS. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42459) where we adopted the Safe Use of Opioids eCQM into the Hospital IQR Program beginning with the CY 2021 reporting period/FY 2023 payment determination.

The Safe Use of Opioids eCQM assesses the proportion of inpatient hospitalizations for patients 18 years of age and older prescribed, or continued on, two or more opioids or an opioid and benzodiazepine concurrently at discharge. The numerator is comprised of patients whose discharge medications include two or more active opioids or an active opioid and benzodiazepine resulting in concurrent therapy at discharge from the hospital-based encounter (84 FR 42452). The denominator consists of patients who have inpatient hospitalizations (inpatient stay less than or equal to 120 days) that end during the measurement period, where the patient is 18 years of age and older at the start of the encounter, and is prescribed a new or continuing opioid or benzodiazepine at discharge (84 FR 42452). Patients who have cancer or are receiving palliative care would be excluded from the denominator (84 FR 42452).

A lower percentage for the measure indicates fewer concurrent prescriptions written. We emphasize that the Safe Use of Opioids eCQM is not expected to have a measure rate of zero (84 FR 42456). Clinician judgment, clinical appropriateness, or both may indicate that concurrent prescribing of two unique opioids, or an opioid and a benzodiazepine is medically necessary. For example, patients who are on medication for opioid use disorder (OUD) would be included in the measure denominator if they continue that active prescription at discharge and would be counted in the numerator if they receive another prescription for an opioid or benzodiazepine (84 FR 42452). We also refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42459) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58939) for more details on the Safe Use of Opioids eCQM.

b. Prior Stakeholder Feedback

We monitor and evaluate quality measures after they are adopted and implemented into the Hospital IQR Program measure set. We also engage with stakeholders through education and outreach opportunities, which include webinars and help desk questions submitted through the Office of the National Coordinator for Health Information Technology (ONC) Project Tracking System (JIRA) eCQM issue tracker for eCQM implementation and maintenance (84 FR 42454).

Since adopting the Safe Use of Opioids eCQM in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42459), stakeholders have expressed concern about potential unintended consequences associated with requiring reporting on the measure. Specifically, these stakeholders have noted their concern that requiring reporting on the Safe Use of Opioids eCQM could disincentivize clinicians from appropriately concurrently prescribing medications for the treatment of OUD, such as methadone and buprenorphine. They believe that if hospitals are required to report on this measure, clinicians might alter their prescribing practices, making it more difficult for patients to access appropriate treatment for OUD, and ultimately leading to patient harm in a vulnerable population.

We note that during measure development, clinicians from our expert panel considered single-condition exclusions such as OUD. After reviewing test results, they recommended continuing to include patients for whom concurrent prescribing is medically necessary, because they stated that those populations: (1) Have the highest risk of receiving concurrent prescriptions; (2) can experience a lag in adverse events; and (3) can experience adverse drug events if an overlap with benzodiazepines occurs (84 FR 42450 through 42451). As we previously noted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42456), the Safe Use of Opioids eCQM is not expected to have a measure rate of zero; however, this is an important topic and a particular focus area of our monitoring efforts as the eCQM data start to be submitted and on which we are currently seeking comment, as further discussed below.

c. National Quality Forum Re-Endorsement

The Safe Use of Opioids eCQM is scheduled to be submitted to the NQF in 2022 for re-endorsement. In support of that effort, our measure development contractor plans to conduct additional testing, which will include substance use disorder treatment and sickle cell disease. Testing will include discussions with the technical expert panel to identify any potential updates to test as well as testing the rate of concurrent morphine/buprenorphine prescribing alongside opioids and benzodiazepines. Testing work will also include recruiting test sites, receiving test site data, reassessing validity, reliability, performance scores, exclusions, and performance gaps. This testing could be used to inform possible future measure updates or exclusions.

3. Current eCQM Reporting and Submission Requirements for the Hospital IQR Program

Beginning with the CY 2021 reporting period/FY 2023 payment determination, the Safe Use of Opioids eCQM was added as part of the eCQM measure set as one of the eCQMs that eligible hospitals can choose from to meet the eCQM reporting requirements for the Hospital IQR and Medicare Promoting Interoperability Programs (84 FR 42449 through 42459 and 84 FR 42598 through 42599, respectively). Beginning with the CY 2022 reporting period/FY 2024 payment determination, hospitals are required to report data for each required eCQM: (a) Three self-selected eCQMs from the set of available eCQMs for CY 2022, and (b) the Safe Use of Opioids eCQM (85 FR 58933 through 58939). We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58939) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42506) for more detailed discussions of the current eCQM reporting and submission requirements for the Hospital IQR Program.

4. Solicitation of Comments

In this RFI, we seek public input on the following:

- *Potential future measure updates of the Safe Use of Opioids eCQM.* We seek additional information or considerations to inform future measure updates to the Safe Use of Opioids eCQM.
- *Required Reporting and Submission Requirement for the Safe Use of Opioids eCQM.* Currently, hospitals are required to report: (a) Three self-selected eCQMs from the set of available eCQMs, and (b)

the Safe Use of Opioid eCQM for the CY 2022 reporting period/FY 2024 and subsequent years. As we consider future reporting on the Safe Use of Opioids eCQM, we seek comments on the appropriateness of maintaining this previously finalized policy or allowing hospitals to self-select the Safe Use of Opioids eCQM from our finalized set of eCQMs.

XXI. Additional Medicare Promoting Interoperability Program Policies

A. Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) and eCQM Reporting Requirements in the Medicare Promoting Interoperability Program—Request for Information

1. Medicare Promoting Interoperability Program Background

We refer readers to the following final rules for detailed discussions regarding the history of the Medicare Promoting Interoperability Program (previously known as part of the Medicare and Medicaid Electronic Health Record Incentive Programs):

- The Electronic Health Record Incentive Program Stage 1 final rule (75 FR 44314);
- The Electronic Health Record Incentive Program Stage 2 final rule (77 FR 53968);
- The Electronic Health Record Incentive Program Stage 3 final rule (80 FR 62762);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 25245 through 25247);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38487 through 38493);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41634 through 41677);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42591 through 42602); and
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58966 through 58977).

We note this is not an exhaustive list of all prior rulemaking for the Medicare Promoting Interoperability Program. We also refer readers to 42 CFR part 495 for the Medicare Promoting Interoperability Program regulations, as well as the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25628 through 25654) for proposed changes to the Medicare Promoting Interoperability Program.

In this request for information (RFI), to maintain alignment with the Hospital Inpatient Quality Reporting Program, we seek input regarding the Safe Use of Opioids—Concurrent Prescribing electronic clinical quality measure (eCQM) (NQF #3316e) (hereinafter referred to as the ''Safe Use of Opioids eCQM'') as well as our previously finalized policy of requiring hospitals to report on the Safe Use of Opioids eCQM beginning with the CY 2022 reporting period (84 FR 42598 through 42600 and 85 FR 58970 through 58975). We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42599) where we adopted the Safe Use of Opioids eCQM into the Medicare Promoting Interoperability Program beginning with the CY 2021 reporting period, as we continued to align with the Hospital IQR Program. We also refer readers to the FY 2020 and FY 2021 IPPS/LTCH PPS final rules (84 FR 42597 through 42600 and 85 FR 58970 through 58975 respectively) in which we finalized our policy requiring hospitals to report on the Safe Use of Opioids eCQM beginning with CY 2022 reporting period. The Safe Use of Opioids eCQM is scheduled to be submitted to the National Quality Forum (NQF) in 2022 as part of the measure maintenance process. The purpose of this RFI is to gather public input for potential measure updates as we prepare for NQF re-endorsement of the endorsed Safe Use of Opioids—Concurrent Prescribing eCQM and to potentially inform any future rulemaking regarding this measure. We provide more detail on both the Safe Use of Opioids eCQM and the eCQM reporting requirements in section XX.A.3.

2. Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e)

a. Overview

The Safe Use of Opioids eCQM seeks to reduce preventable mortality and the costs of adverse events associated with opioid use by encouraging providers to identify patients who have concurrent prescriptions for opioids, or opioids and benzodiazepines, and discouraging providers from prescribing these drugs concurrently, unless medically necessary or appropriate. This measure is intended to support a patient-centric approach to help identify and monitor patients at risk, and ultimately reduce the risk of harm to patients across the continuum of care. Specifically, the measure encourages providers to identify patients on medication combinations that could lead to adverse drug events at discharge and motivates providers to consider whether reevaluation of the current medication regimen is warranted. This measure ultimately seeks to help combat the opioid crisis, which has been declared a public health emergency and is recognized as a priority focus area for measurement by CMS and HHS.

The Safe Use of Opioids eCQM assesses the proportion of inpatient hospitalizations for patients 18 years of age and older prescribed, or continued on, two or more opioids or an opioid and benzodiazepine concurrently at discharge. The numerator is comprised of patients whose discharge medications include two or more active opioids or an active opioid and benzodiazepine resulting in concurrent therapy at discharge from the hospital-based encounter. The denominator consists of patients who have inpatient hospitalizations (inpatient stay less than or equal to 120 days) that end during the measurement period, where the patient is 18 years of age and older at the start of the encounter, and is prescribed a new or continuing opioid or benzodiazepine at discharge. Patients who have cancer or are receiving palliative care would be excluded from the denominator (84 FR 42452).

A lower percentage for the measure indicates fewer concurrent prescriptions written. We emphasize that the Safe Use of Opioids eCQM is not expected to have a measure rate of zero (84 FR 42456). Clinician judgment, clinical appropriateness, or both may indicate that concurrent prescribing of two unique opioids, or an opioid and a benzodiazepine is medically necessary. Patients who are on medication for opioid use disorder (OUD) would be included in the measure denominator if they continue that active prescription at discharge and would be counted in the numerator if they receive another prescription for an opioid or benzodiazepine (84 FR 42452). We also refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42599) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58939) for more details on the Safe Use of Opioids eCQM.

b. Prior Stakeholder Feedback

We monitor and evaluate quality measures after they are adopted and implemented into the Medicare Promoting Interoperability Program measure set. In collaboration with the Hospital IQR Program, we engage with stakeholders through education and outreach opportunities, which include webinars and help desk questions submitted through the Office of the National Coordinator for Health Information Technology (ONC) Project Tracking System (JIRA) eCQM issue tracker for eCQM implementation and maintenance (84 FR 42454).

Since adopting the Safe Use of Opioids eCQM in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42599), stakeholders have expressed concern about the potential unintended consequences associated with requiring reporting on the measure. Specifically, these stakeholders have

noted their concern that requiring reporting on the Safe Use of Opioids eCQM could disincentivize clinicians from appropriately concurrently prescribing medications for the treatment of OUD, such as methadone and buprenorphine. They believe that if hospitals are required to report on this measure, clinicians might alter their prescribing practices, making it more difficult for patients to access appropriate treatment for OUD, and ultimately leading to patient harm in a vulnerable population.

We note that during measure development, clinicians from our expert panel considered single-condition exclusions such as OUD. After reviewing test results, they recommended continuing to include patients for whom concurrent prescribing is medically necessary, because they stated that those populations: (1) Have the highest risk of receiving concurrent prescriptions; (2) can experience a lag in adverse events; and (3) can experience adverse drug events if an overlap with benzodiazepines occurs (84 FR 42450 through 42451). As was explained by the Hospital IQR Program in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42456), the Safe Use of Opioids eCQM is not expected to have a measure rate of zero; however, this is an important topic and a particular focus area of our monitoring efforts as the eCQM data start to be submitted and on which we are currently seeking public comments, as further discussed in section XX.A.4.

c. National Quality Forum Re-Endorsement

The Safe Use of Opioids eCQM is scheduled to be submitted to the NQF in 2022 for re-endorsement. In support of that effort, our measure development contractor plans to conduct additional testing, which will include substance use disorder treatment and sickle cell disease. Testing will include discussions with the technical expert panel to inform potential updates to test as well as testing the rate of concurrent morphine/buprenorphine prescribing alongside opioids and benzodiazepines. Testing work will also include recruiting test sites, receiving test site data, reassessing validity, reliability, performance scores, exclusions, and performance gaps. This testing could be used to inform possible future measure updates or exclusions.

3. Current eCQM Reporting and Submission Requirements for the Medicare Promoting Interoperability Program

Previously finalized Medicare Promoting Interoperability Program policy for the CY 2022 reporting period requires eligible hospitals and CAHs to report three self-selected calendar quarters of data for each required eCQM: (a) Three self- selected eCQMs from the set of available eCQMs for CY 2022, and (b) the Safe Use of Opioids eCQM, for a total of four eCQMs (85 FR 58970 through 58975). We finalized the requirement that hospitals report on the Safe Use of Opioids eCQM in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42600) such that the Medicare Promoting Interoperability Program was in direct alignment with finalized proposals in the Hospital IQR Program.

Beginning with the CY 2021 reporting period, the Safe Use of Opioids eCQM was added as part of the eCQM measure set as one of the eCQMs that eligible hospitals can choose from to meet the eCQM reporting requirements for the Hospital Inpatient Quality Reporting Program and Medicare Promoting Interoperability Program (84 FR 42449 through 42459 and 84 FR 42598 through 42599, respectively). We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58970 through 58975) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42600) for more detailed discussions of the current eCQM reporting and submission requirements for the Medicare Promoting Interoperability Program.

4. Solicitation of Comments

For this RFI, in alignment with a similar RFI pertaining to the Hospital IQR Program, we seek public input on the following:

- *Potential future measure updates of the Safe Use of Opioids eCQM.* We seek additional information or considerations to inform future measure updates of the Safe Use of Opioids eCQM;
- *Required Reporting and Submission Requirement for the Safe Use of Opioids eCQM.* Currently eligible hospitals and CAHs are required to report (a) Three self-selected eCQMs from the set of available eCQMs, and (b) the Safe Use of Opioid eCQM for the CY 2022 reporting period and subsequent years. As we consider future reporting on the Safe Use of Opioids eCQM, we seek comments on the appropriateness of maintaining this previously finalized policy or allowing hospitals to self-select the Safe Use of Opioids eCQM from our finalized set of eCQMs (which includes the Safe Use of Opioids eCQM) for the CY 2022 reporting period and subsequent years.

XXII. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C, by adding a column entitled ''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). For CY 2022, we are proposing to retain these columns, updated to reflect the amount of the 2022 inpatient deductible. In the CY 2021 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 new column to the OPPS addenda, A, B, and C, entitled ''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 2022, we are proposing to retain these columns that are updated to reflect the drug codes for which pass-through payment is expiring in CY 2022.

To view the Addenda to this proposed rule pertaining to proposed CY 2022 payments under the OPPS, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; select ''CMS–1753–P'' from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder entitled ''2022 NPRM OPPS Addenda'' in the related links section at the bottom of the page. To view the Addenda to this proposed rule pertaining to CY 2022 payments under the ASC payment system, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html*; select ''CMS–1753–P'' from the list of regulations. The ASC Addenda to this

proposed rule are contained in a zipped folder entitled ''Addendum AA, BB, DD1, DD2, and EE.'' in the related links section at the bottom of the page.

XXIII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), 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):

B. ICRs for 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 2021 OPPS/ASC final rules with comment periods (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; and 85 FR 86266 through 86267, 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 March 31, 2023. We continue to estimate a total of 3,300 hospitals will submit required measure data for 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 with comment period (82 FR 52617), we finalized a proposal 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. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the Hospital OQR Program. The latest data from the BLS' May 2020 Occupational Employment and Wages data reflects a median hourly wage of $21.20 per hour for a Medical Records and Health Information Technician professional.[438] 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 ($21.20 × 2 = $42.40) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

2. Summary

In section XV.B.4. of this proposed rule, we propose to: (1) Adopt the COVID19 Vaccination Coverage Among Health Care Personnel (HCP) measure, beginning with the CY 2022 reporting period; (2) adopt the Breast Screening Recall Rates measure, beginning with the CY 2022 reporting period; (3) adopt the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM, beginning as a voluntary measure with the CY 2023 reporting period, and then as a mandatory measure beginning with the CY 2024 reporting period; (4) require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure (OP–31) beginning with the CY 2023 reporting period/CY 2025 payment determination; (5) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (OP–37 a–e), with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination; (6) remove the Fibrinolytic Therapy Received Within 30 Minutes measure (OP2), effective with the CY 2023 reporting period; (7) remove the Median Time to Transfer to Another Facility for Acute Coronary Intervention measure (OP–3), effective with the CY 2023 reporting period; (8) remove the option for hospitals to send medical records to the CMS Data Abstraction Center (CDAC) via paper and removable media and require electronic submission for validation; (9) reduce the number of days hospitals have to submit medical records to the CDAC from 45 days to 30 days for validation; (10) enhance the targeting criteria used for hospital selection for validation by adopting criteria currently used in inpatient data validation by adding the following criteria: (a) Having a lower bound confidence interval score of 75 percent or less; and (b) having not been selected in the previous 3 years; (11) expand our Extraordinary Circumstances Exception (ECE) policy to apply to electronic clinical quality measures (eCQMs), to further align with the Hospital IQR Program; (12) require use of technology updated consistent with 2015 Edition Cures Update criteria beginning with the CY 2023 reporting period/CY 2025 payment determination; and (13) provide a review and corrections period for eCQM data submitted to the Hospital OQR Program.

3. Estimated Burden of Hospital OQR Program Proposals for the CY 2024 Payment Determination and Subsequent Years

a. Information Collection Burden Estimate for the Proposed COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure

In section XV.B.4.a. of this proposed rule, we are proposing to adopt the COVID–19 Vaccination Coverage Among HCP measure, beginning with the CY 2022 reporting period/CY 2024 payment determination. Hospitals would submit data through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based surveillance system maintained and provided free by the CDC. Currently, the CDC does not estimate burden for COVID–19

[438] *https://www.bls.gov/oes/current/oes292098.htm* (Accessed April 13, 2021). The hourly rate of $42.40 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

vaccination reporting under the CDC PRA (OMB control number 0920–1317, which expires on January 31, 2024) because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[439] As such, the proposed measure would not impose any additional information collection under the Paperwork Reduction Act for hospitals for the duration of the public health emergency (PHE). Although the burden associated with the COVID–19 Vaccination Coverage Among HCP measure is not accounted for under the CDC PRA 0920–1317 or 0920–0666 (which expires on December 31, 2023) due to the NCVIA waiver, the cost and burden information is included in the Regulatory Impact Analysis section. Upon receiving comment, we will work with CDC to ensure that this burden is accounted for in an updated PRA under OMB control number 0920–1317.

b. Information Collection Burden Estimate for the Proposed Breast Screening Recall Rates Measure

In section XV.B.4.b. of this proposed rule, we are proposing to adopt the Breast Screening Recall Rates measure, beginning with the CY 2023 payment determination using a data collection period of July 1, 2020, to June 30, 2021; for subsequent years, we would use data collection periods from July 1 through June 30 for the 3 years prior to the applicable payment calendar year (for example, for the CY 2024 payment determination, we would use data from July 1, 2021, through June 30, 2022). Because the measure is calculated using claims data that are already reported to the Medicare program for payment purposes, we do not anticipate that adopting this measure will result in any increase in information collection burden.

c. Information Collection Burden Estimate for the Proposed ST-Segment Elevation Myocardial Infarction (STEMI) Measure

In section XV.B.4.c. of this proposed rule, we are proposing to adopt the STEMI eCQM, with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination. For the CY 2023 voluntary reporting period, hospitals would be able to voluntarily report the measure for one or more quarters during the year. In subsequent years, we have proposed to gradually increase the number of quarters of data hospitals would be required to report on the measure starting with one self-selected quarter for the CY 2024 reporting period/CY 2026 payment determination, two self-selected quarters for the CY 2025 reporting period/CY 2027 payment determination, three self-selected quarters for the CY 2026 reporting period/CY 2028 payment determination, and four quarters for the CY 2027 reporting period/CY 2029 payment determination and for subsequent years.

For the voluntary reporting period in CY 2023, we estimate 20 percent of hospitals would report at least one quarter of data for the measure with 100 percent of hospitals reporting the measure as required in subsequent years. Based on experience with reporting of eCQMs on the Hospital IQR program, we are aligning our estimate of the time required for a Medical Records and Health Information Technician professional to submit the data required for the measure to be 10 minutes per quarter for each hospital. For the CY 2023 voluntary reporting period, we estimate an annual burden for all participating hospitals of 110 hours (3,300 hospitals × 20 percent × .1667 hours × 1 quarter) at a cost of $4,664 (110 hours × $42.40). For the CY 2024 reporting period/CY 2026 payment determination, we estimate the annual burden for all hospitals to be 550 hours (3,300 hospitals × .1667 hours × 1 quarters) at a cost of $23,320 (550 hours × $42.40). For the CY 2025 reporting period/CY 2027 payment determination, we estimate the annual burden for all hospitals to be 1,100 hours (3,300 hospitals × .1667 hours × 2 quarters) at a cost of $46,640 (1,100 hours × $42.40). For the CY 2026 reporting period/CY 2028 payment determination, we estimate the annual burden for all hospitals to be 1,650 hours (3,300 hospitals × .1667 hours × 3 quarters) at a cost of $69,960 (1,650 hours × $42.40). For the CY 2027 reporting period/CY 2029 payment determination and subsequent years, we estimate the annual burden for all hospitals to be 2,200 hours (3,300 hospitals × .1667 hours × 4 quarters) at a cost of $93,280 (2,200 hours × $42.40).

The information collection requirement and the associated burden will be submitted as part of a revision of the information collection request currently approved under OMB control number 0938–1109, which expires on March 31, 2023.

d. Information Collection Burden Estimate for the Proposal To Require the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure (OP–31)

In section XV.B.5.b. of this proposed rule, we are proposing to require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure (OP–31), beginning with the CY 2023 reporting period/CY 2025 payment determination. We previously finalized voluntary reporting of this measure in the CY 2015 OPPS/ASC final rule (79 FR 66947 through 66948) and estimated that 20 percent of hospitals would elect to report it annually (79 FR 67014). We continue to estimate it will require hospitals 10 minutes once annually to report this measure using a CMS online tool. As a result of this proposal, we estimate a total annual burden estimate for all hospitals of 550 hours (3,300 hospitals × .1667 hours) at a cost of $23,320 (550 hours × $42.40). In addition to reporting the measure, we also require hospitals to perform chart abstraction and estimate that each hospital would spend 25 minutes (0.417 hours) per case to perform this activity. The currently approved burden estimate is based on an assumption of 384 cases requiring chart abstraction per measure. We are updating this assumption to 242 cases per measure based on data from the CY 2019 reporting period. Updating this assumption results in an annual burden of 101 hours (0.417 hours × 242 cases) at a cost of $4,282 (101 hours × $42.40/hour) per hospital and a total annual burden of 333,300 hours (3,300 hospitals × 101 hours) at a cost of $14,131,920 (333,300 hours × $42.40/hour) for all hospitals. In aggregate, we estimate a total annual burden of 333,850 hours (550 hours + 333,300 hours) at a cost of $14,155,240 ($23,320 + $14,131,920) for all hospitals. This is an increase of 267,080 hours and $11,324,192 per year from the currently approved estimate due to the additional 80 percent of hospitals that would be required to report this measure if our proposal is finalized.

The information collection requirement and the associated burden will be submitted as part of a revision of the information collection request currently approved under OMB control number 0938–1109, which expires on March 31, 2023.

[439] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

e. Information Collection Burden Estimate for the Proposals To Require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures (OP–37a–e) and Add Administration Methods

The information collection requirements associated with the five OAS CAHPS survey-based measures (proposed OP–37a, OP–37b, OP–37c, OP–37d, and OP–37e) are currently approved under OMB control number 0938–1240 which expires December 31, 2021. In section XV.B.5.a. of this proposed rule, we are proposing to require data collection for five OAS CAHPS survey-based measures with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination and subsequent years: (1) OAS CAHPS—About Facilities and Staff (OP–37a); (2) OAS CAHPS—Communication About Procedure (OP–37b); (3) OAS CAHPS—Preparation for Discharge and Recovery (OP–37c); (4) OAS CAHPS—Overall Rating of Facility (OP–37d); and (5) OAS CAHPS—Recommendation of Facility (OP–37e). This proposal will neither require additional questions to be added to the survey nor any other changes which will affect the time required for respondents to complete the survey. Therefore, we are not making any changes to the currently approved burden estimate of 8 minutes per respondent.

In addition, in section XV.D.4.b. of this proposed rule, we are proposing to incorporate two additional administration methods for the OAS CAHPS Survey: (1) Mixed mode web with mail follow-up of non-respondents, and (2) mixed mode web with telephone follow-up of non-respondents. This proposal would allow a total of five methods of survey administration for reporting beginning with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting for the CY 2024 reporting period/CY 2026 payment determination. We currently assume that completion of the OAS CAHPS survey requires approximately 8 minutes per respondent using one of the three current administration methods (mail-only, telephone-only, and mixed-mode (mail with telephone follow-up of non-respondents)). The two proposed administration methods would be utilized to increase the response rate of patients in order to achieve the same required number of 300 patients surveyed per practice, therefore we are not proposing any changes to the number of respondents. We also believe that both of the two proposed administration methods will require approximately the same time to conduct, therefore, we are not proposing any changes to the currently approved estimate.

f. Information Collection Burden Change for the Proposals To Remove the Fibrinolytic Therapy Received Within 30 Minutes (OP–2) and Median Time To Transfer to Another Facility for Acute Coronary Intervention (OP–3) Measures

In section XV.B.3.c. of this proposed rule, we are proposing to remove the Fibrinolytic Therapy Received Within 30 Minutes (OP–2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3) measures effective with the CY 2023 reporting period. The currently approved burden estimate under OMB control number 0938–1109 (which expires on March 31, 2023) for all hospitals is 151,800 hours at a cost of $6,436,320 (151,800 hours × $42.40) for each measure per year. If the proposals to remove both of these measures are finalized, we estimate a total burden decrease of 303,600 hours (151,800 hours × 2 measures) at a cost of $12,872,640 (303,600 hours × $42.40). The information collection under OMB Control number 0938–1109 will be revised and submitted to OMB for approval.

g. Information Collection Burden Estimate for the Proposal To Remove the Option for Hospitals To Send Medical Records to the Validation Contractor via Paper and Removable Media and Require Electronic Submission

As noted in the CY 2015 OPPS/ASC final rule (79 FR 67015), we have been reimbursing hospitals directly for expenses associated with submission of medical records for data validation. Specifically, we reimburse hospitals at 12 cents per photocopied page; for hospitals providing medical records digitally via a rewritable disc, such as encrypted Compact Disc—Read Only Memory, Digital Video Discs, or flash drives, we reimburse hospitals at a rate of 40 cents per disc, along with $3.00 per record; and for hospitals providing medical records as electronic files submitted via secure file transmission, we reimburse hospitals at $3.00 per record. Because we directly reimburse, we do not anticipate any net change in information collection burden associated with our finalized proposal to require electronic file submissions of medical records via secure file transmission for hospitals selected for chart-abstracted measures validation. Hospitals would continue to be reimbursed at $3.00 per record for electronic files submitted via secure file transmission, if our proposal is finalized.

h. Information Collection Burden Estimate for the Proposal To Reduce the Number of Days Hospitals Have To Submit Medical Records to the CDAC From 45 Days to 30 Days

In section XV.D.9.b. of this proposed rule, we are proposing to reduce the number of days hospitals would have to submit medical records to the CDAC from 45 days to 30 days. We expect that our proposal will not yield a change in burden as it does not affect the amount of data required for hospitals to submit. We discuss administrative burdens regarding this proposal in section XXV.C.4.b. of this proposed rule. The existing information collection requirement and the associated burden are currently approved under OMB control number 0938–1109, which expires on March 31, 2023.

i. Information Collection Burden Estimate for the Proposal To Add the Targeting Criteria Used for Hospital Selection by Adopting Criteria Currently Used in Inpatient Data Validation

In section XV.D.9.d.(2). of this proposed rule, we are proposing to add to the targeting criteria used for hospital selection for validation by adopting criteria currently used in inpatient data validation by adding the following criteria: (a) Having a lower bound confidence interval score of 75 percent or less; and (b) having not been selected in the previous 3 years. We expect that our proposal will not yield a change in burden as it does not affect the total number of hospitals selected for data validation nor the data submission requirements for the hospitals selected. The existing information collection requirement and the associated burden are currently approved under OMB control number 0938–1109, which expires on March 31, 2023.

j. Information Collection Burden Estimate for the Proposal To Expand Our Existing ECE Policy To Apply to Electronic Clinical Quality Measures (eCQMs)

In section XV.D.10.b. of this proposed rule, we are proposing to expand our existing ECE policy to apply to eCQMs, to further align with the Hospital IQR Program. The burden associated with submission of the ECE request form is included under OMB control number 0938–1022 which expires on December 31, 2022. As noted in 0938–1022, the total estimated burden for all hospitals

participating in the CMS Quality Reporting Program for completing forms including the ECE request form is 1,100 hours. In CY 2017, 166 ECE requests were submitted by hospitals for an exception from reporting requirements in the Hospital IQR Program. Based on the estimate of 15 minutes per record to submit the ECE Request Form, the total burden calculation for the submission of 166 ECE requests was 2,490 minutes (or 41.5 hours) across 3,300 IPPS hospitals. We are unable to forecast the number of additional ECE requests which may be submitted as a result of this proposal, however we continue to assume that each submission will continue to require approximately 15 minutes to complete. We believe the estimate of 1,100 hours across all IPPS and non-IPPS hospitals is conservative enough to account for any increase in burden that may be associated with this proposal.

k. Information Collection Burden Estimate for the Proposal To Require Use of 2015 Edition Cures Update Certified Technology

In section XV.D.6.c.(1). of this proposed rule, we are proposing hospitals use certified technology updated consistent with the 2015 Edition Cures Update beginning with the CY 2023 reporting period/CY 2025 payment determination and subsequent years, which includes both the voluntary period and required submissions of eCQMs. We do not expect that this proposal, if finalized, would affect our information collection burden estimates currently approved under OMB control number 0938–1109 (which expires on March 31, 2023) because this policy does not require hospitals to submit additional data to CMS. With respect to any costs unrelated to data submission, we refer readers to section XXV.C.4.b. of this proposed rule.

l. Information Collection Burden Estimate for the Proposal To Provide a Review and Corrections Period for eCQM Data Submitted to the Hospital OQR Program

In section XV.D.8. of this proposed rule, we are proposing that hospitals would have a review and corrections period for eCQM data submitted to the Hospital OQR Program. Early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in eCQM reporting is encouraged but not required; therefore, we are unable to estimate the number of hospitals that may elect to submit test data files. We account for the burden of submission of production data files in section XXIII.B.3.C. Similar to our previously finalized burden assumptions regarding a review and corrections period for chart-abstracted measures (79 FR 66964 and 67014) and web-based measures (85 FR 86184 and 86267) this proposal does not require hospitals to submit additional data, therefore we do not believe it will increase burden for these hospitals.

4. Summary of Information Collection Burden Estimates for the Hospital OQR Program

In summary, under OMB control number 0938–1109 which expires on March 31, 2023, we estimate that the policies promulgated in this proposed rule will result in a decrease of 73,344 hours annually for 3,300 OPPS hospitals across a 5-year period from the CY 2022 reporting period/CY 2024 payment determination through the CY 2027 reporting period/CY 2029 payment determination. The total cost decrease related to this information collection is approximately −$3,109,786 (−73,344 hours × $42.40/hour) (which also reflects use of an updated hourly wage rate as previously discussed). Tables 65, 66, 67, 68, and 69 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 2029 payment determination reflects the cumulative burden changes). Note that for the proposed STEMI eCQM, the tables do not reflect the maximum burden for the CY 2025 payment determination, because we estimate only 20 percent of hospitals will voluntarily report the measure during the CY 2023 reporting period. While it is possible that more than 20 percent of hospitals may voluntarily report the measure during the CY 2023 reporting period, this percentage is consistent with our experience implementing eCQM measures with voluntary reporting periods under the Hospital IQR Program. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109.[440]

BILLING CODE 4120–01–P

[440] CY 2020 Final Rule Hospital OQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911–0938–015.*

TABLE 65: Summary of Hospital OQR Program Information Collection Burden Change for the CY 2023 Reporting Period/CY 2025 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2025 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**
Add STEMI Measure	10	4	660	1	0.67	440	N/A	+440
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -75,104							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-75,104) = **-$3,184,410**							

TABLE 66: 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 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**
Add STEMI Measure	10	1	3,300	1	0.167	550	N/A	+550
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -74,994							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-74,994) = **-$3,179,746**							

TABLE 67: 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 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**
Add STEMI Measure	10	2	3,300	1	0.33	1,100	N/A	+1,100
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -74,444							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-74,444) = **-$3,156,426**							

TABLE 68: 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 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**
Add STEMI Measure	10	3	3,300	1	0.50	1,650	N/A	+1,650
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -73,894							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-73,894) = **-$3,133,106**							

TABLE 69: 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**
Add STEMI Measure	10	4	3,300	1	0.67	2,200	N/A	+2,200
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -73,344							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-73,344) = **-$3,109,786**							

BILLING CODE 4120–01–C

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015, CY 2016, CY 2017, CY 2018, CY 2019, CY 2020, and CY 2021 OPPS/ASC final rules with comment period (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; and 85 FR 86267, respectively) for detailed discussions of the Ambulatory Surgical Center Quality Reporting (ASCQR) Program ICRs we have previously finalized. The ICRs associated with the ASCQR Program for the CY 2014 through CY 2023 payment determinations are currently approved under OMB control number 0938–1270, which expires on December 31, 2022.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52619 through 52620), we finalized a proposal to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the BLS, to calculate our burden estimates for the ASCQR Program. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the ASCQR Program. The latest data from the BLS' May 2020 Occupational Employment and Wages data reflects a median hourly wage of $21.20 per hour for a Medical Records and Health Information Technician professional.[441] We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52619 through 52620). 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 ($21.20 × 2 = $42.40) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

Based on an analysis of the CY 2020 payment determination data, we found that of the 6,651 ASCs that met eligibility requirements for the ASCQR Program, 3,494 were required to participate in the Program and did so.

[441] *https://www.bls.gov/oes/current/oes292098.htm* (Accessed April 13, 2021). The hourly rate of $42.40 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

In addition, 689 ASCs that were not required to participate, did so, for a total of 4,183 participating facilities. As noted in section XXV.C.5.a. of the Regulatory Impact Analysis, for the CY 2021 payment determination, all 6,811 ASCs that met eligibility requirements for the ASCQR Program received the annual payment update due to data submission requirements being excepted under the ASCQR Program's ECEs policy in consideration of the COVID–19 PHE; of these 3,957 would have been were required to participate sans the PHE exception. Therefore, we estimate that 3,957 plus 689 or 4,646 ASCs will submit data for the ASCQR Program for the CY 2022 payment determination unless otherwise noted.

2. Summary

In this proposed rule, we propose to: (1) Adopt the COVID–19 Vaccination Coverage Among HCP measure, beginning with the CY 2022 reporting period/CY 2024 payment determination; (2) require four patient safety outcome measures beginning with the CY 2023 reporting period/CY 2025 payment determination: (a) Patient Burn (ASC–1); (b) Patient Fall (ASC–2); (c) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC–3); and (d) All-Cause Hospital Transfer/Admission (ASC–4); (3) require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC–11) measure beginning with the CY 2023 reporting period/CY 2025 payment determination; (4) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (ASC–15 a–e), with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination; and (5) add two additional data collection survey modes of OAS CAHPS measures collection to the existing three modes of collection and provide survey administration requirements.

3. Estimated Burden of ASCQR Program Proposals for the CY 2024 Payment Determination and Subsequent Years

a. Information Collection Burden Estimate for the Proposed COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure

In section XVI.B.3.a. of the preamble of this proposed rule, we are proposing to adopt the COVID–19 Vaccination Coverage Among HCP measure, beginning with the CY 2022 reporting period/CY 2024 payment determination. ASCs would submit data through the CDC/NHSN. The NHSN is a secure, internet-based surveillance system maintained and provided free by the CDC. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA (OMB control number 0920–1317, which expires on January 31, 2024) because the agency has been granted a waiver under section 321 of the NCVIA.[442] As such, the burden associated with the COVID–19 Vaccination Coverage Among HCP measure has not been accounted for under the CDC PRA 0920–1317 or 0920–0666 (which expires on December 31, 2023) due to the NCVIA waiver, however the cost and burden information is included in the Regulatory Impact Analysis section. Upon receiving comment, we will work with CDC to ensure that the burden is accounted for in an updated PRA under OMB control number 0920–1317.

b. Information Collection Burden Estimate for the Proposal To Require Four Patient Safety Outcome Measures: Patient Burn (ASC–1); Patient Fall (ASC–2); Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC–3); and All-Cause Hospital Transfer/Admission (ASC–4)

In section XVI.B.4.a. of this proposed rule, we are proposing to resume and require four patient safety outcome measures beginning with the CY 2023 reporting period/CY 2025 payment determination: (1) Patient Burn (ASC–1); (2) Patient Fall (ASC–2); (3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC–3); and (4) All-Cause Hospital Transfer/Admission (ASC–4). Measure data for these measures would be submitted via the CMS Hospital Quality Reporting (HQR) system secure portal (also known as the CMS QualityNet Secure Portal). Consistent with prior years (78 FR 75171 through 75172), we estimate that each participating hospital will spend 10 minutes per measure per year to collect and submit the data via a CMS web-based tool (OMB control number 0938–1270, which expires on December 31, 2022). As a result of this proposal, we estimate a total annual burden estimate for all ASCs of 3,098 hours (0.1667 hours/measure × 4 measures × 4,646 ASCs) at a cost of $131,355 (3,098 hours × $42.40). The information collection under OMB Control number 0938–1270 will be revised and submitted to OMB for approval.

c. Information Collection Burden Estimate for the Proposal To Require the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (ASC–11) Measure

In section XVI.B.4.b. of this proposed rule, we are proposing to require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC–11) measure beginning with the CY 2023 reporting period/CY 2025 payment determination. We previously finalized voluntary reporting of this measure in the CY 2015 OPPS/ASC final rule (79 FR 66985) and estimated that 20 percent of ASCs would elect to report it annually (79 FR 67016). We continue to estimate it will require ASCs 10 minutes once annually to report this measure. As a result of this proposal, we estimate a total annual burden estimate for all ASCs to report the measure of 774 hours (4,646 ASCs × 0.1667 hours) at a cost of $32,818 (774 hours × $42.40). In addition to reporting the measure, we also require ASCs to perform chart abstraction for a minimum required yearly sample size of 63 cases. We estimate that each ASC would spend 15 minutes per case to perform this activity. As a result of this proposal, we estimate an annual burden of 16 hours (0.25 hours × 63 measures) at a cost of $678 (16 hours × $42.40) per ASC and a total annual burden of 74,336 hours (4,646 ASCs × 16 hours) at a cost of $3,151,846 (74,336 hours × $42.40). In aggregate, we estimate a total annual burden of 75,110 hours (774 + 74,336) at a cost of $3,184,664 (75,110 hours × $42.40) for all ASCs. Taking into account the increase in the number of ASCs submitting data, this is an increase of 60,088 hours (75,110 hours × 80 percent) and $2,547,731 ($3,184,664 × 80 percent) per year from the currently approved estimate (OMB control number 0938–1270, which expires on December 31, 2022) due to the additional 80 percent of ASCs that would be reporting this measure if our proposal is finalized. The information collection under OMB Control number 0938–1270 will be revised and submitted to OMB for approval.

[442] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

d. Information Collection Burden Estimate for the Proposals To Require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures (ASC–15 a–e) and Incorporate Additional Administration Methods

The information collection requirements associated with the five OAS CAHPS Survey-based measures (proposed ASC–15a, ASC–15b, ASC–15c, ASC–15d, and ASC–15e) are currently approved under OMB control number 0938–1240 which expires December 31, 2021.

In section XVI.B.4.c. of this proposed rule, we are proposing to require five OAS CAHPS Survey-based measures with voluntary reporting beginning with the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination and subsequent years: (1) ASC–15a: OAS CAHPS—About Facilities and Staff; (2) ASC–15b: OAS CAHPS—Communication About Procedure; (3) ASC–15c: OAS CAHPS—Preparation for Discharge and Recovery; (4) ASC–15d: OAS CAHPS—Overall Rating of Facility; and (5) ASC–15e: OAS CAHPS—Recommendation of Facility. This proposal will neither require additional questions to be added to the survey nor any other changes which will affect the time required for respondents to complete the survey. Therefore, we are not making any changes to the currently approved burden estimate of 8 minutes per respondent.

In addition, in section XVI.D.1.d.(2). of this proposed rule, we are proposing to incorporate two additional administration methods for the OAS CAHPS Survey: (1) Mixed mode web with mail follow-up of non-respondents, and (2) mixed mode web with telephone follow-up of non-respondents. This proposal would allow a total of five methods of survey administration for reporting beginning with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting for the CY 2024 reporting period/CY 2026 payment determination. We currently assume that completion of the OAS CAHPS survey requires approximately 8 minutes per respondent using one of the three current administration methods (mail-only, telephone-only, and mixed-mode (mail with telephone follow-up of nonrespondents)). We believe that both of the two proposed administration methods will require approximately the same time to conduct, therefore, we are not proposing any changes to the currently approved estimate. In addition, the two proposed administration methods would be utilized to increase the response rate of patients in order to achieve the same required number of 300 patients surveyed per practice, therefore we are not proposing any changes to the number of respondents.

e. Summary of Information Collection Burden Estimates for the ASCQR Program

In summary, under OMB control number 0938–1270 which expires on December 31, 2022, we estimate that the policies promulgated in this proposed rule will result in an increase of 67,085 hours annually for 4,646 ASCs across a 4-year period from the CY 2023 reporting period/CY 2025 payment determination through the CY 2026 reporting period/CY 2028 payment determination. The total cost increase related to this information collection is approximately $2,844,404 (67,085 hours × $42.40). Table 70 summarizes the total burden changes for each respective CY payment determination compared to our currently approved information collection burden estimates. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1270.[443]

[443] CY 2021 Final Rule ASCQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/DownloadDocument?objectID=108544300.*

TABLE 70: Summary of ASCQR Program Information Collection Burden Change for the CY 2023 Reporting Period/CY 2025 Payment Determination through CY 2026 Reporting Period/CY 2028 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2025 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Require ASC 1-4 measures	10	1	4,646	4	0.67	3,098	N/A	+3,098
Require ASC-11 Measure	10	1	4,646	1	.1667	774	116.7	+657
Require Chart Abstraction for ASC-11 Measure	15	1	4,646	63	16	74,336	11,006	+63,330
	Total Change in Information Collection Burden Hours: +67,085							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (+67,085) = **+$2,844,404**							

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by September 17, 2021.

XXIV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XXV. Economic Analyses

A. Statement of Need

This proposed rule is necessary to make updates to the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2022. 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, 2019, through and including December 31, 2019, and processed through June 30, 2020, and prior cost report information, consistent with our proposal to use data prior to the start of the PHE.

This proposed rule also is necessary to make updates to the ASC payment rates for CY 2022, 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 2022. 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. We believe that this policy will help stabilize the differential between OPPS payments and ASC payments, given that the CPI–U has been generally lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate.

B. Overall Impact of Provisions of This Proposed Rule

We have examined the impacts of this proposed rule, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), 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), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). This section of this proposed rule contains the impact and other economic analyses for the provisions we propose for CY 2022.

Executive Orders 12866 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866. Accordingly, this proposed rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of the provisions of this proposed rule. We are soliciting public comments on the regulatory impact analysis in the proposed rule, and we address any public comments we received in this proposed rule, as appropriate.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2022, compared to CY 2021, due only to the changes to the OPPS in this proposed rule, would be approximately $1.35 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2022, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2022 would be approximately $82.7 billion, which is approximately $10.8 billion higher than estimated OPPS expenditures in CY 2021. Because the provisions of the OPPS are part of a proposed rule that is economically significant, as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 71 of this proposed rule displays the distributional impact of the CY 2022 changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that under our proposed CY 2022 policy, drugs and biologicals that are acquired under the 340B Program are proposed to be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable.

We estimate that the proposed update to the conversion factor and other budget neutrality adjustments would increase total OPPS payments by 2.3 percent in CY 2022. The proposed changes to the APC relative payment weights, the changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, the proposed continuation of payment policy for separately payable drugs acquired under the 340B program, and the proposed payment adjustment for cancer hospitals would not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2021 and CY 2022, considering all proposed budget-neutral payment adjustments, changes in estimated total outlier payments, pass-through payments and the proposed adjustment to provide separate payment for a device category, drugs, and biologicals with pass-through status expiring between December 31, 2021, and September 30, 2022, and 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 OPPS payments by 1.8 percent.

We estimate the total decrease (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 2022 compared to CY 2021, to be approximately $20 million. Because the provisions for the ASC payment system are part of a proposed rule that is economically significant, as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of this proposed rule. Tables 72 and 73 of this proposed rule display the redistributive impact of the CY 2022 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in This Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2022 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2022 with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* At the website, select ''regulations and notices'' from the left side of the page and then select ''CMS–1753–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 71. 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 adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of Proposal To Update the 340B Program Payment Policy

In section V.B. of this proposed rule with comment period, we discuss our proposal to adjust the payment amount for nonpass-through, separately payable drugs acquired by certain 340B participating hospitals through the 340B Program. We propose that rural SCHs, children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from this payment policy in CY 2022. Specifically, in this proposed rule for CY 2022, for hospitals paid under the OPPS (other than those that are excepted for CY 2022), we propose to pay for separately payable drugs and

biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 22.5 percent. Because we are proposing to continue current Medicare payment policy for CY 2022, there is no change to the proposed budget neutrality adjustment as a result of the 340B drug payment policy.

c. Estimated Effects of OPPS Changes on Hospitals

Table 71 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-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 71, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2022, we propose to continue to pay CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs) and to pay hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B. of this proposed rule.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase applicable to the OPD fee schedule for CY 2022 is 2.5 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 2.5 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 2022 (which is also the productivity adjustment for FY 2022 in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25436)), resulting in the CY 2022 OPD fee schedule increase factor of 2.3 percent. We are proposing to use the OPD fee schedule increase factor of 2.3 percent in the calculation of the CY 2022 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 71 of this proposed rule.

To illustrate the impact of the CY 2022 changes, our analysis begins with a baseline simulation model that uses the CY 2021 relative payment weights, the FY 2021 final IPPS wage indexes that include reclassifications, and the final CY 2021 conversion factor. Table 71 shows the estimated redistribution of the increase or decrease in payments for CY 2022 over CY 2021 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2021 and CY 2022 (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 2.3 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated impact taking into account all payments for CY 2022 relative to all payments for CY 2021, including the impact of changes in estimated outlier payments, and changes to the pass-through payment estimate and adjustment to provide separate payment for a device category, drugs, and biologicals with pass-through status expiring between December 31, 2021, and September 30, 2022 (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are proposing to maintain the current adjustment percentage for CY 2022. Because the 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 2022 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 will 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 will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2021 and CY 2022 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2022 will increase Medicare OPPS payments by an estimated 1.8 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 1.8 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 71 shows the total number of facilities (3,662), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2019 hospital outpatient and CMHC claims data to model CY 2021 and CY 2022 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 2021 or CY 2022 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 (3,555), 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 39 CMHCs at the bottom of the impact table (Table 71) 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 no change, with the impact ranging from a decrease of 0.1 percent to an increase of 0.2, depending on the number of beds. Rural hospitals will experience an increase of 0.1 overall. Major teaching hospitals will see no change.

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 proposed FY 2022 IPPS post-reclassification wage indexes; the proposed rural adjustment, and the proposed 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 2021 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 proposed updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the CY 2022 proposed changes in wage index policy discussed in section II.C. of this CY 2022 OPPS/ASC proposed rule. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we propose to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2022, as described in section II.E. of this proposed rule. We also did not model 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 2022 is 0.89, the same as the ratio that was reported for the CY 2021 OPPS/ASC final rule with comment period (85 FR 85914). 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 0.90, not the 0.89 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 2022 scaled weights and a CY 2021 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2021 and CY 2022.

Column 4: All Budget Neutrality Changes Combined With the Market Basket Update

Column 4 demonstrates the combined impact of all of the changes previously described and the update to the conversion factor of 2.3 percent. Overall, these changes will increase payments to urban hospitals by 2.3 percent and to rural hospitals by 2.3 percent. The increase for classes of rural hospitals will vary with sole community hospitals receiving a 2.2 percent increase and other rural hospitals receiving an increase of 2.5 percent.

Column 5: All Proposed Changes for CY 2022

Column 5 depicts the full impact of the proposed CY 2022 policies on each hospital group by including the effect of all changes for CY 2022 and comparing them to all estimated payments in CY 2021. 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 the difference in total OPPS payments dedicated to transitional pass-through payments and the proposed adjustment to provide separate payment for the device category, drugs, and biologicals with pass-through status expiring between December 31, 2021, and September 30, 2022.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2021 update (and assumed, for modeling purposes, to be the same number for CY 2022), we included 17 hospitals in our model because they had both CY 2019 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2022 will increase payments to all facilities by 1.8 percent for CY 2022. We modeled the independent effect of all changes in Column 5 using the final relative payment weights for CY 2021 and the proposed relative payment weights for CY 2022. We used the final conversion factor for CY 2021 of $82.797 and the proposed CY 2022 conversion factor of $84.457 discussed in section II.B. of this proposed rule.

Column 5 contains simulated outlier payments for each year. We used the 2-year charge inflation factor used in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039) of 13.2 percent (1.13218) to increase individual costs on the CY 2019 claims, and we used the overall CCR in the April 2020 Outpatient Provider-Specific File (OPSF) with a 1-year CCR adjustment factor of 0.974495 (85 FR 59040) to estimate outlier payments for CY 2021. Using the CY 2019 claims and a 13.2 percent charge inflation factor, we currently estimate that outlier payments for CY 2021, using a multiple threshold of 1.75 and a fixed-dollar threshold of $5,300, will be approximately 1.06 percent of total payments. The estimated current outlier payments of 1.06 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 20.4 percent (1.20469) and the CCRs in the April 2020 OPSF, with an adjustment of 0.974495 multiplied by 0.974495 (86 FR 25718), to reflect relative changes in cost and charge inflation between CY 2019 and CY 2022, to model the proposed CY 2022 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $6,100. The charge inflation and CCR inflation factors are discussed in detail in the FY 2021 IPPS/LTCH PPS proposed rule (84 FR 42629).

Overall, we estimate that facilities will experience an increase of 1.8 percent under this proposed rule in CY 2022 relative to total spending in CY 2021. This projected increase (shown in Column 5) of Table 71 reflects the 2.3 percent OPD fee schedule increase factor, minus 0.40 percent for the change in the pass-through payment estimate between CY 2021 and CY 2022 and the proposed adjustment to provide separate payment for the device category, drugs, and biologicals with pass-through status expiring between December 31, 2021, and September 30, 2022, minus the difference in estimated outlier payments between CY 2021 (1.06 percent) and CY 2022 (1.0 percent). We estimate that the combined effect of all proposed changes for CY 2022 will increase payments to urban hospitals by 1.8 percent. Overall, we estimate that rural hospitals will experience a 1.8 percent increase as a result of the

combined effects of all the proposed changes for CY 2022.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 1.7 percent for major teaching hospitals and an increase of 2.0 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 1.8 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 1.8 percent, proprietary hospitals will experience an increase of 2.0 percent, and governmental hospitals will experience an increase of 2.4 percent.

BILLING CODE 4120–01–P

TABLE 71: Estimated Impact of the Proposed CY 2022 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 and 3) with Market Basket Update**	**All Changes**
ALL PROVIDERS *		3,662	0.0	0.0	2.3	1.8
ALL HOSPITALS		3,555	0.0	0.0	2.3	1.8
	(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS		2,803	0.0	0.0	2.3	1.8
	LARGE URBAN	1,448	0.0	0.1	2.4	1.9
	(GT 1 MILL.)					
	OTHER URBAN	1,355	0.0	-0.1	2.2	1.8
	(LE 1 MILL.)					

		(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 and 3) with Market Basket Update**	**All Changes**
RURAL HOSPITALS		752	0.1	0.0	2.3	1.8
	SOLE COMMUNITY	369	0.0	-0.1	2.2	1.7
	OTHER RURAL	383	0.1	0.1	2.5	2.0
BEDS (URBAN)						
	0 - 99 BEDS	958	0.2	0.0	2.5	2.0
	100-199 BEDS	786	0.1	-0.1	2.3	1.8
	200-299 BEDS	447	0.1	0.0	2.4	1.9
	300-499 BEDS	386	0.0	0.0	2.3	1.9
	500 + BEDS	226	-0.1	0.0	2.2	1.7
BEDS (RURAL)						
	0 - 49 BEDS	330	0.1	-0.3	2.2	1.7
	50- 100 BEDS	256	0.1	-0.1	2.3	1.8
	101- 149 BEDS	90	0.0	-0.2	2.1	1.7
	150- 199 BEDS	38	0.0	0.1	2.4	1.9
	200 + BEDS	38	0.0	0.4	2.6	2.1
REGION (URBAN)						
	NEW ENGLAND	132	0.0	-0.3	2.0	1.5
	MIDDLE ATLANTIC	326	0.0	-0.4	1.9	1.4
	SOUTH ATLANTIC	455	0.0	0.2	2.6	2.1
	EAST NORTH CENT.	440	0.0	0.0	2.3	1.8
	EAST SOUTH CENT.	163	0.0	0.0	2.3	1.8
	WEST NORTH CENT.	186	0.0	0.3	2.6	2.2
	WEST SOUTH CENT.	474	0.1	-0.2	2.2	1.7
	MOUNTAIN	213	0.0	-0.1	2.2	1.6
	PACIFIC	366	0.1	0.3	2.7	2.2
	PUERTO RICO	48	0.3	-0.4	2.3	1.8
REGION (RURAL)						

		(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 and 3) with Market Basket Update**	**All Changes**
	NEW ENGLAND	20	-0.1	-0.3	1.9	1.4
	MIDDLE ATLANTIC	50	0.1	0.1	2.4	1.9
	SOUTH ATLANTIC	113	0.1	0.6	3.0	2.5
	EAST NORTH CENT.	120	0.1	-0.1	2.3	1.8
	EAST SOUTH CENT.	146	0.1	-0.1	2.3	1.8
	WEST NORTH CENT.	91	0.0	-0.4	1.9	1.5
	WEST SOUTH CENT.	141	0.3	-0.1	2.5	2.0
	MOUNTAIN	48	-0.1	0.4	2.6	1.5
	PACIFIC	23	-0.1	-0.1	2.1	1.6
TEACHING STATUS						
	NON-TEACHING	2,388	0.1	0.0	2.5	2.0
	MINOR	792	0.0	-0.1	2.3	1.8
	MAJOR	375	-0.1	0.0	2.2	1.7
DSH PATIENT PERCENT						
	0	14	0.0	-0.4	1.9	1.4
	GT 0 - 0.10	270	0.2	-0.1	2.3	1.9
	0.10 - 0.16	235	0.1	-0.2	2.2	1.7
	0.16 - 0.23	577	0.2	0.0	2.5	2.0
	0.23 - 0.35	1,100	0.0	0.0	2.3	1.8
	GE 0.35	901	0.0	0.1	2.4	1.8
	DSH NOT AVAILABLE **	458	0.3	0.1	2.7	2.2
URBAN TEACHING/DSH						
	TEACHING & DSH	1,048	0.0	0.0	2.2	1.8
	NO TEACHING/DSH	1,303	0.1	0.1	2.5	2.0
	NO TEACHING/NO DSH	14	0.0	-0.4	1.9	1.4
	DSH NOT AVAILABLE2	438	0.3	0.1	2.7	2.2

		(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 and 3) with Market Basket Update**	**All Changes**
TYPE OF OWNERSHIP						
	VOLUNTARY	1,975	0.0	0.0	2.3	1.8
	PROPRIETARY	1,131	0.3	-0.1	2.5	2.0
	GOVERNMENT	449	0.0	0.1	2.4	2.4
CMHCs		39	0.6	-0.8	2.1	1.6
Column (1) shows total hospitals and/or CMHCs.						
Column (2) includes all proposed CY 2022 OPPS policies and compares those to the CY 2021 OPPS.						
Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2022 hospital inpatient wage index. The proposed rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because the proposed CY 2022 target payment-to-cost ratio is the same as the CY 2021 PCR target (0.89).						
Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.3 percent OPD fee schedule update factor (2.5 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, the proposed adjustment to provide separate payment for the device category, drugs, and biologicals with pass-through status expiring between December 31, 2021 and September 30, 2022, and adding estimated outlier payments.						
These 3,662 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.						
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.						

BILLING CODE 4120–01–C

d. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 71 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2021, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2019 claims used for ratesetting in the proposed rule. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs will experience an overall 1.6 percent increase in payments from CY 2021 (shown in Column 5). We note that this includes the trimming methodology as well as the proposed CY 2022 geometric mean costs used for developing the PHP payment rates described in section VIII.B. of this final rule with comment period.

Column 3 shows that the estimated impact of adopting the proposed FY 2021 wage index values will result in a decrease of 0.8 percent to CMHCs. Column 4 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2022 and the proposed FY 2021 wage index updates, will result in an estimated increase of 2.1 percent. Column 5 shows that adding the proposed changes in outlier and pass-through payments will result in a total 1.6 percent increase in payment for CMHCs. This reflects all proposed changes for CMHCs for CY 2022.

e. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For further discussion of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we

refer readers to section II.I. of this CY 2022 OPPS/ASC 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 18.1 percent for all services paid under the OPPS in CY 2022. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2022 comprehensive APC payment policy discussed in section II.A.2.b. of this final rule.

f. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII of the final rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs will be affected by the proposed changes in the proposed rule.

g. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $1.35 billion in program payments for OPPS services furnished in CY 2022. 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 proposed changes in the proposed rule would increase these Medicaid beneficiary payments by approximately $95 million in CY 2022. Currently, there are approximately 10 million dual-eligible beneficiaries, which represent approximately thirty 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 $95 million Medicaid increase, approximately $55 million will be from the Federal Government and $40 million would be from state governments.

h. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout the final rule.

- Alternatives Considered for the Claims Data used in OPPS and ASC Ratesetting due to the PHE.

We refer readers to section X.E. of this proposed rule with comment period for a discussion of our proposed policy of generally using claims, cost report and other data prior to the PHE. We note that in that section we discuss the alternative proposal we considered regarding applying the standard ratesetting process, in particular the selection of data used, which would include claims and cost report data including the timeframe of the PHE. We note that there are potential issues related to that data including the effect of the PHE on the OPPS relative payment weights and the service mix applied in the budget neutrality process, and therefore our primary proposal is to use CY 2019 claims and cost report data generally in CY 2022 OPPS ratesetting. However, we are making the supporting data files typically included as part of the rulemaking process, available online at the CMS website to allow stakeholders the opportunity to provide meaningful comment.

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.

2. Estimated Effects of CY 2022 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 2022 ASC relative payment weights by scaling the proposed CY 2022 OPPS relative payment weights by the proposed ASC scalar of 0.8591. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 72 and 73.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which, in CY 2019, we adopted a policy to be the hospital market basket for CY 2019 through CY 2023) after application of any quality reporting reduction be reduced by a productivity adjustment. 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) (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, we propose that the CY 2022 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which we propose would be the hospital market basket for CY 2022. We calculated the CY 2022 ASC conversion factor by adjusting the CY 2021 ASC conversion factor by 0.9993 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2021 and CY 2022 and by applying the CY 2022 productivity-adjusted hospital market basket update factor of 2.3 percent (which is equal to the projected hospital market basket update of 2.5 percent reduced by a productivity adjustment of 0.2 percentage point). The proposed CY 2022 ASC conversion factor is $50.043 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 2022 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2019 and CY 2022 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2022 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 will 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 on an individual ASC of the proposed update to the CY 2022 payments 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 presents tables that display estimates of the impact of the

proposed CY 2022 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2019 claims data. Table 72 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2021 payments to estimated proposed CY 2022 payments, and Table 73 shows a comparison of estimated CY 2021 payments to estimated proposed CY 2022 payments for procedures that we estimate will receive the most Medicare payment in CY 2021.

In Table 72, 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 72.

- 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 2021 ASC Payments were calculated using CY 2019 ASC utilization data (the most recent full year of ASC utilization) and CY 2021 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2021 ASC payments.
- Column 3—Estimated CY 2022 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 2022 compared to CY 2021.

As shown in Table 72, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2022 will result in a 1-percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, a 3-percent increase in aggregate payment amounts for nervous system procedures, 4-percent increase in aggregate payment amounts for digestive system procedures, a 4-percent increase in aggregate payment amounts for musculoskeletal system procedures, and a 4-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 proposed changes in policy. In general, spending in each of these categories of services is increasing due to the 2.3 percent proposed 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 2.3-percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 4-percent increase in proposed aggregate gastrointestinal procedure payments. The increases in payment weights for gastrointestinal procedure payments is further increased by the proposed 2.3 percent ASC rate update for these procedures. For estimated changes for selected procedures, we refer readers to Table 73 provided later in this section.

TABLE 72: ESTIMATED IMPACT OF THE PROPOSED CY 2022 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2022 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2021 ASC Payments (in Millions) (2)	Estimated CY 2022 Percent Change (3)
Total	$5,681	2
Musculoskeletal	$727	4
Gastrointestinal	$948	4
Genitourinary	$213	4
Skin	$157	3
Eye	$1,918	-1
Nervous System	$1,211	3

Table 73 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2022. The table displays 30 of the procedures receiving the greatest estimated CY 2021 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2021 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2021 ASC Payments were calculated using CY 2019 ASC utilization (the most recent full year of ASC utilization) and the CY 2021 ASC payment rates. The estimated CY 2021 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2022 Percent Change reflects the percent differences between the estimated ASC

payment for CY 2021 and the estimated payment for CY 2022 based on the proposed update.

BILLING CODE 4120–01–P

TABLE 73: ESTIMATED IMPACT OF THE FINAL CY 2022 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2021 ASC Payment (in millions) (3)	Estimated CY 2022 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,293	1
63685	Insrt/redo spine n generator	$293	2
45380	Colonoscopy and biopsy	$251	3
45385	Colonoscopy w/lesion removal	$187	3
63650	Implant neuroelectrodes	$187	3
43239	Egd biopsy single/multiple	$186	3
0191T	Insert ant segment drain int	$128	0
64483	Inj foramen epidural l/s	$122	3
66982	Xcapsl ctrc rmvl cplx wo ecp	$96	1
64635	Destroy lumb/sac facet jnt	$86	4
64493	Inj paravert f jnt l/s 1 lev	$79	3
36902	Intro cath dialysis circuit	$78	3
29827	Sho arthrs srg rt8tr cuf rpr	$76	4
66821	After cataract laser surgery	$67	3
64590	Insrt/redo pn/gastr stimul	$63	3
C9740	Cysto impl 4 or more	$58	3
22869	Insj stablj dev w/o dcmprn	$58	3
62323	Njx interlaminar lmbr/sac	$55	3
G0105	Colorectal scrn; hi risk ind	$53	3
15823	Revision of upper eyelid	$41	3
45378	Diagnostic colonoscopy	$39	3
G0121	Colon ca scrn not hi rsk ind	$39	3
64721	Carpal tunnel surgery	$37	4
63655	Implant neuroelectrodes	$32	3
65820	Relieve inner eye pressure	$30	3
62362	Implant spine infusion pump	$28	3
67042	Vit for macular hole	$28	3
29881	Knee arthroscopy/surgery	$28	4
64490	Inj paravert f jnt c/t 1 lev	$28	3
64561	Implant neuroelectrodes	$28	3

c. Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2022 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 we propose to designate as office-based for CY 2022. For example, using 2019 utilization data and proposed CY 2022 OPPS and ASC payment rates, we estimate that if 10 percent of colpopexy procedures migrate from the hospital outpatient setting to the ASC setting, Medicare payments will be reduced by approximately $7 million in CY 2022 and total beneficiary copayments will decline by approximately $1.4 million in CY 2022. 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 OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will 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 propose to designate as office-based in CY 2022, 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).

3. Accounting Statements and Tables

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-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 74, illustrates the classification of expenditures for the CY 2022 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2022 OPD fee schedule increase. The second accounting statement, Table 75, illustrates the classification of expenditures associated with the 2.3 percent CY 2022 update to the ASC payment system, based on the provisions of the final rule with comment period and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers.

TABLE 74: ACCOUNTING STATEMENT: CY 2022 Estimated Hospital OPPS Transfers from CY 2021 to CY 2022 Associated with the Proposed CY 2022 Hospital Outpatient OPD Fee Schedule Increase

Category	Transfers
Annualized Monetized Transfers	$1,350 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS
Total	$1,350 million

TABLE 75: ACCOUNTING STATEMENT: Classification of Estimated Transfers from CY 2021 to CY 2022 as a Result of the Proposed CY 2022 Update to the ASC Payment System

Category	Transfers
Annualized Monetized Transfers	$90 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$90 million

TABLE 76: Estimated Costs in CY 2022

CATEGORY	Costs
Burden	$4.54 million*
Regulatory Familiarization	$1.195 million**

*The annual estimate includes the impact of OQR and ASCQR program, vaccination coverage data collection across hospitals and ASCs, burden estimate for RO model, and burden reduction for State forensic hospitals.
** Regulatory familiarization costs occur upfront only.

TABLE 77: Accounting Statement Estimated Impacts for the Radiation Oncology Model

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized ($million/year)	-$27 million	2020	7%	2022 – 2026
	-$29 million	2020	3%	2022 – 2026
From Whom to Whom	From the Federal Government to healthcare providers			

BILLING CODE 4120–01–C

4. Effects of Changes in Requirements for the Hospital OQR Program

a. Background

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59492 through 59494), for the previously estimated effects of changes to the Hospital Outpatient Quality Reporting (OQR) Program for the CY 2018, CY 2019, and CY 2021 payment determinations. Of the 3,163 hospitals that met eligibility requirements for the CY 2021 payment determination, 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 Proposals in This CY 2022 OPPS/ASC Proposed Rule

We anticipate that some of the CY 2022 Hospital OQR Program proposed policies, if finalized, will impact the number of facilities that will receive payment reductions. In this proposed rule with comment period, we are proposing to: (1) Adopt the COVID–19 Vaccination Coverage Among HCP measure, beginning with the CY 2022 reporting period; (2) adopt the Breast Screening Recall Rates measure, beginning with the CY 2022 reporting period; (3) adopt the STEMI eCQM, beginning as a voluntary measure with the CY 2023 reporting period, and then as a mandatory measure beginning with the CY 2024 reporting period; (4) require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure (OP–31), beginning with the CY 2023 reporting period/CY 2025 payment determination; (5) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (OP–37a–e), with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination; (6) remove the Fibrinolytic Therapy Received Within 30 Minutes measure (OP–2), effective with the CY 2023 reporting period; (7) remove the Median Time to Transfer to Another Facility for Acute Coronary Intervention measure (OP–3), effective with the CY 2023 reporting period; (8) remove the option for hospitals to send medical records to the validation contractor via paper and removable media and require electronic submission; (9) reduce the number of days hospitals have to submit medical records to the CDAC from 45 days to 30 days; (10) enhance the targeting criteria used for hospital selection by adopting criteria currently used in inpatient data validation by adding the following criteria: (a) Having a lower bound confidence interval score of 75 percent or less; and (b) having not been selected in the previous 3 years; (11) extend our existing ECE policy to apply to eCQMs, to further align with the Hospital Inpatient Quality Reporting (IQR) Program; and (12) require use of technology updated consistent with 2015 Edition Cures Update criteria beginning with the CY 2023 reporting period.

As shown in Table 69 in section XXIII.B.4. (Collection of Information), we estimate a total information collection burden decrease for 3,300 OPPS hospitals of −73,344 hours at a cost of −$3,109,786 annually associated with our proposed policies and updated burden estimates across a 5 year period from the CY 2022 reporting period/CY 2024 payment determination through the CY 2027 reporting period/CY 2029 payment determination, compared to our currently approved information collection burden estimates. We refer readers to section XXII.B. of the preamble 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. As discussed later in this section of the preamble, we detail proposed policies that would have additional economic impact. The proposals not discussed in this section are believed to have no further economic impact beyond information collection burden.

In section XV.B.4.a. of the preamble of this proposed rule, we are proposing to adopt a COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2022 reporting period/CY 2024 payment determination. Hospitals would submit data through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package currently approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[444] Although the burden associated with the COVID–19 Vaccination Coverage Among HCP measure is not accounted for under the CDC PRA 0920–1317 or 0920–0666, the cost and burden information is included here. We estimate that it would take each hospital on average approximately 1 hour per month to collect data for the COVID–19 Vaccination Coverage Among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. This burden is comprised of administrative hours and wages. We believe an Administrative Assistant[445] would spend between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. Beginning with the CY 2022 reporting period/FY 2024 payment determination, hospitals

[444] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[445] *https://www.bls.gov/oes/current/oes436013.htm.* Accessed on April 13, 2021. The adjusted hourly wage rate of $35.92/hr includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

would incur an additional annual burden between 9 hours (0.75 hours/month × 12 months) and 15 hours (1.25 hours/month × 12 months) per hospital and between 29,700 hours (9 hours/hospital × 3,300 hospitals) and 49,500 hours (15 hours/hospital × 3,300 hospitals) for all hospitals. Each hospital would incur an estimated cost of between $323.28 (9 hours × $35.92/hr) and $538.80 annually (15 hours × $35.92/hr). The estimated cost across all 3,300 hospitals would be between $1,066,824 ($323.28/hospital × 3,300 hospitals) and $1,778,040 ($538.80/hospital × 3,300 hospitals) annually thereafter. We recognize that many healthcare facilities are also reporting other COVID–19 data to HHS. We believe the benefits of reporting data on the COVID–19 Vaccination Coverage Among HCP measure to monitor, track, and provide transparency for the public on this important tool to combat COVID–19 outweigh the costs of reporting. We welcome comments on the estimated time to collect data and enter it into the NHSN as well as any additional costs associated with this measure.

In section XV.B.4.c. of this proposed rule, we are proposing to adopt the STEMI eCQM. Similar to the FY 2019 IPPS/LTCH PPS final rule, 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 EHR systems for all of the eCQMs available for use in the Hospital OQR Program (83 FR 41771).

As described in section XV.D.6. of this proposed rule, we are proposing certification requirements requiring the use of the 2015 Edition Cures Update for eCQMs beginning with the CY 2025 payment determination. We expect this proposal to have no impact on information collection burden for the Hospital OQR Program because this policy does not require hospitals to submit new data to CMS. With respect to any costs unrelated to data submission, although this finalized proposal will require some investment in systems updates, the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs) previously finalized a requirement that hospitals use the 2015 Edition Cures Update for eCQMs (85 FR 84818 through 84825). Because all hospitals participating in the Hospital OQR Program are subsection (d) hospitals that also participate in the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs), we do not anticipate any additional costs as a result of this finalized proposal. This is because the burden and costs involved in updating to the 2015 Edition Cures Update is the same regardless of whether the technology is used for eCQMs. Therefore, we believe that the Medicare Promoting Interoperability Program has already addressed the additional costs unrelated to data submission through their previously finalized requirements.

In section XV.D.9.c. of this proposed rule, we are proposing to reduce the number of days hospitals have to submit medical records to the CDAC from 45 days to 30 days. In previous years, charts were requested by the CMS CDAC contractor and hospitals were given 45 days from the date of the request to submit the requested records. This may be an additional administrative burden to hospitals selected for validation. However, this deadline is in line with the Hospital IQR Program's validation policy, the large majority of hospitals that have participated in Hospital OQR Program data validation efforts have submitted their records prior to 30 days in the current process, and outpatient records typically contain significantly fewer pages than the inpatient records. Therefore, we believe the impact of this proposal to be minimal.

5. Effects of Requirements for the ASCQR Program

a. Background

In section XVI. of this proposed rule, we discuss our proposed policies affecting the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. For the CY 2021 payment determination, all 6,811 ASCs that met eligibility requirements for the ASCQR Program received the annual payment update due to data submission requirements being excepted under the ASCQR Program's Extraordinary Circumstances Exceptions policy in consideration of the COVID–19 public health emergency.[446]

b. Impact of Proposals in This CY 2022 OPPS/ASC Proposed Rule

In section XVI. of this proposed rule, we propose to: (1) Require four patient safety outcome measures beginning with the CY 2023 reporting period/CY 2025 payment determination: (a) Patient Burn (ASC–1); (b) Patient Fall (ASC–2); (c) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC–3); and (d) All-Cause Hospital Transfer/Admission (ASC–4); (2) require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC–11) measure, beginning with the CY 2023 reporting period/CY 2025 payment determination; (3) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (ASC–15 a–e), with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination; (4) add two additional data collection survey modes of OAS CAHPS measures collection to the existing three modes of collection and provide survey administration requirements; and (5) adopt the COVID–19 Vaccination Coverage Among HCP measure, beginning with the CY 2022 reporting period/CY 2024 payment determination.

As shown in Table 70 in section XXIII.C.3.e. (Collection of Information), we estimate a total information collection burden increase for 4,646 ACSs of +67,085 hours at a cost of +$2,844,404 annually associated with our proposed policies and updated burden estimates across a 4 year period from the CY 2023 reporting period/CY 2025 payment determination through the CY 2026 reporting period/CY 2028 payment determination, compared to our currently approved information collection burden estimates. We refer readers to section XXIII.C. of the preamble 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.

In section XVI.B.3.a. of the preamble of this proposed rule, we are proposing to adopt a COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2022 reporting period/CY 2024 payment determination. The impacts and benefits associated with this proposal are similar to those previously discussed for the same measure being proposed for the Hospital OQR Program. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package currently approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act

[446] Centers for Medicare & Medicaid Services. COVID–19 Quality Reporting Programs Guidance Memo. Available at *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

(NCVIA).[447] Although the burden associated with the COVID–19 Vaccination Coverage Among HCP measure is not accounted for under the CDC PRA 0920–1317 or 0920–0666, the cost and burden information is included here. We estimate that each ASC will spend on average approximately 1 hour per month to collect data for the COVID–19 Vaccination Coverage Among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity since it could vary based on provider systems and staff availability. This burden is comprised of administrative hours and wages. We believe an Administrative Assistant would spend between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. Beginning with the CY 2022 reporting period/FY 2024 payment determination, ASCs would incur an additional annual burden between 9 hours (0.75 hours/month × 12 months) and 15 hours (1.25 hours/month × 12 months) per ASC and between 41,814 hours (9 hours/hospital × 4,646 ASCs) and 69,690 hours (15 hours/hospital × 4,646 ASCs) for all ASCs. Each ASC would incur an estimated cost of between $323.28 (9 hours × $35.92/hour) and $538.80 annually (15 hours × $35.92/hour). The estimated cost across all 4,646 ASCs would be between $1,501,959 ($323.28/ASC × 4,646 ASCs) and $2,503,265 ($538.80/ASC × 4,646 ASCs) annually thereafter. We welcome comments on the estimated time to collect data and enter it into the NHSN as well as any additional costs associated with this measure.

We anticipate that the proposals affecting the ASCQR Program in this proposed rule may impact the number of ASCs that will receive payment reductions.

6. Effects of Requirements for the RO Model

a. Financial Impact

We have examined the impact of this proposed rule as required by Executive Order 12866 and other laws and Executive Orders, requiring economic analysis of the effects of final rules. We are proposing a different Model performance period than was finalized in the Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs final rule with comment period (CMS–1736–IFC) (85 FR 85866) (hereinafter referred to as ''CY 2021 OPPS/ASC final rule''). We are also proposing an updated baseline period, lower discounts, the removal of brachytherapy from the included modalities, and the removal of liver cancer from the list of included cancer types finalized under the publication of the Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures Final Rule (Specialty Care Models final rule) (85 FR 61114) on September 29, 2020. We have updated our net estimate of the RO Model impact to reflect all of the proposals in this proposed rule. Accordingly, we have prepared an RIA that, to the best of our ability, reflects the economic impact of the policies contained in this proposed rule.

b. Statement of Need for the Radiation Oncology (RO) Model

The statement of need for the RO Model described in the Specialty Care Models final rule (85 FR 61347) and the CY 2021 OPPS/ASC final rule (85 FR 86296) remains unchanged with this proposed rule.

c. Impact of RO Model

Based on the finalized policy of the Specialty Care Models final rule (85 FR 61114), we expected a savings of $230 million for Medicare over a 5-year model performance period. The CY 2021 OPPS/ASC final rule (85 FR 86296) included a savings estimate of $220 million for Medicare over a 4.5-year model performance period. We now expect that the proposals included in this proposed rule, which include a change to a revised model performance period that begins January 1, 2022 and ends December 31, 2026, a revised baseline period, the removal of brachytherapy and liver cancer, as well as the lowered discounts, will reduce savings to $160 million for Medicare.

d. Anticipated Effects

(1) Scale of the Radiation Oncology (RO) Model

Revising the model performance period to begin January 1, 2022 would not affect the number of PGPs or HOPDs we expect to furnish RT services in the simulated selected CBSAs. We currently expect the model performance period that begins January 1, 2022, and ends December 31, 2026, will include approximately 282,000 episodes, 250,000 beneficiaries, and $4.6 billion in total episode spending of allowed charges over the Model performance period. The revision is primarily the result of updated FFS Part B enrollment projections, slower assumed growth in RT episodes per patient, and minor technical changes to the projection process.

(2) Effects of the RO Model on the Medicare Program

(a) Overview

Under the current FFS payment system, RT services are paid on a per service basis to both PGPs (including freestanding radiation therapy centers) and HOPDs through the PFS and the OPPS, respectively. The RO Model would be a mandatory model designed to test a prospectively determined episode payment for RT services furnished to Medicare beneficiaries during episodes initiated between January 1, 2022, and December 31, 2026.

(b) Data and Methods

Similar to the analysis performed for the regulatory impact analysis for the Specialty Care Models final rule (85 FR 61347) and the CY 2021 OPPS/ASC final rule (85 FR 86296), a stochastic simulation based on the policies in this proposed rule was created to estimate the financial impacts of the RO Model relative to baseline expenditures.

(c) Medicare Estimate

Table 78 summarizes the estimated impact of the RO Model with a model performance period that begins January 1, 2022, and ends December 31, 2026. We estimate that on net the Medicare program would save $160 million over the model performance period. As in the Specialty Care Models final rule (85 FR 61350) and the CY 2021 OPPS/ASC final rule (85 FR 86297), this is the net Medicare Part B impact that includes both Part B premium and Medicare Advantage United States Per Capita Costs (MA USPCC) rate financing interaction effects. This estimate excludes changes in beneficiary cost sharing liability to the extent it is not a Federal outlay under the policy.

As codified at § 512.280(d), the APM incentive payment will apply only to the professional episode payment amounts and not the technical episode payment amounts. Moreover, due to the 2-year lag in Quality Payment Program performance and payment periods and quality data reporting starting in 2022, APM incentive payments will only be made during 2024. We are now projecting that 80 percent (down from 83 percent as projected in the Specialty Care Models final rule) of physician participants (measured by unique NPI) would receive the APM incentive payment under the Quality Payment Program for 2022.

[447] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

Complete information regarding the data sources and underlying methodology used to determine amounts for reconciliation were not available at the time of this forecast. Like in the Specialty Care Models final rule, in the case of the incomplete payment withhold, we assume CMS retains payment only in the event that offsetting payment errors were made elsewhere. Moreover, past CMS experience in the and Hospital Value-Based Purchasing (VBP) and Merit-based Incentive Payment System (MIPS) programs that included value-based reporting requirements has shown a low rate of non-compliance on the part of providers and suppliers. Given the limited spending being withheld, scoring criteria, (that is the use of the Aggregate Quality Score (AQS) and its application to the quality withhold, as finalized at 85 FR 61226 through 61231), and specified timeframes involved, we assume that quality and patient experience withholds, on net, would have a negligible financial impact to CMS.

A key assumption underlying the impact estimate is that the volume and intensity (V&I) of the bundled services per episode remains unchanged between the baseline period and when bundled RO payments are made. If V&I were to decrease by 1.0 percent annually for the bundled services absent the RO Model, then we estimate the RO Model to be approximately budget neutral between January 1, 2022 and December 31, 2026. Similarly, if V&I increases by 1.0 percent annually then net Medicare outlays would be reduced by $285 million for this projection period. Although V&I growth from 2014 through 2019 fell within this 1.0 percent range and did not exhibit a secular trend, actual experience may differ. Please also note that due to the current public health crisis caused by the COVID–19 virus, the forecasted impacts for the RO Model are subject to an additional level of uncertainty. The duration of the current COVID–19 pandemic, its severity, and future policy measures taken in response are variables that are significant but unknown at this time. This forecast assumes that Medicare FFS billing and treatment patterns for beneficiaries observed during the 2017 to 2019 baseline period resume by the start of 2022. To the extent that this assumption does not hold, actual experience may vary significantly. Table 78 summarizes our estimated impacts of this proposed rule.

TABLE 78: Estimates of Medicare Program Savings (Millions $) for Radiation Oncology Model (Starting January 1, 2022)

	Year of Model					
	2022	2023	2024	2025	2026	Total*
Net Impact To Medicare Program Spending	-20	-30	-20	-40	-40	-160
Changes to Incurred FFS Spending	-20	-20	-30	-30	-30	-130
Changes to MA Capitation Payments	-10	-20	-20	-20	-30	-100
Part B Premium Revenue Offset	10	10	10	10	10	60
Total APM Incentive Payments	0	0	10	0	0	10
Episode Allowed Charges	830	870	910	960	1,000	4,580
Episode Medicare Payment	650	680	710	750	780	3,570
Total Number of Episodes	53,300	54,900	56,400	58,000	59,600	282,200
Total Number of Beneficiaries	51,900	53,500	54,900	56,500	58,100	250,200

*Negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase.

*Totals may not sum due to rounding and from beneficiaries that have cancer treatment spanning multiple years.

e. Effects on RO Participants

We believe that the proposed changes will not affect the total cost of learning the billing system for the RO Model but will, however, affect the burden estimate for reporting quality measures and clinical data elements.

We believe the burden estimate for quality measure and clinical data element reporting requirements that is provided for Small Businesses in CY 2021 OPPS/ASC final rule (85 FR 86297) apply to RO participants that are not considered small entities. The burden estimate for collecting and reporting quality measures and clinical data for the RO Model may be equal to or less than that for small businesses, which we estimate to be approximately $1,845 per entity per year based on 2020 wages. Since we estimate approximately 500 Professional participants and Dual participants will be collecting and reporting this data, the total annual burden estimate for collecting and reporting quality measures and clinical data is approximately $922,500 for a total of $4,612,500 over 5 years.

f. Regulatory Flexibility Act (RFA)

In the Medicare Specialty Models final rule, we provided an analysis for the RO Model's impact on small businesses based on the finalized policies (85 FR 61358). The policies proposed in this proposed rule do not change those estimates.

Like the Medicare Specialty Models final rule (85 FR 61358), this proposed rule affects: (1) Radiation oncology PGPs that furnish RT services in both freestanding radiation therapy centers and HOPDs; (2) PGPs that furnish RT

services only in HOPDs; (3) PGPs that are categorized as freestanding radiation therapy centers; and (4) HOPDs. Based on the proposed modifications to the design of the RO Model, we believe that on average, Medicare FFS payments to PGPs will increase by 5.5 percent and Medicare FFS payments to HOPDs will be reduced by 9.6 percent over the life of the Model. Under Medicare FFS, PGPs are largely paid through the PFS for RT services while HOPDs are paid through the OPPS. Unit-cost increases under the PFS are projected to be lower than under the OPPS over time. This means that when the payment rates of the PFS and the OPPS (along with the volume of HCPCS codes of non-participant episodes) are used to determine the trend factors for each cancer type, PGPs, on average, are projected to experience incremental gains to payment over time, while HOPDs, on average, are projected to experience incremental losses to payment over time. In other words, the impact for HOPDs and PGPs depends on a combination of the RO Model's discount factor and the RO Model's trend factor, which blends the latest OPPS and PFS payment rates based on their historical claims volume in non-participating RT providers and RT suppliers. Given that PFS rates are not expected to increase between 2019 and 2026 and the OPPS rates are, blending these rates together leads to an average increase in allowed charges expected for PGPs and an average decrease in allowed charges expected for HOPDs (because HOPDs that are RO participants will not get the full OPPS rate increase but rather a trend that blends OPPS with PFS). Table 79 provides additional information about the expected impacts by year:

TABLE 79: Radiation Oncology Model PGP vs HOPD Allowed Charge Impacts 2022 to 2026

% Impact	2022	2023	2024	2025	2026	2022 to 2026
PGP	1.8%	3.5%	5.2%	6.8%	8.5%	5.5%
HOPD	-7.2%	-8.3%	-9.3%	-10.4%	-11.3%	-9.6%

We believe that this impact would be reduced for smaller RO participants, those RO participants that are eligible for the low volume opt-out in some performance years, and that there would be no impact for those RO participants that are eligible for the low volume opt-out for the entire model performance period (See section XVIII.C.3.d.).

7. Effects of Requirements for Hospitals To Make Public a List of Their Standard Charges

In this proposed rule, we are proposing a modification to 45 CFR 180.30(b) and adding new § 180.30(b)(3) to include that State forensic hospitals will deemed to have met requirements, similar to our policy to deem Federally owned/operated hospitals as having met compliance. These State forensic hospitals and have closed populations, are not open to the general public, and the cost of care is funded by the state. This proposal will reduce the overall burden we estimated in the Hospital Price Transparency final rule by removing such hospitals from the obligation to make public standard charges in the form and manner prescribed by the Secretary.

In the Hospital Price Transparency final rule, we estimated the total burden for hospitals to review and post their standard charges for the first year to be 150 hours per hospital at $11,898.60 per hospital for a total burden of 900,300 hours (150 hours × 6,002 hospitals) and total cost of $71,415,397 ($11,898.60 × 6,002 hospitals) (84 FR 65595). We estimated the total annual burden for hospitals to review and post their standard charges for subsequent years to be 46 hours per hospital at $3,610.88 per hospital for a total annual burden for subsequent years of 276,092 hours (46 hours × 6,002 hospitals) and total annual cost of $21,672,502 ($3,610.88 × 6,002 hospitals). For purposes of the proposed changes in this rule, we assume that state forensic hospitals have complied with the Hospital Price Transparency final rule requirements in the first year of implementation (CY 2021) and are therefore basing our burden reduction estimate on the cost of implementation for subsequent years alone. In other words, because state forensic hospitals would no longer be required to make the annual updates as required under the Hospital Price Transparency final rule, the burden reduction applies to CY 2022 and subsequent years.

We estimate that 111 [448] hospitals would meet our definition of 'State forensic hospital'. To estimate the associated burden reduction for State forensic hospitals, we used the hourly cost for each labor category by referencing Bureau of Labor Statistics report on Occupational Employment and Wages (May 2020), as indicated in Table 80.[449]

[448] SAMHSA. National Mental Health Services Survey (N–MHSS): 2019 Data on Mental Health Treatment Facilities. *https://www.samhsa.gov/data/sites/default/files/reports/rpt29388/2019_NMHSS/2019–NMHSS–R.pdf.*

[449] Bureau of Labor Statistics. National Occupational Employment and Wage Estimates, May 2020. Available at *https://www.bls.gov/oes/current/oes_nat.htm.*

TABLE 80: Occupation Titles and Wage Rates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
General Operations Manager	11-1021	$60.45	$60.45	$120.90
Business Operations Specialist	13-1000	$37.66	$37.66	$75.32
Network and Computer System Administrator	15-1244	$43.01	$43.01	$86.02

We estimate a reduction in burden of 2 hours for a general operations manager to review and determine updates in compliance requirements, or a savings of $241.80 (2 hours * $120.90) per hospital. We estimate a total burden reduction of 222 hours (2 hours * 111 hospitals) with a total burden reduction $26,839.80 (222 hours * $120.90).

Next, we estimate a reduction in burden of 32 hours for a business operations specialist because they will no longer be required to update necessary processes and procedures and gather and compile required information, a savings of $2,410.24 (32 hours * $75.32) per hospital. We estimate a total burden reduction of 3,552 hours (32 hours * 111 hospitals) with a total burden reduction $267,536.64 (3,552 hours * $75.32).

Finally, we estimate a reduction in burden of 12 hours for network and computer system administrator because they will no longer be required to maintain the required systems to make this data publicly available, a savings of $1,032.24 (12 hours * $86.02) per hospital. We estimate a total burden reduction of 1,332 hours (12 hours * 111 hospitals) with a total burden reduction $114,578.64 (1,332 hours * $86.02).

Therefore, we believe the total annual burden reduction for the proposal in this rule, for subsequent years, to be 46 hours (2 hours + 32 hours + 12 hours) per hospital, with a savings of $3,684.28 ($241.80 + $2,410.24 + $1,032.24) per hospital. We also estimate a total annual burden reduction for subsequent years of 5,106 hours (46 hours * 111 hospitals) and a total cost of $408,955.08 ($3,684.28 * 111 hospitals), as shown in Table 81.

TABLE 81: Costs per Organization and Total Cost Figures

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)	Subsequent Year Hours
General Operations Manager	11-1021	$60.45	$60.45	$120.90	2
Business Operations Specialist	13-1000	$37.66	$37.66	$75.32	32
Network and Computer System Administrator	15-1244	$43.01	$43.01	$86.02	12
Total Hours per State forensic hospital					46
Total Reduction per state forensic hospital (Dollars)					($3,684.28)
Total hours for State forensic hospitals (hours)					5,106
Total Burden Reduction for all State forensic hospitals					($408,955.08)

D. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review a rule, we assumed that the number of commenters on this CY 2022 OPPS/ASC proposed rule (1,349) will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing proposed rule. It is possible that not all commenters will review the proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. Nonetheless, we believe that the number of commenters on the CY 2022 OPPS/ASC proposed rule is a fair estimate of the number of reviewers of the proposed rule. We welcome any comments on the approach in estimating the number of entities that will review the proposed rule. We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of the proposed rule and the final rule with comment period, and, therefore, for the purposes of our estimate, we assumed that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the 2019 BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rule is $110.74 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 will take approximately 8 hours for the staff to review half of proposed rule. For each facility that reviewed the proposed rule, the estimated cost is $885.92 (8 hours × $110.74). Therefore, we estimated that the total cost of reviewing the proposed rule is

$1,195,106 ($885.92 × 1,349 reviewers on the CY 2022 proposed rule).

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, 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-size-standards*. 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 do not 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 will not 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule would increase payments to small rural hospitals by approximately 3 percent; therefore, it should not have a significant impact on approximately 586 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 2021, that threshold level is currently approximately $175 million. This proposed rule does not mandate any requirements for state, local, or tribal governments, or for the private sector.

G. Conclusion

The changes we are making in this proposed rule will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2022. Table 71 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 1.8 percent increase in payments for all services paid under the OPPS in CY 2022, 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, estimated payment for outliers, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2022.

The updates we propose to the ASC payment system for CY 2022 would affect each of the approximately 5,600 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 72 demonstrates the estimated distributional impact among ASC surgical specialties of the productivity-adjusted hospital market basket update factor of 2.3 percent for CY 2022.

H. Federalism Analysis

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 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 71 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including state and local governmental hospitals) will increase by 2.3 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 will 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.

I, Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 16, 2021.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

45 CFR Part 180

Hospitals, Reporting and recordkeeping requirements.

Centers for Medicare & Medicaid Services

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.3 is amended by revising paragraph (d)(2)(i) to read as follows:

§ 412.3 Admissions.

* * * * *

(d) * * *

(2) * * *

(i) For those services and procedures removed on or after January 1, 2020, the exemption in this paragraph (d)(2) will last for 2 years from the date of such removal.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 3. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 4. Section 416.164 is amended by revising paragraphs (a)(4) and (b)(6) to read as follows:

§ 416.164 Scope of ASC services.

(a) * * *

(4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS), with the exception 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;

* * * * *

(b) * * *

(6) 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.

* * * * *

■ 5. Section 416.166 is revised to read as follows:

§ 416.166 Covered surgical procedures.

(a) *Covered surgical procedures.* Effective for services furnished on or after January 1, 2022, covered surgical procedures are those procedures that meet the general standards described in paragraph (b) of this section (whether commonly furnished in an ASC or a physician's office) and are not excluded under paragraph (c) of this section.

(b) *General standards.* Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

(c) *General exclusions.* Notwithstanding paragraph (b) of this section, covered surgical procedures do not include those surgical procedures that—

(1) Generally result in extensive blood loss;

(2) Require major or prolonged invasion of body cavities;

(3) Directly involve major blood vessels;

(4) Are generally emergent or life-threatening in nature;

(5) Commonly require systemic thrombolytic therapy;

(6) Are designated as requiring inpatient care under § 419.22(n) of this chapter;

(7) Can only be reported using a CPT unlisted surgical procedure code; or

(8) Are otherwise excluded under § 411.15 of this chapter.

(d) *Additions to the list of ASC covered surgical procedures.* Surgical procedures are added to the list of ASC covered surgical procedures as follows:

(1) *Nominations.* On or after January 1, 2023, an external party may nominate a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year.

(2) *Inclusion in rulemaking.* If CMS identifies a surgical procedure that meets the requirements at paragraph (a) of this section, including a surgical procedure nominated under paragraph (d)(1) of this section, it will propose to add the surgical procedure to the list of ASC covered surgical procedures in the next available annual rulemaking.

■ 6. Section 416.171 is amended by revising paragraphs (b)(1) and (4) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(1) Covered ancillary services specified in § 416.164(b), with the exception of radiology services and certain diagnostic tests as provided in § 416.164(b)(5) and non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174.

* * * * *

(4) Notwithstanding paragraph (b)(2) of this section, procedures assigned to Low Volume APCs where the otherwise applicable payment rate calculated based on the standard methodology for such procedures described in paragraph (b) of this section would exceed the payment rate for the equivalent service set under the payment system established under part 419 of this chapter, for which the payment rate will be set at an amount equal to the amount under that payment system.

* * * * *

■ 7. Section 416.174 is added to reads as follows:

§ 416.174 Payment for non-opioid pain management drugs and biologicals that function as supplies in surgical procedures.

(a) *Eligibility for separate payment for non-opioid pain management drugs and biologicals.* Beginning on or after January 1, 2022, a non-opioid pain management drug or biological that functions as a surgical supply is eligible for separate payment if CMS determines it meets the following requirements:

(1) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), generic drug application under an abbreviated new drug application under section 505(j), or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product has an FDA approved indication for pain management or analgesia.

(2) The per-day cost of the drug or biological must exceed the OPPS drug packaging threshold set annually through notice and comment rulemaking.

(b) [Reserved]

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 8. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 9. Section 419.22 is amended by revising paragraph (n) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(n) Services and procedures that the Secretary designates as requiring inpatient care.

* * * * *

■ 10. Section 419.23 is added to read as follows:

§ 419.23 Removal of services and procedures from the Inpatient Only List.

(a) *Inpatient Only List.* CMS maintains a list of services and procedures that the Secretary designates as requiring inpatient care under § 419.22(n) that are not paid under the hospital outpatient prospective payment system. This list is referred to as the Inpatient Only List.

(b) *Removals from the Inpatient Only List.* CMS assesses annually whether a service or procedure on the Inpatient Only List described in paragraph (a) of this section should be removed from the list by determining whether the service or procedure meets at least one of the following criteria:

(1) Most outpatient departments are equipped to provide the service or procedure to the Medicare population.

(2) The simplest service or procedure described by the code may be performed in most outpatient departments.

(3) The service or procedure is related to codes that CMS has already removed from the Inpatient Only List described in paragraph (a) of this section.

(4) CMS determines that the service or procedure is being performed in numerous hospitals on an outpatient basis.

(5) CMS determines that the service or procedure can be appropriately and safely performed in an ambulatory surgical center, and is specified as a covered ambulatory surgical procedure under § 416.166 of this chapter, or CMS has proposed to specify it as a covered ambulatory surgical procedure under § 416.166 of this chapter.

■ 11. Section 419.46 is amended by revising paragraphs (f)(1) and (3) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(f) * * *

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 30 days of the date identified on the written request, in the form and manner specified in the written request.

* * * * *

(3) CMS will select a random sample of 450 hospitals for validation purposes, and will select an additional 50 hospitals for validation purposes based on the following criteria:

(i) The hospital fails the validation requirement that applies to the previous year's payment determination; or

(ii) The hospital has an outlier value for a measure based on the data it submits. An ''outlier value'' is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score; or

(iii) Any hospital that has not been randomly selected for validation in any of the previous 3 years; or

(iv) Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent.

* * * * *

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 12. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 13. Section 512.205 is amended by:

■ a. Adding the definition for ''Baseline period'' in alphabetical order;

■ b. Revising the definition for ''Discount factor'';

■ c. Adding definitions for ''EUC'', ''Legacy CCN'', and ''Legacy TIN'' in alphabetical order;

■ d. Revising the definition for ''Model performance period'';

■ e. Removing the definition of ''Performance year (PY)'';

■ f. Revising the definition for ''PY'' and ''Stop-loss reconciliation amount''; and

■ g. Adding definitions for ''Track One'' and ''Track Two'' in alphabetical order.

The additions and revisions read as follows:

§ 512.205 Definitions.

* * * * *

Baseline period means the three calendar year period that begins on January 1 no fewer than five years but no more than six years prior to the start of the model performance period during which episodes must initiate in order to be used in the calculation of the national base rates, each RO participant's historical experience adjustment for the PC or TC or both for the model performance period, and the RO participant's case mix adjustment for the PC or TC or both for PY1. The baseline period is January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in calendar year (CY) 2022, in which case the baseline period will be delayed based on the new model performance period (for example, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

* * * * *

Discount factor means the percentage by which CMS reduces payment of the professional component and technical component.

(1) The reduction of payment occurs after the trend factor, the geographic adjustment, and the RO Model-specific adjustments have been applied, but before beneficiary cost-sharing and standard CMS adjustments, including sequestration, have been applied.

(2) The discount factor does not vary by cancer type.

(3) The discount factor for the professional component is 3.5 percent; the discount factor for the technical component is 4.5 percent.

* * * * *

EUC stands for ''extreme and uncontrollable circumstance'' and means a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements, and affects an entire region or locale.

* * * * *

Legacy CCN means a CMS certification number (CCN) that an RO participant that is a hospital outpatient department (HOPD) or its predecessor(s) previously used to bill Medicare for included radiotherapy (RT) services but no longer uses to bill Medicare for included RT services.

Legacy TIN means a taxpayer identification number (TIN) that an RO participant that is a PGP, or a freestanding radiation therapy center, or its predecessor(s) previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services.

* * * * *

Model performance period means the five performance years (PYs) during which RO episodes must initiate and terminate. The model performance period begins on January 1, 2022 and ends on December 31, 2026, unless the RO Model is prohibited by law from starting on January 1, 2022, in which case the model performance period begins on the earliest date permitted by law that is January 1, April 1, or July 1.

* * * * *

PY stands for performance year and means each 12-month period beginning on January 1 and ending on December 31 during the model performance

period, unless the model performance period begins on a date other than January 1, in which case, the first performance year (PY1) begins on that date and ends on December 31 of the same year.

* * * * *

Stop-loss reconciliation amount means the amount set forth in § 512.285(f) owed by CMS for the loss incurred under the Model to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation.

* * * * *

Track One means an Advanced APM and MIPS APM track for Dual participants and Professional participants that meet all RO Model requirements as specified in § 512.220, including use of CEHRT.

Track Two means an APM for Dual participants and Professional participants who do not meet the RO Model requirements set forth at § 512.220; and for all Technical participants.

* * * * *

■ 14. Section 512.210 is amended by—

■ a. Revising paragraphs (a) and (b)(5).

■ b. Adding paragraph (b)(6);

■ c. Revising paragraph (c); and

■ d. Adding paragraph (e).

The revisions and additions read as follows:

§ 512.210 RO participants and geographic areas.

(a) *RO participants.* Unless otherwise specified in paragraph (b) or (c) of this section, any Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that furnishes included RT services in a 5-digit ZIP Code linked to a CBSA selected for participation to an RO beneficiary for an RO episode that begins and ends during the model performance period must participate in the RO Model.

(b) * * *

(5) Participates in the Pennsylvania Rural Health Model; or

(6) Participates in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model as a participating hospital.

(c) *Low volume opt-out.* A PGP, freestanding radiation therapy center, or HOPD that would otherwise be required to participate in the RO Model may choose to opt-out of the RO Model as follows:

(1) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 episodes in the calendar year that is two years prior to the start of PY1 across all CBSAs selected for participation, it may opt out of the RO Model for PY1.

(2) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 episodes in the calendar year that is two years prior to the start of PY2 across all CBSAs selected for participation, it may opt out of the RO Model for PY2.

(3) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 RO episodes in PY1 across all CBSAs selected for participation, and PY1 begins on January 1, it may choose to opt out of the RO Model for PY3. In the event that PY1 begins on a date other than January 1, the PGP, freestanding radiation therapy center, or HOPD may opt-out of the RO Model for PY3 if the total number of furnished episodes of the calendar year in which PY1 began and RO episodes in PY1 is fewer than 20 across all CBSAs selected for participation.

(4) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 RO episodes in PY2 across all CBSAs selected for participation, it may opt out of the RO Model for PY4.

(5) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 RO episodes in PY3 across all CBSAs selected for participation, it may opt out of the RO Model for PY5.

(6) At least 30 days prior to the start of each PY, CMS provides notice to RO participants eligible for the low volume opt-out for the upcoming PY of such eligibility. The RO participant must attest that it intends to opt out of the RO Model prior to the start of the upcoming PY.

(7) An entity is not eligible for the low-volume opt out if its current TIN or CCN, or its legacy TIN or legacy CCN, or both were used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services in the two years prior to the applicable PY across all CBSAs selected for participation.

* * * * *

(e) *Notice of change in TIN or CCN.* An RO participant must furnish written notice to CMS in a form and manner specified by CMS at least 90 days before the effective date of any change in TIN or CCN that is used to bill Medicare.

■ 15. Section 512.217 is amended—

■ a. By revising paragraphs (a), (b), and (c)(1);

■ b. In paragraph (c)(3)(i) by removing the word ''and'' at the end of the paragraph;

■ c. In paragraph (c)(3)(ii) by removing the period at the end of the paragraph and adding ''; and'' in its place;

■ d. By adding paragraph (c)(3)(iii); and

■ e. By revising paragraphs (d)(1)(i) and (d)(2)(i).

The revisions and addition read as follows:

§ 512.217 Identification of individual practitioners.

(a) *General.* Upon the start of each PY, CMS creates and provides to each RO participant that is a PGP or a freestanding radiation therapy center an individual practitioner list identifying by NPI each individual practitioner associated with the RO participant. For RO participants that begin participation in the RO Model after the start of a PY, but at least 30 days prior to the last QP determination date as specified at § 414.1325 of this chapter, CMS creates and provides an individual practitioner list to that RO participant.

(b) *Review of individual practitioner list.* Up until the last QP determination date as specified at § 414.1325 of this chapter, the RO participant must review and certify the individual practitioner list, correct any inaccuracies in accordance with paragraph (d) of this section, and certify the list (as corrected, if applicable) in a form and manner specified by CMS and in accordance with paragraph (c) of this section. The RO participant may correct any inaccuracies in their individual practitioner list until the last QP determination date as specified at § 414.1325 of this chapter. Any Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center and joins the RO Model after the start of a PY must review and certify its individual practitioner list by the last QP determination date as specified at § 414.1325 of this chapter.

(c) * * *

(1) Up until the last QP determination date as specified at § 414.1325 of this chapter, an individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the individual practitioner list to the best of his or her knowledge, information, and belief.

* * * * *

(3) * * *

(iii) Technical participants that are freestanding radiation therapy centers are not eligible to receive Improvement Activity credit for their participation in the RO Model under MIPS.

(d) * * *

(1) * * *

(i) An RO participant must notify CMS of an addition to its individual practitioner list when an eligible clinician reassigns his or her rights to receive payment from Medicare to the RO participant. The notice must be submitted in the form and manner specified by CMS up until the last QP determination date as specified at § 414.1325 of this chapter.

* * * * *

(2) * * *

(i) An RO participant must notify CMS when an individual on the RO participant's individual practitioner list ceases to be an individual practitioner up until the last QP determination date as specified at § 414.1325 of this chapter. The notice must be submitted in the form and manner specified by CMS.

* * * * *

■ 16. Section 512.220 is amended by revising paragraphs (a)(1) and (b) to read as follows:

§ 512.220 RO participant compliance with RO Model requirements.

(a) * * *

(1) RO participants must satisfy the requirements of this section to be included in Track One under the RO Model. RO participants that do not meet these RO Model requirements in a PY will be in Track Two for the applicable PY.

* * * * *

(b) *CEHRT.* (1) RO participants must use CEHRT, and ensure that their individual practitioners use CEHRT, in a manner sufficient to meet the applicable requirements of the Advanced APM criteria as specified at § 414.1415(a)(1)(i) of this chapter.

(2) Within 30 days of the start of PY1 and each subsequent PY, the RO participant must certify its use of CEHRT throughout such PY in a manner sufficient to meet the requirements set forth in § 414.1415(a)(1)(i) of this chapter.

(3) An RO participant that joins the RO Model at any time during an ongoing PY must certify their use of CEHRT by the last QP determination date as specified at § 414.1325 of this chapter.

■ 17. Section 512.230 is amended by revising paragraphs (a) and (b) to read as follows:

§ 512.230 Criteria for determining cancer types.

(a) *Included cancer types.* CMS includes in the RO Model cancer types that satisfy the following criteria:

(1) The cancer type is commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines;

(2) The cancer type has one or more associated current ICD–10 codes that have demonstrated pricing stability; and

(3) The Secretary has not determined that the cancer type is not suitable for inclusion in the RO Model.

(b) *Removing cancer types.* CMS removes cancer types in the RO Model if it determines:

(1) That there is a ≥10 percent error in established national base rates; or

(2) The cancer type does not meet the criteria set forth in paragraph (a) of this section.

* * * * *

■ 18. Section 512.240 is revised to read as follows:

§ 512.240 Included modalities.

The modalities included in the RO Model are 3-dimensional conformal RT (3DCRT), intensity-modulated RT (IMRT), stereotactic radiosurgery (SRS), stereotactic body RT (SBRT), proton beam therapy (PBT), and image-guided radiation therapy (IGRT).

■ 19. Section 512.245 is amended by revising paragraph (a) to read as follows:

§ 512.245 Included RO episodes.

(a) *General.* Any RO episode that begins on or after the first day of the model performance period and ends on or before the last day of the model performance period is included in the model performance period.

* * * * *

■ 20. Section 512.250 is amended by revising (b)(1) and (2) to read as follows:

§ 512.250 Determination of national base rates.

* * * * *

(b) * * *

(1) CMS excludes from episode pricing and RO episode pricing any claim containing an RT service furnished:

(i) In Maryland, Vermont, or any of the U.S. Territories;

(ii) In the inpatient setting;

(iii) By an entity classified as an ASC, CAH, or PPS-exempt cancer hospital; or

(iv) By an HOPD participating in the Pennsylvania Rural Health Model at the time the RT service was furnished.

(2) CMS excludes the following episodes from the determination of the national base rates:

(i) Episodes that are not linked to a CBSA selected for participation in the RO Model;

(ii) Episodes that are not attributed to an RT provider or RT supplier;

(iii) Episodes that are not assigned an included cancer type; or

(iv) Episodes for which the total allowed amount for RT services listed on claims used to calculate an episode's payment amount is not greater than $0.

* * * * *

■ 21. Section 512.255 is amended by—

■ a. Revising paragraphs (c)(7), (8), and (10), (c)(12)(iv), and (c)(13); and

■ b. Adding paragraph (c)(14).

The revisions and addition read as follows:

§ 512.255 Determination of participant-specific professional episode payment and participant-specific technical episode payment amounts.

* * * * *

(c) * * *

(7) *Adjustments for RO participants with fewer than 60 episodes during the baseline period.* (i) RO participants that have fewer than 60 episodes in the baseline period do not receive a historical experience adjustment during the model performance period.

(ii) RO participants that have fewer than 60 episodes in the baseline period do not receive a case mix adjustment for PY1.

(iii) RO participants described in paragraph (c)(7)(ii) of this section that continue to have fewer than 60 episodes in the rolling 3-year period used to determine the case mix adjustment for each PY and that have never received a case mix adjustment do not receive a case mix adjustment for that PY.

(iv) RO participants that have fewer than 60 episodes in the baseline period and were furnishing included RT services in the CBSAs selected for participation before the start of the model performance period are eligible to receive a stop-loss reconciliation amount, if applicable, as described in § 512.285(f).

(8) *Discount factor.* CMS reduces each episode payment by the discount factor after applying the trend factor, geographic adjustment, and case mix and historical experience adjustments to the national base rate.

* * * * *

(10) *Quality withhold.* In accordance with § 414.1415(b)(1) of this chapter, CMS withholds 2 percent from each professional episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate. RO participants may earn back this withhold, in part or in full, based on their AQS.

* * * * *

(12) * * *

(iv) In the case of incomplete episodes, the beneficiary coinsurance payment equals 20 percent of the FFS amounts that would have been paid in the absence of the RO Model for the

services furnished by the RO participant that initiated the PC and the RO participant that initiated the TC (if applicable).

* * * * *

(13) *Sequestration.* In accordance with applicable law, CMS deducts a percentage from each episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, discount, withholds, and coinsurance to the national base rate.

(14) *Modifications to the participant-specific adjustments for changes in TINs or CCNs.* (i) CMS calculates the RO participant's case mix adjustments in accordance with paragraph (c)(3) of this section based on all episodes and RO episodes, as applicable, attributed to the RO participant's legacy TIN(s) or legacy CCN(s), and current TIN or CCN, during the 3-year period that determines the case mix adjustment for each PY.

(ii) CMS calculates the RO participant's historical experience adjustments in accordance with paragraph (c)(4) of this section based on all episodes attributed to the RO participant's legacy TIN(s) or legacy CCN(s), and current TIN or CCN, during the baseline period.

■ 22. Section 512.275 is amended by adding paragraph (d) to read as follows:

§ 512.275 Quality measures, clinical data, and reporting.

* * * * *

(d) *Technical participants and reporting of quality measures and clinical data elements.* Technical participants that are freestanding radiation therapy centers and also begin furnishing the professional component during the model performance period must:

(1) Notify CMS within 30 days of when the technical participant begins furnishing the professional component, in a form and manner specified by CMS; and

(2) Must report quality measures and clinical data elements by the next submission period, as described in paragraph (c) of this section.

§ 512.280 [Amended]

■ 23. Section 512.280 is amended by removing and reserving paragraph (f)(4).

■ 24. Section 512.285 is amended by revising paragraphs (c)(3), (c)(4)(i) and (ii), (d), and (f) introductory text to read as follows:

§ 512.285 Reconciliation process.

* * * * *

(c) * * *

(3) *Total incomplete episode amount.* For incomplete episodes initiated in the PY, CMS determines the total incomplete episode amount by calculating the difference between the following amounts:

(i) The sum of all FFS amounts that would have been paid to the RO participant in the absence of the RO Model for any included RT services furnished during such incomplete episodes, as determined by no-pay claims. CMS owes this sum to the RO participant for such incomplete episodes.

(ii) The sum of the participant-specific episode payment amounts paid to the RO participant for such incomplete episodes initiated in the PY.

(4) * * *

(i) If the sum described in paragraph (c)(3)(i) of this section is more than the sum described in paragraph (c)(3)(ii) of this section, the difference is subtracted from the total duplicate RT services amount described in paragraph (c)(2) of this section and the resulting amount is the total incorrect episode payment amount.

(ii) If the sum described in paragraph (c)(3)(i) of this section is less than the sum described in paragraph (c)(3)(ii) of this section, the difference is added to the total duplicate RT services amount described in paragraph (c)(2) of this section and the resulting amount is the total incorrect episode payment amount.

* * * * *

(d) *Quality reconciliation payment amount.* For Professional participants and Dual participants, CMS determines the quality reconciliation payment amount for each PY by multiplying the participant's AQS (as a percentage) by the total quality withhold amount for all RO episodes initiated during the PY.

* * * * *

(f) *Stop-loss reconciliation amount.* CMS determines the stop-loss reconciliation amount for RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation by—

* * * * *

■ 25. Section 512.292 is added to read as follows:

§ 512.292 Overlap with other models tested under Section 1115A and CMS programs.

Participant-specific professional episode payments and Participant-specific technical episode payments made under the RO Model are not adjusted to reflect payments made under models being tested under 1115A of the Act or the Medicare Shared Savings Program under section 1899 of the Act.

■ 26. Section 512.594 is added to read as follows:

§ 512.294 Extreme and uncontrollable circumstances.

(a) If CMS determines that there is an EUC pursuant to paragraph (b) of this section, CMS may grant RO participants exceptions to the RO Model requirements under paragraph (c) of this section and revise the RO Model's payment methodology under paragraph (d) of this section.

(b) CMS determines whether there is an EUC based on the following factors:

(1) Whether the RO participants are furnishing services within a geographic area considered to be within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Social Security Act;

(2) Whether the geographic area within a county, parish, U.S. territory, or tribal government designated under the Stafford Act served as a condition precedent for the Secretary's exercise of the 1135 waiver authority, or the National Emergencies Act; or

(3) Whether a state of emergency has been declared in the geographic area.

(c) CMS may grant RO Participants exceptions to the following RO Model requirements:

(1) *Reporting requirements.* CMS may delay or exempt RO participants from one or more of the RO Model's quality measure or clinical data element reporting requirements if an EUC impacts the RO participants' ability to comply with quality measure or clinical data element reporting requirements.

(2) *Other requirements.* CMS may issue a notice on the RO Model website that may waive compliance with or modify the following RO Model requirements:

(i) The requirement set forth at § 512.220(a)(2)(vii) that RO participants provide Peer Review (audit and feedback) on treatment plans.

(ii) The requirement set forth at § 512.220(a)(3) that RO participants actively engage with an AHRQ-listed patient safety organization (PSO).

(d) If CMS determines that the EUC affects the United States and if CMS determines that the EUC would impact RO participants' ability to implement the requirements of the RO Model prior to the start of the model performance period, CMS may amend the model performance period. CMS will notify RO participants of such a determination via the RO Model website no later than 30 days prior to the start date of the model performance period.

(e) If CMS determines that the EUC affects the entire United States, and if CMS determines that as a result of the EUC, the trend factor (specific to the PC, TC, or both for an included cancer type) for the upcoming PY has increased or decreased by more than 10 percent compared to the corresponding trend factor of the previous CY when FFS payment rates are held constant with the previous CY, CMS may modify the trend factor calculation for the PC, TC, or both the PC and TC of an included cancer type in a manner that ensures the trend factor is consistent with the average utilization from the previous CY.

(f) In response to a national, regional, or local event, CMS may adjust the quality withhold by choosing to repay the quality withhold during the next reconciliation, and award all possible points in the subsequent AQS calculation amount if CMS removes the quality measure and clinical data element reporting requirements pursuant to paragraph (c)(1) of this section.

Department of Health and Human 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

■ 27. The authority citation for part 180 continues to read as follows:

Authority: 42 U.S.C. 300gg–18, 42 U.S.C. 1302.

■ 28. Section 180.20 is amended by adding a definition for ''State forensic hospital'' in alphabetical order to read as follows:

§ 180.20 Definitions.

* * * * *

State forensic hospital means a public psychiatric hospital that provides treatment for individuals who are in the custody of penal authorities.

* * * * *

■ 29. Section 180.30 is amended—

■ a. In paragraph (b) introductory text by removing the phrase ''Federally owned or operated hospitals'' and adding in its place the phrase ''Federal and State hospitals''; and

■ b. By adding paragraph (b)(3).

The addition reads as follows:

§ 180.30 Applicability.

* * * * *

(b) * * *

(3) State forensic hospitals that provide treatment exclusively to individuals who are in the custody of penal authorities.

* * * * *

■ 30. Section 180.50 is amended—

■ a. In paragraph (d)(3)(ii) by removing the word ''and'' at the end of the paragraph;

■ b. In paragraph (d)(3)(iii) by removing the period at the end of the paragraph and adding ''; and'' in its place; and

■ c. By adding paragraph (d)(3)(iv).

The addition reads as follows:

§ 180.50 Requirements for making public hospital standard charges for all items and services.

* * * * *

(d) * * *

(3) * * *

(iv) To automated searches and direct file downloads through a link posted on a publicly available website.

* * * * *

■ 31. Section 180.90 is amended by revising paragraph (c)(2) to read as follows:

§ 180.90 Civil monetary penalties.

* * * * *

(c) * * *

(2) CMS determines the daily dollar amount for a civil monetary penalty for which a hospital may be subject as follows:

(i) For each day during Calendar Year 2021 that a hospital is determined by CMS to be out of compliance, the maximum daily dollar amount for a civil monetary penalty to which the hospital may be subject is $300. Even if the hospital is in violation of multiple discrete requirements of this part, the maximum total sum that a single hospital may be assessed per day is $300.

(ii) Beginning January 1, 2022, for each day a hospital is determined by CMS to be out of compliance:

(A) For a hospital with a number of beds equal to or less than 30, the maximum daily dollar civil monetary penalty amount to which it may be subject is $300, even if the hospital is in violation of multiple discrete requirements of this part.

(B) For a hospital with a number of beds between 31 and 550, the maximum daily dollar civil monetary penalty amount to which it may be subject is the number of beds times $10, even if the hospital is in violation of multiple discrete requirements of this part.

(C) For a hospital with a number of beds greater than 550, the maximum daily dollar civil monetary penalty amount to which it may be subject is $5,500, even if the hospital is in violation of multiple discrete requirements of this part.

(D)(*1*) CMS will use the most recently available, finalized Medicare hospital cost report to determine the number of beds for a Medicare-enrolled hospital, for purposes of determining the maximum daily dollar civil monetary penalty amount under paragraph (c)(2) of this section.

(*2*) If the number of beds for the hospital cannot be determined according to paragraph (c)(2)(ii)(D)(*1*) of this section, CMS will request that the hospital provide documentation of its number of beds, in a form and manner and by the deadline prescribed by CMS in a written notice provided to the hospital. Should the hospital fail to provide CMS with this documentation in the prescribed form and manner, and by the specified deadline, CMS will impose on the hospital the maximum daily dollar civil monetary penalty amount according to paragraph (c)(2)(ii)(C) of this section.

* * * * *

Dated: July 16, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–15496 Filed 7–19–21; 4:15 pm]

BILLING CODE 4120–01–P