DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 412, 414, 416, 419, 482, 485, 512

[CMS–1736–FC, 1736–IFC]

RIN 0938–AU12

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-Owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID–19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID–19)

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

ACTION: Final rule with comment period and interim final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2021 based on our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. In addition, this final rule with comment period establishes and updates the Overall Hospital Quality Star Rating beginning with the CY 2021; removes certain restrictions on the expansion of physician-owned hospitals that qualify as ''high Medicaid facilities,'' and clarifies that certain beds are counted toward a hospital's baseline number of operating rooms, procedure rooms, and beds; adds two new service categories to the Hospital Outpatient Department (OPD) Prior Authorization Process; provides notice of the closure of two teaching hospitals and the opportunity to apply for available slots for purposes of indirect medical education (IME) and direct graduate medical education (DGME) payments; and revises the Clinical Laboratory Date of Service (DOS) policy. This interim final rule with comment period modifies the Radiation Oncology Model (RO Model) Model performance period for CY 2021, and establishes new requirements in the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) for tracking of COVID–19 therapeutic inventory and usage and for tracking of the incidence and impact of Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) during the ongoing COVID–19 public health emergency (PHE).

DATES:

Effective date: This rule is effective January 1, 2021, with the exceptions of amendatory instructions 21 and 23 (amending 42 CFR 482.42 and 485.640) and 25 through 31 (amending 42 CFR 512.205, 512.210, 512.217, 512.220, 512.245, 512.255, and 512.285), which are effective on December 4, 2021.

Comment period: To be assured consideration, comments on the payment classifications assigned to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes in this final rule with comment period (CMS–1736–FC) must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on January 4, 2021.

To be assured consideration, comments on the Reporting Requirements for Hospitals and CAHs to Report Acute Respiratory Illness During the PHE for COVID–19, instructions 21 and 23 amending §§ 482.42 and 485.640, and the Radiation Oncology (RO) Model, instructions 25 through 31 amending 42 CFR 512.205, 512.210, 512.217, 512.220, 512.245, 512.255, and 512.285 in this interim final rule with comment period (CMS–1736–IFC) must be received at one of the addresses provided below, no later than 5 p.m. on February 2, 2021.

Applicability dates: The provisions related to the Radiation Oncology (RO) Model contained in section XXI of this interim final rule with comment period are applicable beginning July 1, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1736–FC or CMS–1736–IFC as appropriate, when commenting on the issues in this final rule with comment period and interim final rule with comment period. 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–1736–FC or CMS–1736–IFC, 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–1736–FC or CMS–1736–IFC, 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 *Scott.Talaga@cms.hhs.gov* or Mitali Dayal via email *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 *Joshua.McFeeters@cms.hhs.gov*. Cancer

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

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

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

Comprehensive APCs (C–APCs), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*, or Mitali Dayal via email *Mitali.Dayal2@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 Nicole P. Crenshaw via email *PNicole.Crenshaw@cms.hhs.gov*.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov*.

Hospital Quality Star Rating Methodology, contact Annese Abdullah-Mclaughlin via email *Annese.Abdullah-Mclaughlin@cms.hhs.gov*.

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

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

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

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

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

OPPS Packaged Items/Services, contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*, or Mitali Dayal via email at *Mitali.Dayal2@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 *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*.

Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services, contact Thomas Kessler via email at *Thomas.Kessler@cms.hhs.gov*.

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

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

Supervision of Outpatient Therapeutic Services in Hospitals and CAHs, contact Josh McFeeters via email *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 *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

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

CAPT Scott Cooper, USPHS, (410) 786–9465, for the hospital and CAH COVID–19 Therapeutic Inventory and Usage reporting requirements and for the Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) reporting requirements.

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 final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 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 in Response to the CY 2021 OPPS/ASC Proposed Rule

G. Public Comments Received on the CY 2020 OPPS/ASC Final Rule With Comment Period
II. Updates Affecting OPPS Payments
A. Recalibration of APC Relative Payment Weights
B. Conversion Factor Update
C. Wage Index Changes
D. Statewide Average Default Cost-to-Charge Ratios (CCRs)
E. 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. Payment Adjustment for Certain Cancer Hospitals for CY 2021
G. Hospital Outpatient Outlier Payments
H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment
I. Beneficiary Copayments
III. OPPS Ambulatory Payment Classification (APC) Group Policies
A. OPPS Treatment of New and Revised HCPCS Codes
B. OPPS Changes—Variations Within APCs
C. New Technology APCs
D. OPPS APC-Specific Policies
IV. OPPS Payment for Devices
A. Pass-Through Payments for Devices
B. Device-Intensive Procedures
V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals
A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals
B. 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. Estimate of Pass-Through Spending
VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services
VIII. Payment for Partial Hospitalization Services
A. Background
B. PHP APC Update for CY 2021
C. Outlier Policy for CMHCs
IX. Services That Will Be Paid Only as Inpatient Services
A. Background
B. Changes to the Inpatient Only (IPO) List
X. Nonrecurring Policy Changes
A. Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)
B. Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2021 and Subsequent Years
XI. CY 2021 OPPS Payment Status and Comment Indicators
A. CY 2021 OPPS Payment Status Indicator Definitions
B. CY 2021 Comment Indicator Definitions
XII. MedPAC Recommendations
A. OPPS Payment Rates Update
B. ASC Conversion Factor Update
C. ASC Cost Data
XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System
A. Background
B. ASC Treatment of New and Revised Codes
C. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services
D. Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services
E. New Technology Intraocular Lenses (NTIOLs)
F. ASC Payment and Comment Indicators
G. Calculation of the ASC Payment Rates and the ASC Conversion Factor
XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program
A. Background
B. Hospital OQR Program Quality Measures
C. Administrative Requirements
D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program
E. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2021 Payment Determination
XV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program
A. Background
B. ASCQR Program Quality Measures
C. Administrative Requirements
D. Form, Manner, and Timing of Data Submitted for the ASCQR Program
E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements
XVI. Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years
A. Background
B. Critical Access Hospitals in the Overall Star Rating
C. Veterans Health Administration Hospitals in the Overall Star Rating
D. History of the Overall Hospital Quality Star Rating
E. Current and Proposed Overall Star Rating Methodology
F. Preview Period
G. Overall Star Rating Suppressions
XVII. Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process
A. Background
B. Controlling Unnecessary Increases in the Volume of Covered OPD Services
XVIII. Clinical Laboratory Fee Schedule: Revisions to the Laboratory Date of Service Policy
A. Background on the Medicare Part B Laboratory Date of Service Policy
B. Medicare DOS Policy and the ''14-Day Rule''
C. Billing and Payment for Laboratory Services Under the OPPS
D. ADLTs Under the New Private Payor Rate-Based CLFS
E. Additional Laboratory DOS Policy Exception for the Hospital Outpatient Setting
F. Revision to the Laboratory DOS Policy for Cancer-Related Protein-Based MAAAs
XIX. Physician-Owned Hospitals
A. Background
B. Prohibition on Facility Expansion
C. Deference to State Law for Purposes of Determining the Number of Beds for Which a Hospital Is Licensed
XX. Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots
A. Background Section
B. Notice of Closure of Westlake Community Hospital, Located in Melrose Park, IL, and the Application Process—Round 18
C. Notice of Closure of Astria Regional Medical Center, Located in Yakima, WA, and the Application Process—Round 19
D. Application Process for Available Resident Slots
XXI. Radiation Oncology (RO) Model
A. Model Performance Period for the Radiation Oncology Model
B. Waiver of Proposed Rulemaking
XXII. Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report COVID–19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID–19)
XXIII. Files Available to the Public via the Internet
XXIV. 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 Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process
E. ICRs for the Overall Hospital Quality Star Ratings
F. ICRs for Physician-Owned Hospitals
XXV. Waiver of the 30-Day and 60-Day Delayed Effective Dates for the Final Rule With Comment Period and Waiver of Proposed Rulemaking for Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID–19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness During the PHE for COVID–19 Interim Final Rule With Comment Period (IFC)
A. Waiver of the 30-Day and 60-Day Delayed Effective Dates for the Final Rule With Comment Period
B. Waiver of Proposed Rulemaking for Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report Acute Respiratory Illness During the PHE for COVID–19 Interim Final Rule With Comment Period (IFC)
XXVI. Response to Comments
XXVII. Economic Analyses
A. Statement of Need
B. Overall Impact for the Provisions of This Final Rule With Comment Period
C. Detailed Economic Analyses
D. Regulatory Review Costs
E. Regulatory Flexibility Act (RFA) Analysis
F. Unfunded Mandates Reform Act Analysis
G. Reducing Regulation and Controlling Regulatory Costs

H. Conclusion
XXVIII. Federalism Analysis

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this final rule with comment period and interim final rule with comment period, we are updating 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, 2021. 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 final rule with comment period 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 final rule with comment period. In addition, this final rule with comment period updates and refines 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 CY 2021, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.4 percent. This increase factor is based on the final hospital inpatient market basket percentage increase of 2.4 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS). 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) 2021 would be approximately $83.888 billion, an increase of approximately $7.541 billion compared to estimated CY 2020 OPPS payments.

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

- *Partial Hospitalization Update:* For CY 2021 OPPS/ASC final rule with comment period, CMS is maintaining the unified rate structure established in CY 2017, with a single PHP APC for each provider type for days with 3 or more services per day. We are using the CMHC and hospital-based PHP (HB PHP) geometric mean per diem costs, consistent with existing policy, using updated data for each provider type. Accordingly, we are calculating the CY 2021 PHP APC per diem rates for HB PHPs and CMHC PHPs based on updated cost and claims data. Given that the final calculated geometric mean per diem costs are much higher than the proposed cost floors, we are not extending the cost floors to CY 2021 and subsequent years.
- *Changes to the Inpatient Only (IPO) List:* For CY 2021, we are eliminating the IPO list over the course of 3 calendar years beginning with the removal of 266 musculoskeletal-related services. We are also removing 32 additional HCPCS codes from the IPO list for CY 2021 based on public comments.
- *Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule):* For CY 2021, we are finalizing a policy to exempt procedures that are removed from the inpatient only (IPO) list under the OPPS beginning on 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) until such procedures are more commonly billed in the outpatient setting.
- 340B—*Acquired Drugs:* We are continuing 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 continuing to exempt Rural SCHs, PPS-exempt cancer hospitals and children's hospitals from our 340B payment policy.
- *Comprehensive APCs:* For CY 2021, we are creating two new comprehensive APCs (C–APCs): C–APC 5378 (Level 8 Urology and Related Services) and C–APC 5465 (Level 5 Neurostimulator and Related Procedures). Adding these C–APCs increases the total number of C–APCs to 69.
- *Device Pass-Through Payment Applications:* For CY 2021, we evaluated five applications for device pass-through payments. Two of these applications (CUSTOMFLEX® ARTIFICIALIRIS and EXALT™ Model D Single-Use Duodenoscope) received preliminary approval for pass-through payment status through our quarterly review process. Based on our review and public comments received, we are continuing the pass-through payment status for CUSTOMFLEX® ARTIFICIALIRIS and EXALT™ Model D Single-Use Duodenoscope and approving the remaining three applications for device pass-through payment status.
- *Changes to the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals:* For CY 2021 and subsequent years, we are changing the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service, including the initiation portion of the service, for which we had previously required direct supervision. This is consistent with the minimum required level of general supervision that currently applies for most outpatient hospital therapeutic services. We are finalizing our proposed policy to permit direct supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services using virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician until the later of the end of the calendar year in which the PHE ends or December 31, 2021.
- *Cancer Hospital Payment Adjustment:* For CY 2021, we are continuing to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other 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, a target PCR of 0.89 will be used to determine the CY 2021 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 2021, we are increasing payment rates under the ASC payment system by 2.4 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a hospital market basket percentage increase of 2.4 percent minus a multifactor productivity adjustment of 0.0 percentage point. Based on this update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2021 would be approximately 5.42 billion, an increase of approximately 120 million compared to estimated CY 2020 Medicare payments.

• *Changes to the List of ASC Covered Surgical Procedures:* For CY 2021, we are adding eleven procedures to the ASC covered procedures list (CPL), including total hip arthroplasty (CPT 27130). Additionally, we are revising the criteria we use to add covered surgical procedures to the ASC CPL, providing that certain criteria we used to add covered surgical procedures to the ASC CPL in the past will now be factors for physicians to consider in deciding whether a specific beneficiary should receive a covered surgical procedure in an ASC, and adopting a notification process for surgical procedures the public believes can be added to the ASC CPL under the criteria we are retaining. Using our revised criteria, we are adding an additional 267 surgical procedures to the ASC CPL beginning in CY 2021.

• *Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs:* For the Hospital OQR and ASCQR Programs, we are updating and refining requirements to further meaningful measurement and reporting for quality of care provided in these outpatient settings while limiting compliance burden. We are revising and codifying previously finalized administrative procedures and are codifying an expanded review and corrections process to further the programs' alignment while clarifying program requirements. We are not making any measure additions or removals for either program.

• *Overall Hospital Quality Star Ratings:* We are establishing and updating the methodology that will be used to calculate the Overall Hospital Quality Star Ratings beginning with 2021 and for subsequent years. We are updating and simplifying how the ratings are calculated, with policies such as adopting a simple average of measure scores instead of the latent variable model and reducing the total number of measure groups from seven to five measure groups due to the removal of measures through the Meaningful Measure Initiative. Additionally, we are increasing the comparability of star ratings by peer grouping hospitals by the number of measure groups. These changes will simplify the methodology, and therefore, reduce provider burden, improve the predictability of the star ratings, and increase the comparability between hospital star ratings. We did not finalize our proposals related to stratification of the Readmissions group by dual-eligible patients.

• *Addition of New Service Categories for Hospital Outpatient Department Prior Authorization Process:* We are adding the following two categories of services to the prior authorization process for hospital outpatient departments beginning for dates of service on or after July 1, 2021: (1) Cervical fusion with disc removal and (2) implanted spinal neurostimulators.

• *Clinical Laboratory Date of Service (DOS) Policy:* We are excluding certain protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs), which are not generally performed in the HOPD setting, from the OPPS packaging policy and adding them to the laboratory DOS exception at 42 CFR 414.510(b)(5).

• *Physician-Owned Hospitals:* We are removing unnecessary regulatory restrictions on high Medicaid facilities and including beds in a physician-owned hospital's baseline consistent with state law.

• *Radiation Oncology Model (RO Model):* On September 29, 2020, we published a final rule in the **Federal Register** (85 FR 61114) entitled ''Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' that finalized the Radiation Oncology Model (RO Model). To ensure that participation in the RO Model during the public health emergency (PHE) for the Coronavirus disease 2019 (COVID–19) pandemic does not further strain RO participants' capacity, we are revising the RO Model's Model performance period to begin on July 1, 2021 and end December 31, 2025 in this interim final rule with comment period. We are requesting comments on this change.

• *Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report COVID–19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID–19):* This interim final rule with comment period establishes new requirements in the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) for tracking COVID–19 therapeutic inventory and usage and for tracking the incidence and impact of Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) during the ongoing COVID–19 PHE; and for providing this information and data to the Secretary of Health and Human Services (Secretary) in such form and manner, and at such timing and frequency, as the Secretary may prescribe during the Public Health Emergency (PHE).

3. Summary of Costs and Benefit

In section XXVII and XXVIII of this final rule with comment period and interim final rule with comment period, we set forth a detailed analysis of the regulatory and federalism impacts that the changes will have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table 79 in section XXVII.C of the CY 2021 OPPS/ASC final rule with comment period 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 the CY 2021 OPPS/ASC final rule with comment period will result in a 2.4 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2021, including beneficiary cost-sharing, to the approximately 3,665 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will increase by approximately $1.61 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 an 11.9 percent increase in CY 2021 payments to CMHCs relative to their CY 2020 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the FY 2021 IPPS final rule wage indexes will result in an estimated increase in payments of 0.2 percent for urban hospitals under the OPPS and an estimated increase in payments of 0.4 percent 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 final rule with comment period.

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

There are no significant impacts of our CY 2021 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not making any change in policies for determining the rural hospital payment adjustments. While we are implementing the reduction to the cancer hospital payment adjustment for CY 2021 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 2020, and therefore has no budget neutrality adjustment.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2021 OPPS/ASC, we are establishing an OPD fee schedule increase factor of 2.4 percent and applying that increase factor to the conversion factor for CY 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 2.6 percent and that rural hospitals would experience an increase in payments of 2.9 percent. Classifying hospitals by teaching status, we estimate nonteaching hospitals will experience an increase in payments of 2.9 percent, minor teaching hospitals will experience an increase in payments of 3.0 percent, and major teaching hospitals will experience an increase in payments of 2.0 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership will experience an increase of 2.6 percent in payments, while hospitals with government ownership will experience an increase of 2.2 percent in payments. We estimate that hospitals with proprietary ownership will experience an increase of 3.5 percent in payments.

e. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2021 payment rates, compared to estimated CY 2020 payment rates, generally ranges between an increase of 2 and 5 percent, depending on the service, with some exceptions. We estimate the impact of applying the hospital market basket update to ASC payment rates will be an increase in payments of $120 million under the ASC payment system in CY 2021.

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; and 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.

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 the CY 2021 OPPS/ASC final 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/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.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.

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 in Response to the CY 2021 OPPS/ASC Proposed Rule

We received approximately 1,350 timely pieces of correspondence on the CY 2021 OPPS/ASC proposed rule that appeared in the **Federal Register** on August 12, 2020 (85 FR 48772). We note that we received some public comments that were outside the scope of the CY 2021 OPPS/ASC proposed rule. Out-of-scope-public comments are not addressed in this CY 2021 OPPS/ASC final rule with comment period. Summaries of those public comments that are within the scope of the proposed rule and our responses are set forth in the various sections of this final rule with comment period under the appropriate headings.

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

We received approximately 22 timely pieces of correspondence on the CY 2020 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 12, 2019 (84 FR 61142), 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). Summaries of the public comments on topics that were open to comment and our responses to them are set forth in various sections of this final rule with comment period under the appropriate subject-matter headings. Summaries of the public comments on new or replacement Level II HCPCS codes are set forth in the CY 2021 OPPS/ASC proposed rule and this final rule with comment period under the appropriate subject matter headings.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for 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 2021 OPPS/ASC proposed rule (85 FR 48779), we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2021, and before January 1, 2022 (CY 2021), using the same basic methodology that we described in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61149), using updated CY 2019 claims data. That is, as we proposed, we recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2021, we began with approximately 167 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 87 million final action claims to develop the proposed CY 2021 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 the CY 2021 OPPS/ASC proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

Addendum N to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website) included the proposed list of bypass codes for CY 2021. The proposed list of bypass codes contained codes that were reported on claims for services in CY 2019 and, therefore, included codes that were in effect in CY 2019 and used for billing, but were deleted for CY 2020. We retained these deleted bypass codes on the proposed CY 2021 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 2021 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 were identified by asterisks (*) in the third column of Addendum N to the proposed rule. HCPCS codes that we proposed to add for CY 2021 were identified by asterisks (*) in the fourth column of Addendum N.

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

For CY 2021, in the CY 2020 OPPS/ASC proposed rule (85 FR 48779), we proposed 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 2021 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 the most recently available hospital cost reports, which, in most cases, are from CY 2018. For the proposed CY 2021 OPPS payment rates, we used the set of claims processed during CY 2019. 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 2021 OPPS payment rates) and updates to the NUBC 2019 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 the proposed rule and this final rule with comment period.

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 the CY 2014 OPPS/ASC proposed rule, commenters reported that some hospitals used a less precise ''square feet'' allocation methodology for the costs of large moveable equipment like CT scan and MRI machines. They indicated that while we recommended using two alternative allocation methods, ''direct assignment'' or ''dollar value,'' as a more accurate methodology for directly assigning equipment costs, industry analysis suggested that approximately only half of the reported cost centers for CT scans and MRIs rely on these preferred methodologies. In response to concerns from commenters, we finalized a policy for 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. Further, we finalized a transitional policy to estimate the imaging APC relative payment weights using only CT and MRI cost data from providers that do not use ''square feet'' as the cost allocation statistic. We provided that this finalized policy would sunset in 4 years to provide sufficient time for hospitals to transition to a more accurate cost allocation method and for the related data to be available for ratesetting purposes (78 FR 74847). Therefore, beginning in CY 2018 with the sunset of the transition policy, we would estimate the imaging APC relative payment weights using cost data from all providers, regardless of the cost allocation statistic employed. However, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228 and 59229) and in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58831), we finalized a policy to extend the transition policy for 1 additional year and we continued to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CT and MRI CCRs for the CY 2018 OPPS and the CY 2019 OPPS.

As we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228), some stakeholders have raised concerns regarding using claims from all providers to calculate CT and MRI CCRs, regardless of the cost allocations statistic employed (78 FR 74840 through 74847). Stakeholders noted that providers continue to use the ''square feet'' cost allocation method and that including claims from such providers would cause significant reductions in the imaging APC payment rates.

Table 1 demonstrates the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using ''square feet'' as the cost allocation method by extracting HCRIS data on Worksheet B–1. Table 2 provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods.

TABLE 1: PERCENTAGE CHANGE IN ESTIMATED COST FOR CT AND MRI APCS WHEN EXCLUDING CLAIMS FROM PROVIDERS USING "SQUARE FEET" AS THE COST ALLOCATION METHOD

APC	APC Descriptor	Percentage Change
5521	Level 1 Imaging without Contrast	-2.8%
5522	Level 2 Imaging without Contrast	5.5%
5523	Level 3 Imaging without Contrast	4.3%
5524	Level 4 Imaging without Contrast	5.3%
5571	Level 1 Imaging with Contrast	6.8%
5572	Level 2 Imaging with Contrast	8.2%
5573	Level 3 Imaging with Contrast	2.3%
8005	CT and CTA without Contrast Composite	13.9%
8006	CT and CTA with Contrast Composite	10.8%
8007	MRI and MRA without Contrast Composite	7.6%
8008	MRI and MRA with Contrast Composite	7.2%

TABLE 2: CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost Allocation Method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0342	0.0483	0.0752	0.1008
Square Feet Only	0.0285	0.0435	0.0660	0.0919
Direct Assign	0.0459	0.0557	0.0910	0.1151
Dollar Value	0.0405	0.0546	0.0858	0.1126
Direct Assign and Dollar Value	0.0406	0.0548	0.0862	0.1128

Our analysis shows that since the CY 2014 OPPS in which we established the transition policy, the number of valid MRI CCRs has increased by 18.7 percent to 2,199 providers and the number of valid CT CCRs has increased by 16.5 percent to 2,280 providers. Table 1 displays the impact on OPPS payment rates for CY 2021 if claims from providers that report using the ''square feet'' cost allocation method were removed. This can be attributed to the generally lower CCR values from providers that use a ''square feet'' cost allocation method as shown in Table 1.

We note that the CT and MRI cost center CCRs have been available for ratesetting since the CY 2014 OPPS in which we established the transition policy. Since the initial 4-year transition, we had extended the transition an additional 2 years to offer providers flexibility in applying cost allocation methodologies for CT and MRI cost centers other than ''square feet.'' In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61152), we finalized a 2-year phased-in approach, as suggested by some commenters, that applied 50 percent of the payment impact from ending the transition in CY 2020 and 100 percent of the payment impact from ending the transition in CY 2021.

We believe we have provided sufficient time for providers to adopt an alternative cost allocation methodology for CT and MRI cost centers if they intended to do so and many providers continue to use the ''square feet'' cost allocation methodology, which we believe indicates that these providers believe this methodology is a sufficient method for attributing costs to this cost center. Additionally, we generally believe that increasing the amount of claims data available for use in ratesetting improves our ratesetting process. Therefore, as finalized in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61152), in the CY 2021 OPPS we are using 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 APCs for CT and MRI identified in Table 1.

The Deficit Reduction Act (DRA) of 2005 requires Medicare to limit Medicare payment for certain imaging services covered by the Physician Fee Schedule (PFS) to not exceed what Medicare pays for these services under the OPPS. As required by law, for certain imaging services paid for under the PFS, we cap the technical component of the PFS payment amount for the applicable year at the OPPS payment amount (71 FR 69659 through

69661). As we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74845), we have noted the potential impact the CT and MRI CCRs may have on other payment systems. We understand that payment reductions for imaging services under the OPPS could have significant payment impacts under the PFS where the technical component payment for many imaging services is capped at the OPPS amount. We will continue to monitor OPPS imaging payments in the future and consider potential impacts of payment changes on the PFS and the ASC payment system.

Comment: Several commenters requested that CMS not use the CT and MRI-specific cost centers and instead estimate cost using the single diagnostic radiology cost center, believing that this will solve the inaccurate reporting of costs for CT and MR services. Commenters stated that many hospitals have ''near zero'' CT and MRI CCRs and the existing cost centers are inaccurate, too low, and depressing the valuation of APCs that include CT and MRI services. One commenter recommended that CMS establish detailed instructions for nonstandard cost centers to improve the accuracy of the cost center data used to calculate CT and MRI CCRs. Commenters also noted that the impact of our proposal may diminish beneficiary access to medical imaging services for beneficiaries, specifically noting low OPPS payments for cardiac computed tomography angiography (CCTA). Several commenters noted that the use of separate CT and MRI CCRs creates unintended consequences on the technical component of CT and MRI codes in the Medicare Physician Fee Schedule and on the payment rate under the ASC payment system for these codes.

Response: We appreciate the thoughtful comments and analysis regarding the use of the CT and MRI cost center CCRs. However, as discussed in the CY 2020 OPPS/ASC final rule (84 FR 61152), we finalized a policy to end the transition policy and use all data submitted (including all providers, regardless of cost allocation method) in the CY 2021 OPPS. We did not propose to make any changes in the CY 2021 OPPS and are not modifying the policy at this time.

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

In this section of this final rule with comment period, we discuss the use of claims to calculate the OPPS payment rates for CY 2021. The Hospital OPPS page on the CMS website on which this final rule with comment period 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 final 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 final payment rates for this CY 2021 OPPS/ASC final rule with comment period.

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 CY 2021, we are finalizing our proposal to continue to use geometric mean costs to calculate the relative weights on which the final CY 2021 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of the CY 2021 OPPS/ASC final rule with comment period to calculate the costs we used to establish the relative payment weights used in calculating the OPPS payment rates for CY 2021 shown in Addenda A and B to the CY 2021 OPPS/ASC final rule with comment period (which are available via the internet on the CMS website). We referred readers to section II.A.4. of the CY 2021 OPPS/ASC final rule with comment period 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 2021 OPPS, we will continue to remove these claim lines with modifier ''PN'' from the ratesetting process.

For details of the claims accounting process used in the CY 2021 OPPS/ASC final rule with comment period, we refer readers to the claims accounting narrative under supporting documentation for this CY 2021 OPPS/ASC final rule with comment period on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

(a) Methodology

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 proposed 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 proposed 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 proposed 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 proposed to calculate the costs upon which the proposed CY 2021 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 this methodology in CY 2021 will 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 proposed 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 will be reflected in the overall costs of the C–APCs (and, as a result, in the proposed payment rates of the C–APCs), we proposed 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 66796)). We refer readers to Addendum B the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website) for the proposed CY 2021 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 2021, we proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology. We did not receive any comments on our proposal to establish payment rates for blood and blood products using our blood-specific CCR methodology and we are finalizing this policy as proposed.

(b) Payment for Blood Not Otherwise Classified (NOC) Code

Recently, providers and stakeholders in the blood products field have reported that product development for new blood products has accelerated. There may be several additional new blood products entering the market by the end of CY 2021, compared to only one or two new products entering the market over the previous 15 to 20 years. To encourage providers to use these new products, providers and stakeholders requested that we establish a new HCPCS code to allow for payment for unclassified blood products prior to these products receiving their own HCPCS code. Under the OPPS, unclassified procedures are generally assigned to the lowest APC payment level of an APC family. However, since blood products are each assigned to their own unique APC, the concept of a lowest APC payment level does not apply in this context.

Starting January 1, 2020, we established a new HCPCS code, P9099 (Blood component or product not otherwise classified) which allows providers to report unclassified blood products. We assigned HCPCS code P9099 to status indicator ''E2'' (Not payable by Medicare when submitted on an outpatient claim) for CY 2020. We took this action because HCPCS code P9099 potentially could be reported for multiple products with different costs during the same period of time. Therefore, we could not identify an individual blood product HCPCS code that would have a similar cost to HCPCS code P9099, and were not able to crosswalk a payment rate from an established blood product HCPCS code to HCPCS code P9099. Some stakeholders expressed concerns that assigning HCPCS code P9099 to a non-payable status in the OPPS meant that hospitals would receive no payment when they used unclassified blood products. Also, claim lines billed with P9099 are rejected by Medicare, which prevents providers from tracking the utilization of unclassified blood products.

Because of the challenges of determining an appropriate payment rate for unclassified blood products, we stated in the CY 2021 OPPS/ASC proposed rule that we were considering packaging the cost of unclassified blood products into their affiliated primary medical procedure. Although we typically do not package blood products under the OPPS, for unclassified blood products, we stated that we do not believe it is possible to accurately determine an appropriate rate that would apply for all of the products (potentially several, with varying costs) that may be reported using HCPCS code P9099. Packaging the cost of unclassified blood products into the payment for the primary medical service by assigning HCPCS code P9099 a status indicator of ''N'' would allow providers to report the cost of unclassified blood products to Medicare. Over time, the costs of unspecified blood products would be reflected in the payment rate for the primary medical service if the blood product remains unclassified. However, we stated that we expect that most blood products would seek and be granted more specific coding such that the unclassified HCPCS code P9099 would no longer be applicable. We also explained that we believe that packaging the costs of unclassified blood products would be an improvement over the current non-payable status for HCPCS code P9099 as it would allow for tracking of the costs and utilization of unclassified blood products.

Another option we considered for the CY 2021 OPPS/ASC proposed rule, but ultimately rejected was similar to our policy under the OPPS to assign NOC codes to the lowest APC within the appropriate clinical family. We stated that we could have cross-walked and assigned the same payment rate for HCPCS code P9099 as HCPCS code P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml), which is the lowest cost blood product with a

proposed CY 2021 payment rate of $8.02 per unit. This option would have provided a small, separate payment for each unclassified blood product service, and, similar to our proposal to package the costs of HCPCS code P9099 into their primary procedure, would have allowed for tracking of the cost and utilization for unclassified blood products. However, given that the cross-walked payment rate is potentially significantly lower than the cost of the product, we concluded that providers may find that packaging the cost of unclassified blood products into another medical service may generate more payment for the products over time.

Thus, for CY 2021, we proposed to package the cost of unclassified blood products reported by HCPCS code P9099 into the cost of the associated primary procedure. We proposed to change the status indicator for HCPCS code P9099 from ''E2'' (not payable by Medicare in the OPPS) to ''N'' (payment is packaged into other services in the OPPS). In addition, we also sought comment on the alternative proposal to make HCPCS code P9099 separately payable with a payment rate equivalent to the payment rate for the lowest cost blood product, HCPCS code P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml), with a proposed CY 2021 payment rate of $8.02 per unit. We stated that if we were to adopt this option as our final policy, we would also change the status indicator for HCPCS code P9099 from ''E2'' (not payable by Medicare in the OPPS) to ''R'' (blood and blood products, paid under OPPS).

Comment: Multiple commenters opposed our proposal to reassign HCPCS code P9099 to status indicator ''N'' and package the payment for unclassified blood products into the associated primary procedure. Commenters were concerned that because blood products are usually separately paid in the OPPS, APC payment rates for the associated procedures would not reflect the cost of the unclassified blood products, and that it would take a long time before providers would see any changes in payments that would include the cost of unclassified blood products. One commenter was also concerned that packaging the cost of unclassified blood products would make providers less likely to report HCPCS code P9099, making it harder to track the utilization of unclassified blood products, and reluctant to use blood products that would not receive separate payment.

Response: We agree with the concerns expressed by the commenters, and we have considered these concerns in determining the payment policy for the blood NOC code.

Comment: One commenter supported our proposal to reassign HCPCS code P9099 to status indicator ''N'' and package the payment for unclassified blood products into the associated primary procedure. The commenter also encouraged us to work with manufacturers and blood product stakeholders to move quickly to establish individual HCPCS codes for these new blood products.

Response: We appreciate the commenter's support for our proposal and we also support the request that codes be established in a timely manner for unclassified blood products.

Comment: Multiple commenters opposed our alternative proposal to pay services billed with HCPCS code P9099 at the lowest payment rate for a blood product in the OPPS, which is $7.79 per unit. The commenters believe the payment rate will be too low for new, unclassified blood products and may discourage manufacturers from pursuing new innovations in the blood products field.

Response: We understand the concerns of the commenters who believe paying for unclassified blood products at the lowest payment rate for a separately payable blood product in the OPPS does not provide adequate payment for new, unclassified blood products. However, our goal is to limit the time it is necessary for providers to report HCPCS code P9099 until a new blood product has an individual HCPCS code established for the product. Once a new blood product has an individual HCPCS code, it will allow for a payment for the new service that is better aligned with its costs and make it easier to track utilization for the service. Establishing a payment rate for the blood NOC code that is equal to the payment rate for the lowest payment rate for a separately payable blood product is consistent with OPPS policy for other major categories of medical care where the payment rate for the unclassified service is equal to the lowest-paying APC in an APC series for that category of service.

Comment: The CMS HOP Panel and multiple commenters requested that unclassified blood products be separately paid using a weighted average of the payment rates of all separately payable blood products in the OPPS. The average payment rate would be weighted by the number of units billed for each service in the OPPS. Commenters believe a weighted average would be consistent with OPPS policy to provide separate payment for all blood products and would encourage the use of HCPCS code P9099 to track the utilization of unclassified blood products until the new products could receive individual HCPCS codes. The weighted average also would provide a higher payment for services billed with HCPCS code P9099 than the alternative proposal of assigning the lowest payment rate for a separately payable blood product as payment for unclassified blood products. Other commenters suggested that unclassified blood products be paid either at charges reduced to cost or at reasonable cost to appropriately compensate providers billing unclassified blood products.

Response: Providing payment for HCPCS code P9099 through a weighted average payment, charges reduced to cost, or reasonable cost could provide incentives to discourage manufacturers of new blood products from seeking individual HCPCS codes for their products. A weighted average payment would encourage manufacturers of relatively inexpensive unclassified blood products not to seek a HCPCS code for their products because the payment using P9099 for the products would be substantially higher than payment the products would receive once an individual code is established for the blood products. In addition, the level of payment from a weighted average payment may reduce the urgency of manufacturers to seek an individual HCPCS cost even for higher-cost products, which would delay our ability to track payment for individual blood products. We have similar concerns about paying unclassified blood products using either charges reduced to cost or reasonable cost. Although these payment methods would accurately reflect the cost of unclassified blood products to providers, there would be no incentive for providers to manage their costs when using unclassified blood products, and no incentives for the manufacturers to seek individual HCPCS codes for the unclassified blood products. The OPPS is a prospective payment system, and we want to limit rather than expand the types of services within the OPPS that do not receive prospective payment.

After reviewing the public comments, we are not finalizing our original proposal to package HCPCS code P9099 into the associated primary procedure. Instead, we are finalizing our alternative proposal to make HCPCS code P9099 separately payable, assign it a status indicator of ''R'', and pay the code at a rate equal to the lowest paid separately payable blood product in the OPPS, which is P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml) with a payment rate of $7.79 per unit. Our alternative proposal aligns

with our general policy in the OPPS to pay NOC codes at the lowest available APC rate for a service category, while providing a payment for unclassified blood products when a service is reported on the claim. We believe our alternative proposal is superior to our original proposal, which would not have provided any separate payment for blood products reported using HCPCS code P9099. Our alternative proposal also provides incentives for manufacturers to seek individual HCPCS codes for new blood products, which helps us to track the utilization of these new blood products and establish a payment rate for these new products that better reflects their cost.

We decided to finalize our alternative proposal, as it gives providers some payment for unclassified blood products, is consistent with OPPS policy for other major categories of medical care where the payment rate for the unclassified service is based on the lowest-paying APC in an APC series for that category of service, while maintaining incentives for manufacturers to establish individual HCPCS codes for their new blood products in a timely manner.

(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 2021, except where otherwise indicated, we proposed to use the costs derived from CY 2019 claims data to set the proposed CY 2021 payment rates for brachytherapy sources because CY 2019 is the year of data we proposed to use to set the proposed payment rates for most other items and services that would be paid under the CY 2021 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter), we proposed to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we proposed for other items and services paid under the OPPS, as discussed in section II.A.2. of the CY 2021 OPPS/ASC proposed rule. We also proposed 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 proposed 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 proposed 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 2021 payment rates for brachytherapy sources are included in Addendum B to the CY 2021 OPPS/ASC 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.

For CY 2021, we proposed to continue to assign status indicator ''U'' to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter). For CY 2020, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2. Our CY 2019 claims data available for the proposed CY 2021 rule included one claim with over 4,000 units of HCPCS code C2645. The geometric mean cost of HCPCS code C2645 from this one claim is $1.07 per mm^2 for CY 2019. We do not believe that this one claim is adequate to establish an APC payment rate for HCPCS code C2645 and to discontinue our use of external data for this brachytherapy source. Therefore, for CY 2021, we proposed to continue assigning the brachytherapy source described by HCPCS code C2645 a payment rate of $4.69 mm^2 for CY 2021

through use of our equitable adjustment authority.

Comment: One commenter recommended that we should review outpatient claims data for low-volume brachytherapy sources and consider removing outliers to ensure appropriate and stable brachytherapy source reimbursement in future years. The commenter contends that brachytherapy source payments have fluctuated significantly since 2013 and may create barriers to access for individual cancer patients.

Response: We thank the commenter for their recommendation. As we have stated in past rulemaking, the OPPS relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a service for a particular patient; however, with the exception of outlier cases, we believe that such a prospective payment is adequate to ensure access to appropriate care. We acknowledge that payment for brachytherapy sources based on geometric mean costs from a small set of claims may be more variable on a year-to-year basis when compared to the geometric mean costs for brachytherapy sources from a larger claims set. We will take the commenter's recommendation into consideration in future rulemaking.

Comment: One commenter recommended that we exclude erroneous claims data for C2642 (Brachytherapy source, stranded, cesium-131, per source) from a particular hospital. The commenter stated the hospital reported costs per source of $42.59 for C2642. Further, the commenter argued the proposed payment rate for C2642 as a result of including the hospital's claims information would threaten access to cancer therapy and would be less than the actual amount paid by any hospital for this source over the past decade.

Response: In our review of CY 2019 brachytherapy claims used for CY 2021 OPPS ratesetting, we did not find any erroneous billing of C2642 with respect to the particular hospital mentioned by the commenter. OPPS relative payment weights based on geometric mean costs capture the range of costs associated with services that are introduced slowly into the system on a case-by-case or hospital-by-hospital basis. For these reasons we believe it would be inappropriate to remove any outliers when determining brachytherapy geometric mean costs and payment rates for C2642.

After consideration of the public comments we received, we are finalizing our proposal to assign the brachytherapy source described by HCPCS code C2645 a payment rate of $4.69 per mm^2 for CY 2021 through use of our equitable adjustment authority.

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 direction 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 2021

(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). Most recently 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).

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 the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

In the interim final 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 two following 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 letter of authorization for 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 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 combination 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 the CY 2021 OPPS/ASC proposed rule, in the originating C–APC (cost threshold).

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

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

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

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

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2021, we proposed 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 listed the complexity adjustments for ''J1'' and add-on code combinations for CY 2021, along with all of the other proposed complexity adjustments, in Addendum J to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

Addendum J to the CY 2021 OPPS/ASC 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 the CY 2021 OPPS/ASC 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 the CY 2021 OPPS/ASC 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.

Comment: A commenter stated that CMS should not use claims data from complexity adjustment code pairs in calculating the geometric mean cost for the next higher paying APC to which the complexity adjusted code pair is assigned and that doing so can decrease the geometric mean cost of APCs with a low number of claims, specifically C–APC 5493—Level 3 Intraocular Procedures. The commenter stated that CMS did not intend to include the costs of complexity-adjusted code pairs in calculating the geometric mean cost for the higher-paying APCs to which the complexity-adjustment code pair is assigned when the C–APC complexity adjustment policy was initially established and that complexity adjustments were intended as payment adjustments for complex versions of the comprehensive service only. To further support their claim that CMS intended for complexity adjustments to only provide higher payment for claims including complex comprehensive services, the commenter noted that, unlike other HCPCS codes with a significant number of claims assigned to an APC, complexity adjusted code pairs are not evaluated for a 2 times rule violation in the higher-paying APC to which they are promoted.

Response: We disagree with the commenter's assertion regarding the policy of including the costs of a complexity adjusted code pair in the calculation of the geometric mean costs of the next higher paying C–APC to which the code pair is assigned. The current C–APC complexity adjustment policy, including the calculation of the geometric mean cost of APCs that include complexity-adjusted code pairs, was initially described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74887). In that rule, we stated the following: ''We then considered reassigning complex subsets of claims for each primary service HCPCS code. All claims reporting more than one procedure described by HCPCS codes assigned to status indicator ''J1'' are evaluated for the existence of commonly occurring combinations of procedure codes reported on claims that exhibit a materially greater comprehensive geometric mean cost relative to the geometric mean cost of the claims reporting that primary HCPCS code. This indicates that the subset of procedures identified by the secondary HCPCS code has increased resource requirements relative to less complex subsets of that procedure. If a combination of procedure codes reported on claims is identified that meets these requirements, that is, commonly occurring and exhibiting materially greater resource requirements, it is further evaluated to confirm clinical validity as a complex subset of the primary procedure and the combination of procedure codes is then identified as complex, and primary service claims with that combination of procedure codes are subsequently reassigned as appropriate. If a combination of procedure codes does not meet the requirement for a materially different cost or does not occur commonly, it is not considered to be a complex, and primary service claims with that combination of procedure codes are not reassigned. All combinations of procedures described by HCPCS codes assigned to status indicator ''J1'' for each primary HCPCS code are similarly evaluated.

Once all combinations of procedures described by HCPCS codes assigned to status indicator ''J1'' have been evaluated, all claims identified for reassignment for each primary service are combined and the group is assigned to a higher level comprehensive APC within a clinical family of comprehensive APCs, that is, an APC with greater estimated resource requirements than the initially assigned comprehensive APC and with appropriate clinical homogeneity. We assessed resource variation for reassigned claims within the receiving APC using the geometric mean cost for all reassigned claims for the primary service relative to other services assigned to that APC using the 2 times rule criteria. For new HCPCS codes and codes without data, we will use the best data available to us to identify combinations of procedures that represent a more complex form of the primary procedure and warrant reassignment to a higher level APC. We will reevaluate our APC assignments, and identification and APC placement of complex claims once claims data become available. *We then recalculate all APC comprehensive geometric mean costs and ensure clinical and resource homogeneity.*''

We believe that the final statement clearly communicates our policy of including the costs of the complexity-adjusted codes pairs in calculating the geometric mean cost for the higher-paying APCs to which the complexity-adjustment code pairs are assigned. While the commenter is correct that we no longer require that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) not create a 2 times rule violation in the higher level or receiving APC, this change was based on our belief that the requirement was not useful because most code combinations fall below our established frequency threshold for considering 2 times rule violations (81 FR 79582). In summary, we do not believe it is necessary to change the current policy that includes the costs of the paired code combinations in the next higher-paying APC at this time.

Comment: Several commenters requested that CMS alter the established C–APC complexity adjustment eligibility criteria to allow additional code combinations to qualify for complexity adjustments. We also received several comments requesting that CMS modify its complexity adjustment criteria by eliminating the claims frequency requirement to determine eligibility for the complexity adjustment and expanding the eligibility for a complexity adjustment to other APCs besides C–APCs to apply the

complexity adjustment to all blue light cystoscopy with Cysview procedures in the HOPD, even those assigned to clinical APCs.

Response: We appreciate these comments. However, at this time, we do not believe changes to the C–APC complexity adjustment criteria are necessary or that we should make exceptions to the criteria to allow claims with the code combinations suggested by the commenters to receive complexity adjustments. As stated previously (81 FR 79582), we continue to believe that the complexity adjustment criteria, which require a frequency of 25 or more claims reporting a code combination and a violation of the 2 times rule in the originating C–APC in order to receive payment in the next higher cost C–APC within the clinical family, are adequate to determine if a combination of procedures represents a complex, costly subset of the primary service. If a code combination meets these criteria, the combination receives payment at the next higher cost C–APC. Code combinations that do not meet these criteria receive the C–APC payment rate associated with the primary ''J1'' service. A minimum of 25 claims is already a very low threshold for a national payment system. Lowering the minimum of 25 claims further could lead to unnecessary complexity adjustments for service combinations that are rarely performed.

With regard to the requests for complexity adjustments for blue light cystoscopy procedures involving the use of Cysview, in CY 2018 we created a HCPCS C-code (C9738—Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure)) to describe blue light cystoscopy with fluorescent imaging agent and allowed this code to be eligible for complexity adjustments when billed with procedure codes used to describe white light cystoscopy of the bladder, although this code is not a ''J1'' service or an add-on code for the primary ''J1'' service. For CY 2021, there is one code combination, of the six total available combinations involving C9738 and procedure codes used to describe white light cystoscopy, that qualifies for a complexity adjustment (HCPCS code 52204 Cystourethroscopy, with biopsy(s) + C9738 Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure)). The remaining five code combinations do not meet the cost and frequency criteria to qualify for a complexity adjustment. At this time, we do not believe that further modifications to the C–APC complexity adjustment policy, including allowing services assigned to clinical APCs to qualify for complexity adjustments, are necessary to allow for complexity adjustments for these procedures.

After consideration of the public comments we received on the proposed complexity adjustment policy, we are finalizing the C–APC complexity adjustment policy for CY 2021, as proposed, without modification.

(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).

(3) Additional C–APCs for CY 2021

For CY 2021 and subsequent years, we proposed 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 did not propose to convert any conventional APCs to C–APCs in CY 2021. However, as discussed in section III.D.7, we proposed to create an additional level in the ''Urology and Related Services'' APC series and, as discussed in section III.D.1, we proposed to create an additional level in the ''Neurostimulator and Related Procedures'' APC series. Table 3 lists the proposed C–APCs for CY 2021, all of which were established in past rules.

Comment: Commenters supported the creation of the two new proposed C–APCs, based on resource cost and clinical characteristics.

Response: We appreciate the commenters' support.

Comment: Several commenters expressed concern that the C–APC payment rates may not adequately reflect the costs associated with services. These comments stated that the C–APC methodology does not account for the complexity of certain care processes, fails to capture the necessary claims, and the resulting data may lead to inaccurate payment rates that will negatively impact access to services.

Commenters also had concerns around the claims data used for ratesetting, due to variations in clinical practice and billing patterns across the hospitals that submit these claims, and urged CMS to consider alternatives to the current methodology. Some commenters were concerned that hospitals are not correctly charging for procedures assigned to C–APCs and urged CMS to invest in policies and education for hospitals regarding correct

billing patterns. These commenters also requested that CMS provide an analysis of the impact of the C–APC policy on affected procedures and patient access to services. One commenter requested that CMS review and use Part B claims data in order to estimate costs for the appropriate C–APCs for CY 2021 ratesetting.

Response: We appreciate the comments. We continue to believe that the current C–APC methodology is appropriate. We also note that, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59246), we conducted an analysis of the effects of the C–APC policy. The analysis used claims data for the CY 2016 OPPS/ASC final rule with comment period, the CY 2017 OPPS/ASC final rule with comment period, and the CY 2018 OPPS/ASC proposed rule, which were for the period from CY 2014 (before C–APCs became effective) to CY 2016. We looked at separately payable codes that were then assigned to C–APCs and, overall, we observed an increase in claim line frequency, units billed, and Medicare payment for those procedures, which suggest that the C–APC payment policy did not adversely affect access to care or reduce payments to hospitals and is working as intended.

Comment: Several commenters requested that CMS discontinue the C–APC payment policy for all surgical insertion codes required for brachytherapy treatment. The commenters stated concerns about how the C–APC methodology impacts radiation oncology, particularly the delivery of brachytherapy for the treatment of cervical cancer. They also stated that they oppose C–APC payment for cancer care given the complexity of coding, serial billing for cancer care, and potentially different sites of service for the initial surgical device insertion and subsequent treatment delivery or other supportive services. These commenters suggested that CMS allow brachytherapy to be reported through the traditional APC methodology, move procedures to a higher C–APC, or separately pay for preparation and planning services to fully account for accurate reflection of the costs associated with these procedures.

Response: While we continue to believe that the C–APC policy is appropriately applied to these surgical procedures, we will continue to examine these concerns and will determine if any modifications to this policy are warranted in future rulemaking.

Comment: One commenter urged CMS to eliminate the C–APC policy for single-session stereotactic radiosurgery codes (77371 and 77372). The commenter requested that CMS continue to make separate payments for the 10 planning and preparation codes related to SRS and include the HCPCS code for IMRT planning (77301) on the list of planning and preparation codes, stating that the service has become more common in single fraction radiosurgery treatment planning.

Response: At this time, we do not believe that it is necessary to discontinue the C–APCs that include single session SRS procedures. We continue to believe that the C–APC policy is appropriately applied to these surgical procedures for the reasons cited when this policy was first adopted and note that the commenters did not provide any empirical evidence to support their claims that the existing C–APC policy does not adequately pay for these procedures. Also, we will continue in CY 2021 to pay separately for the 10 planning and preparation services (HCPCS codes 70551, 70552, 70553, 77011, 77014, 77280, 77285, 77290, 77295, and 77336) adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 1 month of the SRS treatment for CY 2021.

Comment: We received one comment requesting that CMS carefully consider the proper location of care before establishing a C–APC for autologous hematopoietic stem cell transplant.

Response: We thank the commenter for this comment. This comment relates to a recommendation from last year's Advisory Panel on Hospital Outpatient Payment (HOP Panel), which recommended that CMS consider creating a C–APC for autologous stem cell transplantation and that CMS provide a rationale if it decides not to create such an APC. In the CY 2020 OPPS/ASC final rule with comment period, we evaluated the possibility of creating this C–APC and found that it was not appropriate to create a C–APC for autologous hematopoietic stem cell transplant at that time for the reasons discussed in that rule (84 FR 61162).

After consideration of the public comments we received, we are finalizing the proposed C–APCs for CY 2021. Table 3 below lists the final C–APCs for CY 2021. All C–APCs are displayed in Addendum J to this final rule with comment period (which is available via the internet on the CMS website). Addendum J to this final rule with comment period also contains all of the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information for CY 2021.

BILLING CODE 4120–01–P

TABLE 3: CY 2021 C-APCs

C-APC	CY 2021 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 2021 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. 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 proposed 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 proposed 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 2021. In addition, we proposed 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.

We did not receive any public comment on these proposals. Therefore, we are finalizing our proposal, without modification, 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 2021. In addition, we are finalizing our proposal to set the payment rate for composite APC 8010 for CY 2021 at the same payment rate that we set for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital.

(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 12 of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74920 through 74924).

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 2021, we proposed 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.

The proposed CY 2021 payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from CY 2019 claims available for the CY 2021 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 2021 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 2021 OPPS/ASC proposed rule.

For the CY 2021 OPPS/ASC proposed rule, we were able to identify approximately 964,000 ''single session'' claims out of an estimated 4.9 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 14 percent of all eligible claims, to calculate the proposed CY 2021 geometric mean costs for the multiple imaging composite APCs. Table 4 of the CY 2021 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 2021.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to continue the use of multiple imaging composite APCs to pay for services providing more than one imaging procedure from the same family on the same date, without modification. Table 4 lists the HCPCS codes that will be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2021.

BILLING CODE 4120–01–P

TABLE 4: OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2021 APC 8004 (Ultrasound Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $290.63**
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 2021 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2021 Approximate APC Geometric Mean Cost = $218.53**
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 2021 APC 8006 (CT and CTA with Contrast Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $423.88**
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye

73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2021 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2021 Approximate APC Geometric Mean Cost = $509.27**
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 2021 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $821.40**
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. 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), and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173). 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 2021, 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 outpatient hospital 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. In CY 2021, we proposed no changes to this policy. We will 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 the proposed changes to the packaging policies in CY 2021.

Comment: We received one comment asking CMS for an update regarding a comment solicitation from the CY 2018 OPPS/ASC Proposed Rule regarding the ''Comment Solicitation on Packaging of

Items and Services Under the OPPS'' (82 FR 33588).

Response: We thank the commenter for their inquiry. As noted in our response in the CY 2018 OPPS/ASC final rule with comment period, we appreciated the comments we received in response to this comment solicitation and will take them into consideration as we continue to explore and evaluate packaging policies that apply under the OPPS (82 FR 59254).

Comment: We received a comment on balancing packaging policy with market access concerns after pass-through status expires. The commenter noted that some packaging policies create incentives that could limit patient access to certain items, services, and care. They requested that CMS reconsider packaging policies, especially in the ASC and HOPD setting, and review packaging decisions on a case-by-case basis upon pass-through status expiration and not via the ''integral to'' policy, applying a holistic separate payment policy for innovations. Specifically, this commenter asked CMS to evaluate drugs and devices on a case-by-case basis in order to determine the item's packaging status after pass-through expires. This commenter also stated CMS should take into consideration the drug or device's clinical value when determining packaging status.

Response: We thank the commenter for their input. We continue to believe our packaging policies support our strategic goal of using larger payment bundles to maximize incentives to provide care in the most efficient manner. However, we will take this comment into consideration for future rulemaking.

Comment: We received several comments from patient advocates, physicians, drug manufacturers, and professional medical societies regarding payment for blue light cystoscopy procedures involving Cysview® (hexaminolevulinate HCl) (described by HCPCS code C9275). Cysview® is a drug that functions as a supply in a diagnostic test or procedure and therefore payment for this product is packaged with payment for the primary procedure in the OPPS and ASC settings. Commenters stated that utilization of Cysview® is low in the HOPD and ASC settings, which they attributed to the fact that Cysview is packaged as a drug that functions as a supply in a diagnostic test or procedure. Commenters indicated that packaged payment does not adequately pay for the blue light cystoscopy procedures, particularly in the ASC setting where payment is generally approximately 55 percent of the HOPD payment. Commenters believe that providers have been deterred from the use of this technology, especially in the ASC setting, and as a result, a significant percentage of beneficiaries are not able to access the procedure.

Commenters also stated that there has been literature published showing that Blue Light Cystoscopy with Cysview® is more effective than white light cystoscopy alone at detecting and eliminating nonmuscle invasive bladder cancer tumors, leading to a reduction in bladder cancer recurrence.

Commenters made various recommendations for payment for blue light cystoscopy procedures involving Cysview®, including to pay separately for Cysview® when it is used with blue light cystoscopy in the HOPD and ASC settings, similar to the policy finalized for Exparel® in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58860), or to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide an ''add-on'' or ''drug intensive'' payment to ASCs when using Cysview® in blue light cystoscopy procedures. Other commenters requested separate payment for all diagnostic imaging drugs (radiopharmaceuticals and contrast agents).

Response: We acknowledge the concerns of the numerous stakeholders who commented on this issue and understand the importance of blue light cystoscopy procedures involving Cysview®. Cysview has been packaged as a drug, biological, or radiopharmaceutical that functions as a supply in a diagnostic test or procedure since CY 2014 (78 FR 74930). As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59244), we recognize that blue light cystoscopy represents an additional elective but distinguishable service as compared to white light cystoscopy that, in some cases, may allow greater detection of bladder tumors in beneficiaries relative to white light cystoscopy alone. Given the additional equipment, supplies, operating room time, and other resources required to perform blue light cystoscopy in addition to white light cystoscopy, in CY 2018, we created a new HCPCS C–code to describe blue light cystoscopy and since CY 2018 have allowed for complexity adjustments to higher paying C–APCs for qualifying white light and blue light cystoscopy code combinations. At this time, we continue to believe that Cysview® is a drug that functions as a supply in a diagnostic test or procedure, and therefore, payment for this drug should be packaged with payment for the diagnostic procedure. Therefore, we do not believe it is necessary to pay separately for Cysview® when it is used with blue light cystoscopy in either the HOPD or ASC setting. We also do not believe that it would be appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide an ''add-on'' or ''drug intensive'' payment to ASCs when using Cysview® in blue light cystoscopy procedures, as our equitable adjustment authority at section (t)(2)(E) only authorizes adjustments under the OPPS, not the ASC payment system. We do not have any evidence to show that separate payment for blue light cystoscopy procedures involving Cysview is required, based on commenter concerns regarding utilization and access issues for Cysview. However, we will continue to examine payment for blue light cystoscopy procedures involving Cysview to determine if any changes to this policy would be appropriate in future rulemaking.

Comment: Some commenters requested that we eliminate the packaging policy for drugs that function as a supply when used in a diagnostic test or procedure.

Response: In the CY 2014 OPPS/ASC final rule with comment period, we established a policy to package drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. In particular, we referred to drugs, biologicals, and radiopharmaceuticals that function as supplies as a part of a larger, more encompassing service or procedure, namely, the diagnostic test or procedure in which the drug, biological, or radiopharmaceutical is employed (78 FR 74927). At this time, we do not believe it is necessary to eliminate this policy. As previously noted, 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.

Comment: One commenter requested separate payment for add-on codes for Fractional Flow Reserve Studies (FFR/iFR) and Intravascular Ultrasound (IVUS). The commenter stated that they believe the packaging of these codes will disincentivize physicians to perform these adjunct procedures because of cost. The codes are:

• 93571—Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (list separately in addition to code for primary procedure);

• 93572—Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel (list separately in addition to code for primary procedure));

• 92978—Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (ivus) or optical coherence tomography (oct) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (list separately in addition to code for primary procedure); and

• 92979—Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (ivus) or optical coherence tomography (oct) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (list separately in addition to code for primary procedure)).

Response: As stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66630), we continue to believe that IVUS and FFR are dependent services that are always provided in association with a primary service. Add-on codes represent services that are integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment is appropriately packaged into payment for the primary service that they support. As we have noted in past rules, add-on codes do not represent standalone procedures and are inclusive to other procedures performed at the same time (79 FR 66818). We continue to believe it is unnecessary to provide separate payment for the previously mentioned add-on codes at this time.

b. Packaging Policy for Non-Opioid Pain Management Therapies

(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. 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 specific 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 through 58860), we finalized a policy to unpackage and pay separately at ASP+6 percent for the cost of 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.

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, as added by section 6082(a) of the SUPPORT 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 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+6 percent for the cost of 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+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, the only drug that met these criteria in CY 2020 was Exparel.

(2) Evaluation and CY 2021 Payment for Non-Opioid Alternatives

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. Any 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.

As noted in the background section above, we conducted an evaluation to determine whether there are payment incentives for using opioids instead of non-opioid alternatives in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61176 through 61180). The results of our review and evaluation of our claims data did not provide evidence to indicate that the OPPS packaging policy had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. 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. Our updated review of claims data showed a continued decline in the utilization of Exparel® in the ASC setting, which supported our proposal to continue paying separately for Exparel® in the ASC setting. Decreased utilization could potentially indicate that the packaging policy is discouraging use of that treatment and that providers are choosing less expensive treatments. However, it is difficult to attribute causality of changes in utilization to Medicare packaging payment policy only. We believe that unpackaging and paying separately for Exparel addresses decreased utilization because it eliminates any potential Medicare payment disincentive for the use of this non-opioid alternative, rather than prescription opioids.

We believe we fulfilled the statutory requirement to review payments for opioids and evidence-based non-opioid alternatives to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives in CY 2020 OPPS/ASC rulemaking. We are committed to evaluating our current policies to adjust payment methodologies, if necessary, in order to ensure appropriate access for beneficiaries amid the current opioid epidemic. However, we did not believe conducting a similar CY 2021 review would yield significantly different outcomes or new evidence that would prompt us to change our payment policies under the OPPS or ASC payment system.

Therefore, for CY 2021, we proposed to continue our policy to pay separately at ASP+6 percent for the cost of 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.

Comment: Multiple commenters, including medical specialty societies and drug manufacturers, requested that we pay separately for Exparel and other drugs that may function as surgical supplies in the hospital outpatient setting. Some of these commenters noted that Exparel is more frequently used in this setting and the use of non-opioid pain management treatments should also be encouraged in the hospital outpatient department. Commenters believed that separate payment in the hospital outpatient department would significantly increase utilization, which would be beneficial in reducing opioid use.

Response: As we stated in the CY 2019 and CY 2020 OPPS/ASC final rules with comment period (83 FR 58856 and 84 FR 61177, respectively), we do not believe that there is sufficient evidence that non-opioid pain management drugs should be paid separately in the hospital outpatient setting at this time. The commenters did not provide convincing evidence that the OPPS packaging policy for Exparel (or other non-opioid drugs) creates a barrier to use of Exparel in the hospital setting. Further, while we received some public comments suggesting that, as a result of using Exparel in the OPPS setting, providers may prescribe fewer opioids for Medicare beneficiaries, we do not believe that the OPPS payment policy presents a barrier to use of Exparel or affects the likelihood that providers will prescribe fewer opioids in the HOPD setting. Several drugs are packaged under the OPPS and payment for such drugs is included in the payment for the associated primary procedure. We were not persuaded by the information supplied by commenters suggesting that some providers avoid use of non-opioid alternatives in the outpatient hospital setting (including Exparel) solely because of the OPPS packaged payment policy, as there was no evidence in our review and evaluation of claims data in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61176 through 61180) to indicate that the OPPS packaging policy had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. As noted above, we do not believe conducting a similar CY 2021 review would yield significantly different outcomes or new evidence that would prompt us to change our payment policy. Based on previously conducted analysis, we observed increasing Exparel utilization in the HOPD setting with the total units increasing from 14.8 million in 2018 to 19.5 million in 2019, despite the drug payment being packaged into the procedure payment in the OPPS setting. This upward trend has been consistent since 2015, as the data shows approximately 6.5 million total units in 2015 and 8.1 million total units in 2016. Therefore, we do not believe that the current OPPS payment methodology for Exparel or other non-opioid pain management drugs presents a widespread barrier to their use.

In addition, increased use in the hospital outpatient setting not only supports the notion that the packaged payment for Exparel is not causing an access to care issue, but also that the payment rate for primary procedures in the HOPD using Exparel adequately reflects the cost of the drug. That is, because Exparel is commonly used and billed under the OPPS, the APC rates for the primary procedures reflect such utilization. Therefore, the increased utilization in the OPPS setting seems to indicate that the payment amount is sufficient for hospitals to furnish the drug. We remind readers that the OPPS is a prospective payment system, not a cost-based system and, by design, is based on a system of averages under which payment for certain cases may exceed the costs incurred, while for others, it may not. 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. We continue to invite stakeholders to share evidence, such as published peer-reviewed literature, on these non-opioid alternatives. We also intend to continue to analyze the evidence and monitor utilization of non-opioid alternatives in the HOPD setting for potential future rulemaking.

Comment: Some commenters encouraged CMS to establish permanent separate payment for drugs that are currently on drug pass-through status in

the OPPS and ASC settings, such as Dexycu (HCPCS code J1095). Regarding Dexycu specifically, the commenters stated they were conducting a new, comprehensive study of a longitudinal claim dataset that will provide deeper insights into the association between cataract surgery and opioid utilization, as well as the role of Dexycu in reducing the prescribing of opioids.

Response: We refer readers to section V.A., ''OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals'' of this final rule with comment period regarding pass-through payments under the OPPS. Dexycu will receive separate payment due to its drug pass-through status through CY 2021. We will determine whether separate payment for this drug should be applied under the policy to pay separately for non-opioid pain management drugs that function as a surgical supply when furnished in the ASC setting when Dexycu's pass-through status expires. We thank commenters for conducting studies regarding their specific products and look forward to reviewing the results.

Comment: Several commenters requested that the drug Omidria, CPT J1097, (*phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), be excluded from the OPPS policy to package drugs that function as surgical supplies once its pass-through status expires on September 30, 2020. Omidria is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain in cataract or intraocular surgeries. The commenters stated that there is extensive clinical evidence and medical literature which supports their claims that Omidria reduces dependence on opioids for patients undergoing cataract surgery and postoperative prescription opioids. The commenters asserted that Omidria meets all of the requirements in regulation to qualify for separate payment in the ASC setting, as Omidria is FDA-approved for intraocular use in cataract procedures, a pain management drug, a non-opioid, and functions as a surgical supply during cataract surgery according to CMS' definition of a surgical supply. Commenters asserted that the use of Omidria decreases patients' need for fentanyl during surgeries and provided a manuscript stating that Omidria reduces opioid use based on pill counts after surgery.

Response: We thank commenters for their feedback on Omidria. Omidria received pass-through status for a 3-year period from 2015 to 2017. After expiration of its pass-through status, payment for Omidria was packaged under both the OPPS and the ASC payment system. Subsequently, Omidria's pass-through status under the OPPS was reinstated beginning on October 1, 2018 through September 30, 2020, as required by section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141), which means that Omidria continued to be paid separately under the ASC payment system through September 30, 2020.

Our previous review of the clinical evidence submitted indicated that the studies the commenter supplied were not sufficient to demonstrate that Omidria reduces opioid use. Moreover, the results of a CMS analysis of cataract procedures performed on Medicare beneficiaries in HOPDs and ASCs between January 2015 and July 2019, which compared procedures performed with Omidria to procedures performed without Omidria, did not demonstrate a significant decrease in fentanyl utilization during the cataract surgeries in the HOPDs and ASCs when Omidria was used. Our findings also did not suggest any decrease in opioid utilization post-surgery for procedures involving Omidria.

However, we will continue to apply separate payment for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2021, as discussed in section XIII.D.3, and as we have described in regulation at 42 CFR 416.164 and 416.171(b)(1). After careful consideration of the commenters' assertion that Omidria meets this definition, we believe that Omidria does qualify as a non-opioid pain management drug that functions as a surgical supply and are excluding Omidria from packaging under the ASC payment system beginning October 1, 2020 and in CY 2021, in accordance with this policy.

Comment: Two commenters briefly mentioned the drug IV acetaminophen (CPT code J0131), which they believe may reduce opioid usage if CMS paid separately for the drug. These commenters believed IV acetaminophen decreases use of post-operative opioids.

Response: We thank commenters for their comments. We do not find it appropriate to pay separately for IV acetaminophen as suggested by the commenters due to our drug packaging threshold policies. We remind stakeholders of our drug packaging threshold policies, as described in section V.B.1.a to this final rule with comment period. In accordance with section 1833(t)(16)(B) of the Act, we finalized our proposal to set the drug packaging threshold for CY 2021 to $130. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid prescriptions, we encourage providers to use them when medically necessary. Additionally, please see section XIII.D.3 for a full discussion on our policies in the ASC setting.

Comment: Commenters suggested modified payment for ''pain block'' CPT codes 64415, 64416, 64417, 64445, 64446, 64447, 64448, and 64450. Two commenters stated that providers use these pain blocks to mitigate the post-operative pain that is otherwise typically addressed with short-term opioid use. Additionally, a few commenters stated that CPT code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*) used for treatment of ocular inflammation and pain following ophthalmic surgery is administered through CPT code 0356T (*Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each*). These commenters felt CPT code 0356T, which describes the administration of the drug, should also receive separate or additional payment due to the purported clinical benefits of the drug, including treatment of pain.

Response: We thank the commenters for their suggestions. At this time, we have not found compelling evidence for the non-opioid pain management alternatives described above to warrant separate or modified payment under the OPPS or ASC payment systems for CY 2021. Additionally, we do not believe that the ''pain blocks'' described by stakeholders qualify as non-opioid pain management drugs that function as a surgical supply as the codes provided by stakeholders are used to describe procedures under the OPPS and not drugs. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid prescriptions, we encourage providers to use them when medically necessary. For a greater discussion of CPT code 0356T, please see section III. D. (Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus (APC 5692)) of this final rule with comment period.

Comment: Commenters also requested separate payments for various non-opioid pain management treatments, such as ERAS® protocols or spinal cord stimulators (SCS), that they believe decrease the number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure. For SCS, several commenters noted that this therapy may lead to a reduction in the use of opioids

for chronic pain patients. They noted that neurostimulation is a key alternative to opioid prescription for pain management and recommended that CMS increase access to SCS.

Response: We appreciate the commenters' information on this topic. At this time, we have not found compelling evidence for the non-opioid pain management alternatives described above to warrant separate payment under the OPPS or ASC payment systems for CY 2021. However, we plan to take these comments and suggestions into consideration for future rulemaking. We agree that providing incentives to avoid or reduce opioid prescriptions may be one of several strategies for addressing the opioid epidemic. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid drugs, we encourage providers to use them when medically appropriate.

We look forward to working with stakeholders as we further consider suggested refinements to the OPPS and the ASC payment system that will encourage use of medically necessary items and services that have demonstrated efficacy in decreasing opioid prescriptions and/or opioid abuse or misuse during or after an outpatient visit or procedure.

After consideration of the public comments we received, we are finalizing the proposed policy, without modification, to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2021. We will continue to analyze the issue of access to non-opioid pain management alternatives in the OPPS and the ASC settings as part of any subsequent reviews we conduct under section 1833(t)(22)(A)(ii). We are continuing to examine whether there are other non-opioid pain management alternatives for which our payment policy should be revised to allow separate payment. We will be reviewing evidence-based support, such as published peer-reviewed literature, that we could use to determine whether these products help to deter or avoid prescription opioid use and addiction as well as evidence that the current packaged payment for such non-opioid alternatives presents a barrier to access to care and therefore warrants revised, including possibly separate, payment under the OPPS. This policy is also discussed in section XIII.D.3 of this final rule with comment period.

c. Clinical Diagnostic Laboratory Tests Packaging Policy

(1) Background

Prior to CY 2014, clinical diagnostic laboratory tests were excluded from payment under the hospital OPPS because they were paid separately under the Clinical Laboratory Fee Schedule (CLFS). Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. Under this authority, the Secretary excluded from the OPPS those services that are paid under fee schedules or other payment systems. Because laboratory services are paid separately under the CLFS, laboratory tests were excluded from separate payment under the OPPS. We codified this policy at 42 CFR 419.22(l).

However, in CY 2014, we revised the categories of packaged items and services under the OPPS to include certain laboratory tests. We stated that certain laboratory tests, similar to other covered outpatient services that are packaged under the OPPS, are typically integral, ancillary, supportive, dependent, or adjunctive to a primary hospital outpatient service and should be packaged under the hospital OPPS. We stated that laboratory tests and their results support clinical decision making for a broad spectrum of primary services provided in the hospital outpatient setting, including surgery and diagnostic evaluations (78 FR 74939). Consequently, we finalized the policy to package payment for most laboratory tests in the OPPS when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17)). In the same final rule, we clarified that certain laboratory tests would be excluded from packaging. Specifically, we stated that laboratory tests would be paid separately under the CLFS when the laboratory test is the only service provided to a beneficiary or when a laboratory test is conducted on the same date of service (DOS) as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service or when the laboratory test is a molecular pathology test (78 FR 74942). As explained in the CY 2014 OPPS/ASC final rule, we excluded molecular pathology tests from packaging because we believe these tests are relatively new and may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we package (78 FR 74939). Based on these changes, we revised the regulation text at §§ 419.2(b) and 419.22(l) to reflect this laboratory test packaging policy.

In CY 2016, we made some modifications to this policy (80 FR 70348 through 70350). First, we clarified that all molecular pathology tests would be excluded from our packaging policy, including any new codes that also describe molecular pathology tests. In the CY 2014 OPPS/ASC final rule, we stated that only those molecular pathology codes described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 were excluded from OPPS packaging (78 FR 74939 through 74942). However, in 2016, we expanded this policy to include not only the original code range but also all new molecular pathology test codes (80 FR 70348). Secondly, we excluded preventive laboratory tests from OPPS packaging and provided that they would be paid separately under the CLFS. Laboratory tests that are considered preventive are listed in Section 1.2, Chapter 18 of the Medicare Claims Processing Manual (Pub. L. 100–04). As stated in the CY 2016 OPPS/ASC final rule, we make an exception to conditional packaging of ancillary services for ancillary services that are also preventive services (80 FR 70348). For consistency, we excluded from OPPS packaging those laboratory tests that are classified as preventive services. In addition, we modified our conditional packaging policy so that laboratory tests provided during the same outpatient stay (rather than specifically provided on the same DOS as the primary service) are considered as integral, ancillary, supportive, dependent, or adjunctive to a primary service or services, except when a laboratory test is ordered for a different diagnosis and by a different practitioner than the practitioner who ordered the other hospital outpatient services. We explained in the CY 2016 OPPS/ASC final rule that this modification did not affect our policy to provide separate payment for laboratory tests: (1) If they are the only services furnished to an outpatient and are the only services on a claim and have a payment rate on the CLFS; or (2) if they are ordered for a different diagnosis than another hospital outpatient service by a practitioner different than the practitioner who ordered the other hospital outpatient service (80 FR 70349 through 70350).

In CY 2017, we modified the policy to remove the ''unrelated'' laboratory test exclusion and to expand the laboratory

test packaging exclusion to apply to laboratory tests designated as advanced diagnostic laboratory tests (ADLTs) under the CLFS. We clarified that the exception would only apply to those ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act, which are defined as tests that provide an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result (81 FR 79592 through 79594).

(2) Current Categories of Clinical Diagnostic Laboratory Tests Excluded From OPPS Packaging

As we discussed in the CY 2021 OPPS/ASC proposed rule (85 FR 48798), under our current policy, certain clinical diagnostic laboratory tests (CDLTs) that are listed on the CLFS are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. While we package most CDLTs under the OPPS, when a CDLT is listed on the CLFS and meets one of the following four criteria, we do not pay for the test under the OPPS, but rather, we pay for it under the CLFS when it is: (1) The only service provided to a beneficiary on a claim; (2) considered a preventive service; (3) a molecular pathology test; or (4) an ADLT that meets the criteria of section 1834A(d)(5)(A) of the Act. Generally, when laboratory tests are not packaged under the OPPS and are listed on the CLFS, they are paid under the CLFS instead of the OPPS.

(3) New Category of Laboratory Tests Excluded From OPPS Packaging

(a) Background on Protein-Based MAAAs

As part of recent rulemaking cycles, stakeholders have suggested that some protein-based Multianalyte Assays with Algorithmic Analyses tests (MAAAs) may have a pattern of clinical use that makes them relatively unconnected to the primary hospital outpatient service (84 FR 61439). In the CY 2018 OPPS/ASC final rule (82 FR 59299), we stated that stakeholders indicated that certain protein-based MAAAs, specifically those described by CPT codes 81490, 81503, 81535, 81536, 81538, and 81539, are generally not performed in the HOPD setting and have similar clinical patterns of use as the DNA and RNA-based MAAA tests that are assigned to status indicator ''A'' under the OPPS and are paid separately under the CLFS. Notably, all of the tests described by these CPT codes (with the exception of CPT code 81490, which we discuss below) are cancer-related protein-based MAAAs. In the same final rule, stakeholders suggested that, based on the June 23, 2016 CLFS final rule entitled ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System,'' in which CMS defined an ADLT under section 1834A(d)(5)(A) of the Act to include DNA, RNA, and protein-based tests, they believe that the reference to ''protein-based tests'' in the definition applies equally to the tests they identified, that is, protein-based MAAAs. Consequently, the stakeholders believed that protein-based MAAAs should be excluded from OPPS packaging and paid separately under the CLFS. As we noted in the CY 2021 OPPS/ASC proposed rule, one of the protein-based MAAAs previously requested by stakeholders to be excluded from OPPS packaging policy is CPT code 81538 (Oncology (lung), mass spectrometric 8-protein signature, including amyloid a, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival), which has been designated as an ADLT under section 1834A(d)(5)(A) of the Act as of December 21, 2018. Therefore, CPT code 81538 is currently excluded from the OPPS packaging policy and paid under the CLFS instead of the OPPS when it also meets the laboratory DOS requirements.

(b) CY 2021 Cancer-Related Protein-Based MAAAs

As discussed in the CY 2021 OPPS/ASC proposed rule (85 FR 49032), we have continued to consider previous stakeholder requests to exclude some protein-based MAAAs from the OPPS packaging policy. We stated that, after further review of this issue, we believe that cancer-related protein-based MAAAs, in particular, may be relatively unconnected to the primary hospital outpatient service during which the specimen was collected from the patient. Similar to molecular pathology tests, which are currently excluded from the OPPS packaging policy, cancer-related protein-based MAAAs appear to have a different pattern of clinical use, which may make them generally less tied to the primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.

As we noted previously in the CY 2021 OPPS/ASC proposed rule and in this section of the final rule, commenters to the CY 2018 OPPS/ASC final rule identified specific cancer-related protein-based MAAAs as tests that are generally not performed in the HOPD setting (82 FR 59299). In fact, those tests identified by commenters are used to guide future surgical procedures and chemotherapeutic interventions. Treatments that are based on the results of cancer-related protein-based MAAAs are typically furnished after the patient is no longer in the hospital, in which case they are not tied to the same hospital outpatient encounter during which the specimen was collected.

For these reasons, we proposed to exclude cancer-related protein-based MAAAs from the OPPS packaging policy and pay for them separately under the CLFS.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48799), we explained that the AMA CPT 2020 manual currently describes MAAAs, in part, as ''procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid based assays (for example, proteins, polypeptides, lipids, carbohydrates).'' [1] Additionally, the AMA CPT 2020 manual provides a MAAA code descriptor format which includes several specific characteristics, including but not limited to disease type (for example, oncology, autoimmune, tissue rejection), and material(s) analyzed (for example, DNA, RNA, protein, antibody). We noted that as the AMA CPT 2020 manual describes a MAAA, and the code descriptor of each MAAA distinguishes MAAAs that are cancer-related assays from those that test for other disease types, the AMA CPT manual is a potentially instructive tool to identify cancer-related MAAA tests that are ''protein-based''. Accordingly, in following the AMA CPT 2020 manual intent to identify MAAA tests that are cancer-related, and, of those tests, identifying the ones whose test analytes are proteins, we have determined there are currently six cancer-related protein-based MAAAs: CPT codes 81500, 81503, 81535, 81536, 81538 and 81539. As discussed previously in the CY 2021 OPPS/ASC proposed rule and in this section of the final rule, CPT code 81538 has been designated as an ADLT under section 1834A(d)(5)(A) of the Act as of December 21, 2018 and therefore, is already paid under the CLFS instead of the OPPS. As such, we proposed to assign status indicator ''A'' (''Not paid under OPPS. Paid by MACs under a fee schedule or payment system other than

[1] *Current Procedure Terminology* (CPT®) page 586, copyright 2020 American Medical Association. All Rights Reserved.

OPPS'') to cancer-related protein-based MAAAs as described by CPT codes 81500, 81503, 81535, 81536, and 81539. We also proposed that we would apply this policy to cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future. Additionally, we stated that we intend to continue to study the list of laboratory tests excluded from the OPPS packaging policy and determine whether any additional changes are warranted and may consider proposing future changes to the laboratory DOS policy through notice-and-comment rulemaking.

In the CY 2021 OPPS/ASC proposed rule (85 FR 49032), we noted that commenters to the CY 2018 OPPS/ASC proposed rule also identified CPT code 81490 as a protein-based MAAA that should be excluded from the OPPS packaging policy and paid outside of the OPPS. However, we stated that we believed that the results for the test described by CPT code 81490 are used to determine disease activity in rheumatoid arthritis patients, guide current therapy to reduce further joint damage, and may be tied to the primary hospital outpatient service, that is, the hospital outpatient encounter during which the specimen was collected. Therefore, we stated that we believed that payment for CPT code 81490 remains appropriately packaged under the OPPS.

We refer readers to section XVIII. of the CY 2021 OPPS/ASC proposed rule and section XVIII. of this final rule with comment period, which describe the related proposal to revise the laboratory DOS policy for cancer-related protein-based MAAAs.

We received public comments on the proposal to exclude cancer-related protein-based MAAAs from the OPPS packaging policy and pay for them separately under the CLFS. The following is a summary of the comments we received and our responses.

Comment: Generally, commenters supported the proposal to exclude cancer-related protein-based MAAAs from the OPPS packaging policy and add them to the list of test codes subject to the laboratory DOS exception for the hospital outpatient setting, leading to the test being paid at the CLFS rate and requiring that the laboratory bill Medicare for the test instead of seeking payment from the hospital. Commenters stated that changes to this policy will lead to improved beneficiary access to diagnostic tests while also reducing hospital administrative burden.

Response: We appreciate the support from commenters for our proposed revisions to the OPPS packaging policy for CDLTs. We agree that the revisions to the laboratory DOS policy that we proposed in the CY 2021 OPPS/ASC proposed rule and finalized in section XVIII of this final rule with comment period may potentially serve to reduce delay in access to laboratory tests by minimizing the likelihood that a hospital will postpone ordering a test until at least 14 days after the patient is discharged from the hospital outpatient department, or even cancel the order in order to avoid having to bill Medicare for the test under the laboratory DOS policy.

Comment: In addition to excluding the cancer-related protein-based MAAAs from OPPS packaging, several commenters suggested a similar change for pathology tests. Specifically, they recommended revising the existing laboratory test packaging policy to allow separate payment under the CLFS for the technical component of pathology tests.

Response: We appreciate the feedback and will consider the issue for future rulemaking.

Comment: Some commenters recommended further expansion of the list of test codes excluded from OPPS packaging to include various other CDLTs, including all protein-based MAAAs, AMA CPT Proprietary Laboratory Analyses (PLA) test codes that may have similar characteristics to AMA CPT MAAA tests but are not currently categorized as AMA CPT MAAA test codes, and several specific CPT test codes, including the OVERA test from Aspira Labs (CPT 0003U), EPI assay by Bio-Techne (CPT 0005U), TissueCypher assay from Cernostics (CPT 0108U), and KidneyIntelX (CPT 0105U).

Commenters also noted that while PLA test codes are not automatically included in the outpatient laboratory test packaging exclusion, some tests described by PLA codes are included under these policies if they qualify as a molecular pathology test or Criterion A ADLT. Therefore, the commenters asserted that CMS should continue its historical practice of applying the laboratory test packaging exclusion to PLA test codes as occurs with molecular pathology tests and ADLTs that have been assigned PLA codes.

Response: We believe that the commenters' suggested modifications to the list of codes excluded from OPPS packaging to include various CDLTs, including all protein-based MAAAs, AMA CPT PLA test codes that may have similar characteristics to AMA CPT MAAA tests but are not currently categorized as AMA CPT MAAA codes, and several specific AMA CPT test codes, are inconsistent with the current OPPS packaging policy and would result in allowing the laboratory to bill Medicare directly for a test that should be incorporated into the hospital OPPS bundled rate. CMS does not believe that all AMA CPT PLA test codes demonstrate a different pattern of clinical use that makes them less tied to the primary service in the hospital outpatient setting such that they should be included in the list of codes excepted from the OPPS packaging policy. Commenters asserted that these tests, as a group, should be excluded from OPPS packaging policy because the results of these tests may inform future interventions beyond the hospital outpatient encounter during which the specimen was collected and may be used by other health care providers to developed long-term plans for treatment. However, we are not convinced based on the commenters' descriptions of these tests that they are generally unconnected to the hospital encounter, the chief requirement for exclusion from OPPS packaging. Although commenters noted that the recommended tests may be utilized for the development of longer-term treatment plans, it is not clear that the clinical usage of these tests reaches the threshold of being ''generally unconnected'' to the hospital encounter.

Any addition to the list of test codes excluded from OPPS packaging requires careful evaluation as to whether a different pattern of clinical use makes a test generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we package. For instance, as noted in the CY 2021 OPPS/ASC proposed rule (85 FR 49035), in response to the changes in the laboratory DOS policy outlined in the CY 2018 OPPS/ASC final rule with comment period, stakeholders stated that some entities performing molecular pathology testing included on the list of codes excluded from OPPS packaging and subject to the laboratory DOS exception, such as blood banks and blood centers, may perform molecular pathology testing to enable hospitals to prevent adverse conditions associated with blood transfusions, rather than perform molecular pathology testing for diagnostic purposes. This led us to consider whether the molecular pathology testing performed by blood banks and centers is appropriately separable from the hospital stay.

We do not believe all protein-based MAAAs would meet this standard for exclusion from OPPS packaging. CMS has considered expanding the list of codes excluded from OPPS packaging to

include various additional categories of codes, including protein-based MAAAs. However, we note that some protein-based MAAAs include simple and commonly used protein analytes that may also be commonly performed to assist in managing patient care during a hospital outpatient encounter. Therefore, we believe that we cannot conclude that this category of tests is generally less tied to a primary service in the hospital outpatient setting, as some protein-based MAAA tests use common routine protein analytes that are appropriately packaged into OPPS payment. For these reasons, CMS does not believe that all protein-based MAAAs should be included in the list of codes excluded from the OPPS packaging policy.

However, we note that a protein-based MAAA that is designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502 would be added to the list of codes excluded from OPPS packaging, in accordance with our established policy.

Comment: Commenters also recommended that we exclude a particular protein-based MAAA test described by CPT code 81490 from the OPPS packaging policy. Commenters asserted that the use of the test described by CPT code 81490 is unconnected to the hospital outpatient encounter during which the specimen is collected and that the results of the test are used to determine potential future interventions outside of the hospital outpatient encounter. Commenters stated that this test appears to be generally less tied to a primary service in the hospital outpatient setting and does not appear to be a common or routine laboratory test that would otherwise be packaged into OPPS payment.

Response: In the CY 2021 OPPS/ASC proposed rule (85 FR 48799), we stated that we believed the results for the test described by CPT code 81490 are used to determine disease activity in rheumatoid arthritis patients, guide current therapy to reduce further joint damage, and may be tied to the primary hospital outpatient service, that is, the hospital outpatient encounter during which the specimen was collected. Therefore, we stated that we believed that payment for CPT code 81490 remains appropriately packaged under the OPPS.

However, given commenter feedback, we are convinced that the pattern of clinical use for CPT code 81490 is generally unconnected to the hospital outpatient encounter during which the specimen is collected as it is typically used to determine potential interventions outside of the hospital outpatient encounter and is generally used by the rheumatologist to make longer-term changes in RA treatment. Commenters informed us that physicians and patients utilize the objective information provided by the results of the test to make longer-term modifications in treatment, to monitor disease activity, and to prevent joint damage progression, and the results generally would not be utilized for purposes of the hospital outpatient encounter. The commenters further stated that the output of the test is used to assess disease activity, including evaluating response to therapy, directing choice of second-line treatment in patients with inadequate response to the current first line therapy, and identifying patients in stable remission for therapy reduction. The test results appear to guide longer-term therapies and treatments; therefore, we believe that this test, identified by CPT code 81490, is generally less tied to the primary service the patient receives in the hospital outpatient setting and does not appear to be a common or routine laboratory test that would otherwise be packaged into OPPS payment. Consequently, we believe that CPT code 81490 should be excluded from OPPS packaging policy.

As stated previously, we intend to continue to study the list of laboratory tests excluded from the OPPS packaging policy to determine whether any additional changes are warranted and may consider proposing future changes to this policy and the laboratory DOS policy through notice-and-comment rulemaking.

In conclusion, we continue to believe that cancer-related protein-based MAAAs, that is, those represented by CPT codes 81500, 81503, 81535, 81536 and 81539, appear to have a different pattern of clinical use that make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged. We also believe that, given the similarity in its clinical pattern of use to the cancer-related protein-based MAAAs, CPT code 81490 should also be added to the list of codes excluded from the OPPS packaging and subject to the laboratory DOS exception at § 414.510(b)(5), which is discussed in section III.XX in this final rule. For the reasons discussed, we are revising the list of test codes excluded from the OPPS packaging policy to include CPT codes 81500, 81503, 81535, 81536, 81539, and 81490. We are also finalizing that we will exclude cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future, from the OPPS packaging policy.

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 2020 OPPS/ASC final rule with comment period (84 FR 61180 through 61182), we applied this policy and calculated the relative payment weights for each APC for CY 2020 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 2021, as we did for CY 2020, we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2021 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 2021, as we did for CY 2020, we proposed 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 2021, as we did for CY 2020, we proposed 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. We note that the volume control method for clinic visit services furnished by non-excepted off-campus PBDs is subject to litigation. For a full discussion of this policy and the litigation, 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 2021 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we proposed to compare the estimated aggregate weight using the CY 2020 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2021 unscaled relative payment weights.

For CY 2020, we multiplied the CY 2020 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 2021, we proposed to apply the same process using the estimated CY 2021 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scalar by dividing the CY 2020 estimated aggregate weight by the unscaled CY 2021 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 2021 OPPS proposed rule link and open the claims accounting document link at the bottom of the page.

We proposed to compare the estimated unscaled relative payment weights in CY 2021 to the estimated total relative payment weights in CY 2020 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 proposed to adjust the calculated CY 2021 unscaled relative payment weights for purposes of budget neutrality. We proposed to adjust the estimated CY 2021 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4443 to ensure that the proposed CY 2021 relative payment weights are scaled to be budget neutral. The proposed CY 2021 relative payment weights listed in Addenda A and B to the CY 2021 OPPS/ASC 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 the CY 2021 OPPS/ASC 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 2021 OPPS.

We did not receive any public comments on the proposed weight scalar calculation. Therefore, we are finalizing our proposal to use the calculation process described in the proposed rule, without modification, for CY 2021. Using updated final rule claims data, we are updating the estimated CY 2021 unscaled relative payment weights by multiplying them by a weight scalar of 1.4341 to ensure that the final CY 2021 relative payment weights are scaled to be budget neutral. The final CY 2021 relative payments weights listed in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website) were scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this final rule with comment period.

B. 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 2021 IPPS/LTCH PPS proposed rule (85 FR 32738), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2019 forecast of the FY 2021 market basket increase, the proposed FY 2021 IPPS market basket update was 3.0 percent. Accordingly, we proposed a CY 2021 OPD fee schedule increase factor of 3.0 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 2021 IPPS/LTCH PPS proposed rule (85 FR 32739), the proposed MFP adjustment for FY 2021 was 0.4 percentage point.

Therefore, we proposed that the MFP adjustment for the CY 2021 OPPS would be 0.4 percentage point. We also proposed that if more recent data become subsequently available after the publication of the CY 2021 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket increase and/or the MFP adjustment), we would use such updated data, if appropriate, to determine the CY 2021 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 2021 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 proposed for CY 2021 an OPD fee schedule increase factor of 2.6 percent for the CY 2021 OPPS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.0 percent, less the proposed 0.4 percentage point MFP adjustment).

We proposed 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.

The adjustment described in section 1833(t)(3)(F)(ii) was required only through 2019. The requirement in section 1833(t)(3)(F)(i) of the Act that we reduce the OPD fee schedule increase factor by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II), however, applies for 2012 and subsequent years, and thus, continues to apply. In the CY 2020 OPPS/ASC final rule with comment period, we inadvertently did not amend the regulation at 42 CFR 419.32(b)(1)(iv)(B) to reflect that the adjustment required by section 1833(t)(3)(F)(i) of the Act is the only adjustment under section 1833(t)(3)(F) that applies in CY 2020 and subsequent years. Accordingly, we proposed to amend our regulation at 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (b)(1)(iv)(B)(*11*) to provide that, for CY 2020 and subsequent years, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS.

To set the OPPS conversion factor for CY 2021, we proposed to increase the CY 2020 conversion factor of $80.793 by 2.6 percent. In accordance with section 1833(t)(9)(B) of the Act, we proposed further to adjust the conversion factor for CY 2021 to ensure that any revisions made to the wage index and rural adjustment were made on a budget neutral basis. We proposed to calculate an overall budget neutrality factor of 1.0017 for wage index changes. This adjustment was comprised of a 1.0027 proposed budget neutrality adjustment, using our standard calculation of comparing proposed total estimated payments from our simulation model using the proposed FY 2021 IPPS wage indexes to those payments using the FY 2020 IPPS wage indexes, as adopted on a calendar year basis for the OPPS as well as a 0.9990 proposed budget neutrality adjustment for the proposed CY 2021 5 percent cap on wage index decreases to ensure that this transition wage index is implemented in a budget neutral manner, consistent with the proposed FY 2021 IPPS wage index policy (85 FR 32706). We stated in the proposed rule that we believed it was appropriate to ensure that the proposed wage index transition policy (that is, the proposed CY 2021 5 percent cap on wage index decreases) did not increase estimated aggregate payments under the OPPS beyond the payments that would be made without this transition policy. We proposed to calculate this budget neutrality adjustment by comparing total estimated OPPS payments using the FY 2021 IPPS wage index, adopted on a calendar year basis for the OPPS, where a 5 percent cap on wage index decreases is not applied to total estimated OPPS payments where the 5 percent cap on wage index decreases is applied. We stated in the proposed rule that these two proposed wage index budget neutrality adjustments would maintain budget neutrality for the proposed CY 2021 OPPS wage index (which, as we discuss in section II.C of the proposed rule, would use the FY 2021 IPPS post-reclassified wage index and any adjustments, including without limitation any adjustments finalized under the IPPS related to the proposed adoption of the revised OMB delineations).

We did not receive any public comments on our proposed methodology for calculating the wage index budget neutrality adjustment as discussed above. Therefore, for the reasons discussed above and in the CY 2021 OPPS/ASC proposed rule (85 FR 48801), we are finalizing our methodology for calculating the wage index budget neutrality adjustment as proposed, without modification. For CY 2021, based on updated data for this final rule with comment period, we are finalizing an overall budget neutrality factor of 1.0012 for wage index changes. This adjustment is comprised of a 1.0020 budget neutrality adjustment using our standard calculation of comparing total estimated payments from our simulation model using the final FY 2021 IPPS wage indexes to those payments using the FY 2020 IPPS wage indexes, as adopted on a calendar year basis for the OPPS, as well as a 0.9992 budget neutrality adjustment for the CY 2021 5 percent cap on wage index decreases to ensure that this transition wage index is implemented in a budget neutral manner.

For the CY 2021 OPPS, we proposed to maintain the current rural adjustment policy, as discussed in section II.E. of the CY 2021 OPPS/ASC proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment was 1.0000.

We proposed 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 the CY 2021 OPPS/ASC proposed rule. We proposed to calculate a CY 2021 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2021 payments under section 1833(t) of the Act, including the proposed CY 2021 cancer hospital payment adjustment, to estimated CY 2021 total payments using the CY 2020 final cancer hospital payment adjustment, as required under section 1833(t)(18)(B) of the Act. The proposed CY 2021 estimated payments applying the proposed CY 2021 cancer hospital payment adjustment were the same as estimated payments applying the CY 2020 final cancer hospital payment adjustment. Therefore, we proposed 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

proposed to apply 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 the CY 2021 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2021 would equal approximately $783.2 million, which represented 0.93 percent of total projected CY 2021 OPPS spending. Therefore, we stated that the proposed conversion factor would be adjusted by the difference between the 0.88 percent estimate of pass-through spending for CY 2020 and the 0.93 percent estimate of proposed pass-through spending for CY 2021, resulting in a proposed decrease to the conversion factor for CY 2021 of 0.05 percent.

We also estimated a 0.85 percent upward adjustment to nondrug OPPS payment rates as a result of our payment proposal for separately payable nonpass-through drugs purchased under the 340B Program at a net rate of ASP minus 28.7 percent. Applying the proposed payment policy for drugs purchased under the 340B Program, as described in section V.B.6. of the CY 2021 OPPS/ASC proposed rule, would have resulted in an estimated reduction of approximately $427 million in separately paid OPPS drug payments. To ensure budget neutrality under the OPPS after applying this proposed payment methodology for drugs purchased under the 340B Program, we proposed to apply an offset of approximately $427 million to the OPPS conversion factor, which would result in an adjustment of 1.0085 to the OPPS conversion factor.

Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2021. We estimated for the proposed rule that outlier payments would be 1.01 percent of total OPPS payments in CY 2020; the 1.00 percent for proposed outlier payments in CY 2021 would constitute a 0.01 percent decrease in payment in CY 2021 relative to CY 2020.

For the CY 2021 OPPS/ASC proposed rule, we also proposed 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 proposed to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.6 percent (that is, the proposed OPD fee schedule increase factor of 2.6 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2021 of $82.065 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of 1.632 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2021, we proposed to amend § 419.32 by adding a new paragraph (b)(1)(iv)(B)(*11*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2020, CY 2021, and subsequent years to satisfy the statutory requirements of section 1833(t)(3)(F) of the Act. We proposed to use a reduced conversion factor of $82.065 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.632 in the conversion factor relative to hospitals that met the requirements).

For CY 2021, we proposed to use a conversion factor of $83.697 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 2.6 percent for CY 2021, the required proposed wage index budget neutrality adjustment of approximately 1.0017, the proposed cancer hospital payment adjustment of 1.0000, the proposed budget neutrality adjustment of 1.0085 applying the proposed payment methodology of ASP minus 28.7 percent for CY 2021 for drugs purchased under the 340B Program, and the proposed adjustment of 0.05 percentage point of projected OPPS spending for the difference in pass-through spending that resulted in a proposed conversion factor for CY 2021 of $83.697.

Comment: One commenter suggested that we eliminate the MFP adjustment because of economic uncertainty as a result of the COVID–19 pandemic. The commenter stated that CMS rules for fiscal year 2021 had a 0.0 percent multifactor productivity adjustment.

Response: We note that under section 1886(b)(3)(B)(xi)(I) of the Act, the Secretary is required to reduce the hospital market basket percentage increase by the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP.

Comment: Multiple commenters supported our proposed CY 2021 OPD fee schedule increase factor percentage increase of 2.6 percent.

Response: We appreciate the support of the commenters.

After reviewing the public comments we received, we are finalizing these proposals with modification. For CY 2021, we proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act (discussed in section II.F. of this final rule with comment period). Based on the final rule updated data used in calculating the cancer hospital payment adjustment in section II.F. of this final rule with comment period, the target payment-to-cost ratio for the cancer hospital payment adjustment, which was 0.89 for CY 2020, is also 0.89 for CY 2021. As a result, we are applying a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. We are implementing our alternative proposal for CY 2021 for the payment of drugs acquired through the 340B program. Drugs obtained through the 340B program will be paid at a net rate of ASP minus 22.5 percent. This has been the payment rate for drugs acquired through the 340B program in the OPPS since the policy was initially established in CY 2018. Since there is no change in the net payment rate, the final budget neutral adjustment factor regarding the payment of drugs acquired through the 340B program is 1.0000.

For this CY 2021 OPPS/ASC final rule with comment period, as published in the FY 2021 IPPS/LTCH PPS final rule, based on IGI's 2020 second quarter forecast with historical data through the first quarter of 2020, the hospital market basket update for CY 2021 is 2.4 percent.

As described in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58797), it has typically been our practice to base the projection of the market basket price proxies and MFP for the IPPS/LTCH final rule on the second quarter IGI forecast. At the time of the FY 2021 IPPS/LTCH final rule, the 10-year moving average growth of MFP for FY 2021 based on IGI's second quarter 2020 forecast was 0.7 percentage point. However, for the FY 2021 IPPS/LTCH final rule, we finalized the use of the IGI June 2020 macroeconomic forecast for MFP because it represented a more recent forecast, and we believed it was important to use more recent data during this period when economic trends, particularly employment and labor productivity, are notably uncertain because of the COVID–19 pandemic. Based on these more recent data available for the FY 2021 IPPS/LTCH final rule, the current estimate of the 10-year moving average growth of MFP for FY 2021 was −0.1 percentage point (85 FR 58797).

Mechanically subtracting the negative 10-year moving average growth of MFP from the hospital market basket percentage increase using the data from the IGI June 2020 macroeconomic forecast would have resulted in a 0.1 percentage point increase in the FY 2021 market basket update. However, we explained that under section 1886(b)(3)(B)(xi)(I) of the Act, the Secretary is required to reduce (not increase) the hospital market basket percentage increase by changes in economy-wide productivity. Accordingly, we applied a 0.0 percent MFP adjustment to the FY 2021 IPPS market basket percentage increase.

Section 1833(t)(3)(F)(i) of the Act also requires us to reduce (not increase) the OPD fee schedule increase factor by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Accordingly, we are applying a 0.0 percentage point MFP adjustment to the CY 2021 OPD fee schedule increase factor for the OPPS.

As a result of these finalized policies, the OPD fee schedule increase factor for the CY 2021 OPPS is 2.4 percent (which reflects the 2.4 percent final estimate of the hospital inpatient market basket percentage increase with a 0.0 percentage point MFP adjustment since the 10-year moving average growth in MFP was estimated to be less than 0.0 percent). For CY 2021, we are using a conversion factor of $82.797 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 OPD fee schedule increase factor of 2.4 percent for CY 2021, the required wage index budget neutrality adjustment of 1.0012, the budget neutrality adjustment of 1.0000 applying the final payment methodology for drugs purchased under the 340B Program for CY 2021 of ASP minus 22.5 percent, and the adjustment of 0.04 percentage point of projected OPPS spending for the difference in pass-through spending that results in a conversion factor for CY 2021 of $82.797.

We also are finalizing our proposal to amend the regulation at 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (b)(1)(iv)(B)(*11*) to provide that, for CY 2020 and subsequent years, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS.

C. 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 the CY 2021 OPPS/ASC 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 proposed to continue this policy for the CY 2021 OPPS (85 FR 48802). We referred readers to section II.H. of the CY 2021 OPPS/ASC 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. We did not receive any public comments on this proposal. Accordingly, for the reasons discussed above and in the CY 2021 OPPS/ASC proposed rule, we are finalizing our proposal, without modification, to continue this policy for the CY 2021 OPPS.

As discussed in the claims accounting narrative included with the supporting documentation for this final rule with comment period (which is available via the internet on the CMS website), for estimating APC costs, we are standardizing 60 percent of estimated claims costs for geographic area wage variation using the same FY 2021 pre-reclassified wage index that we use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For CY 2021, we proposed to implement this provision in the same manner as we have since CY 2011 (85 FR 48802). 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, we stated that the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We referred readers to the FY 2011 through FY 2020 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; and for FY 2020, 84 FR 42312. We did not receive any public comments on this proposal. Accordingly, for the reasons discussed above and in the CY 2021 OPPS/ASC proposed rule, we are finalizing our proposal, without modification, to continue to implement the frontier State floor under the OPPS in the same manner as we have since CY 2011.

In addition to the changes required by the Affordable Care Act, we noted in the CY 2021 OPPS/ASC proposed rule (85

FR 48802) that the FY 2021 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. We referred readers to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32695 through 32734) for a detailed discussion of all proposed changes to the FY 2021 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), 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. 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, as we stated in the FY 2021 IPPS/LTCH PPS proposed and final rules (85 FR 32696 through 32697 and 58743), 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 material modifications that have a number of downstream effects, such as IPPS hospital 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. A copy of OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wpcontent/uploads/2018/09/Bulletin-18-04.pdf*. According to OMB, ''[t]his bulletin 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 (75 FR 37246), and Census Bureau data.''

As noted previously, while OMB Bulletin No. 18–04 is not based on new census data, it includes some material changes to the OMB statistical area delineations. Specifically, as we stated in the CY 2021 OPPS/ASC proposed rule (85 FR 48803), under the revised OMB delineations, there would be some new CBSAs, urban counties that would become rural, rural counties that would become urban, and some existing CBSAs that would be split apart. In addition, we stated in the FY 2021 IPPS/LTCH PPS proposed rule that the revised OMB delineations would affect various hospital reclassifications, the outmigration adjustment (established by section 505 of Pub. L. 108–173), and treatment of hospitals located in certain rural counties (that is, ''Lugar'' hospitals) under section 1886(d)(8)(B) of the Act. In the CY 2021 OPPS/ASC proposed rule, we referred readers to the FY 2021 IPPS/LTCH PPS proposed rule for a complete discussion of the revised OMB delineations we proposed to adopt under the IPPS and the effects of these revisions on the FY 2021 IPPS wage indexes (85 FR 32696 through 32707, 32717 through 32728). We stated in the FY 2021 IPPS/LTCH PPS proposed rule that we believe using the revised delineations based on OMB Bulletin No. 18–04 would increase the integrity of the IPPS wage index system by creating a more accurate representation of geographic variations in wage levels. Therefore, in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index. In addition, in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to apply a 5 percent cap for FY 2021 on any decrease in a hospital's final wage index from the hospital's final wage index for FY 2020 as a proposed transition wage index to help mitigate any significant negative impacts of adopting the revised OMB delineations (85 FR 32706 through 32707). As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742 through 58755), as we proposed, we adopted the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index and a 5 percent cap for FY 2021 on any decrease in a hospital's final wage index from the hospital's final wage index for FY 2020.

As further discussed below, in the CY 2021 OPPS/ASC proposed rule (85 FR 48803), we proposed to use the FY 2021 IPPS post-reclassified wage index including the updated OMB delineations and related IPPS wage index adjustments to calculate the CY 2021 OPPS wage indexes. Similar to our discussion in the FY 2021 IPPS/LTCH PPS proposed rule, we stated in the CY

2021 OPPS/ASC proposed rule that we believe using the revised delineations based on OMB Bulletin No. 18–04 would increase the integrity of the OPPS wage index system by creating a more accurate representation of geographic variations in wage levels.

A summary of the comments we received regarding the updated OMB delineations and our responses to those comments appear below:

Comment: One commenter supported our proposed adoption of the revised OMB delineations, but several commenters opposed our proposed implementation of the revised OMB delineations. These commenters stated that CMS is not bound to adopt the revised delineations, and suggested that CMS delay adoption of the revised delineations until the completion of the 2020 decennial census. Several comments specifically cited the lack of advance notice and the significant negative financial impacts to hospitals in several counties in the New York-Newark-Jersey City MSA resulting from the adoption of the revised delineations. Additional commenters recommended that CMS engage further with stakeholders to develop more comprehensive wage index reform to address the disparities that exist within the current wage index system.

Response: We appreciate these comments. We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58744 through 58753) for a detailed discussion of the implementation of the revised OMB delineations and for responses to these and other comments relating to the revised delineations.

Consistent with our longstanding policy, we proposed in the CY 2021 OPPS/ASC proposed rule (85 FR 48803) to use the FY 2021 IPPS post-reclassified wage index, which is based on the updated statistical area delineations set forth in OMB Bulletin No. 18–04, in determining the wage adjustments for both the OPPS payment and copayment rates for CY 2021. Thus, as discussed in the CY 2021 OPPS/ASC proposed rule (85 FR 48803), any adjustments for the FY 2021 IPPS post-reclassified wage index, including without limitation a one year 5 percent cap on any wage index decrease, would be reflected in the final CY 2021 OPPS wage index beginning on January 1, 2021. As we explained in the CY 2021 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. For this reason, as discussed later in this section, we are finalizing our proposal to use the FY 2021 IPPS post-reclassified wage index and applicable IPPS wage index adjustments in determining the wage adjustments for both the OPPS payment rate and the copayment rates for CY 2021. As noted above, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742 through 58755), for purposes of calculating the IPPS wage index, we adopted the revised OMB delineations as described in OMB Bulletin No. 18–04 effective October 1, 2020. Thus, effective January 1, 2021, the OPPS wage index also will be based on these updated OMB delineations. As we explained in the CY 2021 OPPS/ASC proposed rule, we believe using the revised delineations based on OMB Bulletin No. 18–04 will increase the integrity of the wage index system by creating a more accurate representation of geographic variations in wage levels.

We concur with commenters that CMS is not bound by statute to use the OMB definitions in calculating the OPPS wage index. However, we believe we have broad authority under section 1833(t)(2)(D) of the Act to determine the methodology for calculating the OPPS wage index, including the labor market areas used for the OPPS wage index. As discussed above, we believe using the IPPS post-reclassified wage index, which is based on the revised OMB delineations, in determining the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2021 is reasonable and logical given the inseparable, subordinate status of the HOPD within the hospital overall. In addition, consistent with our discussion in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58745), we believe it is important to use the updated labor market area delineations in order to maintain a more accurate and up-to-date payment system that reflects the reality of current labor market conditions. In response to comments citing a lack of advance notice provided to hospitals regarding the proposed adoption of the revised delineations, as we stated in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58746), the delineation files produced by OMB have been public for nearly 2 years, and OMB definitions and criteria are subject to separate notice and comment rulemaking. Finally, we note that to help mitigate significant negative impacts of the revised OMB delineations, consistent with the FY 2021 IPPS wage index, the CY 2021 OPPS wage index will reflect a 5 percent cap on any wage index decrease compared to a hospital's final CY 2020 wage index. For these reasons, we do not believe it is necessary or appropriate to delay or alter implementation of the revised delineations.

In response to commenters who recommended that CMS engage further with stakeholders to develop a more comprehensive wage index reform to address wage index disparities, we appreciate the continued interest in wage index reform. As we noted in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58745), as a first step toward comprehensive wage index reform, the FY 2021 President's Budget proposes the Secretary conduct and report on a demonstration to improve the Medicare inpatient hospital wage index.

After consideration of the public comments we received, for the reasons discussed above and in the CY 2021 OPPS/ASC proposed rule, we are finalizing, without modification, our proposal to adopt the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, and related IPPS wage index adjustments to calculate the CY 2021 OPPS wage index effective beginning January 1, 2021.

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 2021, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48803), we proposed to use the FY 2021 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 2021. Therefore, we stated that any adjustments for the FY 2021 IPPS post-reclassified wage index, including, but not limited to, any adjustments that we may finalize related to the proposed adoption of the revised OMB delineations (such as a cap on wage index decreases and revisions to hospital reclassifications), would be reflected in the final CY 2021 OPPS wage index beginning on January 1, 2021. (In the proposed rule, we referred readers to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32695 through 32734) and the proposed FY 2021 hospital wage index files posted on the CMS website.) With regard to budget neutrality for the CY 2021 OPPS wage index, in the proposed rule, we referred readers to section II.B. of the CY 2021 OPPS/ASC proposed rule. We stated that 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.

We received comments regarding certain adjustments included in the FY 2021 IPPS post-reclassified wage index (which would be reflected in the CY 2021 OPPS wage index). A summary of those comments and our responses appear below:

Comment: Some commenters, while opposing the proposed adoption of revised OMB delineations, generally supported the concept of the 5 percent cap on any wage index decrease for FY 2021 (if the delineations are finalized). Some commenters requested that CMS reduce the amount of potential reduction in FY 2021, and extend transition adjustments to affected hospitals in future years. Other commenters suggested a multiple year transition period. One commenter requested that we apply the 5 percent cap policy to wage index increases as well.

Response: We thank the commenters for their suggestions. We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 85753 through 58755) for a detailed discussion of our rationale for adopting a one year 5 percent cap on any wage index decrease and for responses to these and other comments regarding this transition wage index.

As discussed previously, in the CY 2021 OPPS/ASC proposed rule (85 FR 48803), we proposed to use the FY 2021 IPPS post-reclassified wage index, including any adjustments such as the one year 5 percent cap on wage index decreases, as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2021. We continue to believe that using the IPPS post-reclassified wage index, including any adjustments, 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, and thus, as discussed below, we are finalizing this proposal without modification.

In response to the commenter that requested we also apply the 5 percent cap to wage index increases, we note that as we explained in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58753 through 58755), the purpose of the 5 percent cap is to mitigate significant wage index decreases and provide wage index stability for affected hospitals in light of our adoption of the revised OMB delineations. The purpose of the 5 percent cap is not to curtail the positive impact of such revisions. Thus, we do not think it would be appropriate to apply the cap to wage index increases as well.

Comments: Many commenters thanked CMS for implementing the IPPS low wage index hospital policy (pursuant to which CMS increases the IPPS wage index for certain low wage index hospitals) beginning in FY 2020 in response to rural and other health care stakeholders' requests that CMS address ''circularity'' in the wage index (the cyclical effect of hospitals with relatively high wages receiving higher reimbursement due to relatively high wage indexes, which allows them to afford paying higher wages) and halt the ''death spiral'' perpetuating wage index disparities where relatively low wage index hospitals are forced to keep wages low due to low Medicare reimbursements that lag behind areas with higher wage indexes.

Other commenters opposed continuing the low wage index hospital policy in FY 2021. The commenters stated that the policy fails to recognize the legitimate differences in geographic labor markets. Commenters also noted that there is no requirement for hospitals to use the increased reimbursement to boost employee compensation, and suggested CMS begin evaluating the cost report data filed by hospitals in the lowest quartile to ascertain whether the increased funds are being used to raise employee compensation in deciding whether to continue this policy for FY 2022. Some commenters stated that the data lag CMS described in its rationale applies equally to all hospitals, not only those in the lowest quartile. Commenters questioned CMS's statutory authority to promulgate this IPPS policy under 42 U.S.C. 1395ww(d)(3)(E), which requires the agency to adjust payments to reflect area differences in wages, because it artificially inflates wage index values and creates a wage index system not based on actual data. These commenters stated that CMS is using the wage index as a policy vehicle, not as a technical correction, and needs Congressional authority to provide additional funding to low-wage hospitals.

Response: We appreciate the many comments we received regarding our policy to provide an increase in the IPPS wage index beginning in FY 2020 for hospitals with wage index values below the 25th percentile wage index value for a year (referred to as the low wage index hospital policy). We note that we did not propose or finalize any changes to this policy in the FY 2021 IPPS/LTCH PPS proposed and final rules. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42332) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58765 through 58768) for a detailed discussion of the IPPS low wage index hospital policy and for responses to these and other comments regarding this policy. In the CY 2021 OPPS/ASC proposed rule (85 FR 48803), we proposed to use the FY 2021 IPPS post-reclassified wage index including any adjustments, such as the IPPS low wage index hospital policy, as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2021. We continue to believe that using the IPPS post-reclassified wage index, including any adjustments, 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, and thus, as discussed below, we are finalizing this proposal without modification.

Comment: Many commenters supported increasing the wage index values of low-wage hospitals, but suggested that CMS do so in a non-budget-neutral manner. Commenters stated that this redistribution is counterproductive to CMS's larger goals

of high quality care and healthcare access because it forces high-wage, mostly urban hospitals to bear the cost of supporting lower-wage hospitals. Commenters stated that the budget neutrality adjustment penalizes many hospitals, including rural hospitals. Other commenters requested that CMS ensure that the budget neutrality adjustment factor not apply to hospitals falling below the 25th percentile.

Response: We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42328 through 42332) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58765 through 58768) for a detailed discussion of the budget neutrality adjustment for the IPPS low wage index hospital policy and for responses to these and other comments regarding this adjustment.

We refer readers to section II.B. of this final rule with comment period for a discussion of the OPPS wage index budget neutrality adjustment.

Comment: Many commenters recommended that CMS develop a comprehensive, long-term approach to wage index reform in place of the low wage index hospital policy finalized in the FY 2020 IPPS/LTCH PPS final rule. Two commenters suggested alternative solutions to address wage index disparities, including a national wage index floor for all hospitals. Other commenters recommended that CMS proactively address the effects of COVID–19, which the commenters believed would exacerbate wage index disparities, by excluding wage data collected during the public health emergency from future wage index calculations.

Response: We appreciate the commenters' suggested alternatives. We received similar comments in response to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 58767 through 58768). In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58768), we stated that we considered these comments to be outside the scope of the FY 2021 IPPS/LTCH PPS proposed rule, and thus we did not address them in that final rule but stated that we may consider them in future rulemaking. Similarly, we consider these comments to be outside the scope of the CY 2021 OPPS/ASC proposed rule and thus are not addressing them in this final rule with comment period.

Comment: Multiple commenters specifically supported CMS's continuation of the policy, adopted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), to exclude the wage data of urban hospitals that reclassify to rural when calculating each state's rural floor. Commenters stated that the change to the calculation of the rural floor limits the ability of hospitals to game the system and supports the overall goal of making the wage index reflective of variances in labor markets.

Response: We appreciate the commenters' support of our policy to exclude the wage data of hospitals reclassified under § 412.103 from the IPPS rural floor calculation. As stated in the FY 2020 IPPS/LTCH PPS final rule, we believe this policy is necessary and appropriate to address the unanticipated effects of rural reclassifications on the rural floor and the resulting wage index disparities, including the effects of the manipulation of the rural floor by certain hospitals (84 FR 42333 through 42336). We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58768) for a detailed discussion of this policy and for responses to these and other comments regarding this policy.

Comment: One commenter supported our proposals regarding the wage index and requested that we carry over policies from the IPPS to the OPPS to ensure consistency in hospital payments.

Response: We appreciate the commenter's support of our proposals regarding the wage index. As we discuss below, we are finalizing our proposal to use the FY 2021 IPPS post-reclassified wage index for urban and rural areas (including any applicable adjustments for the FY 2021 IPPS post-reclassified wage index), as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2021.

After consideration of the comments received, for the reasons discussed in this final rule with comment period and in the CY 2021 OPPS/ASC proposed rule, we are finalizing, without modification, our proposal to use the FY 2021 IPPS post-reclassified wage index for urban and rural areas, based on the revised OMB delineations set forth in OMB Bulletin No. 18–04, as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2021. Therefore, any applicable adjustments for the FY 2021 IPPS post-reclassified wage index (including, but not limited to, the low wage index hospital policy, the one year 5 percent cap on wage index decreases, the rural floor, and the frontier State floor) will be reflected in the final CY 2021 OPPS wage index beginning on January 1, 2021. 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 the CY 2021 OPPS/ASC proposed rule, we proposed to continue this policy for CY 2021, and included a brief summary of the major FY 2021 IPPS wage index policies and adjustments that we proposed to apply to these hospitals under the OPPS for CY 2021, which we have summarized below. We referred readers to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32695 through 32734) for a detailed discussion of the proposed changes to the FY 2021 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 applies if the hospital were paid under the IPPS. For CY 2021, we proposed 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 stated in the proposed rule that the wage index that would apply for CY 2021 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and adjustments to the wage index finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities (84 FR 42325 through 42337). In addition, we proposed that the wage index that would apply to non-IPPS hospitals paid under the OPPS would include any adjustments we may finalize for the FY 2021 IPPS post-reclassified wage index related to the adoption of the revised OMB delineations, as discussed in the CY 2021 OPPS/ASC proposed rule. We did not receive any public comments on these proposals. Accordingly, for the

reasons discussed above and in the CY 2021 OPPS/ASC proposed rule, we are finalizing these proposals, without modification.

For CMHCs, for CY 2021, we proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. We also proposed that the wage index that would apply to CMHCs would include any adjustments we may finalize for the FY 2021 IPPS post-reclassified wage index related to the adoption of the revised OMB delineations, as discussed in the CY 2021 OPPS/ASC proposed rule. In addition, we proposed that the wage index that would apply to CMHCs for CY 2021 would continue to include the rural floor adjustment and adjustments to the wage index finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities. Also, we proposed that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals. We did not receive any public comments on these proposals. Therefore, for the reasons discussed above and in the CY 2021 OPPS/ASC proposed rule, we are finalizing these proposals without modification.

Table 4A associated with the FY 2021 IPPS/LTCH PPS final rule (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) identifies counties eligible for the out-migration adjustment. Table 2 associated with the FY 2021 IPPS/LTCH PPS final rule (available for download via the website above) identifies IPPS hospitals that receive the out-migration adjustment for FY 2021. We are including the outmigration adjustment information from Table 2 associated with the FY 2021 IPPS/LTCH PPS final rule as Addendum L to this CY 2021 OPPS/ASC final rule with comment period with the addition of non-IPPS hospitals that will receive the section 505 outmigration adjustment under this CY 2021 OPPS/ASC final rule with comment period. 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 final FY 2021 IPPS wage index tables and Addendum L.

D. 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 2021 OPPS proposed rule Claims Accounting Narrative that is posted on our website. We proposed to update the default ratios for CY 2021 using the most recent cost report data. We stated that we would update these ratios in this final rule with comment period if more recent cost report data are available.

We are no longer publishing 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.

We did not receive any public comments on our proposal to use statewide average default CCRs if a MAC cannot calculate a CCR for a hospital and to use these CCRs to adjust charges to costs on claims data for setting the final CY 2021 OPPS relative payment weights. Therefore, we are finalizing our proposal without modification.

E. 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

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 2020. 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 2021, we proposed 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.

Comment: Multiple commenters supported the proposal to continue the 7.1 percent payment adjustment.

Response: We appreciate the commenters' support.

Comment: Multiple commenters requested that CMS make the 7.1 percent rural adjustment permanent. The commenters appreciated the policy that CMS adopted in CY 2019 and reaffirmed in CY 2020 where we stated that the 7.1 percent rural adjustment would continue to be in place until our data support establishing a different rural adjustment percentage. However, the commenters believed that this policy still does not provide enough certainty for rural SCHs and EACHs to know whether they should take into account the rural SCH adjustment when attempting to calculate expected revenues for their hospital budgets.

Response: We thank the commenters for their input. We believe that our current policy, which states that the 7.1 percent payment adjustment for rural SCHs and EACHs will remain in effect until our data show that a different percentage for the rural payment adjustment is necessary, provides sufficient budget predictability for rural SCHs and EACHs. Providers would receive notice in a proposed rule and have the opportunity to provide comments before any changes to the rural adjustment percentage would be implemented.

Comment: One commenter requested that CMS expand the payment adjustment for rural SCHs and EACHs to additional types of hospitals. The commenter requested that the payment adjustment apply to include urban SCHs because, according to the commenter, urban SCHs care for patient populations similar to rural SCHs and EACHs, face similar financial challenges to rural SCHs and EACHs, and act as safety net providers for rural areas despite their designation as urban providers. The same commenter requested that the payment adjustment also apply to Medicare-dependent hospitals (MDHs) because, according to the commenter, these hospitals face similar financial challenges to rural SCHs and EACHs, and MDHs play a similar safety net role to rural SCHs and EACHs, especially for Medicare. The commenter asked that CMS study whether it would be appropriate to provide a payment adjustment to MDHs that is similar to the current adjustment for rural SCHs.

Response: We thank the commenters for their comments. The analysis we did to compare costs of urban providers to those of rural providers did not support an add-on adjustment for providers other than rural SCHs and EACHs. In addition, section 1833(t)(13)(B) of the Act authorizes an adjustment for rural hospitals only. Accordingly, we do not believe we have a basis to expand the payment adjustment to any providers other than rural SCHs and EACHs under our authority at section 1833(t)(13)(B) of the Act.

After consideration of the public comments we received, we are finalizing our proposal, without modification, 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, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. 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 established section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (often referred to as ''held harmless'').

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 42 CFR 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. For CYs 2012 and 2013, the target PCR for purposes of the cancer hospital payment adjustment was 0.91. For CY 2014, the target PCR was 0.90. For CY 2015, the target PCR was 0.90. For CY 2016, the target PCR was 0.92, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70362 through 70363). For CY 2017, the target PCR was 0.91, as discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79603 through 79604). For CY 2018, the target PCR was 0.88, as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59265 through 59266). For CY 2019, the target PCR was 0.88, as discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58871 through 58873). For CY 2020, the target PCR was 0.89, as discussed in the CY 2020 OPPS/ASC final rule with comment period (83 FR 61190 through 61192).

2. Policy for CY 2021

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 proposed 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 did not propose an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) for CY 2021. To calculate the proposed CY 2021 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of this CY 2021 OPPS/ASC proposed rule, used to estimate costs for the CY 2021 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2019 claims data that we used to model the impact of the proposed CY 2021 APC relative payment weights (3,527 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2021 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2014 to 2019. We then removed the cost report data of the 49 hospitals located in Puerto Rico from our dataset because we did not believe their cost structure reflected the costs of most hospitals paid under the OPPS, and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 14 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,464 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimate that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 90 percent of reasonable cost (weighted average PCR of 0.90). Therefore, after applying the 1.0 percentage point reduction, as required by section 16002(b) of the 21st Century Cures Act, we proposed that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.89 for each cancer hospital.

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposed cancer hospital payment adjustment methodology without modification. For this final rule with comment period, we are using the most recent cost report data through June 30, 2020 to update the adjustment. This update yields a target PCR of 0.90. We limited the dataset to the hospitals with CY 2019 claims data that we used to model the impact of the CY 2021 APC relative payment weights (3,555 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2021 OPPS. The cost report data for the hospitals in the dataset were from cost report periods with fiscal year ends ranging from 2014 to 2019. We then removed the cost report data of the 47 hospitals located in Puerto Rico from our dataset because we do not believe their cost structure reflects the cost of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 14 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost report in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to an analytic file of 3,494 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated a target PCR of 0.90. Therefore, after applying the 1.0 percentage point reduction as required by section 1602(b) of the 21st Century

Cures Act, we are finalizing that the payment amount associated with the cancer hospital adjustment to be determined at cost report settlement will be the additional payment needed to result in a PCR equal to 0.89 for each cancer hospital.

Table 5 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2021, due to the cancer hospital payment adjustment policy. The actual amount of the CY 2021 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2021 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 5: ESTIMATED CY 2021 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 2021 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	11.6%
100271	H. Lee Moffitt Cancer Center & Research Institute	19.2%
220162	Dana-Farber Cancer Institute	34.3%
330154	Memorial Sloan-Kettering Cancer Center	37.9%
330354	Roswell Park Cancer Institute	12.3%
360242	James Cancer Hospital & Solove Research Institute	11.5%
390196	Fox Chase Cancer Center	9.2%
450076	M.D. Anderson Cancer Center	40.3%
500138	Seattle Cancer Care Alliance	43.2%

G. 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 2020, 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 $5,075 (the fixed-dollar amount threshold) (84 FR 61192 through 61194). 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 the CY 2021 OPPS/ASC proposed rule, was 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 2021 OPPS/ASC final rule, we estimate that we paid approximately 0.97 percent of the total aggregated OPPS payments in outliers for CY 2019.

For the CY 2021 OPPS/ASC proposed rule, using CY 2019 claims data and CY

2020 payment rates, we estimated that the aggregate outlier payments for CY 2020 would be approximately 1.01 percent of the total CY 2020 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 2021

In the CY 2021 OPPS/ASC proposed rule (85 FR 48807 through 48808), for CY 2021, we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We proposed 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. As discussed in section VIII.C. of the CY 2021 OPPS/ASC proposed rule, we proposed 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 the CY 2021 OPPS/ASC proposed rule and this final rule with comment period.

To ensure that the estimated CY 2021 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed 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 $5,300.

We calculated the proposed fixed-dollar threshold of $5,300 using the standard methodology most recently used for CY 2020 (84 FR 61192 through 61194). 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 2021 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2019 claims using the same inflation factor of 1.131096 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32908). We used an inflation factor of 1.06353 to estimate CY 2020 charges from the CY 2019 charges reported on CY 2019 claims. The methodology for determining this charge inflation factor is discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 through 42630). 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 proposed to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2021 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2021 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2021, we proposed to apply an adjustment factor of 0.975271 to the CCRs that were in the April 2020 OPSF to trend them forward from CY 2020 to CY 2021. The methodology for calculating the proposed adjustment is discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32908 through 32909).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2020 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.97571 to approximate CY 2021 CCRs) to charges on CY 2019 claims that were adjusted (using the proposed charge inflation factor of 1.131096 to approximate CY 2021 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 $5,300, 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 proposed 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, as we proposed, we are continuing 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 CY 2021 OPPS/ASC final rule with comment period.

We received no public comments on our proposal. Therefore, we are finalizing our proposal, without modification, to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS and to use our established methodology to set the OPPS outlier fixed-dollar loss threshold for CY 2021.

3. Final Outlier Calculation

Consistent with historical practice, we used updated data for this final rule with comment period for outlier calculations. For CY 2021, we are

applying the overall CCRs from the October 2020 OPSF file after adjustment (using the CCR inflation adjustment factor of 0.974495 to approximate CY 2021 CCRs) to charges on CY 2019 claims that were adjusted using a charge inflation factor of 1.13218 to approximate CY 2021 charges. These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar threshold for the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039 through 59040). We simulated aggregated CY 2021 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple-threshold constant and assuming that outlier payments will 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 payment equaled 1.0 percent of aggregated estimated total CY 2021 OPPS payments. We estimated that a fixed-dollar threshold of $5,300 combined with the multiple-threshold of 1.75 times the APC payment rate, will allocate the 1.0 percent of aggregated total OPPS payments to outlier payments.

For CMHCs, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times APC 5853.

H. 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 2021 OPPS/ASC final rule with comment period, 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 final rule with comment period and the relative payment weight determined under section II.A. of this final rule with comment period. Therefore, the national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (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 final rule with comment period (which is available via the internet on the CMS website) was calculated by multiplying the final CY 2021 scaled weight for the APC by the CY 2021 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 final rule with comment period.

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 final 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 noted 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 this final rule with comment period (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 2021 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.

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

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that, for the CY 2021 OPPS wage index, we are adopting the updated OMB delineations based on OMB Bulletin No. 18–04 and any related IPPS wage index adjustments that were finalized in the FY 2021 IPPS/LTCH PPS final rule, as discussed in section II.C. of this final rule with comment period. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2021 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 also are continuing to apply for the CY 2021

OPPS wage index any other adjustments for the FY 2021 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment, a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010, and an adjustment to the wage index for certain low wage index hospitals. For further discussion of the wage index we are applying for the CY 2021 OPPS, we refer readers to section II.C. of this final rule with comment period.

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 final rule with comment period (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the final FY 2021 IPPS wage index, which are listed in Table 2 associated with the FY 2021 IPPS/LTCH PPS final 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 2021 IPPS Final Rule Home Page'' and select ''FY 2021 Final 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 final CY 2021 full national unadjusted payment rate for APC 5071 is $621.97. The reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $609.84. This reduced rate is calculated by multiplying the reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

The final FY 2021 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of IPPS 2021 wage index policies, is 1.3468. The labor-related portion of the final full national unadjusted payment is approximately $502.60 (.60 * $621.97 * 1.3468). The labor-related portion of the reduced national unadjusted payment is approximately $492.80 (.60 * $609.84 * 1.3468). The nonlabor-related portion of the full national unadjusted payment is approximately $248.79 (.40 * $621.97). The nonlabor-related portion of the reduced national unadjusted payment is approximately $243.94 (.40 * $609.84). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is approximately $751.39 ($502.60 + $248.79). The sum of the portions of the reduced national adjusted payment is approximately $736.74 ($492.80 + $243.94).

We did not receive any public comments on these steps under the methodology that we included in the proposed rule to determine the APC payments for CY 2021. Therefore, we are using the steps in the methodology specified above, to demonstrate the calculation of the final CY 2021 OPPS payments using the same parameters.

I. 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. OPPS Copayment Policy

For CY 2021, we proposed 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 proposed 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, 2021 are included in Addenda A and B to the proposed rule with comment period (which are available via the internet on the CMS website).

We did not receive any public comments on the proposed copayment amounts for new and revised APCs using the same methodology we implemented beginning in CY 2004 or the standard rounding principles we apply to our copayment amounts. Therefore, we are finalizing our proposed copayment policies, without modification.

As discussed in section XIV.E. of the CY 2021 OPPS/ASC proposed rule and this final rule with comment period, for CY 2021, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

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

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

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

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

3. 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, $124.40 is approximately 20 percent of the full national unadjusted payment rate of $621.97. For APCs with only a minimum unadjusted copayment in Addenda A and B to this final 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 final rule with comment period. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H. of this final rule with comment period.

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

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this final rule with comment period, 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 finalized unadjusted copayments for services payable under the OPPS that will be effective January 1, 2021, are shown in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website). We note that the finalized national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the CY 2021 OPD fee schedule increase factor discussed in section II.B. of this final rule with comment period.

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. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, Healthcare Common Procedure Coding System (HCPCS) codes, that are reported on hospital outpatient department (HOPD) claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of Current Procedural Terminology (CPT), 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 Centers for Medicare & Medicaid Services (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 AMA while 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 with comment period. This quarterly process offers hospitals access to codes that more accurately describe 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 and finalize policies for these codes 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 paid separately under the hospital OPPS are assigned to appropriate SIs. Certain payment SIs provide separate payment while other payment SIs do not. In section XI. (CY 2021 OPPS Payment Status and Comment Indicators) of this final rule with comment period, we discuss the various SIs used under the OPPS. We also provide a complete list of the SIs and their definitions in Addendum D1 to this CY 2021 OPPS/ASC final rule with comment period.

1. HCPCS Codes That Were Effective April 1, 2020 for Which We Solicited Public Comments in the CY 2021 OPPS/ASC Proposed Rule

For the April 2020 update, there were no new CPT codes. However, thirteen new Level II HCPCS codes were established and made effective on April 1, 2020. These codes and their long descriptors were included in Table 6 of the proposed rule and are now listed in Table 6 of this final rule with comment period. Through the April 2020 OPPS quarterly update CR (Transmittal 10013, Change Request 11691, dated March 25, 2020), we recognized several new Level II HCPCS codes for separate payment under the OPPS. In the CY 2021 OPPS/ASC proposed rule (85 FR 48812 through 48813), we solicited public comments on the proposed APC and status indicator (SI) assignments for these Level II HCPCS codes, which were listed in Table 6 of the proposed rule.

We did not receive any public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes implemented in April 2020. Therefore, we are finalizing the proposed APC and SI assignments for these codes, as indicated in Table 6. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2021. Their replacement codes are listed in Table 6. The final payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, the SI definitions can be found in Addendum D1 to this final rule with comment period. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

BILLING CODE 4120–01–P

TABLE 6: New HCPCS Codes Effective April 1, 2020

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
C9053*	J0791	Injection, crizanlizumab-tmca, 5 mg	G	9359
C9056**	J0223	Injection, givosiran, 0.5 mg	G	9343
C9057#	J1201	Injection, cetirizine hydrochloride, 0.5 mg	G	9361
C9058##	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo)	G	9345
0163U	0163U	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas	E1	N/A
0164U	0164U	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results	Q4	N/A
0165U	0165U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy	Q4	N/A
0166U	0166U	Liver disease, 10 biochemical assays (α2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation	Q4	N/A
0167U	0167U	Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood	Q4	N/A
0168U	0168U	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy	Q4	N/A
0169U	0169U	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	A	N/A
0170U	0170U	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic	A	N/A

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
		analysis, and results reported as predictive probability of ASD diagnosis		
0171U	0171U	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence	A	N/A

*HCPCS code C9053, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0791 (Injection, crizanlizumab-tmca, 5 mg) effective July 1, 2020.

**HCPCS code C9056, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0223 (Injection, givosiran, 0.5 mg) effective July 1, 2020.

#HCPCS code C9057, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J1201 (Injection, cetirizine hydrochloride, 0.5 mg) effective July 1, 2020.

##HCPCS code C9058, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code Q5120 (Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg) effective July 1, 2020.

TABLE 7: NEW HCPCS CODES EFFECTIVE JULY 1, 2020

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
C1748	C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	H	2029
C1849	C1849	Skin substitute, synthetic, resorbable, per square centimeter	N	N/A
C9059	J1738	Injection, meloxicam, 1 mg	G	9371
C9061	J3241	Injection, teprotumumab-trbw, 10 mg	G	9355
C9063	J3032	Injection, eptinezumab-jjmr, 1 mg	G	9357
C9122	C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346
C9759	C9759	Transcatheter intraoperative blood vessel microinfusion(s) (for example, intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed	N	N/A
C9760	C9760	Non-randomized, non-blinded procedure for NYHA Class II, III, IV heart failure; transcatheter implantation of interatrial shunt-including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1592
C9762	C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging	Q3	5524
C9763	C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging	Q3	5524
C9764	C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	J1	5192
C9765	C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and	J1	5193

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
		transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed		
C9766	C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	J1	5193
C9767	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	J1	5194
G2170*	G2170*	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (eg, transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed	J1	5194
G2171**	G2171**	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (eg, vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	J1	5194
J0223	J0223	Injection, givosiran, 0.5 mg	G	9343
J0591	J0591	Injection, deoxycholic acid, 1 mg	E1	N/A
J0691	J0691	Injection, lefamulin, 1 mg	G	9332
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362
J0791	J0791	Injection, crizanlizumab-tmca, 5 mg	G	9359
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347
J1201	J1201	Injection, cetirizine hydrochloride, 0.5 mg	G	9361
J1429	J1429	Injection, golodirsen, 10 mg	G	9356
J1558	J1558	Injection, immune globulin (Xembify), 100 mg	K	9372
J3399	J3399	Injection, Onasemnogene abeparvovec-xioi, per treatment, up to 5x1015 vector genomes	K	9373
J7169	J7169	Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 10 mg	G	9198

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354
J7333	J7333	Hyaluronan or derivative, visco-3, for intraarticular injection, per dose	N	N/A
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387
J9246	J9246	Injection, melphalan (evomela), 1 mg	K	9375
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353
Q4227#	Q4227#	Amniocore, per square centimeter	N	N/A
Q4228#	Q4228#	BioNextPATCH, per square centimeter	N	N/A
Q4229#	Q4229#	Cogenex amniotic membrane, per square centimeter	N	N/A
Q4230#	Q4230#	Cogenex flowable amnion, per 0.5 cc	N	N/A
Q4231#	Q4231#	Corplex P, per cc.	N	N/A
Q4232#	Q4232#	Corplex, per square centimeter	N	N/A
Q4233#	Q4233#	Surfactor or Nudyn, per 0.5 cc	N	N/A
Q4234#	Q4234#	Xcellerate, per square centimeter	N	N/A
Q4235#	Q4235#	Amniorepair or altiply, per square centimeter	N	N/A
Q4236#	Q4236#	CarePATCH, per square centimeter	N	N/A
Q4237#	Q4237#	Cryo-cord, per square centimeter	N	N/A
Q4238#	Q4238#	Derm-maxx, per square centimeter	N	N/A
Q4239#	Q4239#	Amnio-maxx or Amnio-maxx lite, per square centimeter	N	N/A
Q4240#	Q4240#	Corecyte, for topical use only, per 0.5 cc	N	N/A
Q4241#	Q4241#	Polycyte, for topical use only, per 0.5 cc	N	N/A
Q4242#	Q4242#	Amniocyte plus, per 0.5 cc	N	N/A
Q4244#	Q4244#	Procenta, per 200 mg	N	N/A
Q4245#	Q4245#	Amniotext, per cc	N	N/A
Q4246#	Q4246#	Coretext or Protext, per cc	N	N/A
Q4247#	Q4247#	Amniotext patch, per square centimeter	N	N/A
Q4248#	Q4248#	Dermacyte Amniotic Membrane Allograft, per square centimeter	N	N/A
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367
Q5120	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg	G	9345
Q5121	Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381
0594T	0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of	J1	5114

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
		adjustment schedules, and management of the intramedullary lengthening device		
0596T	0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	T	5372
0597T	0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	T	5372
0598T	0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity)	T	5722
0599T	0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (eg, upper extremity) (List separately in addition to code for primary procedure)	N	N/A
0600T	0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	J1	5362
0601T	0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	J1	5362
0602T	0602T	Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent	Q4	N/A
0603T	0603T	Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours	Q4	N/A
0604T	0604T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; initial device provision, set-up and patient education on use of equipment	V	5012
0605T	0605T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days	Q1	5741
0606T	0606T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days	M	N/A

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
0607T	0607T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment	V	5012
0608T	0608T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional	S	5741
0609T	0609T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data, per disc, on biomarkers (ie, lactic acid, carbohydrate, alanine, laal, propionic acid, proteoglycan, and collagen) in at least 3 discs	Q3	5523
0610T	0610T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); transmission of biomarker data for software analysis	N	N/A
0611T	0611T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); postprocessing for algorithmic analysis of biomarker data for determination of relative chemical differences between discs	S	5523
0612T	0612T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); interpretation and report	M	N/A
0613T	0613T	Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed	E1	N/A
0614T	0614T	Removal and replacement of substernal implantable defibrillator pulse generator	J1	5231
0615T	0615T	Eye-movement analysis without spatial calibration, with interpretation and report	Q1	5734
0616T	0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed;	J1	5491

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
		without removal of crystalline lens or intraocular lens, without insertion of intraocular lens		
0617T	0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens	J1	5492
0618T	0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange	J1	5492
0619T	0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	J1	5375
0172U	0172U	Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score	A	N/A
0173U	0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes	A	N/A
0174U	0174U	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents	Q4	N/A
0175U	0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes	A	N/A
0176U	0176U	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)	Q4	N/A
0177U	0177U	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status	A	N/A
0178U	0178U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction	Q4	N/A
0179U	0179U	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of	A	N/A

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
		partner/breakpoint, copy number variations), with report of significant mutation(s)		
0180U	0180U	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene, including subtyping, 7 exons	A	N/A
0181U	0181U	Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1	A	N/A
0182U	0182U	Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10	A	N/A
0183U	0183U	Red cell antigen (Diego blood group) genotyping (DI), gene analysis, SLC4A1 (solute carrier family 4 member 1 [Diego blood group]) exon 19	A	N/A
0184U	0184U	Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2	A	N/A
0185U	0185U	Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4	A	N/A
0186U	0186U	Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2	A	N/A
0187U	0187U	Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, ACKR1 (atypical chemokine receptor 1 [Duffy blood group]) exons 1-2	A	N/A
0188U	0188U	Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4	A	N/A
0189U	0189U	Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, GYPA (glycophorin A [MNS blood group]) introns 1, 5, exon 2	A	N/A
0190U	0190U	Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, GYPB (glycophorin B [MNS blood group]) introns 1, 5, pseudoexon 3	A	N/A
0191U	0191U	Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6	A	N/A
0192U	0192U	Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, SLC14A1 (solute carrier family 14 member 1 [Kidd blood group]) gene promoter, exon 9	A	N/A

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
0193U	0193U	Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26	A	N/A
0194U	0194U	Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metallo-endopeptidase [Kell blood group]) exon 8	A	N/A
0195U	0195U	KLF1 (Kruppel-like factor 1), targeted sequencing (ie, exon 13)	A	N/A
0196U	0196U	Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, BCAM (basal cell adhesion molecule [Lutheran blood group]) exon 3	A	N/A
0197U	0197U	Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]) exon 1	A	N/A
0198U	0198U	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, RHD (Rh blood group D antigen) exons 1-10 and RHCE (Rh blood group CcEe antigens) exon 5	A	N/A
0199U	0199U	Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, ERMAP (erythroblast membrane associated protein [Scianna blood group]) exons 4, 12	A	N/A
0200U	0200U	Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (X-linked Kx blood group) exons 1-3	A	N/A
0201U	0201U	Red cell antigen (Yt blood group) genotyping (YT), gene analysis, ACHE (acetylcholinesterase [Cartwright blood group]) exon 2	A	N/A

*HCPCS code C9754, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2170 effective July 1, 2020.
**HCPCS code C9755, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2171 effective July 1, 2020.
#HCPCS codes Q4227 through Q4248: 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.

BILLING CODE 4120–01–C

3. October 2020 HCPCS Codes for Which We Are Soliciting Public Comments in This CY 2021 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new HCPCS codes that are effective October 1 in the final rule with comment period, thereby updating the OPPS for the following calendar year, as displayed in Table 8 of the proposed rule and reprinted as Table 8 of this final rule with comment period. These codes are released to the public through the October OPPS

quarterly update CRs and via the CMS HCPCS website (for Level II HCPCS codes). For CY 2021, these codes are flagged with comment indicator ''NI'' in Addendum B to this OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. Specifically, the interim SI and APC assignments for codes flagged with comment indicator ''NI'' are open to public comment in this final rule with comment period, and we will respond to these public comments in the OPPS/ASC final rule with comment period for the next year's OPPS/ASC update.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48823), we proposed to continue this process for CY 2021. Specifically, for CY 2021, we proposed to include in Addendum B to the CY 2021 OPPS/ASC final rule with comment period the new HCPCS codes effective October 1, 2020 that would be incorporated in the October 2020 OPPS quarterly update CR. Also, as stated above, the October 1, 2020 codes are flagged with comment indicator ''NI'' in Addendum B to this CY 2021 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2021. We are inviting public comments on the interim SI and APC assignments for these codes, if applicable, that will be finalized in the CY 2021 OPPS/ASC final rule with comment period.

We note that we received a comment related to HCPCS codes 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) and P9099 (Blood component or product not otherwise classified), which were assigned to comment indicator ''NI'' (new code; comments will be accepted on the interim APC assignment) in Addendum B of the CY 2020 OPPS/ASC final rule with comment period. The comments and our responses can be found in section II.A.2(a)(1) (Blood Products) and III.D. (APC-Specific Policies) of this CY 2021 OPPS/ASC final rule with comment period.

4. January 2021 HCPCS Codes

a. New Level II HCPCS Codes for Which We Are Soliciting Public Comments in this CY 2021 OPPS/ASC Final Rule With Comment Period

As shown in Table 8, and as stated in the CY 2021 OPPS/ASC proposed rule (85 FR 48823 through 48825), consistent with past practice, we solicit comments on the new Level II HCPCS codes that will be effective January 1 in the OPPS/ASC final rule with comment period, thereby allowing us to finalize the SIs and APC assignments for the codes in the next 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, 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 2021, we proposed to include in Addendum B to the CY 2021 OPPS/ASC final rule with comment period the new Level II HCPCS codes effective January 1, 2021, that would be incorporated in the January 2021 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 2021, the Level II HCPCS codes effective January 1, 2021 are flagged with comment indicator ''NI'' in Addendum B to this CY 2021 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2021. We are inviting public comments on the interim SI and APC assignments for these codes, if applicable, that will be finalized in the CY 2021 OPPS/ASC final rule with comment period.

b. CPT Codes For Which We Solicited Public Comments in the CY 2021 OPPS/ASC Proposed Rule

For CY 2021, we received the CY 2021 CPT code updates that would be effective January 1, 2021, from AMA in time for inclusion in the CY 2021 OPPS/ASC proposed rule. We note that 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 SIs 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 SI assignments for them, and to finalize the APC and SI 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 SI assignments for a year until we can propose APC and SI 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 SI assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the annual proposed rule, and to avoid the resort to 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 SI 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), solicit public comments, and finalize the specific APC and SI assignments for those codes in the following year's final rule.

As stated above, for the CY 2021 OPPS update, we received the CY 2021 CPT codes from AMA in time for inclusion in the CY 2021 OPPS/ASC proposed rule. The new, revised, and deleted CY 2021 Category I and III CPT codes were included in Addendum B to the proposed rule (which is available via the internet on the CMS website). We noted in the proposed rule that the new and revised codes are assigned to new 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 current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC and SI assignments.

Further, we reminded readers 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 included the 5-digit placeholder codes and their long descriptors for the new and revised CY 2021 CPT codes in Addendum O to

the proposed rule (which is available via the internet on the CMS website) so that the public could adequately comment on the proposed APCs and SI assignments. The 5-digit placeholder codes were included in Addendum O, specifically under the column labeled ''CY 2021 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code,'' to the proposed rule. We noted that the final CPT code numbers would be included in this CY 2021 OPPS/ASC final rule with comment period. We also noted that not every code listed in Addendum O is subject to public comment. For the new and revised Category I and III CPT codes, we requested public comments on only those codes that are assigned comment indicator ''NP''.

In summary, in the CY 2021 OPPS/ASC proposed rule, we solicited public comments on the proposed CY 2021 SI and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2021. The CPT codes were listed in Addendum B to the proposed rule with short descriptors only. We listed them again in Addendum O to the proposed rule with long descriptors. We also proposed to finalize the SI and APC assignments for these codes (with their final CPT code numbers) in the CY 2021 OPPS/ASC final rule with comment period. The proposed SI and APC assignments for these codes were included in Addendum B to the proposed rule (which is available via the internet on the CMS website).

Commenters addressed several of the new CPT codes that were assigned to comment indicator ''NP'' in Addendum B to the CY 2021 OPPS/ASC proposed rule. We have responded to those public comments in sections III.C. (New Technology APCs), III.D. (OPPS APC-Specific Policies), and IV. (OPPS Payment for Devices) of this CY 2021 OPPS/ASC final rule with comment period.

The final SIs, APC assignments, and payment rates for the new CPT codes that are effective January 1, 2021 can be found in Addendum B to this final rule with comment period. In addition, the SI meanings can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2021) to this final rule with comment period. Both Addendum B and D1 are available via the internet on the CMS website.

Finally, Table 8, which is a reprint of Table 8 from the CY 2021 OPPS/ASC proposed rule, shows the comment timeframe for new and revised HCPCS codes. The table provides information on 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 8: COMMENT TIMEFRAME FOR NEW AND REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2020	HCPCS (CPT and Level II codes)	April 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
July 2020	HCPCS (CPT and Level II codes)	July 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
October 2020	HCPCS (CPT and Level II codes)	October 1, 2020	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period
January 2021	CPT Codes	January 1, 2021	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2021	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period

BILLING CODE 4120–01–C

B. OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. 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 final rule with comment period.

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. In the CY 2021 OPPS/ASC proposed rule (85 FR 48799), for CY 2021, we proposed 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 Hospital Outpatient Payment (HOP) Panel recommendations for specific services for the CY 2021 OPPS update are discussed in the relevant specific sections throughout this CY 2021 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 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 the CY 2021 OPPS/ASC proposed rule (85 FR 48826 through 48827), for CY 2021, we proposed 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.

In the CY 2021 OPPS/ASC proposed rule, we identified the APCs with violations of the 2 times rule. Therefore, we proposed changes to the procedure codes assigned to these APCs in Addendum B to the proposed rule. We noted that Addendum B does not appear in the printed version of the **Federal Register** as part of the CY 2021 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 proposed 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 2021 included in the proposed rule were related to changes in costs of services that were observed in the CY 2019 claims data newly available for CY 2021 ratesetting. Addendum B to the CY 2021 OPPS/ASC proposed rule identified with a comment indicator ''CH'' those procedure codes for which we proposed a change to the APC assignment or SI, or both, that were initially assigned in the July 1, 2020 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*), which was the latest payment rate file for 2019 prior to issuance of the proposed rule.

3. APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we proposed to make for CY 2021 in the CY 2021 OPPS/ASC proposed rule, 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 the CY 2021 proposed rule, we found 18 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we proposed to make exceptions under the 2 times rule for CY 2021, and found that all of the 18 APCs we identified met the criteria for an exception to the 2 times rule based on the CY 2019 claims data available for the 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 a similar geometric mean costs and do not create a 2 time rule violation. Therefore, we only identified those APCs, including those with criteria-based costs, 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 9 of the proposed rule listed the 18 APCs for which we proposed to make an exception for 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 December 31, 2019. In the proposed rule, we stated that for the final rule with comment period, we intended to use claims data for dates of service between January 1, 2019, and December 31, 2019, that were processed on or before June 30, 2020, and updated CCRs, if available. We stated that the proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of the proposed rule could be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

Based on the updated final rule CY 2019 claims data used for this CY 2021 final rule with comment period, we found a total of 23 APCs with violations of the 2 times rule. Of these 23 total APCs, 18 were identified in the proposed rule and five are newly identified APCs. The five newly identified APCs with violations of the 2 times rule include the following:

- APC 5101 (Level 1 Strapping and Cast Application)
- APC 5161 (Level 1 ENT Procedures)
- APC 5593 (Level 3 Nuclear Medicine and Related Services)
- APC 5673 (Level 3 Pathology)
- APC 5734 (Level 4 Minor Procedures)

Although we did not receive any comments on Table 9 of the proposed rule, we did receive comments on APC assignments for specific HCPCS codes. The comments, and our responses, can be found in section III.D. (OPPS APC-Specific Policies) of this final rule with comment period.

After considering the public comments we received on APC assignments and our analysis of the CY 2019 costs from hospital claims and cost report data available for this CY 2021 final rule with comment period, we are finalizing our proposals with some modifications. Specifically, we are finalizing our proposal to except 18 of the 18 proposed APCs from the 2 times rule for CY 2021 and also excepting five additional APCs (APCs 5101, 5161, 5593, 5673, and 5734) for a total of 23 APCs.

In summary, Table 9 lists the 23 APCs that we are excepting from the 2 times rule for CY 2021 based on the criteria described earlier and a review of updated claims data for dates of service between January 1, 2019 and December 31, 2019, that were processed on or before June 30, 2020, and updated CCRs, if available. 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 generally accept the HOP Panel's recommendation because those recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates. The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

BILLING CODE 4120–01–P

TABLE 9: APC EXCEPTION TO THE 2 TIMES RULE FOR CY 2021

CY 2021 APC	CY 2021 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. 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 2020, 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 inpatient market basket increase adjusted for multifactor productivity. 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 payment amounts 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 2021, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this CY 2021 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 believe it is 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 believe that it is 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 define 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 believe 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 believe 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 will 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 will 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 identify the most appropriate payment rate for a service, we will assign the service to the New Technology APC with the cost band that includes its payment rate.

Accordingly, for CY 2021, we proposed to continue the policy we adopted in CY 2019 under which we will utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using multiple 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. Additional details on our policy is available in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58892 through 58893).

We did not receive any public comments on our proposal. Therefore, we are finalizing our proposal without modification.

3. Procedures Assigned to New Technology APC Groups for CY 2021

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 2021, we proposed to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been obtained (66 FR 59902). We received no public comments on our proposal. Therefore, we will implement our proposal without modification.

a. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS)

Currently, there are four CPT/HCPCS codes that describe magnetic resonance image-guided, high-intensity focused ultrasound (MRgFUS) procedures, three of which we proposed to continue to assign to standard APCs, and one that we proposed to continue to assign to a New Technology APC for CY 2021. These codes include CPT codes 0071T, 0072T, and 0398T, and HCPCS code C9734. CPT codes 0071T and 0072T describe procedures for the treatment of uterine fibroids, CPT code 0398T describes procedures for the treatment of essential tremor, and HCPCS code C9734 describes procedures for pain palliation for metastatic bone cancer.

For the procedure described by CPT code 0398T, we have identified 169 paid claims for CY 2019 with a geometric mean of $12,027.76. The number of claims for the service means that the procedure is no longer a low-volume new technology service, and we will use the geometric mean of the CY 2019 claims data to determine the cost of the service for its APC assignment. We reviewed the OPPS to determine whether CPT code 0398T could be assigned to a clinical APC. The most appropriate clinical APC family for the service would be the Neurostimulator and Related Procedures APC series (APCs 5461 through 5464). However, there was a large payment rate difference between Level 2 Neurostimulator and Related Procedures (APC 5462) with a payment rate of $6,169.27 and Level 3 Neurostimulator and Related Procedures (APC 5463) with a payment rate of $19,737.37. Based on the geometric mean cost of CPT code 0398T available for the CY 2021 OPPS/ASC proposed rule, we believe the payment rate for APC 5462 would be too low for CPT code 0398T since it is more than $6,000 less than the geometric mean cost for CPT code 0398T, and we believe the payment rate for APC 5463 would be too high since it is around $6,800 more than the geometric mean cost for CPT code 0398T.

In addition, given the significant difference in the payment rate between APC 5462 and 5463, we believed a restructuring of the APC family would be appropriate. We believed that creating an additional payment level between the two existing APC levels would allow for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Please refer to section III.D.1 for detailed explanation of our proposal to reorganize the Neurostimulator and Related Procedures APCs (APCs 5461–5464). Reorganizing the Neurostimulator and Related Procedures APCs would create a proposed Level 3 APC to be referred to as ''Proposed APC 5463'' with a payment rate of approximately $12,286 that is close to the geometric mean of CPT code 0398T which is approximately $12,798. The payment rate of proposed APC 5463 is representative of the cost of the service described by CPT code 0398T. Therefore, we proposed to reassign the service described by CPT code 0398T to the proposed new Level 3 APC for Neurostimulator and Related Procedures (Proposed APC 5463) for CY 2021.

Comment: Multiple commenters supported our proposal to reassign CPT code 0398T to proposed new APC 5463 (Level 3 Neurostimulator and Related Procedures).

Response: We appreciate the support of the commenters for our proposal.

The final rule data shows the payment rate for the new APC 5463 (Level 3 Neurostimulator and Related Procedures) is $11,236.21. While this payment rate is lower than what was calculated for the proposed rule, we continue to believe APC 5463 is an appropriate placement for CPT code 0398T. After our review of the public comments, we have decided to

implement our proposal to assign CPT code 0398T to APC 5463 for CY 2021. The final APC assignment, status indicator, and payment rate for CPT code 0398T are found in Table 10. We refer readers to Addendum B of the final rule for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 10: FINAL CY 2021 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRGFUS) PROCEDURE

CPT/ HCPCS Code	Long Descriptor	CY 2020 OPPS SI	CY 2020 OPPS APC	CY 2020 OPPS Payment Rate	Final CY 2021 OPPS SI	Final CY 2021 OPPS APC	Final CY 2021 OPPS Payment Rate
0398T	Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed.	S	1575	$12,500.50	J1	5463	Refer to OPPS Addendum B.

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. Pass-through payment status was granted for the Argus® II device under HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) beginning October 1, 2013, and this status expired on December 31, 2015. We note that after pass-through payment status expires for a medical device, the payment for the device is packaged into the payment for the associated surgical procedure. Consequently, for CY 2016, the device described by HCPCS code C1841 was assigned to OPPS status indicator ''N'' to indicate that payment for the device is packaged and included in the payment rate for the surgical procedure described by CPT code 0100T. For CY 2016, the procedure described by CPT code 0100T was assigned to New Technology APC 1599, with a payment rate of $95,000, which was the highest paying New Technology APC for that year. This payment included both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). However, stakeholders (including the device manufacturer and hospitals) believed that the CY 2016 payment rate for the procedure involving the Argus® II System was insufficient to cover the hospital cost of performing the procedure, which includes the cost of the retinal prosthesis at the retail price of approximately $145,000.

For CY 2017, analysis of the CY 2015 OPPS claims data used for the CY 2017 OPPS/ASC final rule with comment period showed 9 single claims (out of 13 total claims) for the procedure described by CPT code 0100T, with a geometric mean cost of approximately $142,003 based on claims submitted between January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on the CY 2015 OPPS claims data available for the final rule with comment period and our understanding of the Argus® II procedure, we reassigned the procedure described by CPT code 0100T from New Technology APC 1599 to New Technology APC 1906, with a final payment rate of $150,000.50 for CY 2017. We noted that this payment rate included the cost of both the surgical procedure (CPT code 0100T) and the retinal prosthesis device (HCPCS code C1841).

For CY 2018, the reported cost of the Argus® II procedure based on CY 2016 hospital outpatient claims data for 6 claims used for the CY 2018 OPPS/ASC final rule with comment period was approximately $94,455, which was more than $55,000 less than the payment rate for the procedure in CY 2017, but closer to the CY 2016 payment rate for the procedure. We noted that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS. In addition, the number of claims submitted has been very low and has not exceeded 10 claims within a single year. We believed that it is important to mitigate significant payment differences, especially shifts of several tens of thousands of dollars, while also basing payment rates on available cost information and claims data. In CY 2016, the payment rate for the Argus® II procedure was $95,000.50. The payment rate increased to $150,000.50 in CY 2017. For CY 2018, if we had established the payment rate based on updated final rule claims data, the

payment rate would have decreased to $95,000.50 for CY 2018, a decrease of $55,000 relative to CY 2017. We were concerned that these large fluctuations in payment could potentially create an access to care issue for the Argus® II procedure, and we wanted to establish a payment rate to mitigate the potential sharp decline in payment from CY 2017 to CY 2018.

In accordance with section 1833(t)(2)(B) of the Act, we must establish that services classified within each APC are comparable clinically and with respect to the use of resources. Therefore, for CY 2018, we used 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 payment rate for this procedure, despite the lower geometric mean costs available in the claims data used for the final rule with comment period. For CY 2018, we reassigned the Argus® II procedure to APC 1904 (New Technology—Level 50 ($115,001–$130,000)), which established a payment rate for the Argus® II procedure of $122,500.50, which was the arithmetic mean of the payment rates for the procedure for CY 2016 and CY 2017.

For CY 2019, the reported cost of the Argus® II procedure based on the geometric mean cost of 12 claims from the CY 2017 hospital outpatient claims data was approximately $171,865, which was approximately $49,364 more than the payment rate for the procedure for CY 2018. In the CY 2019 OPPS/ASC final rule with comment period, we continued to note that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS (83 FR 58897 through 58898). In addition, the number of claims submitted continued to be very low for the Argus® II procedure. We stated that we continued to believe that it is important to mitigate significant payment fluctuations for a procedure, especially shifts of several tens of thousands of dollars, while also basing payment rates on available cost information and claims data because we are concerned that large decreases in the payment rate could potentially create an access to care issue for the Argus® II procedure. In addition, we indicated that we wanted to establish a payment rate to mitigate the potential sharp increase in payment from CY 2018 to CY 2019, and potentially ensure a more stable payment rate in future years.

As discussed in section III.C.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58892 through 58893), we used 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 establish a payment rate that is more representative of the likely cost of the service. We stated that we believed the likely cost of the Argus® II procedure is higher than the geometric mean cost calculated from the claims data used for the CY 2018 OPPS/ASC final rule with comment period but lower than the geometric mean cost calculated from the claims data used for the CY 2019 OPPS/ASC final rule with comment period.

For CY 2019, we analyzed claims data for the Argus® II procedure using 3 years of available data from CY 2015 through CY 2017. These data included claims from the last year that the Argus® II received transitional device pass-through payments (CY 2015) and the first 2 years since device pass-through payment status for the Argus® II expired. We found that the geometric mean cost for the procedure was approximately $145,808, the arithmetic mean cost was approximately $151,367, and the median cost was approximately $151,266. As we do each year, we reviewed 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 OPPS payments remain appropriate for procedures like the Argus® II procedure as they transition into mainstream medical practice (77 FR 68314). We noted that the proposed payment rate included both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). For CY 2019, the estimated costs using all three potential statistical methods for determining APC assignment under the New Technology low-volume payment policy fell within the cost band of New Technology APC 1908, which is between $145,001 and $160,000. Therefore, we reassigned the Argus® II procedure (CPT code 0100T) to APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2019.

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 continues 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 continues 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. Therefore, for CY 2021, we proposed 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 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.

For CY 2021, 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 $148,807, the arithmetic mean cost to be approximately $154,504, and the median cost to be approximately $151,974. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fall within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000.

Accordingly, we proposed to maintain the assignment of the procedure

described by CPT code 0100T in APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a proposed payment rate of $152,500.50 for CY 2021. We note that the proposed payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). We refer readers to Addendum B to the proposed rule for the proposed payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

For our analysis for the CY 2021 final rule, 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. The slight differences from the calculations using the proposed rule data are caused by changes to the wage indexes of a few providers. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fall within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000.

We received no public comments on our proposal. Therefore, we are finalizing our proposal without modification. We will maintain the assignment of the procedure described by CPT code 0100T in APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2021. We note that the final payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). We refer readers to Addendum B to the final rule for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

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

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.[2] 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.'' [1]

Stakeholders, including the manufacturer of Luxturna®, recommended HCPCS code 67036 (*Vitrectomy, mechanical, pars plana approach*) for the administration of the gene therapy.[3] However, the manufacturer contends the administration is not currently described by any existing codes as HCPCS code 67036 (*Vitrectomy, mechanical, pars plana approach*) does not account for the administration itself. For HCPCS code J3398, a typical patient would receive a standard dose of 150 billion vector genomes, with an approximate payment rate of $432,480 (we refer readers to Addendum B of the CY 2021 OPPS/ASC Final Rule with comment period rule for the payment rate associated with HCPCS code J3398).

It is important to note that HCPCS code J3398 was granted drug pass-through status under the OPPS as of July 1, 2018 and is assigned status indicator ''G''. (We refer readers to Addendum D of the CY 2021 OPPS/ASC Final rule for the list of status indicator definitions for CY2021). HCPCS code J3398 is scheduled to have its drug pass-through status expire June 30, 2021, at which point the code would be packaged into the payment for any primary service with which it is billed when that primary service is assigned to a comprehensive APC (C–APC). A C–APC packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure. (For a full discussion and background on C–APCs, see section II.A.2.b). Based on information from the manufacturer of Luxturna, we believe that HCPCS code J3398 (*Injection, voretigene neparvovec-rzyl, 1 billion vector genomes*) would commonly be billed with the service described by HCPCS code 67036 (*Vitrectomy, mechanical, pars plana approach*), which describes the administration of the gene therapy, and which is assigned to a comprehensive APC, (APC 5492—Level 2 Intraocular Procedures). Thus, when its pass-through status expires, payment for HCPCS code J3398, the primary therapy, would be packaged into payment for HCPCS code 67036, its administration procedure.

CMS recognizes the need to accurately describe the unique administration procedure that is required to administer the therapy described by HCPCS code J3398. 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 believe that this new HCPCS code accurately describes the service associated with intraocular administration of HCPCS code J3398. CMS recognized that HCPCS code 67036 represents a similar procedure and process that approximates similar resource utilization that is associated with C97X1. CMS also recognized that it is not prudent for the code that describes the administration of this 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.

For CY 2021, we proposed to assign the services described by C97X1 to a new technology payment band based on the geometric mean cost for HCPCS code 67036. For the CY 2021 OPPS/ASC Proposed Rule, HCPCS code 67036 had a geometric mean cost of $3,407.84. Therefore, for the proposed rule we proposed to assign C97X1 to APC 1561—New Technology—Level 24 ($3001–$3500). See Table 11 for proposed descriptors and APC assignment.

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

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

TABLE 11: CY 2021 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C97X1 ASSIGNED TO NEW TECHNOLOGY APC

CY 2021 Placeholder HCPCS Code	Long Descriptor	Proposed CY 2021 OPPS SI	Proposed CY 2021 OPPS APC
C97X1	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1561

Comment: Commenters were largely supportive of our proposal to create a ''C'' code to describe the administration of J3398 and assign this newly created ''C'' code to New Technology APC 1561. Commenters largely advised CMS to finalize our proposal as proposed.

Response: We thank the commenters for their support on our proposal.

Comment: A small minority of commenters supported our approach to create a ''C'' code to describe the administration of J3398 and assign the newly created ''C'' code to a New Technology APC, but suggested alternate APC placements. The commenters' suggested alternate APC placements included APC 1562, based on a crosswalk of HCPCS code 67042, as well as APC 1564. Additionally, one commenter expressed uncertainty about when it would be appropriate to bill this code.

Response: We thank commenters for their feedback. Based on our review, we believe assigning C9770 to APC 1561 based on the geometric mean costs of HCPCS code 67036 is the most appropriate APC placement for this code. Our clinical review along with an overwhelming number of stakeholders have found that HCPCS code 67036 represents a similar procedure and process that approximates similar resource utilization that is associated with C9770. Additionally, regarding when C9770 may be billed, we remind stakeholders that HOPDs and ASCs may bill C9770 under Medicare in the HOPD and ASC settings when reasonable and necessary services are furnished. HCPCS C-codes are reportable only on Medicare OPPS and ASC claims. HOPDs and ASCs are expected to make appropriate coding decisions based on instructions and other information available to them (for example, federal regulations, CMS instructions, MAC instructions, etc.).

Based on the above discussion, for CY 2021 we are finalizing our proposal without modification to establish C9770 and assign the code to a New Technology APC based on the geometric mean cost of HCPCS code 67036. For CY 2021, HCPCS code 67036 has a geometric mean cost of $3,435.61. Therefore, as shown in Table 12, for CY 2021 we are finalizing our proposal to create C9770 (*Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent*) and assign this code to APC 1561 (New Technology—Level 24 ($3001–$3500)).

TABLE 12: CY 2021 FINALIZED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9770 ASSIGNED TO NEW TECHNOLOGY APC

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

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

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3–D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (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 proposed rule, 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 $4,051, the arithmetic mean cost to be approximately $4,067, and the median cost to be approximately $4,067. All three potential statistical methodologies used to estimate the cost of the service procedure fall within the cost band for New Technology APC 1563, with the estimated cost being between $4,001 and $4,500. Accordingly, we proposed to change the assignment of the HCPCS code C9751 to APC 1563 (New Technology—Level 26 ($4001–$4500)), with a proposed payment rate of $4,250.50 for CY 2021.

Comment: Two commenters did not support our proposal to assign HCPCS code C9751 to APC 1563 (New Technology—Level 26 ($4001–$4500)), with a proposed payment rate of $4,250.50 for CY 2021. The commenters stated that there was not enough claims data to change the APC assignment for HCPCS code C9751, and that HCPCS code C9751 should continue to be assigned to APC 1571 (New Technology—Level 34 ($8001–$8500)) with a proposed payment rate of $8,250.50.

Response: Because of the low number of claims for HCPCS C9751, we utilized our equitable adjustment authority under section 1833(t)(2)(E) of the Act for our final rule analysis to calculate the geometric mean, arithmetic mean, and median costs to calculate a payment rate to assign bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. Even though the number of claims are small, it is the best data available to determine the cost of the procedure. The assignment of HCPCS code C9751 to APC 1571 was based on guidance from the developer of the procedure and our best estimates of the cost of the procedure. The claims data, however limited, provide evidence of the cost of the procedure based on service utilization rather than having to forecast the cost of procedure.

Therefore, we decided to use our low-volume methodology for new technology services to determine the payment rate for the service described by HCPCS code C9751. We found for our final rule analysis that 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 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 within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Based on our updated analysis of the data, we have decided to implement our original proposal with modifications. For CY 2021, we will change the assignment of HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3501–$4000)) using our equitable adjustment authority under section 1833(t)(2)(E) of the Act and our low-volume new technology service methodology. The payment rate for C9751 will be based on the median cost of claims reported for the service since CY 2019 as the median cost is the highest estimated cost for the service, and the median provides a reasonable estimate of the midpoint cost of the three claims that have been paid for this service. Details regarding HCPCS code C9751 are shown in Table 13. We refer readers to Addendum B of the final rule for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 13: CY 2021 OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9751 ASSIGNED TO NEW TECHNOLOGY APC

CY 2021 HCPCS Code	Long Descriptor	Final CY 2021 OPPS SI	Final CY 2021 OPPS APC	Final CY 2021 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	Refer to OPPS Addendum B.

e. 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 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 frequency claims for CPT code 0503T was below the low-volume payment policy threshold for the proposed rule, and the number of single frequency 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 that 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–$1000)) 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 that were available for the CY 2021 OPPS/ASC proposed rule. Specifically, using the most recently available data for the CY 2021 OPPS/ASC proposed rule (that is, CY 2019), we identified 2,820 claims billed with CPT code 0503T including 415 single frequency claims. These totals were well above the threshold of 100 claims for a procedure to be evaluated using the new technology APC low-volume policy. Therefore, we proposed to use our standard methodology rather than the low-volume methodology we previously used to determine the cost of CPT code 0503T.

Our analysis of the available claims data for the proposed rule found the geometric mean cost for CPT code 0503T was approximately $851. Therefore, we proposed to reassign the service described by CPT code 0503T in order to adjust the payment rate to better reflect the cost for the service. While we considered proposing to reassign CPT code 0503T to APC 5724 (Level 4—Diagnostic Tests and Related Services), which had a proposed payment rate of around $903 based on the clinical and resource similarity to other services within that APC, we did not propose such reassignment because the payment rate for the new technology APC was closer to the geometric mean costs of CPT code 0503T. Nonetheless, we welcomed comments on whether reassignment to the clinical APC would be more appropriate. Therefore, we proposed to reassign the service described by CPT code 0503T to New Technology APC 1510 (New Technology—Level 10 ($801–$900)), with a proposed payment rate of $850.50 for CY 2021.

Comment: The developer of HeartFlow and multiple other commenters stated that the CPT code 0503T should not be assigned to New Technology APC 1510. Instead, they suggested that the HeartFlow procedure be assigned to APC 5593 (Level 3 Nuclear Medicine and Related Services) with a payment rate of around $1,270. The developer asserted that even though the payment for APC 5593 is substantially higher than the estimated cost of CPT code 0503T, the cost of the service fits reasonably well with the cost of other procedures assigned to APC 5593. The developer and other commenters also assert that the HeartFlow procedure has enough clinical similarity to other procedures currently assigned to the nuclear medicine and related services family. According to the developer and the other commenters, HeartFlow is comparable to other nuclear medicine procedures that are image analysis tests characterizing organ-specific function. The developer and the other commenters also note that cardiac CT procedures, which are used to identify coronary artery disease, are assigned to the nuclear medicine APC family. Finally, the developer cited two examples of procedures in the OPPS that are assigned to APCs where the procedure in question does not have clinical similarity to the other procedures in the APC.

Response: We disagree with the suggestion that CPT code 0503T should be assigned to APC 5593. The nuclear medicine and related procedures APC family describes diagnostic and therapeutic procedures, many of them involving imaging, where radiopharmaceuticals and other nuclear materials are critical supplies for the performance of the procedure. In comparison, HeartFlow is a computer algorithm that does not directly take images nor is it used on its own to generate a diagnosis for a patient. Instead, HeartFlow analyzes diagnostic images obtained through other medical procedures and assists with the interpretation of those diagnostic images to determine if a patient has coronary artery disease. There is little clinical similarity between the HeartFlow procedure and the procedures currently assigned to the nuclear medicine and related procedures, and we cannot support assigning CPT code 0503T to APC 5593.

Comment: Several commenters asserted the proposed payment rate for CPT code 0503T is too low and does not reflect their individual hospital's cost to use HeartFlow. Commenters mentioned cost issues, including the $1,100 list price for each individual HeartFlow service and the staff resources involved to transmit data to the HeartFlow analysis facility and review the results of the analyses performed by HeartFlow. Commenters suggested a range of potential payments for a HeartFlow procedure from $1,051 up to $1,451, and they encouraged CMS to use our equitable adjustment authority at section 1833(t)(2)(E) of the Act to establish a payment rate that would more closely reflect the costs the

commenters believe they are incurring to perform the HeartFlow procedure.

Response: For this CY 2021 OPPS/ASC final rule, we identified 3,188 claims billed with CPT code 0503T including 465 single frequency claims for CPT code 0503T. Our analysis has found that the geometric mean for CPT code 0503T is $804.35, and the geometric mean cost falls within the cost band for New Technology APC 1510 (New Technology—Level 10 ($801–$900)), which is similar to our results for the proposed rule. However, multiple commenters 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.

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. This is especially the case for allocating the cost of staff resources between the HeartFlow procedure and the coronary CT imaging services. Therefore, we feel 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. As mentioned earlier in this section, CPT code 0503T was assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50 for CY 2020, and we will continue to assign CPT code 0503T to New Technology APC 1511 for CY 2021.

After reviewing all of the public comments, we have decided to finalize our proposal with modification by using our equitable adjustment authority under section 1833(t)(2)(E) of the Act to continue to assign CPT code 0503T to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) for CY 2021. We refer readers to Addendum B of the final rule for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

f. 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. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50.

We had not received any claims billed with CPT codes 78431, 78432, or 78433 prior to the proposed rule. Therefore, we proposed to continue to assign these CPT codes to the same new technology APCs as they were in CY 2020. The proposed CY 2021 payment rate for the codes can be found in Addendum B to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

Comment: Several commenters expressed their support for our proposal to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50, and to assign CPT codes 78432 and 78433 to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50.

Response: We appreciate the support of the commenters for our proposal.

We have not received any claims for these services prior to this final rule. After our review of the public comments, we have decided to implement our proposal without modification. Table 14 reports code descriptors, status indicators, and APC assignments for these CPT codes.

TABLE 14: CY 2021 OPPS APC AND STATUS INDICATOR FOR CPT CODES 78431, 78432, AND 78433 ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2020 OPPS SI	OPPS CY 2020 APC	Final CY 2021 OPPS SI	Final OPPS CY 2021 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

g. Pathogen Test for Platelets/Rapid Bacterial Testing

For the July 2017 update, the HCPCS Workgroup established HCPCS code Q9987 (Pathogen(s) test for platelets) effective July 1, 2017. This new code and the OPPS APC assignment was announced in the July 2017 OPPS quarterly update CR (Transmittal 3783, Change Request 10122, dated May 26, 2017). Because HCPCS code Q9987 represented a test to identify bacterial or other pathogen contamination in blood platelets, we assigned the code to a new technology APC, specifically, New Technology APC 1493 (New Technology—Level 1C ($21–$30)) with a status indicator ''S'' and a payment rate of $25.50. We note that temporary HCPCS code Q9987 was subsequently deleted on December 31, 2017, and replaced with permanent HCPCS code P9100 (Pathogen(s) test for platelets) effective January 1, 2018. For the January 2018 update, we continued to assign the new code to the same APC and status indicator as its predecessor code. Specifically, we assigned HCPCS code P9100 to New Technology APC 1493 and status indicator ''S''. For the CY 2019 update, we made no change to the APC or status indicator assignment for P9100, however, for the CY 2020 update, we revised the APC assignment from New Technology APC 1493 to 1494 (New Technology—Level 1D ($31–$40) based on the latest claims data used to set the payment rates for CY 2020. We discussed the revision in the CY 2020 OPPS/ASC final rule (84 FR 61219) and indicated that the reassignment to APC 1494 appropriately reflected the cost of the service.

For the CY 2021 OPPS/ASC proposed rule, we stated that we believed we had sufficient claims data to reassign the code from a New Technology APC to a clinical APC, and noted that HCPCS code P9100 has been assigned to a New Technology APC for over 3 years. As stated in section III.D. (New Technology APCs), a service is paid under a New Technology APC until sufficient claims data have been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. We expect this to occur within two to three years from the time a new HCPCS code becomes effective. However, if we are able to collect sufficient claims data in less than 2 years, we would consider reassigning the service to an appropriate clinical APC. Since HCPCS code P9100 has been assigned to a new technology APC since July 2017, we believe that we should reassign the code to a clinical APC. Specifically, our claims data for the CY 2021 OPPS/ASC proposed rule showed a geometric mean cost of approximately $30 for HCPCS code P9100 based on 70 single claims (out of 1,835 total claims).

Based on resource cost and clinical homogeneity to the other services assigned to APC 5732 (Level 2 Minor Procedures), we believed that HCPCS code P9100 should be reassigned to clinical APC 5732, which had a geometric mean cost of approximately $33.

As we have stated several times since the implementation of the OPPS on August 1, 2000, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For the CY 2021 OPPS update, based on claims submitted between January 1, 2019, and December 30, 2019, our analysis of the latest claims data for the CY 2021 OPPS/ASC proposed rule supports reassigning HCPCS code P9100 to APC 5732 based on its clinical and resource homogeneity to the procedures and services in the APC. Therefore, we proposed to reassign HCPCS code P9100 from New Technology APC 1494 to clinical APC 5732 for CY 2021. The proposed CY 2021 payment rate for HCPCS code P9100 can be found in Addendum B to the CY 2021 OPPS/ASC proposed rule with comment period. In addition, we refer readers to Addendum D1 of the CY 2021 OPPS/ASC proposed rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

Comment: Two commenters expressed their support for our proposal.

Response: We appreciate the support of the commenters.

After reviewing the public comments for this proposal, we have decided to finalize our proposal without modification to reassign HCPCS code P9100 from New Technology APC 1494 to clinical APC 5732 for CY 2021. The final rule data supports our decision. The data show a geometric mean cost of approximately $31 for HCPCS code P9100 based on 75 single claims (out of 2,038 total claims), which is close to the payment rate of around $33 for APC 5732. The final CY 2021 payment rate for HCPCS code P9100 can be found in Addendum B to this CY 2021 OPPS/ASC final rule with comment period. In addition, we refer readers to Addendum D1 of this CY 2021 OPPS/ASC final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

h. 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, 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)).

No claims have been reported for HCPCS code C9758. Therefore, we proposed to continue to assign the service to New Technology APC 1589 for CY 2021. The proposed CY 2021 payment rate for V-Wave interatrial shunt procedure can be found in Addendum B to the proposed rule (which is available via the internet on the CMS website).

Comment: Three commenters including the developer of the V-Wave interatrial shunt procedure and the developer of the Corvia Medical interatrial shunt procedure requested that we delete HCPCS code C9758 because V-Wave has decided to no longer seek Medicare payment for its interatrial shunt procedure trial. The commenters believe that deleting HCPCS code C9758 will help prevent provider confusion with billing procedures describing the implementation of interatrial shunts.

Response: We do not intend to delete HCPCS code C9758 and believe that HCPCS code C9758 is sufficiently distinct from 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) that providers will not be confused about the appropriate service code to report.

Comment: Two commenters, including the developer of the V-Wave interatrial shunt procedure and the developer of the Corvia Medical interatrial shunt procedure, provided information about procedures that had comparable non-device service costs similar to the interatrial shunt procedures. One commenter suggested using the non-device cost of CPT code 93580 (Percutaneous transcatheter closure of congenital interatrial communication (that is, fontan fenestration, atrial septal defect) with implant) to approximate non-device costs for this procedure. The other commenter suggested that interatrial septal shunt procedures and percutaneous intracardiac closure procedures (CPTs 93580–93591) assigned to APC 5194 (Level 4—Endovascular Procedures) would describe the non-device costs of the interatrial shunt procedures.

Response: Based on the suggestions of the commenters, we averaged the non-device costs of the interatrial septal shunt procedures and percutaneous intracardiac closure procedures to estimate the non-device costs of the interatrial shunt procedures. Our estimate of the non-device costs of both the V-Wave interatrial shunt and Corvia Medical interatrial shunt procedures was around $6,500.

Comment: One commenter requested that we assign the V-Wave interatrial shunt procedure to a New Technology APC that reflects the cost of the procedure.

Response: We will assign the V-Wave interatrial shunt procedure to an APC that reasonably reflects the cost of the

procedure both when the device is implanted and when a placebo treatment occurs.

After reviewing the public comments and analyzing the cost of both the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure, we will finalize our proposal with modifications. We believe that similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure. 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. Therefore, we will reassign 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. Details about the HCPCS code and its APC assignment are shown in Table 15. The final CY 2021 payment rate for the V-Wave interatrial shunt procedure can be found in Addendum B to the final rule.

TABLE 15: CY 2021 OPPS APC AND STATUS INDICATOR FOR BLINDED INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	2021 OPPS SI	2021 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

i. Corvia Medical Interatrial Shunt Procedure

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

In the CY 2021 OPPS/ASC proposed rule, we proposed to assign HCPCS code C9760 to New Technology APC 1589. The proposed CY 2021 payment rate for Corvia Medical interatrial shunt procedure was found in Addendum B to the proposed rule (which is available via the internet on the CMS website).

Comment: Several commenters recommended revising the code descriptor for HCPCS code C9760 since the current descriptor inaccurately suggests that the code may include placebo control subjects who would not receive a shunt implant. The commenters specifically requested deleting the phrase ''or placebo control'' to eliminate any confusion on how this code should be reported.

Response: We agree with the commenters and have revised the long descriptor effective January 1, 2021 to read ''*Non-randomized, non-blinded procedure for NYHA Class II, III, IV heart failure; transcatheter implantation of interatrial shunt, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study.*'' The revised long descriptor for HCPCS code C9760 can also be found in the 2021 Alpha Numeric HCPCS File that is posted on the CMS HCPCS website, specifically, at *https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS*.

Comment: Two commenters, including the developer of the Corvia Medical interatrial shunt procedure and the developer of the V-Wave interatrial shunt procedure, provided information about procedures that had comparable non-device service costs similar to the interatrial shunt procedures. One commenter suggested using the non-device cost of CPT code 93580 (Percutaneous transcatheter closure of congenital interatrial communication (that is, fontan fenestration, atrial septal defect) with implant). The other commenter suggested that interatrial septal shunt procedures and percutaneous intracardiac closure procedures (CPTs 93580–93591) assigned to APC 5194 (Level 4—Endovascular Procedures) would describe the non-device costs of the interatrial shunt procedures.

Response: Based on the suggestions of the commenters, we averaged the non-device costs of the interatrial septal shunt procedures and percutaneous intracardiac closure procedures to estimate the non-device costs of the interatrial shunt procedures. Our estimated cost of the non-device costs of the both the Corvia Medical interatrial shunt and V-Wave interatrial shunt procedures was around $6,500.

Comment: Multiple commenters, including the developer of the Corvia Medical interatrial shunt procedure and the developer of the V-Wave interatrial shunt procedure, requested a higher payment rate for the procedure. Several commenters were concerned that the payment rate established for HCPCS

code C9760 would discourage providers from participating in the clinical trial, and the developer of the Corvia Medical interatrial shunt procedure stated that they had to assume all costs for the trial because of inadequate payment for the Corvia Medical interatrial shunt procedure. The developer of the V-Wave interatrial shunt procedure mentioned that HCPCS code C9760 is the service code they will use to report interatrial shunt procedures for their continuing study.

Response: As mentioned earlier, we decided to estimate the non-device costs of both the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure. We also plan to combine the non-device costs of the procedures with the costs of the interatrial shunt device to create a new estimate of the payment rate for HCPCS code C9760. HCPCS code C9760 can be used to report any non-randomized, non-blinded study related to the implantation of interatrial shunts where the device is implanted for every procedure reported.

After our review of the public comments, we intend to finalize our proposal with modifications. We believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure. 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, we will reassign HCPCS code C9760 to New Technology APC 1592. We also will implement the commenters' suggestion to modify the code descriptor for HCPCS code C9760 to remove the phrase ''or placebo control,'' from the descriptor. Details about the HCPCS code and its APC assignment are shown in Table 16. The final CY 2021 payment rate for the Corvia Medical interatrial shunt procedure can be found in Addendum B to the final rule.

TABLE 16: CY 2021 OPPS APC AND STATUS INDICATOR FOR NON-RANDOMIZED, NON-BLINDED INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	2021 OPPS SI	2021 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

j. 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 56mg 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–$1000)) with a payment rate of $950.50.

No Medicare OPPS claims had been reported for either HCPCS code G2082 or G2083 prior to the CY 2021 OPPS/ASC proposed rule. Therefore, we proposed to continue to assign HCPCS code G2082 to New Technology APC 1508 and to assign HCPCS code G2083 to New Technology APC 1511. The proposed CY 2021 payment rate for esketamine self-administration can be found in Addendum B to proposed rule (which is available via the internet on the CMS website).

Comment: Two commenters supported our proposal.

Response: We appreciate the support of the commenters.

We have not received any OPPS claims for this code prior to this final rule. After reviewing the public comments for this proposal, we have decided to implement our proposal without modification to assign HCPCS code G2082 to New Technology APC 1508 and to assign HCPCS code G2083 to New Technology APC 1511. Details about the HCPCS codes and their APC assignments are shown in Table 17. The final CY 2021 payment rate for esketamine self-administration can be found in Addendum B to the proposed rule (which is available via the internet on the CMS website).

TABLE 17: CY 2021 OPPS APC AND STATUS INDICATOR FOR ESKETAMINE SELF-ADMINISTRATION HCPCS CODES ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2020 OPPS SI	OPPS CY 2020 APC	Final CY 2021 OPPS SI	Final 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

D. APC-Specific Policies

1. Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus (APC 5692)

HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*) is a drug indicated ''for the treatment of ocular inflammation and pain following ophthalmic surgery.''[4] Stakeholders assert that this drug is administered through CPT code 0356T (*Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each*). Stakeholders also state the drug is inserted in a natural opening in the eyelid (called the punctum) and that the drug is designed to deliver a tapered dose of dexamethasone to the ocular surface for up to 30 days.

HCPCS code J1096 is currently on pass-through status and assigned to APC 9308 (Dexametha opth insert 0.1 mg) with status indicator ''G''. Please see section V.A.5. of this final rule with comment period for further information

[4] 1 Dextenza. FDA Package Insert. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208742s001lbl.pdf.*

regarding the pass-through status of J1096. CPT code 0356T is currently assigned to status indicator ''Q1,'' indicating conditionally packaged payment under the OPPS. Packaged payment applies if a code assigned status indicator ''Q1'' is billed on the same claim as a HCPCS code assigned status indicator ''S'', ''T'', or ''V''. Accordingly, based on the OPPS assigned status indicator, CPT code 0356T is assigned to payment indicator ''N1'' in the ASC setting, meaning a packaged service/item.

We refer readers to Addendum D1 of this final rule for a list of OPPS status indicators and their definitions, available via the internet on the CMS website. We also refer readers to Addendum AA for ASC payment indicator assignments and to Addendum DD1 for payment indicator definitions, available via the internet on the CMS website.

CPT code 0356T is assigned to APC 5692 (Level 2 Drug Administration). With regards to APCs 5691 (Level 1 Drug Administration) and APC 5692 (Level 2 Drug Administration), and as stated in the CY 2018 OPPS/ASC final rule with comment period, our overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule. To achieve this goal, it is important that we are consistent in our approach to packaging items and services under the established packaging categories. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, after consideration of the public comments we received, we finalized, without modification, the proposed policy to conditionally package low-cost drug administration services assigned to APC 5691 and APC 5692 (82 FR 52391 through 52393). Additionally, conditional packaging for Levels 1 and 2 Drug Administration services is consistent with the ancillary packaging policy that was adopted in the 2015 OPPS/ASC Final Rule with comment period (79 FR 66819 through 66822). Accordingly, in the CY 2021 OPPS/ASC Proposed Rule, we did not propose to change the OPPS status indicator assignment and APC placement, or ASC payment indicator assignment for CPT code 0356T.

Comment: Several commenters had concerns with continuing the same APC placement of APC 5692 for CPT code 0356T for CY 2021. Commenters generally advocated for separate payment for this CPT code through a change in status indicator. A few commenters suggested alternative APC placements, such as APC 5501 (Level 1 Extraocular, Repair, and Plastic Eye Procedures), APC 5693 (Level 3 Drug Administration), or APC 1504 (New Technology—Level 4), whereas other commenters requested a larger payment in general without a specific APC placement suggestion. Several stakeholders commented that the clinical importance of providing HCPCS code J1096 to patients is that it reduces ocular pain, inflammation, and reduces the burden of topical eyedrop application.

Additionally, providers stated that they usually perform CPT code 0356T to administer HCPCS code J1096 after the conclusion of ophthalmic surgeries. Most commonly, providers cited using CPT code 0356T to administer HCPCS code J1096 after surgeries such as cataract, glaucoma, and corneal surgeries. Commenters believe the procedure is a distinct surgical procedure that requires additional operating room time and resources. Commenters were concerned that the lack of increased or separate payment may reduce access to HCPCS J1096, particularly in the ASC setting.

Response: We thank commenters for their feedback. After careful consideration of the statements from commenters, we continue to believe that assignment of CPT code 0356T to APC 5692, with an OPPS status indicator ''Q1'' and an associated ASC payment indicator of ''N1'', is appropriate based on its clinical and resource use similarity to other services assigned to that APC. Commenters have stated that CPT code 0356T is performed during ophthalmic surgeries such as cataract surgeries. We do not find it appropriate to compare CPT code 0356T to that of an independent procedure when performed during these other ophthalmic surgeries. We continue to believe that conditionally packaging the payment for CPT code 0356T into the payment for these primary procedures is appropriate. This is consistent with our policy to conditionally package low-cost drug administration services assigned to APC 5691 (Level 1 Drug Administration) and APC 5692 (Level 2 Drug Administration). We note the policy established in the CY 2018 OPPS to conditionally package low-cost drug administration services assigned to APC 5691 and APC 5692 (82 FR 52391 through 52393). Also, we note that the conditional packaging of drug administration supports our overarching goal to make payments for all services paid under the OPPS and ASC payment system more consistent with those of a prospective payment system and less like those of a per-service fee schedule. We believe that packaging encourages efficiency and is an essential component of a prospective payment system, and that packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service is a fundamental part of the OPPS.

After consideration of the public comments, we are finalizing our proposed policy without modification to assign CPT code 0356T to APC 5692 (Level 2 Drug Administration) with OPPS status indicator ''Q1'' in the CY 2021 OPPS. Based on those assignments, we are also finalizing an ASC payment indicator for CPT code 0356T of ''N1'' under the CY 2021 ASC payment system.

2. Chimeric Antigen Receptor T-Cell (CAR T-Cell) Therapy (APCs 5694, 9035, 9194, and 9391)

Chimeric Antigen Receptor T-Cell (CAR T-cell) therapy is a cell-based gene therapy in which T-cells are collected and genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient's cancerous cells. The CAR T-cells are then administered to the patient to attack certain cancerous cells and the individual is observed for potential serious side effects that would require medical intervention. We refer readers to previous discussions in the OPPS/ASC final rules with comment period for background regarding the specific CAR T-cell products, in both the CY 2020 OPPS/ASC final rule with comment period (84 FR 61231 through 61234) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58904 through 58908). In addition, for discussion about CY 2021 OPPS payment policies for separately paid drugs with pass-through status expiring or continuing in CY 2021, please see sections V.A.4. and V.A.5. of this final rule with comment period.

The AMA created four Category III CPT codes that are related to CAR T-cell therapy, effective January 1, 2019. As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58904 through 58908) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61231 through 61234), we finalized our proposal to assign procedures described by CPT codes 0537T, 0538T, and 0539T to status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) to indicate that the services are not paid under the OPPS. The procedures described by CPT codes 0537T, 0538T, and 0539T describe the various steps required to collect and

prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological. We also finalized that the procedures described by CPT code 0540T would be assigned status indicator ''S'' (Procedure or Service, Not Discounted when Multiple) and APC 5694 (Level 4 Drug Administration) for CY 2019 and CY 2020, and made no proposal to change the assignment for CY 2021. Additionally, the National Uniform Billing Committee (NUBC) established CAR T-cell-related revenue codes and a value code to be reportable on Hospital Outpatient Department (HOPD) claims effective for claims received on or after April 1, 2019.

We made no specific proposal related to the CAR T-cell preparation codes, as described by CPT codes 0537T, 0538T, 0539T. As listed in Addendum B of the CY 2021 OPPS/ASC proposed rule, we proposed to continue to assign procedures described by these CPT codes, 0537T, 0538T, and 0539T, to status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) to indicate that the services are not paid under the OPPS. We proposed to continue to assign CPT code 0540T to status indicator ''S'' (Procedure or Service, Not Discounted when Multiple) and APC 5694 (Level IV Drug Administration).

Comment: Several commenters opposed our proposal to continue to assign status indicator ''B'' to CPT codes 0537T, 0538T, and 0539T for CY 2021. Commenters stated that a change in status indicator would be appropriate, with a preference for assigning CPT codes 0537T, 0538T, and 0539T to status indicator ''Q1''. Commenters believed that the procedures these CPT codes describe did not represent the steps required to manufacture the CAR T-cell product, as CMS has stated. Generally, those advocating for a change in status indicator contend this change is necessary to allow services furnished to the patient to be eligible for payment and for hospitals to be paid appropriately for the services they provide during each step of the CAR T-cell process. Commenters asked CMS to release new cost centers and to revise the instructions in MLN Matters Article SE19009 accordingly.

Response: We thank the commenters for their feedback. CMS does not believe that separate or packaged payment under the OPPS is necessary for the procedures described by CPT codes 0537T, 0538T, and 0539T for CY 2021. The procedures described by CPT codes 0537T, 0538T, and 0539T describe the various steps required to collect and prepare the genetically modified T-cells and Medicare does not generally pay separately for each step used to manufacture a drug or biological product. Additionally, we note that CAR T-cell therapy is a unique therapy approved as a biologic, with unique preparation procedures, that cannot be directly compared to other therapies or existing CPT codes. We note that the current HCPCS coding for the currently approved CAR T-cell therapies include leukapheresis and dose preparation procedures, as these services are included in the manufacturing of these biologicals. Therefore, payment for these services is incorporated into the drug codes. Please see Table 18 for HCPCS coding for CAR T-cell therapies.

TABLE 18. – CAR-T THERAPIES FINAL SI AND APC ASSIGNMENT FOR HCPCS CODES Q2041, Q2042, AND C9073 FOR CY 2021

HCPCS Code	Long Descriptor	Final CY 2021 APC
Q2041*	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9035
Q2042*	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9194
C9073*	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9391

*The final CY 2021 OPPS payment rates are located in Addendum B to this CY 2021 OPPS/ASC final rule.

We note that although there is no payment associated with CPT codes 0537T, 0538T, and 0539T for reasons stated previously, these codes can still be reported to CMS for tracking purposes. We thank commenters for their feedback related to cost centers and our guidance contained in MLN Matters Article SE19009.[5] We are not revising this document at this time, but appreciate the feedback from stakeholders. Also, we would like to note that HOPDs can bill Medicare for reasonable and necessary services that are otherwise payable under the OPPS, and we believe that the comments in reference to payment for services in settings not payable under the OPPS are outside the scope of this proposed rule. Accordingly, we are not revising the existing codes for CAR T-cell therapies to remove leukapheresis and dose preparation procedures, and we are not accepting the recommendations at this time to revise the status indicators for procedures described by CPT codes 0537T, 0538T, and 0539T. We will continue to evaluate and monitor payment for CAR T-cell therapies.

In summary, after consideration of the public comments we received, we are finalizing our proposal to assign status indicator ''B'' to CPT codes 0537T, 0538T, and 0539T for CY 2021. Additionally, we are continuing our policy from CY 2019 to assign status indicator ''S'' to CPT code 0540T for CY 2021. Table 19 below shows the final SI

[5] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19009.pdf.*

and APC assignments for HCPCS codes 0537T, 0538T, 0539T, and 0540T for CY 2021. For more information on CY 2021 OPPS final status indicators, APC assignments, and payment rates for HCPCS codes, including the CAR T-cell drug codes, we refer readers to Addendum B to this final rule with comment period. In addition, the status indicator definitions can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2021) to this final rule with comment period. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 19.-CAR-T PREPARATION AND ADMINISTRATION FINAL SI AND APC ASSIGNMENT FOR CPT CODES 0537T, 0538T, 0539T, AND 0540T FOR CY 2021

CPT Code	Long Descriptors	Proposed CY 2021 SI	Final CY 2021 SI	Final CY 2021 APC
0537T	Chimeric antigen receptor t-cell (car-t) therapy; harvesting of blood-derived t lymphocytes for development of genetically modified autologous car-t cells, per day	B	B	N/A
0538T	Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (eg, cryopreservation, storage)	B	B	N/A
0539T	Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration	B	B	N/A
0540T	Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous	S	S	5694

3. Eustachian Tube Balloon Dilation Procedure (APC 5165)

For the CY 2021 update, the CPT Editorial Panel established CPT codes 69705 and 69706 to describe the eustachian tube balloon dilation (ETBD) surgical procedure effective January 1, 2021. Prior to CY 2021, this surgical procedure was described by HCPCS code C9745.

In 2017, CMS received a new technology application for the transnasal flexible balloon catheter eustachian tube dilation surgical procedure, which is associated with the Acclarent Aera Eustachian Tube Balloon Dilation System, and established a new code, specifically, HCPCS code C9745. Based on the estimated cost for the bilateral placement of the eustachian tube balloon dilation devices, we assigned the code to APC 5165 (Level 5 ENT Procedures) with a payment rate of $4,130.94 effective July 1, 2017. We announced the new code, interim SI and APC assignments, and payment rate in the July 2017 quarterly update to the OPPS (Transmittal 3783, Change Request 10122, dated May 26, 2017).

For the CY 2018 update, we made no change to the APC assignment and continued to assign HCPCS code C9745 to APC 5165 with a payment rate of $4,338.79. We note that OPPS payment rates for the CY 2018 update were based on claims submitted between January 1, 2016 through December 30, 2016, that were processed on or before June 30, 2017. Because HCPCS code C9745 was established on July 1, 2017, we had no claims data for the procedure for use in CY 2018 ratesetting.

For the CY 2019 update, based on our analysis of the claims data, we made no change to the payment assignment and continued to assign HCPCS code C9745 to APC 5165. Specifically, our claims data showed a geometric mean cost of approximately $4,385 for HCPCS code C9745 based on 217 single claims (out of 218 total claims), which was consistent with the geometric mean cost of about $4,462 for APC 5165. Consequently, we retained HCPCS code C9745 in APC 5165.

Similarly, for CY 2020, we made no change to the APC assignment for HCPCS code C9745, consistent with our claims data. Based on claims submitted between January 1, 2018 through December 30, 2018, that were processed on or before June 30, 2019, the geometric mean cost for HCPCS code C9745 was approximately $4,547 based on 577 single claims (out of 582 total claims), which is in line with the geometric mean cost of $4,746 for APC 5165. Therefore, we maintained HCPCS code C9745 in APC 5165.

For CY 2021, we proposed to delete HCPCS code C9745 and assign CPT code 69705 to APC 5164 (Level 4 ENT Procedures) with a proposed OPPS payment of $2,776.63 and assign CPT code 69706 to APC 5165 (Level 5 ENT Procedures) with a proposed OPPS payment of $5,150.60. Because HCPCS code C9745 was on the ASC Covered Surgical Procedures list, we also proposed to assign CPT code 69705 to ASC payment indicator ''J8'' (device-intensive) with a proposed ASC payment of $1,564.17. Similarly, we proposed to assign CPT code 69706 to ASC payment indicator ''J8'' (device-intensive) with a proposed ASC payment of $3,453.23. We note that CPT codes 69705 and 69706 were listed as placeholder codes 697XX and 697X1, respectively, in OPPS Addendum B and ASC Addendum AA to the CY 2021 OPPS/ASC proposed rule.

Comment: Some commenters expressed concern with the proposed assignment to APC 5164 for CPT code 69705 (unilateral procedure) and stated that the proposed assignment will negatively affect the reimbursement of the procedure in the ASC setting, and ultimately decrease access to the procedure. They stated that the major portion of the procedure cost is the device used in the procedure, and reported the device cost is about $2,180, which is used for each procedure, regardless of whether it is a unilateral or bilateral procedure. In addition, they stated that in the CY 2021 Physician Fee Schedule (PFS) proposed rule, the

estimate for the non-facility payment for CPT codes 69705 and 69706 includes the full cost of the device kit, specifically, $3,092.81 for CPT code 69705 (unilateral) and $3,183.14 for CPT code 69706 (bilateral). To ensure fair reimbursement for unilateral procedures, they recommended that CMS assign both codes to APC 5165. However, in the event the recommendation is not accepted, they urged CMS to reconsider the device-intensive calculation for CPT code 69705 to reflect the cost of the device kit for unilateral procedures in the ASC setting; otherwise, commenters contended the ASC payment will be reduced below the actual cost of the device kit.

Response: Our medical advisors advised that the procedure described by CPT code 69705, while performed in the hospital outpatient setting, will primarily be performed in either the physician office or ASC setting. To ensure that Medicare beneficiaries have access to the procedure, we believe that it is appropriate to reassign CPT code 69705 (unilateral) to the same APC as CPT code 69706 (bilateral). That is, we believe that reassigning CPT code 69705 to APC 5165 will better reflect the device cost to perform this procedure either unilaterally or bilaterally when furnished in either the hospital outpatient or the ASC setting.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign CPT code 69706 to APC 5165. However, we are finalizing our proposal, with modification, to assign CPT code 69705 to APC 5165 for CY 2021. We note that we are deleting HCPCS code C9745 on December 31, 2020, since it has been replaced with CPT codes 69705 and 69706 effective January 1, 2021. Table 20 lists the final SI and APC assignments for the two codes. The final CY 2021 OPPS payment rate for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 20.— FINAL APC AND SI ASSIGNMENTS FOR CPT CODES 69705 and 69706 FOR CY 2021

CPT Code	CY 2021 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
C9745	N/A	Nasal endoscopy, surgical; balloon dilation of eustachian tube	D	N/A	D	N/A
69705	697XX	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral	J1	5164	J1	5165
69706	697X1	Nasopharyngoscopy, surgical, with dilation of eustachian tube (that is, balloon dilation); bilateral	J1	5165	J1	5165

4. Eye-Movement Analysis Without Spatial Calibration (APC 5734)

For July 2020, the CPT Editorial Panel established a new CPT code 0615T, effective July 1, 2020, to describe eye-movement analysis without spatial calibration that involves the use of the EyeBOX system as an aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI). The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion within one week of head injury in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion. A negative EyeBOX classification may correspond to eye movement that is consistent with a lack of concussion. A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without a concussion.

We included this new code in the July quarterly OPPS update CR (Transmittal 10224, Change Request 11814, dated July 15, 2020). Effective July 1, 2020, we assigned CPT code 0615T to APC 5734 (Level 4 Minor Procedures) with status indicator ''Q1'' (conditionally packaged) and a CY 2020 OPPS payment rate of $109.03 as reflected in the Addendum B to the July 2020 quarterly OPPS update.

As displayed in the Addendum B to the 2021 ASC/OPPS Proposed Rule, we proposed to assign 0615T to APC 5734 with status indicator ''Q1'' and a proposed OPPS payment rate of $113.23 for CY 2021. We also assigned this code to comment indicator ''NP'' in Addendum B to indicate that this code is new effective July 1, 2020, and that public comments would be accepted on its proposed status indicator assignment.

Comment: A commenter was concerned that what they believed was a lack of adequate, separate payment would strongly discourage hospitals from providing this important new technology to their patients. The commenter urged CMS to: (1) Change the APC assignment of CPT code 0615T to APC 5722 (Level 2 Diagnostic Tests and Related Services) with a proposed OPPS payment rate of $269.85 and (2) change the status indicator for the service to ''S'' to allow for a separate payment under the OPPS.

The commenter asked that CMS assign CPT code 0615T to APC 5722 for two reasons: (1) The current and proposed reimbursement rates for services in APC 5734 are inadequate to pay hospitals appropriately for the costs

of furnishing the EyeBOX test; and (2) the clinical characteristics and resources associated with 0615T are more similar to codes in APC 5722 than services in APC 5734.

Response: We note that OPPS payment rates for the CY 2021 final rule are based on claims submitted between January 1, 2019 through December 31, 2019, that were processed on or before June 30, 2020. Because HCPCS code 0615T was established on July 1, 2020, we did not have claims data for CY 2021 OPPS ratesetting.

In terms of the resource similarity of CPT code 0615T to other eye-related diagnostic tests that are assigned to APC 5722, such as CPT code 92240 (Indocyanine-green angiography (includes multiframe imaging) with interpretation and report, unilateral or bilateral) and CPT code 92242 (Fluorescein angiography and indocyanine-green angiography (includes multiframe imaging) performed at the same patient encounter with interpretation and report, unilateral or bilateral), the EyeBOX test does not involve an injection. Therefore, we do not believe that the resource costs for CPT code 0615T are comparable to other eye-related diagnostic tests in APC 5722. Updated claims data for this final rule with comment period indicate that the geometric mean cost of APC 5722 is $257.61, while the geometric mean cost of APC 5734 is $109.05. However, because there were no claims for CPT code 0615T in the CY 2021 updated data set, we have decided not to make any changes to the proposed CY 2021 APC assignment and to assign the code to the APC with the lower geometric mean cost. Based on these findings, we believe that maintaining assignment of APC 5734 for CPT code 0615T for CY 2021 is appropriate.

In response to the comment related to status indicator ''Q1'', we note that status indicator ''Q1'' listed in the OPPS Addendum D1 to this 2021 OPPS/ASC final rule with comment period allows for up to three potential payment assignments:

- Packaged APC payment if billed on the same claim as a HCPCS code assigned status indicator ''S'', ''T'', or ''V''; or
- Composite APC payment if billed with specific combinations of services based on OPPS composite-specific payment criteria. Payment is packaged into a single payment for specific combinations of services; or
- In other circumstances, payment is made through a separate APC payment.

Depending on the procedures submitted on the claim and whether the procedure described by CPT code 0615T is performed with any other services on the same day, the procedure described by CPT code 0615T may be paid separately through an APC (in this case APC 5734) or receive packaged payment when accompanying a more significant procedure that is reported on the claim. Based on the nature of this procedure, which may be performed by itself or with other procedures on the same claim, we believe that the continued assignment of status indicator ''Q1'' is appropriate for the procedure described by CPT code 0615T.

As we do every year, we will reevaluate the APC assignment for CPT code 0615T for the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to assign CPT code 0615T to status indicator ''Q1'' and APC 5734 for CY 2021. The final CY 2021 payment rate for the CPT code can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

5. Gynecologic Procedures and Services (APC 5416)

For CY 2021, we proposed to continue to assign CPT code 0404T (Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency) to APC 5416 (Level 6 Gynecologic Procedures) with a proposed payment of $6,929.92. CPT code 0404T describes the procedure associated with the Sonata System, which is used for the treatment of symptomatic uterine fibroids. We note that CPT code 0404T was effective on January 1, 2016.

Comment: Several commenters stated that the proposed APC payment rate is insufficient to compensate hospital outpatient departments for the resources needed to perform the procedure. They indicated that the combined cost of the single-use handpiece, capital equipment, supplies, screening labs, anesthesia, medication, and facility and personnel overhead are higher than the OPPS payment rate. The commenters asserted that the proposed payment will significantly limit patient access to the procedure because it does not cover the total cost of the surgery. One commenter acknowledged that the proposed payment appropriately reimburses for hospital outpatient costs, but believed the ASC proposed payment of $2,763.68 significantly underpays for the procedure in the ASC setting. The same commenter explained that CMS has no claims data for the code because the procedure is rarely performed on Medicare patients, and also due to the device's commercial availability. Although the CPT code was effective January 2016, because of manufacturing issues, the company was unable to submit their FDA application until a couple of years later. The company eventually received market approval from the FDA in August 2018 and the device was commercially available in late summer/early Fall 2019. To ensure access to the procedure, the commenters suggested reassigning CPT code 0404T to either:

- APC 5362 (Level 2 Laparoscopy and Related Services) with a proposed payment rate of $9,041.94 because the procedure cost is similar to these procedures:
  - CPT code 43210 (Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed);
  - CPT code 50593 (Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy);
  - CPT code 58546 (Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g); and
  - CPT code 58674 (Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency), or
- APC 5376 (Level 6 Urology and Related Services) with a proposed payment of $8,395.62 because the procedure cost is similar to these procedures:
  - CPT code 55873 (Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring); and
  - CPT code 0421T (Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)).

Response: For CY 2021, OPPS payments are developed based on claims submitted between January 1, 2019 through December 31, 2019, and processed through June 30, 2020. For this final rule with comment period, we have no claims data for this code. As explained by a commenter, CPT code 0404T is a procedure not commonly performed on Medicare beneficiaries. In addition, we disagree with the commenters' assessment that CPT code

0404T is similar to the codes they have referenced. CPT code 0404T is not a urology, kidney, or esophagogastroduodenum-related procedure, nor is it a laparoscopy procedure. We believe that the code is appropriately placed in APC 5416 based on its clinical homogeneity and resource costs to the other gynecology-related procedures in the APC. We agree with the commenter who believed that the proposed OPPS payment for the service is adequate to cover the cost of providing the procedure in the hospital outpatient setting.

For a discussion on the ASC payment for CPT code 0404T, we refer readers to the ASC payment section of this CY 2021 OPPS/ASC final rule with comment period, specifically, section XIII. (Updates to the Ambulatory Surgical Center (ASC) Payment System).

Comment: Some commenters suggested designating CPT code 0404T as device-intensive under the OPPS so that facilities can be paid appropriately for furnishing the procedure in the ASC setting. They also recommended establishing an offset percentage that is higher than the default 31 percent based on invoice pricing data provided to CMS by the device manufacturer so that payment for the procedure in the ASC setting includes the cost of the device.

Response: We refer readers to section IV. B. (Device-Intensive Procedures) for the discussion related to the OPPS device offset for the code. For a discussion of the ASC procedures designed as device intensive, please see section XIII.C.1. of this final rule with comment period.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, and assigning CPT code 0404T to APC 5416 for CY 2021. The final CY 2021 OPPS payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) assignments for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

6. Hemodialysis Arteriovenous Fistula (AVF) Procedures (APC 5194)

For CY 2019, based on two new technology applications received by CMS for hemodialysis arteriovenous fistula creation, CMS established two new HCPCS codes to describe the surgical procedure associated with the two technologies since no specific CPT codes exist. Specifically, CMS established HCPCS code C9754 for the Ellipsys System and C9755 for the WavelinQ System effective January 1, 2019. The complete descriptors for both codes are as follows:

- C9754 (Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (*e.g.,* transluminal balloon angioplasty, coil embolization, when performed))
- C9755 (Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (*e.g.,* vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed)

Both HCPCS codes were assigned to APC 5193 (Level 3 Endovascular Procedures) with a payment rate of $9,669.04 for CY 2019. For CY 2020, as discussed in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61246), we revised the assignment for both codes to APC 5194 (Level 4 Endovascular Procedures) with a payment rate of $15,939.97.

For the July 2020 update, we deleted HCPCS codes C9754 and C9755 on June 30, 2020, and replaced them with G-codes effective July 1, 2020 to enable physicians to report the procedures when performed in the physician office setting. Specifically, we deleted HCPCS code C9754 on June 30, 2020 because it was replaced with HCPCS code G2170 effective July 1, 2020. Similarly, we deleted HCPCS code C9755 on June 30, 2020 because it was replaced with HCPCS code G2171 effective July 1, 2020. Below are the complete descriptors for HCPCS codes G2170 and G2171:

- G2170 (Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (*e.g.,* transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed)
- G2171 (Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (*e.g.,* vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed)

We deleted the C-codes based on concerns from stakeholders that physicians are reluctant to perform the Ellipsys procedure in the physician office setting without a specific HCPCS code. With the deletion of the C-codes, we crosswalked the APC assignment and payment rate for the C-codes to the new G-codes. We note that C-codes are not reportable on Medicare physician office claims, whereas G-codes are reportable on physician office, hospital outpatient, and ambulatory surgical center claims.

For CY 2021, we proposed to reassign HCPCS code G2170 (Ellipsys System) from APC 5194 to APC 5193 (Level 3 Endovascular Procedures) with a proposed payment rate of $10,222.32, based on the latest claims data. Specifically, based on the predecessor HCPCS code C9754, our claims data for the proposed rule showed a HCPCS geometric mean cost of approximately $10,068 based on 57 single claims (out of 57 total claims), which is comparable to the geometric mean cost of about $9,850 for APC 5193 rather than the geometric mean cost of approximately $15,753 for APC 5194. In addition, we proposed to maintain the assignment to APC 5194 for G2171 (WavelinQ System) because our claims data for the proposed rule, based on predecessor HCPCS code C9755, showed a geometric mean cost of about $13,519 based on 182 single claims (out of 186 total claims), which is consistent with the geometric mean cost of about $15,753 for APC 5194.

At the August 31, 2020 HOP Panel Meeting, a presenter requested that we maintain the assignment for the WavelinQ procedure (HCPCS code G2170) to APC 5194. The presenter stated that the number of single claims is too small to support a reassignment to APC 5193. Based on the discussion during the meeting, the HOP Panel recommended that CMS maintain the assignment of HCPCS code G2170 in APC 5194 for CY 2021.

Comment: Most commenters opposed the reassignment to APC 5193 for G2170 and suggested that we continue to assign the code to APC 5194 based on the HOP Panel recommendation at the August 31, 2020 meeting. They argued that the number of single claims on which to base the reassignment is too low, and recommended that CMS maintain the current assignment to APC 5194 until more claims data can be gathered for appropriate APC assignment. However, one commenter suggested that we reassign HCPCS code G2170 to APC 5193 based on the 1-year

claims data, and stated that the HOP Panel recommendation to maintain the assignment to APC 5194 is not supported by the hospital claims data. This same commenter suggested that the 1-year hospital claims data does support maintaining HCPCS code G2171 in APC 5194. One commenter reported that reassigning the code to APC 5193 would be insufficient to cover the cost of the procedure in the ASC setting. According to the commenter, the proposed CY 2021 ASC payment for HCPCS code G2170 is $5,887.63, which does not cover the cost of the $6,000 device used in the procedure.

Response: As noted above, HCPCS codes G2170 and G2171 are two technologies used for hemodialysis arteriovenous fistula creation. We note that these procedures are furnished to dialysis patients with chronic kidney disease, which affects thousands of Medicare beneficiaries. To ensure Medicare access to these dialysis-related procedures in both the hospital outpatient and ASC settings, which is in line with various HHS initiatives, including the HHS Initiative on ''Advancing American Kidney Health'', we believe that we should maintain both codes in APC 5194 for CY 2021. In addition, maintaining the assignment to APC 5194 for both codes is consistent with the HOP Panel's recommendation at the August 31, 2020 meeting. Moreover, given the low frequency of claims for HCPCS code G2170 (predecessor HCPCS code C9754), we also reviewed the arithmetic mean and median costs for the code, as we would do for New Technology APC services with fewer than 100 claims. We noted that HCPCS code G2170 and HCPCS code G2171 (predecessor HCPCS code C9755) have very similar median costs, and combined with the low claims data for HCPCS code G2170, the fact that this is the first year of claims data available for these services, as well as the public comments and the HOP Panel recommendation, we believe that it would be inappropriate to assign these two services to different APCs. As a result, we are using 1833(t)(2)(E) to assign HCPCS code G2170 (predecessor HCPCS code C9754) to APC 5194 because its cost is similar to HCPCS code G2171 and both procedures are performed for ESRD patients that need dialysis. Therefore, we are using 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 assign G2170 to APC 5194. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS, and continue to monitor the updated claims data for these codes as they become available.

In summary, after consideration of the public comments, we are finalizing our proposal with modification. Specifically, we are finalizing our APC proposal to assign HCPCS code G2171 to APC 5194, and assigning HCPCS code G2170 to APC 5194 for CY 2021 using our equitable adjustment authority. The final CY 2021 OPPS payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

7. Health and Behavior Services (APC 5822)

For CY 2021, we proposed to revise the payment rate associated with APC 5822 (Level 2 Health and Behavior Services) from $78.54 to $75.26 based on the latest OPPS claims data.

Comment: Some commenters expressed concern with the proposed payment decrease for APC 5822. Several commenters noted that the APC includes a number of needed behavioral health services. Those services include group therapy as well as outpatient programs that are less intensive than PHPs but are still important for those who may not need a full day of treatment all week, but who still require substantial support. The commenters noted that the proposed payment rate decrease of $3.10 per group per patient equates to a reduction of approximately $9.30 per patient per day and that group psychotherapy makes up well over 95 percent of the services provided by programs under Hospital Partial Hospitalization Services. The commenters urged CMS to reexamine the data used in developing the payment for APC 5822. Other commenters requested we reconsider the proposed 4.2 percent payment rate decrease for APC 5822.

Response: The CY 2021 OPPS payment rates are based on claims submitted January 1, 2019 through December 31, 2019, processed through June 30, 2020. Based on our evaluation of the claims data for this final rule with comment period, the geometric mean cost of APC 5822 is approximately $72.94 based on 1,069,622 single claims (out of 1,085,044 total claims).

Based on our review, we have no reason to believe that the services are miscoded. In addition, based on our analysis of the CY 2021 claims data used for this final rule with comment period, we are unable to determine whether facilities are misreporting the services. It is generally not our policy to judge the accuracy of provider coding and charging for purposes of ratesetting. We rely on providers to accurately report the use of HCPCS codes in accordance with their code descriptors and CPT and CMS instructions, and to report services on claims and charges and costs for the services on their Medicare hospital cost report appropriately. Also, we generally do not specify the methodologies that providers use to set charges for this or any other service. Furthermore, we state in Chapter 4 of the Medicare Claims Processing Manual that it is extremely important that facilities report all HCPCS codes consistent with their descriptors; CPT and/or CMS instructions; and correct coding principles, and that all charges for services they furnish, whether payment for the services is made separately paid or is packaged, are reported to enable CMS to establish future ratesetting for OPPS services. Therefore, we are finalizing our proposal, without modification, for APC 5822.

8. High-Density Lipoprotein (HDL) Therapy (APC 5243)

For CY 2021, we proposed to continue to assign CPT code 0342T (Therapeutic apheresis with selective hdl delipidation and plasma reinfusion) to APC 5243 (Level 3 Blood Product Exchange and Related Services) with a proposed payment of $4,074.81.

Comment: One commenter reported that their company expects FDA Humanitarian Device Exemption approval in Q4 of 2020 for its ''PDS–2 System,'' an HDL Therapy system that is designed to reduce plaque in coronary arteries and increase HDL levels in patients diagnosed with homozygous familial hypercholesterolemia (HoFH). The commenter indicated that the code associated with their device is CPT code 0342T. The commenter stated that they intend to apply to CMS for a new technology APC in early 2021. According to the commenter, the cost of the therapy described by CPT code 0342T is $77,100. The commenter suggested that the proposed payment of $4,074.81 for APC 5243 (Level 3 Blood Product Exchange and Related Services) and $37,470.54 for APC 5244 (Level 4 Blood Product Exchange and Related Services) does not capture the cost of providing the therapy, and

consequently, the company intends to submit an application for a new technology APC in 2021.

Response: We thank the commenter for making us aware of their intent to submit a new technology APC application. Once we receive the application, we will review it and make the appropriate determination.

9. Imaging With and Without Contrast (APCs 5523, 5524, 5571, 5572, and 5573)

a. Cardiac Computed Tomography (CT) (APC 5571)

For CY 2021, we proposed to continue to assign the following cardiac CT exam codes to APC 5571 (Level 1 Imaging with Contrast) with a proposed payment rate of $181.41.

- 75572 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3d image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed))
- 75573 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3d image postprocessing, assessment of lv cardiac function, rv structure and function and evaluation of venous structures, if performed))
- 75574 (Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3d image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed))

We received many comments related to our proposed payment for the cardiac CT codes. Below is a summary of the public comments and our responses to the comments.

Comment: Many commenters opposed the assignment of CPT codes 75572, 75573, and 75574, which are the codes that describe cardiac CT exams, to APC 5571. They stated that the proposed CY 2021 OPPS payment rate of $181.41 for APC 5571 is inadequate to cover the total cost of providing the service. They also indicated that the proposed payment will result in decreased reimbursement for cardiac CT for the fourth consecutive year. Commenters were particularly concerned with the proposed payment for CPT code 75574, for which, according to the commenters, the payment rate has decreased by 30 percent over the past 3 years. They reported that the cardiac CT exam is a complex exam and more time-consuming to perform and interpret than any other type of contrast CT scan. They also believe that the resource costs required to perform cardiac CT scans are similar to the tests that are assigned to APC 5573 rather than APC 5571. They noted that the low payment for the test limits patient access, and requested that CMS take action to increase reimbursement to levels in line with the actual testing costs. The commenters requested an APC reassignment for all three codes. Specifically, the commenters suggested reassigning CPT codes 75572 and 75573 to APC 5572 and CPT code 75574 to APC 5573. Most of the commenters reported that cardiac CT scans are more resource intensive than other CT and x-ray scans and are similar to other cardiac stress imaging modalities like nuclear stress testing; therefore, cardiac CT scans should be reimbursed accordingly.

Another commenter reported that the test described by CPT code 75574 generally takes about four times longer to perform than a CT scan of the thorax with contrast that is described by CPT code 71260 (Computed tomography, thorax; with contrast material(s)) and also assigned to APC 5571. The commenters noted that based on clinical indications and performance/interpretation, CPT code 75574 is very much like a SPECT nuclear scan, which is described by CPT code 78452 (Myocardial perfusion imaging, tomographic (spect) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection) and assigned to APC 5593 (Level 3 Nuclear Medicine and Related Services) with a proposed payment rate of $1,336.28, rather than a CT scan of the thorax. The commenters further asserted that cardiac CT scans prior to invasive angiography lead to lower utilization of cardiac catheterization, PCI, and costs.

Response: Payments under the OPPS are based on our analysis of the latest available claims and cost report data submitted to Medicare. We have many years of claims data for CPT codes 75572, 75573, and 75574. The AMA established specific CPT codes for cardiac CT services beginning in 2006 when they were first described by Category III codes. The Category III CPT codes were subsequently deleted on December 31, 2009, and replaced with Category I CPT codes 75572, 75573, and 75574, which were effective on January 1, 2010. Because OPPS payments are updated every year based on our analysis of the latest claims data, the payment rates have varied each year based on that data.

For CY 2021, OPPS payments are based on claims submitted between January 1, 2019 through December 31, 2019, that were processed on or before June 30, 2020. Based on our evaluation of the claims data for this final rule, the geometric mean costs for the cardiac CT scan codes range between $157 and $196. Specifically, as shown in Table 21, our analysis show a geometric mean cost of approximately $157 for CPT code 75572 based on 14,262 single claims, approximately $194 for CPT code 75573 based on 317 single claims, and approximately $196 for CPT code 75574 based on 32,556 single claims. Based on the geometric mean costs for these codes, we do not believe that CPT codes 75572, 75573, and 75574 utilize similar resources as the exams assigned to APC 5572 or APC 5573. The geometric mean costs for the tests placed in APC 5571 range between $157 and $196, while the tests in APC 5572 range between $265 and $510, and for APC 5573, between $534 and $961.

In addition, our data shows that the resources associated with cardiac CT exams are unlike those of single photon emission CT (SPECT) nuclear scans (CPT code 78452). As listed in Table 21, our data shows that SPECT nuclear scans are more often performed on Medicare patients than cardiac CT exams. Specifically, CPT code 78452 shows a geometric mean cost of approximately $1,288 based on 591,344 single claims compared to 47,135 single claims for cardiac CT (CPT codes 75572, 75573, and 75574). Although the commenters have indicated that the resource costs associated with cardiac CT exams are similar to SPECT nuclear scans, our analysis of the latest OPPS claims data reveal otherwise. Similarly, we found the same results for nuclear stress tests (CPT codes 93350 and 93351). That is, that the estimated resource costs to perform nuclear stress tests are higher than for cardiac CT. As noted in Table 21, the geometric mean costs for nuclear stress test range between $529 and $671 based on 92,670 single claims for CPT codes 93350 and 93351, while the geometric mean costs for the cardiac CT codes range between $157 and $196.

TABLE 21.—GEOMETRIC MEAN COSTS FOR CARDIAC CT, SPECT, AND STRESS TESTS

Exam	CPT Code	Short Descriptor	APC	Final Rule 2021 Single Claims Frequency	Final Rule 2021 Geometric Mean Cost
Cardiac CT	75572	Ct hrt w/3d image	5571	14,262	$157.27
Cardiac CT	75573	Ct hrt w/3d image congen	5571	317	$193.52
Cardiac CT	75574	Ct angio hrt w/3d image	5571	32,556	$195.72
SPECT	78452	Ht muscle image spect mult	5593	591,344	$1,287.68
Stress Echocardiogram	93350	Stress tte only	5524	44,048	$670.93
Stress Echocardiogram	93351	Stress tte complete	5524	48,622	$528.91

We believe our claims data accurately reflects the resources associated with providing cardiac CT exams in the HOPD setting. Because CPT codes 75572, 75573, and 5574 have been active for some time now, we have no reason to believe that HOPDs have issues with coding or reporting these exams correctly. We believe that HOPDs have had sufficient time to learn how to code and report these services accurately using the Category I CPT codes that were established in 2010.

Moreover, we believe that we have substantial claims data for the cardiac CT services upon which to base the CY 2021 final OPPS payment rates. As noted in Table 22, the total number of claims for these codes has increased each year. The historical OPPS payments for cardiac CT services does not appear to have affected Medicare beneficiaries' access to these services. Given that these services have been paid under the OPPS for many years, with payments based on the latest hospital claims and Medicare cost report data, we believe we are providing a stable and consistent payment methodology that appropriately reflects the hospital resources required for cardiac CT.

TABLE 22.—VOLUME FOR CARDIAC CT EXAMS FROM CY 2014 THROUGH CY 2021

CPT Code	CY 2014 OPPS Single Claims Frequency	CY 2015 OPPS Single Claims Frequency	CY 2016 OPPS Single Claims Frequency	CY 2017 OPPS Single Claims Frequency	CY 2018 OPPS Single Claims Frequency	CY 2019 OPPS Single Claims Frequency	CY 2020 OPPS Single Claims Frequency	CY 2021 OPPS Single Claims Frequency
75572	3,090	3,855	4,188	4,905	5,703	7,256	12,299	14,262
75573	225	164	275	256	177	143	323	317
75574	11,418	10,820	10,481	11,154	12,848	14,785	25,434	32,556

Further, reassigning CPT codes 75572 and 75573 from APC 5571 to APC 5572, and CPT code 75574 from APC 5571 to APC 5573 would potentially significantly overpay for the exams. As noted in Table 23, which shows the percent change for each code, reassigning the codes to APC 5572 and APC 5573 would pay at a rate that is two and three times the estimated cost of the service as reflected in the hospital outpatient claims data, and we do not believe that overpaying for the exams is appropriate. We note that we monitor our claims data every year to assess the appropriateness of the APC assignments for all services under the hospital OPPS.

TABLE 23.—PERCENT CHANGE FOR THE CARDIAC CT EXAM CODES BASED ON COMMENTERS SUGGESTED APC ASSIGNMENTS

CPT Code	Proposed CY 2021 OPPS APC	Proposed CY 2021 OPPS APC Title	Proposed CY 2021 OPPS Payment Rate	Commenters Suggested Proposed CY 2021 OPPS APC	Commenters Suggested Proposed CY 2021 OPPS APC Title	Commenters Suggested Proposed CY 2021 OPPS Payment Rate	**Percent Change**
75572	5571	Level 1 Imaging with Contrast	$181.41	5572	Level 2 Imaging with Contrast	$375.33	**107%**
75573	5571	Level 1 Imaging with Contrast	$181.41	5572	Level 2 Imaging with Contrast	$375.33	**107%**
75574	5571	Level 1 Imaging with Contrast	$181.41	5573	Level 3 Imaging with Contrast	$722.74	**298%**

Every year, since the implementation of the OPPS on August 1, 2000, we receive many requests from specialty associations, device manufacturers, drug manufacturers, and consultants to increase the payments for codes associated with specific drugs, devices, services, and surgical procedures. Under the OPPS, one of our goals is to make payments that are appropriate for the items and services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are generally limited to the annual payment update factor. As a budget neutral payment system, the OPPS does not pay the full hospital costs of services, however, we believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries. Furthermore, we believe that our payment rates are adequate to ensure access to services.

Comment: Commenters stated that the current methodology for determining OPPS payments disadvantages cardiac CT exams disproportionately and requested that CMS exercise its authority to create an exception to the current payment methodology for the three cardiac CT codes. As an alternative to the current methodology for establishing OPPS payment rates, the commenters suggested using the general cardiology revenue code to set the payment rates for CPT codes 75572, 75573, and 75574. They stated that based on their study that used claims data from CY 2021 OPPS proposed rulemaking, the use of a general cardiology revenue code to set the payment rates matches the actual cost of cardiac exams. Specifically, their results reveal a geometric mean cost of about $400.55 for CPT code 75572, $479.74 for CPT code 75573, and $505.89 for CPT code 75574. Based on their analysis, the commenters contended that the geometric mean costs for CPT codes 75572 and 75573 justify their assignment to APC 5572, and CPT code 75574 to APC 5573.

Response: It is our standard ratesetting methodology to rely on hospital cost and charge information as it is reported to us through the claims and cost report data. We believe that the assignment to APC 5571 for the cardiac CT codes is fully consistent with our standard ratesetting methodology, which provides appropriate incentives for efficiency. The OPPS is a prospective payment system that relies on hospital charges on the claims and cost report data from the hospitals that furnish the services in order to determine relative costs for OPPS ratesetting. We believe that the prospective payment rates for CPT codes 75572, 75573, and 75574, calculated based on the costs of those providers that furnished the services in CY 2019, provide appropriate payment to the providers who will furnish the services in CY 2021. We continue to believe that this standard ratesetting methodology accurately provides payment for cardiac CT exams furnished to hospital outpatients.

Comment: One commenter recommended that we decrease the payment for CPT code 78452 because the commenter believes SPECT is an outdated test for chest pain evaluation. The commenter also stated that the test is overutilized with no evidence of improvement in patient outcomes.

Response: As stated above, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For CY 2021, OPPS payments are based on claims data submitted between January 1, 2019 through December 30, 2019, that were processed on or before June 30, 2020. Based on our analysis, and as shown in Table 21 above, the claims data for CPT code 78452 show a geometric mean cost of approximately $1,288 based on 591,344 single claims, which is consistent with the geometric mean cost of about $1,272 for APC 5593 (Level 3 Nuclear Medicine and Related Services). We believe that CPT code 78452 is appropriately assigned to APC 5593. Therefore, based on the latest claims data, we have no basis to reassign the SPECT exam CPT code 78452 to another APC with a lower payment rate.

Comment: Some commenters recommended that CMS allow facilities to submit charges for cardiac CT using revenue codes that they believe would more accurately estimate costs. They added that CMS should provide explicit permission via a line item to allow hospitals to submit charges for cardiac

CT tests under the cardiology stress testing revenue/cost centers. They noted that CMS guidance for all non-CT and MR CPT codes is for hospitals to submit claims utilizing revenue codes that most accurately reflect clinical and resource homogeneity. They believe that making an exception to the current policy and allowing HOPDs to submit charges for cardiac CT tests under the cardiology stress testing revenue/cost centers would provide better data in the future that reflects actual resource costs for cardiac CT.

Response: Hospital outpatient facilities make the final determination for reporting the appropriate cost centers and revenue codes. As stated in section 20.5 in Chapter 4 (Part B Hospital) of the Medicare Claims Processing, CMS ''does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPPS since hospitals' assignment of cost vary. Where explicit instructions are not provided, providers should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.'' Therefore, HOPDs must determine the most appropriate cost center and revenue code for the cardiac CT exams.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign the cardiac CT exam codes, specifically, CPT codes 75572, 75573, and 75574 to APC 5571. The final CY 2021 OPPS payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

b. Cardiac Magnetic Resonance (CMR) Imaging (APC 5523, 5524, 5572, and 5573)

For CY 2021, we proposed to continue to assign the following cardiac magnetic resonance imaging (MRI) CPT codes to APC 5523, 5524, 5572, and 5573, respectively:

- CPT code 75557 (Cardiac magnetic resonance imaging for morphology and function without contrast material) to APC 5523 (Level 3 Imaging without Contrast) with a proposed payment of $235.05;
- CPT code 75559 (Cardiac magnetic resonance imaging for morphology and function without contrast material; with stress imaging) to APC 5524 (Level 3 Imaging without Contrast) with a proposed payment of $490.52;
- CPT code 75561 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences) to APC 5572 (Level 2 Imaging with Contrast) with a proposed payment of $375.33; and
- CPT code 75563 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with stress imaging) to APC 5573 (Level 3 Imaging with Contrast) with a proposed payment of $722.74.

Comment: Some commenters expressed concern with the lack of payment stability for cardiac MRI services, specifically, those described by CPT codes 75557, 75559, 75561, and 75563. They indicated that the payments for these codes have decreased in the last several years, and prior to CY 2017, the codes were placed in appropriate APCs. Of significant concern are the payment rates for CPT codes 75561 and 75563, which, according to the commenters, are grouped with services that are not clinically similar. The commenters stated that CPT code 75561 is unlike CT of the abdomen or pelvis or MRI of the neck and spine in APC 5572, and instead, the code should be placed in APC 5573 with comparable services. The commenters further added that CPT code 75563 is labor-intensive and should be assigned to APC 5593 (Level 3 Nuclear Medicine and Related Services).

Response: Payment changes from one year to the next are unavoidable in a relative weight payment system that depends on updated hospital charges and costs and in which reassignment of HCPCS codes from one APC to another is required by law in cases of 2 times rule violations. The statutory design of the OPPS and the evolution in the delivery of outpatient hospital services include elements that are responsible for some of the fluctuation in payment rates from year to year. The OPPS is based on HCPCS coding for which there are hundreds of changes each year. In addition, the entry of new technology into a budget neutral payment system results in a shift of funds away from previously existing services to provide payments for new services. These factors are reflections of the changes in services in the outpatient department, and shifts in payment mirror those changes.

Moreover, 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 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. Consequently, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For CY 2021, OPPS payments are based on claims data submitted between January 1, 2019 through December 30, 2019, that were processed on or before June 30, 2020. Based on our analysis, and as shown in Table 24, the claims data for CPT code 75557 show a geometric mean cost of approximately $250 based on 1,941 single claims, which is consistent with the geometric mean cost of about $224 for APC 5523 (Level 3 Imaging Without Contrast). Similarly, the geometric mean cost for CPT code 75559 is approximately $403 based on 57 single claims, which is in line with the geometric mean cost of about $470 for APC 5524. For CPT code 75561, the geometric mean cost is approximately $426 based on 17,216 single claims, which is in line with the geometric mean cost of approximately $359 for APC 5572. We note that the geometric mean cost of approximately $426 for CPT code 75561 is within the range of the significant geometric mean cost for APC 5572, which is between approximately $265 (for CPT code 74174) and about $510 (for CPT code 73525). For CPT code 75563, the geometric mean cost is about $761 based on 2,370 single claims, which is close to the geometric mean cost of approximately $697 for APC 5573. The geometric cost of approximately $761 for CPT code 75563 is within the range of the significant geometric mean cost for APC 5573, which is approximately between $534 (for CPT code C8923) and about $961 (for HCPCS code C8928). Based on the latest claims data, we believe that the cardiac MRI codes are appropriately assigned to APCs 5523, 5524, 5572, and 5573.

TABLE 24.—GEOMETRIC MEAN COSTS (GMC) FOR CARDIAC MRI

HCPCS	Short Descriptor	SI	APC	Final Rule 2021 Single Claims Frequency	Final Rule 2021 HCPCS Geometric Mean Cost
75557	Cardiac mri for morph	S	5523	1,941	$249.73
75559	Cardiac mri w/stress img	S	5524	57	$403.20
75561	Cardiac mri for morph w/dye	S	5572	17,216	$425.66
75563	Card mri w/stress img & dye	S	5573	2,370	$760.81

In addition, based on the commenters' belief that the APC assignments for the cardiac MRI codes were appropriately placed prior to CY 2017 and not currently, we reviewed the OPPS payment rates from CY 2016 through CY 2021. Based on our evaluation, we believe that the payments for the cardiac MRI codes are appropriate. The OPPS, like other Medicare payment systems, is a prospective payment system based on averages. In some individual cases payment exceeds the average cost and in other cases payment is less than the average cost. Based on our review, we believe that the historical and current payment rates for CPT codes 75557, 75559, 75561, and 75563, reflect the geometric mean costs associated with the service that are consistent with providing cardiac MRI to Medicare beneficiaries in cost efficient settings.

Comment: Some commenters expressed concern with the clinical homogeneity in the Imaging APCs and requested more transparency. They also questioned the criteria for assigning HCPCS codes to specific APCs and as well as why the Imaging APCs were reduced from 17 to 7 APCs.

Response: Every year we publish an OPPS/ASC proposed rule that informs the public of our proposed policies, which include payment rates for specific HCPCS codes, for the upcoming year that will become effective on January 1. The proposed rules are subject to a 60-day public comment period, and comments received by the due dates are addressed in the final rules. In the April 7, 2000 OPPS final rule, we defined the term ''clinical homogeneity.'' As stated in the April 7, 2000 final rule, ''The definition of each APC group should be 'clinically meaningful,' that is, the procedures or services included within the APC group relate generally to a common organ system or etiology, have the same degree of extensiveness, and utilize the same method of treatment, for example, surgical, endoscopic, etc. The definition of clinical meaningfulness is, of course, dependent on the goal of the classification system. For APCs, the definition of clinical meaningfulness relates to the medical rationale for differences in resource use. If, on the other hand, classifying patient prognosis were the goal, the definition of patient characteristics that were clinically meaningful might be different.'' (68 FR 18457).

In addition, we believe that the combined annual proposed and final rules with their accompanying addenda and cost statistics files, as well as the quarterly OPPS and ASC update change request documents that are issued by CMS provide substantial transparency on APCs and, overall, the OPPS payment system.

With regard to the reduction from 17 to 7 APCs for the Imaging APCs, we discussed the issue in the CY 2017 OPPS/ASC final rule (81 FR 79628 through 79631) and stated that the change was based on stakeholder recommendations. As a part of our CY 2016 (80 FR 70392 through 70397) and CY 2017 (81 FR 79628 through 79631) comprehensive review of the structure of the imaging APCs and procedure code assignments, we examined the APCs that contained imaging services. For CY 2017, we proposed and updated the restructuring of the OPPS APC groupings for imaging services to more appropriately reflect the costs and clinical characteristics of the procedures within each APC grouping in the context of the OPPS. We believe that the updated restructuring and reconfiguration of the Imaging APCs appropriately reflect the similar resource costs and clinical characteristics of the procedures within each APC. We also believe that the current broader categories of Imaging APCs are appropriate for ratesetting under the OPPS because they support greater similarities in clinical characteristics and resource use of procedures assigned to the APCs, while improving the homogeneity of the APC structure.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign CPT code 75557 to APC 5523, CPT code 75559 to APC 5524, CPT code 75561 to APC 5572, and CPT code 75563 to APC 5573. The final CY 2021 payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

10. IDx–DR: Artificial Intelligence System To Detect Diabetic Retinopathy (APC 5733)

As stated in a press release issued by the FDA on April 11, 2018, the IDx–DR is the ''first medical device to use artificial intelligence (AI) to detect greater than a mild level of the eye disease diabetic retinopathy in adults who have diabetes'' (*https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-based-device-detect-certain-diabetes-related-eye*). Approved for marketing by the FDA in April 2018, the artificial intelligence

algorithm provides a clinical decision without the need for a clinician to also interpret the image. A provider uploads the digital images of the patient's retinas to a cloud server on which the IDx–DR software is installed, and once analysis is completed, the provider is given one of the following two results:

- More than mild diabetic retinopathy detected: Refer to an eye care professional; or
- negative for more than mild diabetic retinopathy; rescreen in 12 months.

The test itself generally takes about 5 minutes to complete and does not need to be performed by a clinician. The test associated with the IDx–DR technology received a new CPT code effective January 1, 2021, specifically, CPT code 92229. With the establishment of the new code, the CPT Editorial Panel also revised the descriptors associated with existing CPT codes 92227 and 92228 to appropriately differentiate them from the IDx–DR test. Below are the complete descriptors for CPT codes 92227, 92228, and 92229 for CY 2021. We note that CPT code 92229 was listed as placeholder 9225X in Addendum B of the CY 2021 OPPS/ASC proposed rule:

- 92227 (Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral);
- 92228 (Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral); and
- 92229 (Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral).

As stated in the CY 2021 OPPS/ASC proposed rule (85 FR 48839), based on our evaluation of the service, we believe that IDx–DR is a diagnostic test that should be payable under the hospital OPPS, similar to existing CPT codes 92227 and 92228, which are assigned to APC 5732 (Level 2 Minor Procedures) and status indicator ''Q1.'' Based on its clinical similarity to CPT codes 92227 and 92228, we believe that the IDx–DR test should also be assigned to APC 5732. Consequently, for CY 2021, we proposed to assign the new IDx–DR CPT code to APC 5732 with a proposed payment rate of $33.16. We also proposed to assign the code to status indicator ''Q1'' to indicate that the code is conditionally packaged when performed with another service on the same day. Because the IDx–DR test will most often be performed as part of a visit, we believed that packaging the cost into the primary service is appropriate. We note that under the OPPS, the HOPD E&M visit code (G0463; CY 2021 OPPS proposed payment rate of $120.88) is paid separately when not billed with a C–APC, and we believed that payment would include the cost of providing the IDx–DR test. Generally, our policy for tests with minimal costs is to package the cost into the primary service.

Comment: Some commenters disagreed with the proposed payment amount and requested a revision in the assignment from APC 5732 to APC 5734 (Level 4 Minor Procedures) with a proposed payment rate of $113.23 and assignment to status indicator ''Q1''. The commenters reported that the service described by new CPT code 92229, which was listed as placeholder CPT code 9225X in Addendum B to the CY 2021 OPPS/ASC proposed rule), is similar to the technical components described by existing CPT code 92250 (Fundus photography with interpretation and report), which was proposed for assignment to APC 5734 and status indicator ''Q1''. They stated that providers are currently billing on an interim basis under CPT code 92250 for the same service. The commenters further disagreed with the comparison to CPT code 92227 and 92228, which are assigned to APC 5732 with a status indicator ''Q1'' and stated that the tests described by these codes involve human readers while the service described by CPT code 92229 is artificial (AI) intelligence-related. The commenters indicated that APC 5734, which is the APC assigned to the predecessor CPT code 92250, is the more appropriate assignment for new CPT code 92229 until sufficient Medicare claims data can be collected by CMS to either retain that assignment or reassign to another APC.

Response: We stated in the CY 2021 OPPS/ASC proposed rule with comment period (85 FR 48839) that the CPT Editorial Panel revised the descriptors associated with existing CPT codes 92227 and 92228 to appropriately differentiate them from the IDx–DR test, which is described by new CPT code 92229. We note that the descriptors for all three codes involve tests that use imaging of the retina for detection or monitoring of disease. Based on the revisions to CPT code 92227 and 92228 and placement of the new code, we believe that the IDx–DR test is similar to CPT code 92227 and 92228. We do not believe that CPT code 92250, which the commenters reported to be the predecessor code, is similar to the IDx–DR test; otherwise, the placement of the new IDx–DR code would have been close to CPT code 92250. However, after further review and consideration of the issue, we believe that CPT code 92229 should be assigned to APC 5733 (Level 3 Minor Procedures) rather than APC 5732 (Level 2 Minor Procedures).

We note that 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 a prospective payment system. The payment rates that are established reflect the geometric mean costs associated with items and services assigned to an APC and we believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries in cost efficient settings. Moreover, we strive to establish rates that are adequate to ensure access to medically necessary services for Medicare beneficiaries.

For many emerging technologies there is a transitional period during which utilization may be low, often because providers are first learning about the techniques and their clinical utility. Quite often, the requests for higher payment amounts are for new procedures in that transitional phase. These requests, and their accompanying estimates for expected Medicare beneficiary or total patient utilization, often reflect very low rates of patient use, 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 Medicare beneficiary projected utilization and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment.

We note that in a budget neutral environment, payments may not fully cover hospitals' costs, 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 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 annually review the claims data and any available new information regarding the clinical aspects of new procedures to confirm that OPPS payments remain appropriate for procedures as they transition into mainstream medical practice.

Comment: Several commenters requested a reassignment from proposed APC 5732 to APC 5733 (Level 3 Minor Procedures) consistent with the APC assignment for CPT codes 92285 (External ocular photography with interpretation and report for documentation of medical progress (e.g., close-up photography, slit lamp photography, goniophotography, stereo-photography) and 92134 (Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; retina).

Response: The IDx–DR test generally takes about 5 minutes to complete and does not need to be performed by a clinician. Based on our evaluation of the service, we believe that IDx–DR is a diagnostic test that should be payable under the hospital OPPS. We do not believe that the services described by CPT code 92285 or 92134 are appropriate comparisons for the IDx–DR test because these tests generally involve physician work and require approximately 10 minutes to perform. However, after further review and deliberation of the issue, we believe that CPT code 92229 should be assigned to APC 5733 (Level 3 Minor Procedures) rather than APC 5732 (Level 2 Minor Procedures).

Comment: Some commenters requested a change in the proposed status indicator assignment for CPT code 92229 from ''Q1'' to ''S'' to ensure that the test is separately reimbursed when provided with an outpatient clinic visit or other service. The commenters indicated that assigning the code to ''Q1'' will not support patient access in the outpatient setting and will encourage less efficient care. They suggested that HOPDs would likely schedule patients to receive only the IDx–DR test during an outpatient visit, instead of performing the test during a clinic visit, and could discourage hospitals from offering the test altogether. They further suggested that diabetic patients receiving diabetic care in the outpatient setting would likely be asked to make separate appointments as a result of the status indicator ''Q1'' assignment.

Response: With regard to HOPDs potentially scheduling the IDx–DR test on a separate day from the clinic visit to receive separate payment, we have concerns about this kind of manipulation of patient scheduling because such a practice could create an undue burden for Medicare beneficiaries. We expect HOPDs to furnish services in the most efficient way that meets the needs of the patient. After further review and deliberation on the issue, we are revising the status indicator to ''S'' to ensure patient access to the test.

In summary, after consideration of the public comments, we are finalizing our proposal, with modification. Specifically, we are assigning CPT code 92229 to APC 5733 with status indicator ''S.'' The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

11. Implantable Interstitial Glucose Sensor System (APC 5051 and 5054)

For CY 2021, we proposed to assign CPT code 0447T to APC 5051 (Level 1 Skin Procedures) with a proposed OPPS payment of $182.38. In addition, we proposed to assign CPT codes 0446T and 0448T to APC 5053 (Level 3 Skin Procedures) with a proposed OPPS payment of $530.98. We note that the long descriptors for these codes can be found in Table 25 below.

Comment: A commenter agreed with the proposed APC assignment for CPT code 0447T to APC 5051 but opposed the proposed assignment for CPT codes 0446T and 0448T to APC 5053. The commenter stated that the payment for APC 5053 does not include the provision of the service associated with the Eversense Implantable Continuous Glucose System (CGS), which is a technology that provides real-time glucose monitoring. Specifically, the payment for APC 5053 does not account for providing the glucose sensor and wireless transmitter, as well as implanting, removing, and replacing the glucose sensor. In contrast, the commenter believed that CPT codes 0446T and 0448T include those costs, referring to the discussion in the CY 2020 PFS final rule (84 FR 62627). The commenter added that assignment to APC 5053 is inappropriate based on clinical homogeneity and resource cost, and suggested reassigning CPT codes 0446T and 0448T to either APC 5054 (Level 4 Skin Procedures) with a proposed OPPS payment of $1,733.06 or New Technology APC 1523 (New Technology—Level 23 ($2501–$3000)) with a proposed OPPS payment of $2,750.50.

Response: Although CPT codes 0446T, 0447T, and 0448T were effective January 1, 2017, the Eversense CGM technology was only recently approved for marketing by the FDA on June 6, 2019. For CY 2021, OPPS payments are developed based on claims submitted between January 1, 2019 through December 31, 2019, and processed through June 30, 2020. For this final rule with comment period, we have no claims data for CPT codes 0446T, 0447T, or 0448T for OPPS ratesetting purposes. However, based on our review of the issue, and feedback from our medical advisors, as well as the expected device costs associated with CPT codes 0446T and 0448T as discussed in the CY 2021 PFS proposed rule (85 FR 50174), we believe that these codes should be reassigned to APC 5054 (Level 4 Skin Procedures) rather than New Technology APC 1523 (New Technology—Level 23 ($2501–$3000)). Because we have neither claims data nor specific HOPD costs, including the cost to perform each exam (other than the supply cost discussed in the CY 2021 PFS proposed rule), we believe that APC 5054 is the most appropriate assignment at this time for CPT codes 0446T and 0448T.

Therefore, after consideration of the public comment, we are finalizing our proposal, with modification. Specifically, we are finalizing our proposal for CPT code 0447T and assigning the code to APC 5051, however, we are reassigning CPT codes 0446T and 0448T to APC 5054. Table 25 list the long descriptors and final SI and APC assignments for the codes. The final CY 2021 payment rate for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 25.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0446T, 0447T, and 0448T FOR CY 2021

CY 2021 CPT Code	Long Descriptor	Proposed CY 2021 OPPS SI	Proposed CY 2021 OPPS APC	Final CY 2021 OPPS SI	Final CY 2021 OPPS APC
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	T	5053	T	5054
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision	Q2	5051	Q2	5051
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	T	5053	T	5054

12. Intervertebral Disc Allogeneic Cellular and/or Tissue-Based Product Percutaneous Injection (APC 5115)

In the CY 2021 OPPS/ASC Proposed Rule, we proposed to assign the procedures described by CPT codes 0627T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level) and 0629T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level) to status indicator ''T'', APC 5443 (Level 3 Nerve Injections) with a proposed OPPS payment rate of $836.26 based on the estimated costs of these procedures.

We proposed to assign the procedures described by CPT codes 0628T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure) and 0630T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure) to status indicator ''N'' to indicate that they are packaged under OPPS since they are add-on codes. These codes were listed as 0X32T, 0X33T, 0X34T, and 0X37T (the 5-digit CMS placeholder codes) in Addendum B with the short descriptor and also in Addendum O with the long descriptor, to the CY 2021 OPPS/ASC proposed rule.

We also proposed to assign these codes to comment indicator ''NP'' in Addendum B to indicate that the codes are new for CY 2021 and that public comments would be accepted on the proposed status indicator assignment. We note that these codes will be effective January 1, 2021.

Comment: Some commenters disagreed with the assignment of codes 0627T and 0629T to APC 5443 based on what the commenters believed was a lack of clinical and resource coherence with other procedures in this APC. They stated that CPT codes 0627T and 0629T involve percutaneous placement of an allogeneic cellular and/or tissue-based biologics to supplement and support deteriorating vertebral discs in patients suffering from degenerative disc disease. They believe that these procedures are not comparable to a simple nerve injection.

One commenter explained that the cost of these procedures is significantly higher than the proposed Level 3 Nerve Injection APC payment, which is $836.26. The cost of the VIA Disc Matrix Kit used for these procedures is $8,000 per kit. Therefore, they believed that a higher APC payment level more appropriately covers both the cost of the device and the non-device costs of the procedure.

Another commenter noted that the non-device costs of procedures 0627T and 0629T are most appropriately crosswalked to CPT code 22514 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (*e.g.* kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar) that is assigned to APC 5114 (Level 4 Musculoskeletal Procedures) with the payment rate of $6,368.58.

A medical device company recently submitted a new technology APC application to CMS for VIA® Disc Allograft Supplementation described by codes 0627T and 0629T and requested that CMS assign CPT codes 0627T and 0629 to APC 1575 (New Technology APC Level 38 ($10,001–$15,000)) for CY 2021 based on total estimated non-device-related cost of APC 5114 ($4,524) plus the device-related costs ($8,000) or $12,524 which is closest to APC 1575 with a CY 2021 proposed payment rate of $12,500.50.

The same device company recommended, because 0628T and 0630T are add-on codes used in conjunction with their primary procedural codes 0627T and 0629T, that CMS uses the device-related cost for each additional VIA Disc mixing system kit of $8,000 plus an incremental thirty minute non-device cost to capture the additional operative time and costs in performing a separate intervertebral disc injection.

The commenter requested that CMS assign CPT codes 0628T and 0630T to APC 1571 (New Technology APC Level 34 ($8001–$8500)) for CY 2021 since the total estimated cost of these codes is closest to APC 1571 with a CY 2021 proposed payment rate of $8,250.50.

Response: Based on our review of the application and input from our clinical advisors, we agree that the codes would be appropriately placed in an alternative APC that might better reflect their resource costs. Our updated claims data for this final rule with comment period shows that the geometric mean cost of APC 5115 is about $11,996.45, which is more similar to the device and procedure costs associated with these codes. Therefore, we are assigning CPT codes 0627T and 0629T to comprehensive APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator ''J1'' for the CY 2021 OPPS.

CPT codes 0628T and 0630T would be assigned to status indicator ''N'' under OPPS for CY 2021 because the cost of an add-on code is packaged into the primary procedure under OPPS packaging policy, as discussed in the CY 2014 OPPS/ASC final rule (78 FR 74942).

In summary, after consideration of the public comments and our analysis of updated claims data for this final rule and other additional information, we are finalizing our proposal related to codes 0627T and 0629T with modification. Specifically, we are revising the APC assignment for CPT codes 0627T and 0629T to APC 5115 and revising their status indicator to ''J1'' for the CY 2021 OPPS. For CPT codes 0628T and 0630T, we are finalizing our proposal without modification and maintaining the assignment of status indicator ''N'' to these codes.

The final CY 2021 OPPS payment rate for CPT codes 0627T and 0629T and final status indicator assignment for 0628T and 0630T can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

The final CY 2021 APC and SI assignments for 0627T through 0630T can be found in Table 26.

TABLE 26.—FINAL APC AND SI ASSIGNMENTS FOR CPT CODES 0627T-0630T FOR CY 2021

CPT Code	Long Descriptor	Final OPPS SI	Final OPPS APC
0627T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level	J1	5115
0628T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)	N	N/A
0629T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level	J1	5115
0630T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)	N	N/A

13. Intraocular Procedures (APCs 5491 Through 5495)

In prior years, CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) was assigned to the APC 5495 (Level 5 Intraocular Procedures) based on its estimated costs. In addition, its relative payment weight has been based on its median cost under our payment policy for low-volume device-intensive procedures because the APC contained a low volume of claims. The low volume device-intensive procedures payment policy was discussed in more detail in section III.C.2. of the proposed rule.

In the CY 2019 OPPS, we assigned procedure code CPT code 0308T to the APC 5494 (Level 4 Intraocular Procedures) (83 FR 58917 through 58918). We made this change based on the similarity of the estimated cost for the single claim of $12,939.75 to that of the APC ($11,427.14). However, this created a discrepancy in payments between the OPPS setting and the ASC setting in which the ASC payments would be significantly lower than the OPPS payments for the same service because of the difference in estimated cost for the encounter determined under a comprehensive methodology within the OPPS and the estimated cost determined under the payment methodology for device intensive services within the ASC payment system.

In CY 2020 OPPS/ASC rulemaking, we reestablished APC 5495 (Level 5 Intraocular Procedures) because we believed that the procedure described by CPT code 0308T would be most appropriately placed in the APC based on its estimated cost (84 FR 61249 through 61250). Assignment of the procedure to the Level 5 Intraocular Procedures APC was consistent with its historical placement and would also address the large discrepancy in payment for the procedure between the OPPS and the ASC payment system. We note that we also implemented a policy where the payment for a service when performed in an ASC (84 FR 61399 through 61400), would be no higher than the OPPS payment rate for the

service when performed in the hospital outpatient setting.

In reviewing the claims data available for CY 2021 ratesetting, there was a single claim containing the code 0308T that was unable to be used for the ratesetting process. In addition, this code and its APC have historically had relatively low claims volume for ratesetting purposes. While there were no claims usable for ratesetting in the CY 2021 OPPS proposed data under our standard process, we still needed to determine a payment weight for the APC. We believed that the most recently available data that we used to set payment for this service in the CY 2020 OPPS final rule was an appropriate proxy for both the procedure's estimated cost and its relative payment weight. We note that the proposed policy to use prior year claims data in ratesetting is similar to the application of a geometric mean cost floor to the Partial Hospitalization APCs, as initially established in the CY 2020 OPPS/ASC final rule (84 FR 61339 through 61347). Therefore, we believed it was appropriate to propose to use the median cost of $20,229.78 for CPT 0308T, calculated from claims data used in the CY 2020 OPPS final rule with comment period, to establish the payment weight for the CY 2021 OPPS for CPT code 0308T. We will continue to monitor the claims available for the procedure for ratesetting purposes.

To summarize, for CY 2021, we proposed to assign 0308T a payment weight based on the most recently available data, from the CY 2020 OPPS final rule, and therefore proposed to assign CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures). Under the proposal, the proposed CY 2021 OPPS payment rate for the service would be established based on the median cost, as discussed in section V.A.5. of the proposed rule, because it is a device intensive procedure assigned to an APC with fewer than 100 total annual claims within the APC. Therefore, the proposed APC assignment for CPT code 0308T would be based on the CY 2020 OPPS final rule median cost of $20,229.78.

Comment: We received one comment supporting our proposal to continue to assign the CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) and use the CY 2020 median cost as a proxy for use in developing the CY 2021 OPPS payment rate.

Response: We appreciate the commenter's support. While the updated final rule claims data includes two claims containing the code 0308T, those claims are unusable for OPPS ratesetting purposes. Therefore, we are finalizing our proposed policy to assign CPT code 0308T to APC 5495 and use the CY 2020 median cost in determining a CY 2021 OPPS payment rate.

After consideration of the public comment we received, we are finalizing our proposal to continue to assign CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) for the CY 2021 OPPS and, as a device intensive procedure assigned to an APC with fewer than 100 total claims, to establish the CY 2021 OPPS payment rate for the service using its CY 2020 median cost. Therefore, the CY 2021 OPPS payment rate for CPT 0308T will be based on the CY 2020 OPPS final rule median cost of $20,229.78.

14. Irreversible Electroporation Ablation of Tumors (NanoKnife® System) (APC 5362)

Electroporation is a technique in which an electrical field is applied to cells in order to increase the permeability of the cell membranes through the formation of nanoscale defects in the lipid bilayer. The result is creation of nanopores in the cell membrane and disruption of intra-cellular homeostasis, ultimately causing cell death. After the NanoKnife® System delivers a sufficient number of high voltage pulses; the cells surrounded by the electrodes will be irreversibly damaged. This mechanism, which causes permanent cell damage, is referred to as Irreversible Electroporation (IRE). The NanoKnife® System with six outputs for the treatment of Stage III pancreatic cancer received FDA Breakthrough Device designation on January 18, 2018 and approval of an FDA investigational device exemption (IDE G180278) on March 28, 2019.

The CPT Editorial Panel established two new codes; specifically CPT codes 0600T and 0601T, to describe NanoKnife® System procedures effective July 1, 2020. The manufacturer also submitted a new technology application requesting new technology APC assignments for CPT codes 0600T and 0601T. Based on our review of the new technology APC application for the NanoKnife® System, we provided temporary APC and status indicators assignments for 0600T and 0601T. The temporary APC and SI assignments were publicly released in the July 2020 quarterly update to the OPPS (Transmittal 10224, Change Request 11814, and dated July 15, 2020). In addition, in the CY 2021 OPPS/ASC proposed rule with comment period, we proposed to assign the codes to APC 5361 (Level 1 Laparoscopy and Related Procedures) with a payment rate of $5,148.34, and status indicator 'J1'' (Hospital Part B services paid through a comprehensive APC) based on clinical and resource similarities between 0600T, 0601T and other procedures in the same APC. We also proposed to assign these codes to comment indicator (CI) ''NP'' in Addendum B to the proposed rule to indicate that the codes are new for CY 2020 and that public comments would be accepted on their proposed APC assignments.

Comment: We received one comment from the applicant on the proposed assignment to APC 5361 (Level 1 Laparoscopy and Related Procedures). According to the applicant, new Category III CPT codes 0600T and 0601T should not be assigned to APC 5361 because the clinical characteristics and resource costs associated with the procedures are significantly different from existing procedures assigned to that APC. The applicant noted that under the IPPS, the NanoKnife® System was estimated to have a technology added cost of approximately $11,086, and that the procedures for which the system would apply generally were not significantly different in the inpatient and outpatient settings. They believe that the codes would be more appropriately placed in New Technology APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50, based on the estimated costs and complexity of the procedures.

Response: We thank the applicant for their comment and the additional information they have provided regarding the procedures and in particular their estimated costs. While we recognize that there are differences between the various ablation modalities, we believe that the APC levels 5361 and 5362 for ''Laparoscopy and Related Services'' appropriately describe the resource costs and clinical characteristics of these procedures. However, we agree with the commenter that an alternative APC might better reflect the resource costs of the procedures. Therefore, we are revising the CY 2021 APC assignments for these codes. Specifically, we are assigning CPT codes 0600T and 0601T to APC 5362 (Level 2 Laparoscopy and Related Procedures) with a status indicator of ''J1'' in the CY 2021 OPPS.

After consideration of the public comment for the new irreversible electroporation codes, and based on our evaluation of the new technology application which provided the estimated costs for the services and described the components and characteristics of the new codes, we are finalizing our proposal with

modification, and reassigning CPT codes 0600T and 0601T to the final CY 2021 OPPS APC 5362 (Level 2 Laparoscopy and Related Services). Table 27 lists the four Category III CPT codes for the NanoKnife® System and their APC and SI assignments for CY 2021. The final CY 2021 OPPS payment rate for the codes can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 27.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0600T AND 0601T FOR CY 2021

CPT Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	J1	5361	J1	5362
0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	J1	5361	J1	5362

15. Medical Physics Dose Evaluation (APC 5611)

For CY 2021, we proposed to assign CPT code 76145 (Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report (medical physicist/dosimetrist)) in APC 5611 (Level 1 Therapeutic Radiation Treatment Preparation) with a proposed payment rate of $129.86. We note this is a new code that will be effective on January 1, 2021. Because the code is new, we requested public comments on the APC assignment for CY 2021. We also note that CPT code 76145 was listed as placeholder code 7615X in Addendum B and Addendum O of the CY 2021 OPPS/ASC proposed rule.

Comment: Several commenters disagreed with the assignment to APC 5611 and requested a reassignment to APC 5724 (Level 4 Diagnostic Tests and Related Services) with a proposed payment rate of $936.70. The commenters indicated that CPT code 76145 is not a radiation oncology code, rather, it is a service that will be performed in interventional radiology or interventional cardiology. The commenters stated that the resource consumption in APC 5724 more closely aligns with the resources used to perform CPT code 76145. One commenter explained that CPT code 76145 is used to describe the medical physicist's work in performing a patient-specific peak organ dose calculation subsequent to an interventional radiology or interventional cardiology procedure. The same commenter expressed concern that the new code will be included on the Deficit Reduction Act (DRA) cap designation list.

Response: Section 5102(b) of the Deficit Reduction Act of 2005 (DRA) added section 1848(b)(4) to the statute to place a payment cap on the technical component (TC) of certain diagnostic imaging procedures and the TC portions of the global diagnostic imaging services at the amount paid under the OPPS. To implement this provision, the physician fee schedule (PFS) amount is compared to the OPPS payment amount and the lower amount is used for payment under the PFS. However, we note that the OPPS cap is a policy that applies to the PFS payment and is not applicable under the OPPS; and the list of services that are subject to the OPPS cap is published as part of the annual PFS final rules. In addition, based on our review of the service associated with CPT code 76145 and input from our medical advisors, we believe that APC code 5611 is the most appropriate assignment for the code. The code is new for CY 2021 and therefore we have no claims data available for OPPS ratesetting. However, once we have claims data, we will review the APC assignment and determine whether a change is necessary. We note that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, and assigning CPT code 76145 to APC 5611 for CY 2021. The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

16. Musculoskeletal Procedures (APCs 5111 Through 5116)

Prior to CY 2016, OPPS payment for musculoskeletal procedures was primarily divided according to anatomy and the type of musculoskeletal procedure. As part of the CY 2016 reorganization to better structure the OPPS payments towards prospective payment packages, we consolidated those individual APCs so that they became a general Musculoskeletal APC series (80 FR 70397 through 70398).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59300), we continued to apply a six-level structure for the Musculoskeletal APCs because doing so provided an appropriate distinction for resource costs at each level and provided clinical homogeneity. However, we indicated that we would continue to review the structure of these APCs to determine whether additional granularity would be necessary.

In the CY 2019 OPPS proposed rule (83 FR 37096), we recognized that commenters had previously expressed concerns regarding the granularity of the current APC levels and, therefore, requested comment on the establishment of additional levels. Specifically, we solicited comments on the creation of a new APC level between the current Level 5 and Level 6 within

the Musculoskeletal APC series. While some commenters suggested APC reconfigurations and requests for change to APC assignments, many commenters requested that we maintain the current six-level structure and continue to monitor the claims data as they become available. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we maintained the six-level APC structure for the Musculoskeletal Procedures APCs (83 FR 58920 through 58921).

Based on the claims data available for the CY 2021 OPPS/ASC proposed rule, we stated that we continued to believe that the six-level APC structure for the Musculoskeletal Procedures APC series is appropriate. Therefore, we proposed to maintain the APC structure for the CY 2021 OPPS update.

In the CY 2020 OPPS/ASC final rule, we discussed issues related to the APC assignment of CPT code 22869 (Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level) to APC 5115 (84 FR 61253 through 61254). Specifically, commenters believed that the code was inappropriately assigned to APC 5115 due to one hospital inaccurately reporting its costs and charges. While we recognized the concerns that the commenters described, we noted that it is generally not our policy to judge the accuracy of hospital coding and charging for purposes of ratesetting. For the proposed CY 2021 OPPS, the geometric mean cost of CPT code 22869 increased slightly relative to the prior year, from $11,023.45 to $12,788.56. However, the proposed geometric mean costs of the Level 5 and Level 6 Musculoskeletal Procedures APCs were $12,102.02 and $15,975.08, respectively, and so, based on the data that was available, we continued to believe that it is appropriate to assign CPT code 22869 to APC 5115 (Level 5 Musculoskeletal Procedures APC).

For the CY 2021 OPPS, we also proposed to eliminate the Inpatient Only (IPO) list over a three-year transition and to assign codes removed from the IPO list to clinical APCs. Many of the codes proposed to be removed from the IPO list are musculoskeletal procedures that we proposed to assign to APCs in the Musculoskeletal Procedures APC series, and so there may be effects on the geometric means as the limited claims data for those codes is included in OPPS ratesetting. For a more detailed discussion of the proposal to remove certain codes from the IPO list, please see section IX.B. of the CY 2021 OPPS/ASC proposed rule.

Table 28 displays the final CY 2021 Musculoskeletal Procedures APC series' structure and APC geometric mean costs.

TABLE 28.—FINAL MUSCULOSKELETAL PROCEDURES APCS FOR CY 2021

APC	Group Title	HCPCS Codes Assigned to APC in this CY 2021 OPPS/ASC Final Rule	CY 2020 Final APC Geometric Mean Cost	CY 2021 Final APC Geometric Mean Cost
5111	Level 1 Musculoskeletal Procedures	103	$210.99	$200.86
5112	Level 2 Musculoskeletal Procedures	136	$1,326.17	$1,356.36
5113	Level 3 Musculoskeletal Procedures	411	$2,678.42	$2,757.24
5114	Level 4 Musculoskeletal Procedures	445	$5,852.95	$6,103.01
5115	Level 5 Musculoskeletal Procedures	122	$11,644.09	$11,996.45
5116	Level 6 Musculoskeletal Procedures	50	$15,602.23	$15,457.97

Comment: One commenter recommended that CMS create a seventh Musculoskeletal APC level above APC 5116 to account for complex procedures that were proposed to be removed from the IPO list. Another commenter requested that CMS consider the development of an additional Musculoskeletal APC between current APCs 5114 and 5115.

Response: We appreciate the commenters' recommendation. We understand that the addition of codes removed from the IPO list may affect the geometric means of the Musculoskeletal Procedures APCs and we will continue to monitor the claims data as they become available. We also appreciate the goal of developing APC levels that appropriately reflect resource costs. At this time, we believe the six-level structure for the Musculoskeletal APCs continues to be appropriate. However, we will take these comments into consideration for future rulemaking

Comment: We received one comment recommending that CMS reassign CPT codes 28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method) and 28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint) to APC 5115 (Level 5 Musculoskeletal Procedures) to resolve any 2 times rule violations.

Response: We appreciate the commenter's recommendation regarding the APC assignment of CPT 28297 and 28740. CPT codes 28297 and 28740 are currently assigned to APC 5114 (Level 4 Musculoskeletal Procedures). Our review did not find that APC 5114 violates the 2 times rule. We also note that for purposes of identifying significant procedure codes for examination under the 2 times rule, we only 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). Neither of these codes met this requirement and therefore were not considered significant procedure codes for 2 times rule purposes. Therefore, we are finalizing our proposal to continue to assign CPT codes 28297 and 28740 to APC 5114 in the CY 2021 OPPS.

Comment: Commenters supported our proposal to continue to assign CPT code 22869 to APC 5115 (Level 5 Musculoskeletal Procedures). One commenter requested that CMS continue to monitor the geometric mean cost for CPT code 22869 and reestablish the code with assignment to APC 5116 (Level 6 Musculoskeletal Procedures) when appropriate.

Response: We appreciate commenters' support. We will continue to review the most recent data and update the APC assignment for CPT code 22869 as necessary.

Comment: One commenter requested that we assign CPT code 23473 (Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component) from APC 5115 to APC 5116, based on their belief that the claims data was inaccurate and that the time required to perform the procedure was not reflected in the resource costs of the proposed APC placement.

Response: We note that CPT code 23473 has been established for some time, with an effective date of January 1, 2013 and that it was the initially established with a status indicator of ''T'' in the CY 2013 OPPS. Therefore, some of the issues related to codes transitioning off the IPO list do not necessarily apply in this case and the actual data for the claims are more appropriate in ratesetting than alternative proxies. In the updated final rule claims data available for ratesetting, the estimated geometric mean cost of CPT 23473 is approximately $10,634 based on 287 claims, which is within the range of the significant procedure costs of APC 5115 from approximately $9,644 to $12,902. As a result, we believe that the code is appropriately placed in APC 5115.

Comment: For the CY 2020 OPPS/ASC final rule, HCPCS code 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) was assigned to comment indicator ''NI'' in the OPPS Addendum B to indicate that the code was new and that we would be accepting comments on the interim APC assignment. A commenter supported the assignment to APC 5115 (Level 5 Musculoskeletal Procedures) with a CY 2020 payment rate of $11,900.71.

Response: As we stated in the CY 2020 OPPS/ASC final rule, we accepted comments on the interim OPPS payment assignment for new codes effective January 1, 2020 that are assigned to comment indicator ''NI'' in the OPPS Addendum B (84 FR 61207). We further stated that the comments would be addressed, and if applicable, the APC assignment would be finalized in the CY 2021 OPPS/ASC final rule comment period. We appreciate the feedback. We note that for CY 2021, we are finalizing the assignment to APC 5115 (Level 5 Musculoskeletal Procedures) for HCPCS code C9757. The final payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, the status indicator definitions can be found in Addendum D1 to this final rule with comment period. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

After consideration of the comments, we are finalizing our proposal to maintain the six-level Musculoskeletal Procedures APC structure. We are also finalizing the proposed assignment of CPT codes 28297 and 28740 to APC 5114, and the proposed assignment of CPT codes 22869 and 23473 to APC 5115 for the CY 2021 OPPS.

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

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

In reviewing the claims data available for the CY 2021 OPPS proposed rule, we believed that it was appropriate to create an additional Neurostimulator and Related Procedures level, between the current Level 2 and 3 APCs. Creating this APC allows for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Therefore, for the CY 2021 OPPS, we proposed to establish a five-level APC structure for the Neurostimulator and Related Procedures series. We noted that in addition to creating the new level, we also proposed to assign CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to the new Level 3 APC, as discussed in further detail in section III.C.3.A of the CY 2021 OPPS/ASC proposed rule with comment period.

Comment: Multiple commenters requested that we add a Level 6 Neurostimulator and Related Procedures APC. The commenters are concerned that the payment rate for the current Level 4 APC and the proposed Level 5 APC is dominated by CPT code 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling) which has a geometric mean of $29,123.02. The commenter indicated this means that higher cost neurostimulator services that have relatively low utilization are substantially underpaid. The commenters believe the lack of payment for these services is discouraging their use, and they want a Level 6 APC to establish a payment rate that more closely reflects the cost of these expensive, low utilization services.

Response: We appreciate the concerns of the commenters, but we reiterate that the OPPS is a prospective payment system. We group procedures with similar clinical characteristics and resource costs into APCs and establish a payment rate that reflects the geometric mean of all services in the group even though the cost of each service within the APC may be higher or lower than the APC's geometric mean. As a result, in the OPPS any individual procedure may potentially be overpaid or underpaid because the payment rate is based on the geometric mean of the entire group of services in the APC. However, the impact of these payment differences should be mitigated when distributed across a large number of APCs. If we were to establish a Level 6 APC for Neurostimulators and Related Procedures based on the commenters' request, we would find the payment rate for the APC would be closer to some of the services assigned to that APC but

other services would continue to receive payment that is substantially lower than those services' geometric mean cost. In the end, the only way to ensure each service receives payment equivalent to the cost of the service would be to establish separate APCs for each service the commenters believe is underpaid. That solution would be contrary to payment principles of the OPPS, which is based on prospective payment. Therefore, we believe it is appropriate to maintain the same five level structure as proposed in the CY 2021 OPPS.

Comment: Most commenters supported our proposal to create an additional Neurostimulator and Related Procedures level, between the current Level 2 and 3 APCs, which is described as the Level 3 Neurostimulator and Related Procedures APC in our proposal.

Response: We appreciate the support of the commenters for our proposal.

Comment: One commenter noted that our proposal to establish an additional APC level would lead to a decrease in payment for services described by CPT codes 63650 (Percutaneous implantation of neurostimulator electrode array, epidural), 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling), and 63688 (Revision or removal of implanted spinal neurostimulator pulse generator or receiver).

Response: We did not find that there would be a substantial decrease in the payment for the procedures described by CPT codes 63650, 63685, and 63688 due to our proposal. Based on a review of our claims data, we found only a modest payment decrease for CPT code 63650 and modest payment increases for CPT codes 63685 and 63688.

In addition, for CY 2021, we proposed to continue to assign CPT code 0587T to APC 5442 (Level 2 Nerve Injections) with a proposed payment of $644.55. We also proposed to continue to assign CPT code 0588T to APC 5441 (Level 1 Nerve Injections) with a proposed payment of $267.50. We note that because both codes were effective on January 1, 2020, we have no claims data available for OPPS ratesetting, as the CY 2021 OPPS payment rates are based on claims submitted between January 1, 2019 through December 31, 2019, and processed through June 30, 2020. The long descriptors for both codes can be found in Table 29 below.

Comment: A commenter explained that in May 2019 the AMA CPT Editorial Panel approved four (4) Category III CPT codes to describe the surgical procedures associated with the PROTECT PNS Neurostimulation System, specifically, CPT codes 0587T, 0588T, 0589T, and 0590T. The PROTECT PNS device is used for the treatment of overactive bladder (OAB) symptoms. The commenter added that on October 19, 2016, CMS approved Medicare coverage for the Category B IDE study associated with the PROTECT PNS device. In addition, the commenter also stated that CMS incorrectly assigned CPT codes 0587T and 0588T to inappropriate APC assignments.

For CPT code 0587T, the commenter clarified that CPT code 0587T is not an injection; rather, the code describes an implantation or replacement of an integrated single device neurostimulation system, similar to the procedures assigned to the Neurostimulator and Related Procedures (APCs 5461 through 5465) family. The commenter recommended reassigning CPT code 0587T to one of these APCs to adequately capture the correct clinical characteristics and resource costs of the technology similar to other neurostimulation devices in APCs 5461 through 5465. The commenter specifically recommended the reassignment to APC 5464 (Level 4 Neurostimulator and Related Procedures) with a proposed payment rate of $20,789.82, since the procedure is very similar to CPT code 64590 (Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling), which is assigned to APC 5464. According to the commenter, the cost of the PROTECT implantable device and transmitter kit that is used in the procedure is about $15,820. Based on the commenter's estimated cost of approximately $20,032, which includes the non-device cost of $2,737 and the PROTECT device cost of $15,820, the appropriate assignment for the code until OPPS claims are available is APC 5464.

For CPT code 0588T, the commenter explained that the code is not an injection procedure, rather, the code describes the surgical removal of the device. The commenter suggested reassigning the code to APC 5461 (Level 1 Neurostimulator and Related Procedures) with a proposed payment of $3,498.13 because it is comparable to CPT code 64595 (Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver) based on clinical similarity and resource costs.

Response: We do not agree that CPT code 0587T is comparable to CPT code 64590. Based on our review of the clinical characteristics of the procedure and input from our medical advisors, we believe CPT code 0587T is more similar to the procedures assigned to APC 5462 (Level 2 Neurostimulator and Related Procedures). However, we agree that CPT code 0588T is similar to the procedures in APC 5461, and are therefore assigning the code to APC 5461 in the CY 2021 OPPS.

In summary, after consideration of the public comment, we are finalizing our proposal with modification, and reassigning CPT code 0587T to APC 5462 and CPT code 0588T to APC 5461. Table 29 below list the four Category III CPT codes for the PROTECT PNS System and their APC and SI assignments for CY 2021. The final CY 2021 OPPS payment rates for the codes can be found in Addendum B of this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS for CY 2021. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

BILLING CODE 4120–01–P

TABLE 29.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0587T THROUGH 0590T FOR CY 2021

CY 2021 HCPCS Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
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	T	5442	J1	5462
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	T	5441	J1	5461
0589T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters	S	5742	S	5742
0590T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters	S	5742	S	5742

Comment: Two commenters supported our proposal to change the APC assignment for CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to the proposed new Level 3 Neurostimulator and Related Procedures APC.

Response: We appreciate the support of the commenters for our proposal.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to establish a five-level APC structure for the Neurostimulator and Related Procedures series. In addition to creating this new level, we also finalizing our proposal to assign CPT 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to this new Level 3 APC. Table 30 displays the proposed and final CY 2021 Neurostimulator and Related Procedures APC series' structure and APC geometric mean costs.

TABLE 30. —FINAL GEOMETRIC MEAN COST FOR THE NEUROSTIMULATOR AND RELATED PROCEDURES APCS FOR CY 2021

APC	APC Descriptor	SI	CY 2020 OPPS Final Geometric Mean Cost	CY 2021 Proposed Geometric Mean Cost	CY 2021 Final Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	$3,080.60	$3,370.70	$3,190.64
5462	Level 2 Neurostimulator and Related Procedures	J1	$6,053.71	$6,105.05	$6,001.45
5463	Level 3 Neurostimulator and Related Procedures	J1	$18,863.68	$12,286.43	$10,945.77
5464	Level 4 Neurostimulator and Related Procedures	J1	$28,490.84	$20,032.49	$19,950.42
5465	Level 5 Neurostimulator and Related Procedures	J1	N/A	$28,876.14	$28,683.43

BILLING CODE 4120–01–C

18. Noncontact Real-Time Fluorescence Wound Imaging/MolecuLight (APC 5722)

For the July 2020 update, the CPT Editorial Panel established two new codes, specifically, CPT codes 0598T and 0599T, to report noncontact real-time fluorescence wound imaging for bacterial presence in chronic and acute wounds. The codes and their long descriptors were listed in Table 7 (New HCPCS Codes Effective July 1, 2020) of the CY 2021 OPPS/ASC final rule with comment period (85 FR 48815 through 48823). We note that CMS recently received a new technology application for the MolecuLight i: X procedure, which is described by CPT codes 0598T and 0599T. In determining the appropriate payment for CPT code 0598T, we considered whether there should be separate or conditionally packaged payment for the procedure since the use of the MolecuLight imaging device will most often involve another procedure or service during the same session (for example, debridement of the wound, laboratory service, or another skin-related procedure). In addition, we considered whether the code should be placed in either the Diagnostic Procedures or Minor Procedures APC group. Based on our review of the application and input from our physicians, we assigned CPT code 0598T to APC 5722 (Level 2 Diagnostic Tests and Related Services) and status indicator ''T'' with a payment rate of $253.10 effective July 1, 2020. In addition, because CPT code 0599T is an add-on code, we assigned the code to status indicator ''N'' to indicate that the payment is included in the primary procedure. We note that the new technology application indicated a higher projected cost involving care in an operating room (OR), however, based on our review of the MolecuLight service, we removed OR-associated costs because it was not clear to us that the test would routinely be performed in the OR setting. However, in the CY 2021 OPPS/ASC proposed rule we solicited public comments from hospital-based providers that have used MolecuLight on the appropriate OPPS payment, particularly with respect to the cost of providing the service in the hospital outpatient setting.

For CY 2021, we proposed to continue to assign CPT code 0598T to APC 5722 (Level 2 Diagnostic Tests and Related Services) with a proposed payment rate of $269.85. We proposed to maintain a status indicator of ''N'' for CPT code 0599T, which is an add-on code, to indicate that the payment is included in the primary procedure. The long descriptors and proposed SI and APC assignments for both codes can be found in Table 31 below.

Comment: Some commenters agreed with the APC assignment to APC 5722 for CPT code 0598T, however, they had concerns with the packaged status indicator assignment for CPT code 0599T, and suggested assigning the code to a different APC and revising the status indicator from ''N'' (packaged) to ''S'' (Procedure or Service, Not Discounted When Multiple). One commenter indicated that the payment is insufficient to cover the cost of the procedure and contended that the low reimbursement will dissuade hospitals from offering the service. The commenter reported that the procedure requires the use of a Dark Drape technology and also requires significant time because the second ulcer and subsequent ulcers typically involve different anatomical locations. Another commenter reported that hospital outpatient charges for CPT code 0598T are between $850 and $2,500 for the first wound and between $850 and $1,850 for subsequent anatomic sites. The same commenter suggested that OPPS payment is inadequate, especially in cases that involve additional wounds in different anatomic sites such as the sacrum, abdomen, toe, or leg, all of which require additional resource costs. Consequently, the commenter requested a revision in the APC assignment for both codes. Specifically, the commenter recommended reassigning CPT code 0598T from APC 5722 to APC 5723 (Level 3 Diagnostic Tests and Related Services) with a proposed payment of $497.96, and to assign CPT code 0599T to APC 5722 with a proposed payment of $269.85. In addition, the commenter recommended assigning both codes status indicator ''S''.

Response: With regard to CPT code 0598T, based on our evaluation of the new technology application submitted to CMS as well as input from our physicians, we believe that we should maintain the assignment to APC 5722 for CY 2021. In addition, because CPT code 0599T is an add-on code, we are maintaining its status indicator assignment of ''N'' (packaged). As specified in section § 419.2(b)(18), add-on codes are generally packaged under

the hospital OPPS. As explained in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74942 through 74945), we finalized a policy to unconditionally package procedures described by add-on codes. Procedures described by add-on codes represent an extension or continuation of a primary procedure, which means that they are typically supportive, dependent, or adjunctive to a primary service. The primary code defines the purpose and typical scope of the patient encounter and the add-on code describes incremental work, when the extent of the procedure encompasses a range rather than a single defined endpoint applicable to all patients. Given the dependent nature and adjunctive characteristics of procedures described by add-on codes and in light of longstanding OPPS packaging principles, we finalized a policy to unconditionally package add-on codes with the primary procedure.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign CPT code 0598T to APC 5722 with status indicator ''T'' and to assign CPT code 0599T status indicator ''N'' for CY 2021. The final CY 2021 payment rate for CPT code 0598T can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 31.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0598T AND 0599T FOR CY 2021

CY 2021 CPT Code	Long Descriptor	Proposed CY 2021 OPPS SI	Proposed CY 2021 OPPS APC	Final CY 2021 OPPS SI	Final CY 2021 OPPS APC
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity)	T	5722	T	5722
0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (for example, upper extremity) (List separately in addition to code for primary procedure)	N	N/A	N	N/A

19. Nuclear Medicine Services: Single-Photon Emission Computed Tomography (SPECT) Studies (APC 5593)

For CY 2021, we proposed to reassign CPT code 78803 (Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (spect), single area (*e.g.*, head, neck, chest, pelvis), single day imaging) from APC 5593 (Level 3 Nuclear Medicine and Related Services) with a payment rate of $1,272.19 to APC 5592 (Level 2 Nuclear Medicine and Related Services) with a proposed payment rate of $501.45.

Comment: Several commenters objected to the reassignment of CPT code 78803 to APC 5592 and requested that we not finalize our proposal but rather maintain the current placement in APC 5593. They stated that the significant payment decrease would limit patient access, affect patient care, and restrict hospitals from offering the test. One commenter reported that the Medicare payment for CPT code 78803 is insufficient, and as a result, many hospitals refuse to offer the service. This same commenter reported that lowering the payment for the test may force some hospitals that currently offer the test to stop providing it altogether. The commenter added that many patients travel hours to access a SPECT scan exam and lowering the payment for the test would not improve patient care. Some commenters reminded us that for CY 2020, CPT code 78803 replaced seven codes that were deleted on December 31, 2019. Most commenters stated that the more appropriate placement for CPT code 78803 is APC 5593, based on resource use and clinical similarity to the other procedures in the APC.

Response: We discussed the issue related to the seven deleted codes in the CY 2020 OPPS/ASC final rule (84 FR 61257 through 61258) and noted that based on the geometric mean costs for CPT code 78803 and the deleted codes, we believe it was necessary for us to maintain the APC assignment for CPT code 78803 in APC 5593. Because the CY 2021 OPPS payments are based on claims submitted between January 1, 2019 through December 31, 2019, and processed through June 30, 2020, we again reviewed the claims data for the deleted codes to determine the appropriate placement for CPT code 78803. As listed in Table 32, the range of geometric mean costs for CPT code 78803 and the seven deleted codes is between $408 and $1,508. Similar to our CY 2020 findings, we note that several of the deleted codes were assigned to APC 5593, and based on our review of these codes, we believe it would be appropriate to maintain assignment of CPT code 78803 to APC 5593 for CY 2021.

TABLE 32.--GEOMETRIC MEAN COSTS FOR CPT CODE 78803 AND ITS DELETED PREDECESSOR CPT CODES

CPT Code	Status	Long Descriptor	SI	APC	Geometric Mean Cost
78205	DELETED	Liver imaging; with vascular flow	S	5592	$541.27
78206	DELETED	Liver imaging (spect);	S	5592	$494.65
78320	DELETED	Bone and/or joint imaging; tomographic (spect)	S	5592	$408.09
78607	DELETED	Brain imaging, tomographic (spect)	S	5593	$1,508.47
78647	DELETED	Cerebrospinal fluid flow, imaging (not including introduction of material); tomographic (spect)	S	5592	$487.74
78710	DELETED	Kidney imaging morphology; tomographic (spect)	S	5592	$447.65
78803	ACTIVE	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); tomographic (spect)	S	5593	$528.97
78807	DELETED	Radiopharmaceutical localization of inflammatory process; tomographic (spect)	S	5592	$632.56

Comment: One commenter agreed with the proposal to maintain the four levels of nuclear medicine APCs for CY 2021 but requested that CMS consider establishing additional APCs as needed to ensure that the nuclear medicine APCs do not violate the 2-times rule when the cost of packaged diagnostic radiopharmaceuticals drugs are included.

Response: We appreciate the feedback and will consider in future rulemaking whether establishing additional nuclear medicine APCs would be appropriate.

In summary, after consideration of the public comments, and after our analysis of the updated claims data for this final rule with comment period, we are finalizing a modification to our proposal. Specifically, we are revising the APC assignment for CPT code 78803 to APC 5593 for CY 2021. The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

As we do every year, we will reevaluate the APC assignment for CPT code 78803 for the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

20. Pathogen Test for Platelets/Rapid Bacterial Testing (APC 5732)

For the July 2017 update, the HCPCS Workgroup established HCPCS code Q9987 (Pathogen(s) test for platelets) effective July 1, 2017. This new code and the OPPS APC assignment were announced in the July 2017 OPPS quarterly update CR (Transmittal 3783, Change Request 10122, dated May 26, 2017). Because HCPCS code Q9987 represented a test to identify bacterial or other pathogen contamination in blood platelets, we assigned the code to a new technology APC, specifically, New Technology APC 1493 (New Technology—Level 1C ($21–$30)) with a status indicator ''S'' and a payment rate of $25.50. We note that temporary HCPCS code Q9987 was subsequently deleted on December 31, 2017, and replaced with permanent HCPCS code P9100 (Pathogen(s) test for platelets) effective January 1, 2018. For the January 2018 update, we continued to assign the new code to the same APC and status indicator as its predecessor code. Specifically, we assigned HCPCS code P9100 to New Technology APC 1493 and status indicator ''S''. For the CY 2019 update, we made no change to the APC or status indicator assignment for P9100, however, for the CY 2020 update, we revised the APC assignment from New Technology APC 1493 to 1494 (New Technology—Level 1D ($31–$40)) based on the latest claims data used to set the payment rates for CY 2020. We discussed the revision in the CY 2020 OPPS/ASC final rule (84 FR 61219) and indicated that the reassignment to APC 1494 appropriately reflected the cost of the service.

For the CY 2021 proposed rule, we believed that we had sufficient claims data to reassign the code from a New Technology APC to a clinical APC, and noted that HCPCS code P9100 had been assigned to a New Technology APC for over 3 years. As stated in section III.D. (New Technology APCs), a service is paid under a New Technology APC until sufficient claims data have been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. We expect this to occur within two to three years from the time a new HCPCS code becomes effective. However, if we are able to collect sufficient claims data in less than 2 years, we would consider reassigning the service to an appropriate clinical APC. Since HCPCS code P9100 has been assigned to a new technology APC since July 2017, we believed that we should reassign the code to a clinical APC. Specifically, our claims data for the proposed rule showed a geometric mean cost of approximately $30 for HCPCS code P9100 based on 70 single claims (out of 1,835 total claims). Based on resource cost and clinical homogeneity to the other services assigned to APC 5732 (Level 2 Minor Procedures), we believed that HCPCS code P9100 should be reassigned to clinical APC 5732, which had a geometric mean cost of approximately $33.

As we have stated several times since the implementation of the OPPS on August 1, 2000, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For the CY 2021 OPPS update, based on claims submitted between January 1, 2019, and December

30, 2019, our analysis of the latest claims data for the proposed rule supported reassigning HCPCS code P9100 to APC 5732 based on its clinical and resource similarity to the procedures and services in the APC. Therefore, we proposed to reassign HCPCS code P9100 from New Technology APC 1494 to clinical APC 5732 for CY 2021.

Comment: A commenter supported our proposal to revise the APC assignment for HCPCS code P9100 to APC 5732.

Response: We appreciate the support for our proposal. Based on our review of the updated claims data for this final rule with comment period, which is based on claims submitted between January 1, 2019, and December 30, 2019, and processed through June 30, 2020, we continue to believe that reassigning HCPCS code P9100 to APC 5732 is appropriate. Specifically, our claims data show a geometric mean cost of approximately $30.86 for HCPCS P9100 based on 75 single claims (out of 2,038 total claims), which is consistent with the geometric mean cost of about $32.97 for APC 5732.

In summary, after consideration of the public comment, and after our analysis of the updated claims data for this final rule with comment period, we are finalizing our proposal, without modification, to assign HCPCS code P9100 to APC 5732 for CY 2021. The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

21. Payment for Radioisotopes Derived From Non-Highly Enriched Uranium (Non-HEU) Sources (APC 1442)

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States would like to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, and conversion to such production has begun. We expect that this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68321).

Comment: One commenter requested that we increase the payment rate for HCPCS add-on code Q9969 from $10. The commenter noted that we have not increased the payment rate for Q9969 since the code was established in CY 2013. The commenter suggested increasing the payment for Q9969 by the annual market basket increase for CY 2021 along with a one-time increase to reflect prior increases to the market basket between CY 2013 and CY 2021. Alternatively, the commenter suggested the payment rate could be increased by the change in the drug cost threshold packaging amount between CY 2013 and CY 2021.

Response: We appreciate the information we received from the commenter supporting an increase to the payment rate of $10 for HCPCS code Q9969. As discussed in the CY 2013 OPPS/ASC final rule with comment period, we did not finalize a policy to use the usual OPPS methodologies to update the non-HEU add-on payment (77 FR 68317). The purpose of the additional payment is limited to mitigating any adverse impact of transitioning to non-HEU sources and we believe the add-on is appropriate at this time.

Comment: Multiple commenters supported the current payment amount for HCPCS code Q9969 and they requested that we finalize our proposed payment rate for the add-on.

Response: We appreciate the support of the commenters for the proposed payment rate for HCPCS code Q9969.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue the policy of providing an additional $10 payment for radioisotopes produced by non-HEU sources for CY 2021 and subsequent years as represented by HCPCS code Q9969.

22. Percutaneous Transcatheter Ultrasound Nerve Ablation

The Therapeutic Intra-Vascular Ultrasound System (TIVUS™) is a high intensity, non-focused, ultrasound catheter system, which enables remote, localized, controlled and repeatable thermal modulation of nerves adjacent to arterial vessel wall for performing therapeutic pulmonary artery sympathetic denervation and is used for the treatment of pulmonary arterial hypertension (PAH). In 2020, the TIVUS™ system was approved by FDA for a Category B (Nonexperimental/investigational) Investigational Device Exemption (IDE) for the device to be used in a clinical study. The study sponsors have also requested Medicare coverage of the Category B IDE study to allow for coverage of the TIVUS™ system and the routine care items and services in the clinical trial. To date, CMS has not established approval of Medicare coverage for the Category B IDE study for the TIVUS™ system.

The TIVUS™ system is used with CPT code 0632T (Percutaneous transcatheter ultrasound ablation, nerves innervating the pulmonary arteries, including right heart catheterization, radiological supervision and interpretation and pulmonary artery angiography), which will become effective January 1, 2021. In the CY 2021 OPPS/ASC proposed rule, CPT code 0632T was assigned status indicator ''E1'', which describes items, codes, and services not covered by any Medicare outpatient benefit category, statutorily excluded by Medicare, or not reasonable and necessary. These items, codes, and services are not paid by Medicare when submitted on outpatient claims.

Comment: One commenter, the manufacturer of the TIVUS™ system, requested that, in anticipation of approval of Medicare coverage for the Category B IDE study for the TIVUS™ system, CMS assign CPT code 0632T status indicator ''J1'', which describes services paid through a comprehensive APC (C–APC) instead of status indicator ''E1'' for CY 2021. The commenter also requested that CMS assign CPT code 0632T to C–APC 5213 (Level 3 Electrophysiologic Procedures) for CY 2021, stating that the procedure is similar in clinical characteristics and resource costs to CPT code 93656 (Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia including

left or right atrial pacing/recording, when necessary, right ventricular pacing/recording when necessary, and his bundle recording when necessary with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation), which is assigned to C–APC 5213 for CY 2021.

Response: For approved Category B IDE studies, CMS allows for coverage of the Category B device and the routine care items and services in the clinical trial. To date, coverage for the Category B IDE clinical study for the TIVUS™ system has not been approved by CMS. We do not believe that it is appropriate to assign a payable status indicator under the OPPS to CPT code 0632T prior to the approval of the Category B IDE study. Therefore, for CY 2021, we are finalizing the assignment of status indicator ''E1'' to CPT code 0632T.

23. Peripheral Intravascular Lithotripsy (IVL) Procedure (APCs 5192, 5193, and 5194)

The IVL system has three components: A proprietary IVL Catheter, an IVL Generator, and an IVL Connector Cable. It is a lithotripsy-enhanced balloon catheter used to dilate lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. The IVL catheter has integrated lithotripsy emitters and is designed to enhance percutaneous transluminal angioplasty by enabling delivery of the calcium disrupting capability of lithotripsy prior to full balloon dilatation at low pressures. The application of lithotripsy mechanical pulse waves alters the structure of an occlusive vascular deposit (stenosis) prior to low-pressure balloon dilation of the stenosis and facilitates the passage of blood and is used for the treatment of peripheral artery disease (PAD).

In 2019, FDA cleared 510(k) submission based on a determination of substantial equivalence to a legally marketed predicate device. The manufacturer also submitted a new technology application requesting new technology APC assignment for IVL procedures. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing APCs in the OPPS, we created four new HCPCS codes for these services and assigned these codes to existing clinical APCs. Specifically, CMS proposed to add HCPCS code C9764 (Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed), C9765 (Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed) C9766 (Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed), and C9767 (Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed), effective July 1, 2020. We assigned code C9764 to APC 5192 (Level 2 Endovascular Procedures) with a payment rate of $4,953.91; C9765 and C9766 to APC 5193 (Level 3 Endovascular Procedures) with a payment rate of $9,908.48; and C9767 to APC 5194 (Level 4 Endovascular Procedures) with a payment rate of $15,939.97 for CY 2020. In the CY 2021 OPPS/ASC proposed rule, we proposed to maintain these APC assignments for these codes in CY 2021.

At the August 31, 2020 HOP Panel Meeting, a presenter requested that we reassign IVL procedure C9764 to APC 5193 and procedures C9765 and C9766 to APC 5194. The presenter indicated that the APC payment associated with HCPCS code(s) C9764, C9765 and C9766 is inadequate to cover the cost of the procedures. According to the presenter, the proposed CY 2021 geometric mean cost for the procedures range from $6,619.26 to $22,305.36, not including the additional cost of the IVL catheter. The presenter reported that the cost of one catheter is $2,800 but each procedure requires an average of 1.2 catheters, bringing the total cost of catheters to $3,360 per procedure. The presenter stated that the payment rate for the IVL procedures on tibial and peroneal vessels was lower than the payment rate for similar procedures without IVL. The presenter believed that hospitals will limit access to IVL, reducing patient access, because payment for the procedure is inadequate. They argued that limiting IVL access to patients suffering from critical limb ischemia in tibial and peroneal arteries could lead to higher complications associated with current treatment modalities. They believe that traditional treatments are associated with higher risk of distal embolization, perforation and possible amputation. Based on the information presented at the meeting, the HOP Panel recommended CMS reassign HCPCS code C9764 to APC 5193 and HCPCS codes C9765 and C9766 to APC 5194, as long as the cost of the IVL device is within 10 percent of other devices currently available. However, we are unable to identify devices that are similar to IVL and therefore cannot complete the data analysis recommended by the HOP Panel.

Comment: Several commenters disagreed with CMS' proposed APC assignments for the peripheral intravascular lithotripsy service described by HCPCS codes C9764, C9765 and C9766. They reported that, based on the resource cost of the service described by HCPCS code C9764, APC 5192 does not provide adequate reimbursement for the service, and recommended reassignment to APC 5193 (Level 3 Endovascular Procedures) with a proposed payment rate of $10,222.32. Similarly, for HCPCS codes C9765 and C9766, the commenters indicated that APC 5193 would not adequately cover the resource costs associated with these procedures, and recommended their reassignment to APC 5194 (Level 4 Endovascular Procedures) with a proposed payment rate of $16,348.66.

Response: APC assignment for a code is based on similarity to other codes within an APC in terms of clinical homogeneity and resource costs. As specified in 42 CFR 419.31(a)(1), CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. As we stated in the CY 2012 OPPS/ASC final rule (76 FR 74224), the OPPS is a prospective payment system that provides payment for groups of services that share clinical and resource use characteristics. For all new codes, our policy has been to assign the service or procedure to an APC informed by a variety of sources, including but not limited to, review of the clinical similarity of the service to existing procedures; advice from CMS medical advisors; information from interested specialty societies; and review of all other information available to us, including information provided to us by the public, whether through meetings with stakeholders or additional information that is mailed or otherwise communicated to us.

Based on the comments we received, the HOP Panel recommendation, information provided in the new technology application, and advice from our medical advisors, we believe we should add new HCPCS codes to describe tibial and peroneal IVL procedures, for a total of eight IVL procedure codes, and revise the long

descriptors for HCPCS codes C9764, C9765, C9766, and C9767 by deleting the words ''any vessel(s)'' and replacing with ''lower extremity artery(ies), except tibial/peroneal'' effective January 1, 2021. We agree with commenters that the resources associated with tibial and peroneal IVL procedures are higher than iliac, femoral and popliteal procedures. Therefore, we are creating new HCPCS codes C9772, C9773, C9774, and C9775 to describe tibial and peroneal procedures and assigning these codes to APCs as listed in the Table 33 below.

In summary, after consideration of public comments, we are finalizing our proposal with modification, to provide new HCPCS codes C9772, C9773, C9774 and C9775 and assign these codes to APCs listed in Table 33. Table 33 also lists revised long descriptors for HCPCS codes C9764, C9765, C9766, and C9767, and final SI and APC assignments for all eight codes. The final CY 2021 payment rate for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

BILLING CODE 4120–01–P

TABLE 33.—FINAL SI AND APC ASSIGNMENTS FOR HCPCS CODES C9764 THROUGH C9767 AND C9772 THROUGH C9775 FOR CY 2021

CY 2021 HCPCS Code	Long Descriptor	Final OPPS SI	Final OPPS APC
C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	J1	5192
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	J1	5193
C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	J1	5193
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	J1	5194
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	J1	5193
C9773	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	J1	5194
C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	J1	5194
C9775	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	J1	5194

BILLING CODE 4120–01–C

24. Remote Physiological Monitoring (APC 5741)

a. Initial Remote Monitoring of Physiologic Parameters (APC 5741)

For the CY 2019 update, the CPT Editorial Panel established a new code, specifically, CPT code 99454, to describe initial remote monitoring of physiological parameters effective January 1, 2019. In the CY 2019 update, we assigned this code to APC 5741 (Level 1 Electronic Analysis of Devices) with status indicator ''Q1'' (conditionally packaged) and a payment rate of $37.16 effective January 1, 2019, based on the clinical and resource similarity with CPT code 93270 (External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)). The new code appeared in the OPPS Addendum B of the CY 2019 OPPS/ASC final rule.

For CY 2020 OPPS/ASC final rule, we maintained the assignment of CPT code 99454 to APC 5741 with a payment rate of $36.25. We note that we had no claims data for CPT code 99454 for the CY 2020 final rule since the code was established on January 1, 2019. For the CY 2021 OPPS/ASC proposed rule, we proposed to maintain the assignment of CPT code 99454 to APC 5741 with the proposed payment rate of $37.76.

Comment: One commenter was concerned that the current reimbursement rate is too low, which the commenter believes discourages providers from using much-needed equipment and services. The commenter stated that CMS must ensure that life-saving RPM technology would be available to Medicare beneficiaries by updating the status indicator and increasing reimbursement rate for CPT code 99454. The commenter requested: (1) A change in the status indicator for CPT code 99454 from ''Q1'' to ''S,'' so that it will be paid when used in conjunction with other services; and (2) reassignment of CPT code 99454 from APC 5741 (Level 1 Electronic Analysis of Devices) to APC 5742 (Level 2 Electronic Analysis of Devices).

Response: As we have stated every year since the implementation of the OPPS on August 1, 2000, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For CY 2021, based on claims submitted between January 1, 2019 through December 31, 2019, that were processed on or before June 30, 2020, our analysis of the latest claims data for this final rule with comment period supports continuing to assign CPT code 99454 to APC 5741. Specifically, our claims data shows a geometric mean cost of approximately $28.06 for CPT 99454 based on 185 single claims (out of 275 total claims), which is comparable to the geometric mean cost of about $36.19 for APC 5741, rather than the geometric mean cost of approximately $97.72 for APC 5742.

We proposed to assign code 99454 to status indicator ''Q1'' for CY 2021 to indicate that the payment for CPT code 99454 is packaged when the code is billed on the same claim as a HCPCS code assigned to OPPS status indicator ''S'', ''T'', or ''V'', but is paid separately when it is the only major service on the claim. Because the service described by CPT code 99454 will most often be performed as part of another significant procedure, we believe that packaging the cost associated with CPT code 99454 into the primary service is appropriate. Therefore, assignment of status indicator ''Q1'' to CPT 99454 is appropriate.

In summary, after consideration of the public comments and after evaluation of our claims data for this final rule with comment period, we are finalizing our proposal, without modification, for CPT code 99454. The final CY 2021 payment rate for the CPT code 99454 can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

As we do every year, we will reevaluate the APC assignment for CPT code 99454 for the next rulemaking cycle. We remind hospitals that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on the latest claims data.

b. Remote Physiological Monitoring Services, Virtual Check-In, E-Visits, Telephone E/M, and Medication Management Services

For CY 2021, we proposed to continue to assign CPT code 99091 (Collection and interpretation of physiologic data (*e.g.*, ecg, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days) to status indicator ''N'' (packaged) to indicate that the payment for the service is included in the primary service reported with the code. We also proposed to continue to assign CPT codes 99457 (Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes) and 99458 (Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (list separately in addition to code for primary procedure)) to status indicator ''B'' (not recognized under OPPS) to indicate that the codes are not paid under the hospital OPPS but may be paid under a different Medicare payment system other than the OPPS. However, if the services described by either CPT code 99457 or 99458 are performed in the hospital outpatient facility, the facility should report an alternate code. These codes are listed in Table 34 along with the descriptors and status indicator assignments. In addition, the definitions for all the OPPS status indicators can be found in Addendum D1.

We note that for CY 2020, we revised the status indicator for CPT code 99457 from ''M'' (Items and Services Not Billable to the MAC. Not paid under OPPS) to ''B,'' and for CPT code 99458, which is an add-on code, from ''N'' (packaged) to ''B'' effective March 1, 2020. We made the changes to enable Critical Access Hospitals (CAHs) to bill under CAH's Method II for these waiver services so that claims with these codes would process appropriately in the Integrated Outpatient Code Editor (IOCE). We announced the revisions in the July 2020 OPPS Quarterly Update CR (Transmittal 10224, Change Request 11814, dated July 15, 2020).

At the August 31, 2020 HOP Panel Meeting, a presenter requested that we revise the status indicators for these codes. Specifically, the presenter suggested that CPT codes 99091 and 99457 should be treated similar to HCPCS G0463 (Hospital outpatient clinic visit for assessment and management of a patient), which is assigned to status indicator ''V'' (Clinic or Emergency Department Visit) and APC 5012 (Clinic Visits and Related Services) which has a CY 2021 proposed payment rate of $120.88. Based on the discussion at the Panel Meeting, the HOP Panel recommended that the status indicator for CPT codes 99091 and 99457 be revised to ''V'' and the status indicator for CPT code 99458 be revised

to ''N''. We note that we are not accepting the Panel's recommendation because we believe that we need further review to determine whether these type of services (*i.e.,* remote physiologic monitoring) should be paid separately under the OPPS. We appreciate the HOP Panel's recommendations on the status indicator revisions for CPT codes 99091, 99457, and 99458, and will consider them in future rulemaking.

Comment: For CPT code 99091, one commenter disagreed with the status indicator assignment of ''N,'' and stated the code should not be packaged because the service may be the only OPPS service furnished during a month for a registered hospital outpatient. The commenter recommended assigning the code to either status indicator ''V'' or treating it similar to CPT code 99454 (Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days), which has a payable status indicator of ''Q1'' (STV-Packaged Codes) and assigned to APC 5741 (Level 1 Electronic Analysis of Devices) with a CY 2021 proposed payment of $37.76.

Response: Although we are sensitive to the concern raised by the commenter, we do not believe that revising the status indicator for CPT code 99091 would be appropriate at this time. We believe we need further review of this code, along with all the remote physiological monitoring (PRM) service codes, to determine whether these types of services should be separately payable under the OPPS. Therefore, for CY 2021, we are finalizing our proposal, without modification and will continue to assign CPT code 99091 to status indicator ''N,'' and consider the suggestion to revise the status indicator in future rulemaking. The final CY 2021 status indicator for CPT code 99091 can also be found in Table 34 below.

Comment: For CPT code 99457, several commenters suggested reassigning the code to status indicator ''V,'' similar to CPT code 99453 (Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment), which has a payable status indicator of ''V'' and assigned to APC 5012 with a CY 2021 proposed payment of $120.88. The commenters stated that in the CY 2020 Physician Fee Schedule (PFS), CMS clarified that ''CPT codes 99457 and 99458 can be furnished by clinical staff under the general supervision of the physician or NPP.'' Based on this statement, the commenters believe that CPT code 99457 should be paid separately under the OPPS. The commenters reported that because the code is currently assigned to status indicator ''B,'' hospital outpatient facilities do not receive any reimbursement when the service is provided by clinical staff in a hospital outpatient setting. One commenter stated that the status indicator should be revised to ''V'' to support the service being provided to Medicare beneficiaries under the order of a physician.

Response: We appreciate the commenters' suggestions, however, we believe we need further evaluation of this code, along with the rest of the RPM service codes, to determine whether this type of service should be separately payable under the OPPS. Therefore, for CY 2021, we are finalizing our proposal, without modification, to assign CPT code 99457 to status indicator ''B.'' We will consider the commenters' suggestion to revise the status indicator for future rulemaking. The final CY 2021 status indicator for CPT code 99457 can also be found in Table 34 below. Also, as noted above, we revised the status indicator for CPT code 99457 from ''M'' to ''B'' effective March 1, 2020, to enable Critical Access Hospitals (CAHs) to bill under CAH's Method II for these waiver services so that claims with this code would process appropriately in the Integrated Outpatient Code Editor (IOCE). We announced the revisions in the July 2020 OPPS Quarterly Update CR (Transmittal 10224, Change Request 11814, dated July 15, 2020).

Comment: For CPT code 99458, the commenters suggested the reassignment to status indicator ''N'' because this is an add-on code.

Response: As noted above, similar to CPT code 99457, we revised the status indicator for CPT code 99458 to ''B'' effective March 1, 2020, to enable Critical Access Hospitals (CAHs) to bill under CAH's Method II for the service so that claims with this code would process appropriately in the Integrated Outpatient Code Editor (IOCE). We announced the revisions in the July 2020 OPPS Quarterly Update CR (Transmittal 10224, Change Request 11814, dated July 15, 2020). We appreciate the commenters' suggestions, however, we believe we need further evaluation of this code, along with the rest of the RPM service codes, to determine whether this type of service should be separately payable under the OPPS. Therefore, for CY 2021, we are finalizing our proposal, without modification, to assign CPT code 99458 to status indicator ''B,'' and we will consider the suggestion to revise the status indicator in future rulemaking. The final CY 2021 status indicator for CPT code 99458 can be found in Table 34 below.

Comment: One commenter indicated that CMS is currently paying separately for certain RPM services and have assigned the codes to separately payable status indicator ''V,'' ''S,'' or ''Q1,'' however, some other RPM codes are assigned to non-payable status indicators such as ''B'' and ''M''. The commenter added that the status indicator assignments for the RPM codes are inconsistent and confusing to providers. The same commenter suggested that CMS recognize each distinct RPM CPT code that require hospital resources and assign the codes consistently to payable status indicators. The commenter recommended reassigning CPT codes 93264, 93268, 93297, 93298 from status indicator ''M'' to ''S'' and assigning the code to either APC 5741 (Level 1 Electronic Analysis of Devices) with a proposed CY 2021 payment rate of $37.76, APC 5742 (Level 2 Electronic Analysis of Devices) with a proposed CY 2021 payment rate of $101.76, or APC 5743 (Level 3 Electronic Analysis of Devices) with a proposed CY 2021 payment rate of $272.91. The commenter stated that CPT codes 93264, 93268, 93297, 93298 should be covered and payable, similar to CPT code 93296 (Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results), which is assigned to APC 5741 with a proposed CY 2021 payment rate of $37.76. The same commenter suggested reassigning CPT code 99474 from status indicator ''B'' to ''V'' and assigning it to APC 5012, similar to CPT code 99453 (Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment).

Response: We appreciate the commenter's suggestions, however, we believe that we need further evaluation of the codes to determine whether all RPM CPT codes should be paid separately under the OPPS. Therefore, for CY 2021, we are finalizing our proposal, without modification, to assign CPT codes 93264, 93268, 93297, and 93298 to status indicator ''M,'' and consider the suggestions to revise the status indicator and assign appropriate APCs to the codes in future rulemaking. Similarly, we are finalizing our

proposal, without modification, to assign CPT code 99474 to status indicator B'' for CY 2021. The final status indicators for CPT codes 93264, 93268, 93297, 93298, and 99474 can be found in Table 34 below.

Commenter: One commenter suggested revising the status indicator for 19 CPT codes that describe virtual check-ins, e-visits, and telephone evaluation and management services from non-payable to separately payable under the OPPS. The 19 codes, along with the proposed status indicator assignments and descriptors, can be found in Table 34 below. The commenter explained that when clinicians furnish virtual check-ins, e-visits, and telephone E/M services to hospital outpatients, hospital resources are used to support the clinician. The commenter stated that while the codes are separately payable under the PFS, the hospital resources are not paid separately under the OPPS. The commenter believes that under 42 CFR 419.22, virtual or remote services are not excluded from OPPS and, therefore, the facility expense should be paid separately under the OPPS.

Response: We appreciate the commenter's suggestions, however, we believe that we need further evaluation of the 19 codes to determine whether the services should be paid separately under the OPPS. Therefore, for CY 2021, we are finalizing our proposal, without modification, to assign the codes to either status indicator ''A'' or ''B'' for the 19 codes listed in Table 34 as virtual check-in, e-visit, and telephone E/M services.

Comment: One commenter suggested revising the status indicator for two medication therapy management (MTM) codes from ''E1'' to ''B,'' and indicated that the codes should be assigned to the same status indicator as genetic counseling code CPT 96040 (Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family), which is assigned to status indicator ''B'' under the OPPS. Specifically, the commenter recommended reassigning CPT codes 99605 (Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, new patient) and 99606 (Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, established patient) from ''E1'' to ''B.'' The commenter explained that the CY 2021 PFS proposed rule clarified that genetic counseling and pharmacist services can be considered ''incident to'' a professional service in the office setting. Specifically, the commenter noted that the 2021 PFS proposed rule (85 FR 50146) states ''Medication management is covered under both Medicare Part B and Part D. We are reiterating the clarification we provided in the May 1st COVID–19 IFC (85 FR 27550 through 27629), that pharmacists fall within the regulatory definition of auxiliary personnel under our regulations at § 410.26. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit.'' In light of the statements, the commenter believes that when MTM services are furnished in the HOPD setting, the hospital outpatient facility is reporting for the pharmacists' services, which the commenter believes meet the definition of outpatient services at 42 CFR 410.27 and the definition of OPPS services at 42 CFR 419.21. Consequently, the commenter believes that MTM services should be paid separately under the OPPS.

Response: We appreciate the commenter's suggestions, however, we believe that we need further evaluation of the two MTM codes to determine whether the services should be paid separately under the OPPS. We note that policies discussed in the PFS proposed rules typically do not apply to OPPS policies; however, we will review the issue. Therefore, for CY 2021, we are finalizing our proposal, without modification, to assign the codes to status indicator ''E1'' for the 2 MTM codes listed in Table 34.

Comment: One commenter suggested that CMS treat all telehealth and communication technology-based services (CTBS) consistently with OPPS payable status indicators and ambulatory payment classification (APC) assignments. The commenter explained that these issues were discussed in the 2021 PFS proposed rule.

Response: We appreciate the commenter's suggestion, however, we believe that we need further evaluation of the issue to determine whether all the codes that describe telehealth and communication technology-based services (CTBS) should be paid separately under the OPPS. In addition, we made no proposals regarding these issues in the CY 2021 OPPS/ASC proposed rule. As stated above, the proposed policies discussed in the PFS proposed rules typically do not apply to OPPS policies because they are two different Medicare payment systems. However, we will review the issue for potential future rulemaking.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, for the 29 codes listed in Table 34 for CY 2021. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

BILLING CODE 4120–01–P

TABLE 34.—FINAL SI ASSIGNMENTS FOR THE REMOTE PHYSIOLOGICAL MONITORING, VIRTUAL CHECK-INS, E-VISITS, TELEPHONE E/M, AND MEDICATION THERAPY MANAGEMENT CODES

HCPCS Code	Short Descriptor	Proposed CY 2021 OPPS SI	Commenters Suggested SI	Commenters Suggested APC	Category	Final CY 2021 OPPS SI
93264	Rem mntr wrls p-art prs snr	M	S	5741, 5742 or 5743	Remote Physiological Monitoring (RPM)	M
93268	Ecg record/review	M	S	5741, 5742 or 5743	Remote Physiological Monitoring (RPM)	M
93297	Rem interrog dev eval icpms	M	S	5741, 5742 or 5743	Remote Physiological Monitoring (RPM)	M
93298	Rem interrog dev eval scrms	M	S	5741, 5742 or 5743	Remote Physiological Monitoring (RPM)	M
99091	Collj & interpj data ea 30 d	N	V	5012	Remote Physiological Monitoring (RPM)	N
99457	Rem physiol mntr 1st 20 min	B	V	5012	Remote Physiological Monitoring (RPM)	B
99458	Rem physiol mntr ea addl 20	B	N	N/A	Remote Physiological Monitoring (RPM)	B
99474	Self-meas bp 2 readg bid 30d	B	V	5012	Remote Physiological Monitoring (RPM)	B
98966	Hc pro phone call 5-10 min	A	V	5012	Telephone E/M	A

HCPCS Code	Short Descriptor	Proposed CY 2021 OPPS SI	Commenters Suggested SI	Commenters Suggested APC	Category	Final CY 2021 OPPS SI
98967	Hc pro phone call 11-20 min	A	V	5012	Telephone E/M	A
98968	Hc pro phone call 21-30 min	A	V	5012	Telephone E/M	A
99441	Phone e/m phys/qhp 5-10 min	B	V	5012	Telephone E/M	B
99442	Phone e/m phys/qhp 11-20 min	B	V	5012	Telephone E/M	B
99443	Phone e/m phys/qhp 21-30 min	B	V	5012	Telephone E/M	B
98970	Qnhp ol dig e/m svc 5-10min	B	V	5012	E-visit	B
98971	Qnhp ol dig em svc 11-20min	B	V	5012	E-visit	B
98972	Qnhp ol dig e/m svc 21+ min	B	V	5012	E-visit	B
99421	Ol dig e/m svc 5-10 min	B	V	5012	E-visit	B
99422	Ol dig e/m svc 11-20 min	B	V	5012	E-visit	B
99423	Ol dig e/m svc 21+ min	B	V	5012	E-visit	B
G2061	Qual nonmd est pt 5-10m	A	V	5012	E-visit	A
G2062	Qual nonmd est pt 11-20m	A	V	5012	E-visit	A
G2063	Qual nonmd est pt 21>min	A	V	5012	E-visit	A

HCPCS Code	Short Descriptor	Proposed CY 2021 OPPS SI	Commenters Suggested SI	Commenters Suggested APC	Category	Final CY 2021 OPPS SI
G2010	Remot image submit by pt	A	V	5012	Virtual Check-in	A
G2012	Brief check in by MD/QHP	A	V	5012	Virtual Check-in	A
Placeholder code G20X2	Placeholder code G20X2	in PFS	V	5012	Virtual Check-in	A
Placeholder code G20X0	Placeholder code G20X0	in PFS	V	5012	Virtual Check-in	A
99605	Mtms by pharm np 15 min	E1	B	N/A	Medication Therapy Management (MTM)	E1
99606	Mtms by pharm est 15 min	E1	B	N/A	Medication Therapy Management (MTM)	E1

BILLING CODE 4120–01–C

25. Review of Electrocorticograms From an Implanted Brain Neurostimulator (APC 5741)

For CY 2021, we proposed to continue to assign CPT code 95836 (Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days) to APC 5741 (Level 1 Electronic Analysis of Devices) with a proposed payment of $37.76.

Comment: A commenter urged CMS to reassign CPT code 95836 from APC 5741 to APC 5742 (Level 2 Electronic Analysis of Devices) with a proposed payment rate of $101.76, and stated that the payment for APC 5741 does not adequately reflect the resources used by HOPDs in performing this procedure.

Response: Based on our analysis of the hospital outpatient claims data for this final rule, we disagree that the resource cost to perform the service is inappropriate. Our evaluation of the latest claims data show a geometric mean cost of about $14 based on 21 single claims (out of 213 total claims). We believe that reassigning the code to APC 5742, whose geometric mean cost is approximately $98, would significantly overpay for the service. Additionally, we believe that the payment for CPT code 95836 is sufficient to cover the hospital cost of performing the service.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to continue to assign CPT code 95836 to APC 5741 for CY 2021. The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

As we do every year, we will reevaluate the APC assignment for CPT code 95836 in the next rulemaking cycle. We remind hospitals that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on the latest claims data available to us.

26. Therapeutic Apheresis

The LIXELLE® β2-microglobulin Apheresis Column is indicated for use in the treatment of dialysis-related amyloidosis (DRA), a disease that affects people with end-stage renal disease (ESRD) who have been receiving dialysis for five or more years. The LIXELLE® device is used in an apheresis procedure that selectively removes β2-microglobulin (''β2m'') from the circulating blood of patients with DRA. LIXELLE® is used pursuant to a physician prescription in conjunction with hemodialysis and is intended to be used at each hemodialysis session (*i.e.,* frequency of treatment is expected to be three times per week).

In March 2015, FDA approved LIXELLE® as a Class III Humanitarian Use Device (HUD) with an approved Humanitarian Device Exemption (HDE). FDA regulations require the manufacturer to conduct a post-approval study (PAS) to evaluate the safety of the LIXELLE® Apheresis procedure in U.S. patients on chronic hemodialysis with clinically-diagnosed DRA, and assess the probable benefit of LIXELLE® Apheresis to increase the β2m reduction rate in these patients in successive dialysis sessions (compared to dialysis without LIXELLE®). Currently, there is no payment under the OPPS for the apheresis procedure used with the LIXELLE® device.

Comment: One commenter, the manufacturer of the LIXELLE® device,

requested that CMS provide payment for the apheresis procedure used with the device under the OPPS. The commenter stated that the LIXELLE® apheresis procedure may be administered in either a dialysis facility or the hospital outpatient department and that the HOPD was the more clinically appropriate setting. Specifically, the commenter requested that CMS provide payment through the OPPS via one of three potential pathways: (1) Allow payment for the apheresis procedure used with the LIXELLE® device through CPT code 36516 (Therapeutic apheresis with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion), which was proposed to be assigned to APC 5243 (Level 3 Blood Product Exchange and Related Services) for CY 2021, and require the use of a modifier or add-on code when the LIXELLE® apheresis procedure is billed to reduce the payment for the procedure to the payment rate for APC 5242 (Level 2 Blood Product Exchange and Related Services); (2) allow payment for the dialysis performed as part of LIXELLE® apheresis procedure through HCPCS code G0257 (Unscheduled or emergency dialysis treatment for an ESRD patient in a hospital outpatient department that is not certified as an ESRD facility), which is assigned to APC 5401 (Dialysis) for CY 2021, and require the use of a modifier or add-on code to provide additional payment beyond that provided by APC 5401; or (3) create a HCPCS C code or G code for the LIXELLE® apheresis procedure and assign the code to APC 5242 (Level 2 Blood Product Exchange and Related Services). Finally, the commenter also noted that they have been unable to complete the FDA-required post-approval study as a condition of the HDE, due to difficulty in securing patient enrollment because of lack of CMS payment for the LIXELLE® apheresis procedure.

Response: We appreciate these comments and understand the various issues related to coverage and payment for the LIXELLE® apheresis procedure. We will consider these comments for future rulemaking.

27. Tympanostomy Using an Automated Tube Delivery System (APC 5163)

As displayed in Addendum B to the CY 2021 OPPS/ASC proposed rule, we proposed to assign CPT code 0583T (Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia) to status indicator (SI) ''E1'' to indicate that the code is not payable by Medicare when submitted on outpatient claims (any outpatient bill type) because the services associated with these codes are either not covered by any Medicare outpatient benefit category, are statutorily excluded from Medicare payment, or are not reasonable and necessary.

Comment: Some commenters reported that the device associated with CPT code 0583T received FDA approval in November 2019 and requested separate payment for the code. They specifically requested assignment to APC 5164 (Level 4 ENT Procedures), with a proposed payment of $2,776.63, and also requested assignment to either status indicator ''S'' (Procedure or Service, Not Discounted When Multiple) or ''T'' (Procedure or Service, Multiple Procedure Reduction Applies). They reported that assignment to APC 5164 would match the resources furnished when providing this service. The manufacturer for the device associated with the code explained that while the surgical procedure described by CPT code 0583T is primarily performed on children, the device is approved for all ages above 6 months. The manufacturer also indicated that the procedure will be extremely important for the Medicaid population and Medicaid programs who often refer to Medicare to establish coverage and payment. One commenter reported that the total cost for the complete procedure is approximately $2,776, while the device manufacturer reported a cost of about $1,400 for the device.

Response: Based on our review of the procedure and input from our medical advisors, we believe that the surgical procedure described by CPT code 0583T is most similar, in terms of clinical homogeneity and resource cost, to CPT code 69436 (Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia), which is assigned to APC 5163 (Level 3 ENT Procedures) with a proposed payment of about $1,395. Both procedures (as described by CPT codes 0583T and 69436) require ventilating tubes that require anesthesia. Therefore, we believe that the most appropriate APC assignment for CPT code 0583T is APC 5163, which is associated with status indicator ''J1'' (Hospital Part B services paid through a comprehensive APC).

In summary, after consideration of the public comments, we are finalizing our proposal with modification, and assigning CPT code 0583T to APC 5163 with a status indicator of ''J1'' for CY 2021. The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

28. Unlisted Dental Procedure (APC 5161)

For CY 2021, we proposed to continue to assign CPT code 41899 (Unlisted procedure, dentoalveolar structures) to APC 5161 (Level 1 ENT Procedures) with a payment rate of $213.59.

Comment: Two dental specialty societies expressed concern with the payment rate for CPT code 41899. They explained that this is the only CPT code available for dental surgery and its low reimbursement is insufficient to cover the facility costs. The commenters added that the low payment rate has resulted in many dentists, especially pediatric dentists, experiencing difficulty in obtaining operating room (OR) time to perform surgical procedures under general anesthesia. They stated that the problem has been exacerbated by the COVID–19 pandemic, with further limited access to ORs to address patient dental needs.

Response: CPT code 41899 is designated as an unlisted code. Some HCPCS codes are used to report items, services, and procedures that do not define the exact item, service, or surgical procedure furnished. They are commonly called ''unlisted'' codes. The code descriptors often contain phrases such as: ''unlisted procedure,'' ''not otherwise classified,'' or ''not otherwise specified.'' The unlisted codes typically fall within a clinical or procedural category, but they lack the specificity needed to describe the resources used. Until a more specific HCPCS code is established, as an interim, the unlisted code provides a way for providers to report items, services, and procedures furnished. In general, unlisted codes are reported when no other specific CPT or Level II HCPCS code accurately describes the item, procedure, or service. Because of the lack of specificity, unlisted codes are assigned to the lowest level, clinically appropriate APC group under the OPPS. The assignment of the unlisted codes to the lowest level APC in the clinical category specified in the code provides a reasonable means for interim payment until such time as there is a code that specifically describes what is being paid. It also encourages the creation of codes where appropriate and protects against overpayment of services that are not clearly identified on the claim. As a reminder, unlisted codes are not used in establishing the percent of claims contributing to the APC, nor are their

costs used in the calculation of the APC geometric mean (80 FR 70321), because, by the code's definition, we do not know what service or combination of services is reflected in the claims billed with the unlisted code. Currently, we have five levels of ENT Procedure APCs, Levels 1 through 5, with Level 1 assigned to the lowest paying of the five APCs. Because the code is designated as an unlisted code, we believe that CPT 41899 code is appropriately assigned to APC 5161, which is the lowest level ENT APC.

In addition, because unlisted codes are non-specific, HOPDs are reminded that Medicare Administrative Contractors (MACs) may have additional documentation requirements for how the codes should be reported to receive payment. Refer to section 180.3 (Unlisted Service or Procedure) in Chapter 4 (Part B Hospital) of the Medicare Claims Processing Manual for information on how MACs review claims with unlisted codes.

We note that AMA establishes new CPT codes, depending on the code type, quarterly and annually. Interested parties that desire more specific codes for unlisted codes should consult the AMA. Information on CPT codes and the process for requesting new codes can be found on the AMA website: *https://www.ama-assn.org/about/cpt-editorial-panel/cpt-code-process*.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign CPT code 41899 to APC 5161 for CY 2021. The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

29. Urology and Related Services (APCs 5371 Through 5378)

We received comments on the CY 2020 OPPS/ASC proposed rule suggesting we revise the APC assignments for the services assigned to the Urology & Related Services APCs. The commenter specifically noted that a reorganization for APCs 5374 through 5376 would be appropriate, but added that there were other adjustments across services within the Urology APCs that could improve the structure of these APCs. In response to this comment, we stated in the CY 2020 OPPS/ASC final rule with comment period that we would consider revisions to the urology APCs in future rulemaking.

Currently, for CY 2020, there are seven levels of APCs for urology services. We reviewed the geometric mean cost for APCs 5371 through 5377 and, after our analysis of the claims data for the CY 2021 OPPS/ASC proposed rule, we believed that a modification to the urology APCs would be appropriate.

For the CY 2021 OPPS/ASC proposed rule, we evaluated the claims data and noted the large difference in geometric mean cost between APC 5376 (level 6) and APC 5377 (level 7) has continued to grow. This difference in the geometric mean cost from APC 5376 to APC 5377 would have been about $9,700, with the geometric mean cost for APC 5377 at approximately 220 percent of the geometric mean cost of APC 5376. Based on the proposed rule claims data, which showed an unusually large difference between the geometric mean costs of the Level 6 Urology APC and the Level 7 Urology APC on both a dollar and percentage basis, we believed that creating an additional APC in the urology and related series would provide an appropriate structure, distinguishing between clinical and cost similarity for the procedures in the different levels. Therefore, for CY 2021, we proposed to establish an additional level for the urology and related services APCs, specifically, APC 5378 (Level 8 Urology and Related Services) and to re-organize the current APCs 5376 (Level 6 Urology and Related Services) and 5377 (Level 7 Urology and Related Services). We believed this re-organization would address the lack of an appropriate level for procedures with geometric mean costs that fall between current APC 5376 and current APC 5377.

As we stated in the proposed rule (85 FR 48842), the proposed reorganization would reassign CPT 53440 (Male sling procedure) and CPT 0548T (Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy) from the current APC 5376 to APC 5377.

In addition, the proposed revision would reassign the following services from APC 5377 to APC 5378:

- CPT 54416 (Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session).
- CPT 53444 (Insert tandem cuff).
- CPT 54410 (Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session).
- CPT 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).
- CPT 54401 (Insertion of penile prosthesis; inflatable (self-contained)).
- CPT 54405 (Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir).
- CPT 53447 (Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session).
- CPT 53445 (Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff).

As further stated in the proposed rule, the proposed APC reassignment for these 10 codes results in geometric mean costs for Levels 6, 7, and 8 of the Urology APCs that we believe more appropriately align with the geometric mean costs for services in these APCs than the current structure. Specifically, as listed in Table 19 of the proposed rule, and reprinted below, the geometric mean cost of $8,089.78 for APC 5376, $11,275.15 for APC 5377, and $18,015.54 for APC 5378 reduces the unusually large gaps on both a dollar and percentage basis in geometric mean costs between each APC level.

TABLE 19*. —PROPOSED CY 2021 GEOMETRIC MEAN COST FOR THE UROLOGY AND RELATED APCS 5371 THROUGH 5378

APC	Group Title	SI	CY 2020 OPPS Geometric Mean Cost	Proposed CY 2021 OPPS Geometric Mean Cost
5371	Level 1 Urology and Related Services	T	$229.83	$262.04
5372	Level 2 Urology and Related Services	T	$544.53	$565.10
5373	Level 3 Urology and Related Services	J1	$1,733.35	$1,758.24
5374	Level 4 Urology and Related Services	J1	$2,953.45	$3,010.01
5375	Level 5 Urology and Related Services	J1	$4,140.38	$4,324.38
5376	Level 6 Urology and Related Services	J1	$7,893.96	$8,089.78
5377	Level 7 Urology and Related Services	J1	$17,195.00	$11,275.15
5378	Level 8 Urology and Related Services	J1	N/A	$18,015.54

* Table19 of the CY 2021 OPPS/ASC proposed rule

We received many comments on our proposal. Below are the comments and our responses.

Comment: Several commenters supported our proposal to establish an additional Urology and Related Services APC, specifically, APC 5378 (Level 8 Urology and Related Services), and re-organize the current APCs 5376 (Level 6 Urology and Related Services) and 5377 (Level 7 Urology and Related Services). These commenters agreed that the addition of APC 5378 within the Urology APCs would better align procedures based on their resource cost and clinical homogeneity.

Response: We appreciate the commenters' support for our proposal to establish new APC 5378 and to re-organize the procedures in the Urology APCs. We note that each year, under the OPPS, we revise and make changes to the APC groupings based on the latest hospital outpatient claims data to appropriately place procedures and services in APCs based on clinical characteristics and resource similarity. We note that based on our review of the claims data for the final rule, we are also finalizing our proposal without modification to reassign CPT codes 53440 and 0548T to APC 5377. Similarly, we are finalizing our proposal without modification to reassign CPT codes 54416, 53444, 54410, 54411, 54401, 54405, 53447, and 53445 to APC 5378.

Comment: A commenter supported the continued assignment of HCPCS code C9739 (Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants) to APC 5375 and HCPCS C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) to APC 5376.

Response: We appreciate the commenter's support for our APC assignments, which are based on our review of the latest claims data. We are finalizing our proposal and assigning these codes to the proposed APCs in this final rule.

Comment: Several commenters also recommended additional changes within APCs 5371 to APC 5376. Specifically, for APCs 5371 and 5372, the commenters recommended the following reassignments from APC 5371 to APC 5372:

- CPT 51720 (Bladder instillation of anticarcinogenic agent (including retention time);
- CPT 43763 (lacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; requiring revision of gastrostomy tract);
- 51725 Simple cystometrogram (cmg) (*e.g.,* spinal manometer);
- 51726 Complex cystometrogram (*i.e.,* calibrated electronic equipment); and
- 51040 Cystostomy, cystotomy with drainage.

Also, the commenters suggested the reassignment of the following codes from APC 5373 to APC 5374:

- 52287 Cystourethroscopy, with injection(s) for chemodenervation of the bladder
- 52276 Cystourethroscopy with direct vision internal urethrotomy
- 54840 Excision of spermatocele, with or without epididymectomy
- 53854 Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy

In addition, the commenters recommended reassigning the following codes from APC 5375 to APC 5376:

- 53420 Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; first stage;
- C9747 Ablation of prostate, transrectal, high intensity focused ultrasound (hifu), including imaging guidance;
- 53410 Urethroplasty, 1-stage reconstruction of male anterior urethra;
- 50553 Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization, with or without dilation of ureter;
- 54111 Excision of penile plaque (peyronie disease); with graft to 5 cm in length;
- 55875 Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy;
- 54660 Insertion of testicular prosthesis (separate procedure);
- 50576 Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy; and
- 0549T Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy;

Further, the commenters suggested revising the assignment for these codes from APC 5376 to APC 5377:

- 55873 Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring);
- 50081 Percutaneous nephrostolithotomy or pyelostolithotomy, with or without dilation, endoscopy, lithotripsy, stenting, or basket extraction; over 2 cm; and
- 50562 Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with resection of tumor.

Response: Based on our review of the claims data for the final rule, we do not believe that reassigning these 21 urology procedures to the suggested APCs is appropriate. Our review of the claims data for this CY 2021 OPPS/ASC final rule with comment period show that the procedures are appropriately placed in the proposed APCs based on clinical homogeneity and resource costs. Consequently, we are finalizing our proposal without modification for the 21 urology procedures discussed above.

In summary, after consideration of the public comments, and after our analysis of the updated claims data for this final rule with comment period, we are finalizing our proposal, without modification, to reorganize the Urology and Related Services APCs. The final CY 2021 payment rate for the codes for all the codes discussed above can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

a. High-Intensity Focused Ultrasound of the Prostate (HIFU) Procedure (APC 5375)

In 2017, CMS received a new technology application for the prostate HIFU procedure and established a new code, specifically, HCPCS code C9747 (Ablation of prostate, transrectal, high intensity focused ultrasound (hifu), including imaging guidance). Based on the estimated cost provided in the new technology application, we assigned the new code to APC 5376 (Level 6 Urology and Related Services) with a payment rate of $7,452.66 effective July 1, 2017. We announced the SI and APC assignment in the July 2017 OPPS quarterly update CR (Transmittal 3783, Change Request 10122, dated May 26, 2017).

For the CY 2018 update, we maintained the assignment of HCPCS code C9747 to APC 5376 with a payment rate of $7,596.26. We note that the payment rates for the CY 2018 OPPS update were based on claims submitted between January 1, 2016 through December 30, 2016, that were processed on or before June 30, 2017. Since HCPCS code C9747 was established on July 1, 2017, we had no claims data for the procedure for use in ratesetting for CY 2018.

However, for the CY 2019 update, based on the latest claims data for the final rule, we revised the APC assignment for HCPCS code C9747 from APC 5376 to APC 5375 with a payment rate of $4,020.54. We note that the payment rates for CY 2019 were based on claims submitted between January 1, 2017 through December 30, 2017, that were processed on or before June 30, 2018. Our claims data showed a geometric mean cost of approximately $5,000 for HCPCS code C9747 based on 64 single claims (out of 64 total claims), which was significantly lower than the geometric mean cost of about $7,717 for APC 5376. We believed that the geometric mean cost for HCPCS code C9747 was more comparable to the geometric mean cost of approximately $4,055 for APC 5375. Consequently, we reassigned the code from APC 5376 to APC 5375 (Level 5 Urology and Related Services) for CY 2019 and C9747 remained in APC 5376 for CY 2020.

For CY 2021, we proposed to continue to assign HCPCS code C9747 to APC 5375 with a proposed payment rate $4,487.87. In addition, we noted that HCPCS C9747 will be replaced with CPT 55880 beginning January 2021.

Comment: Many commenters stated that the APC 5375 payment rate does not cover the hospital facility cost for this procedure, and thus, discourages hospitals from providing this procedure for Medicare patients. Some commenters argued that HIFU is a device-intensive procedure, believed that the average cost of the HIFU procedure is closer to the APC 5376 proposed payment rate of $8,395.87, and requested a reassignment to enable Medicare beneficiaries to receive the treatment. They projected that maintaining the assignment in APC 5375 will deter HOPD facilities from offering the HIFU treatment to Medicare beneficiaries because the payment is insufficient to cover the cost of the procedure. Several commenters recommended we assign this procedure to APC 5376 because they believe the service is clinically similar and comparable in terms of resources to cryoablation of the prostate, which is described by CPT code 55873 (Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring) and assigned to APC 5376 (Level 6 Urology and Related Services), with a proposed payment rate of $8,395.62.

Response: As we have stated every year since the implementation of the OPPS on August 1, 2000, we review, on an annual basis, the APC assignments for all services and items (including devices) paid under the OPPS based on our analysis of the latest claims data. For CY 2021, based on claims submitted between January 1, 2019 through December 30, 2019, that were processed on or before June 30, 2020, our analysis of the latest claims data for this final rule supports maintaining HCPCS code C9747 in APC 5375. Specifically, our claims data shows a geometric mean cost of approximately $5,744 for HCPCS code C9747 based on 279 single claims, which is more comparable to the geometric mean cost of about $4,300 for APC 5375, rather than the geometric mean cost of approximately $8,045 for APC 5376. Furthermore, the claims data do not indicate that HCPCS code C9747 meets the device-intensive threshold of 30 percent. Therefore, we are not designating HCPCS code C9747 as a device-intensive procedure.

With regard to the issue of similarity to CPT code 55873, while we agree both procedures are intended to treat prostate cancer, we disagree that the resource costs associated with the prostate HIFU procedure are necessarily similar to those of cryoablation of the prostate. Specifically, our claims data for cryoablation of the prostate shows a geometric mean cost of about $8,423 based on 1,226 single claims. The geometric mean cost for CPT code 55873 is reasonably consistent with APC 5376, which has a geometric mean cost of approximately $8,045.

In summary, after careful consideration of the public comments and after our analysis of the updated claims data for this final rule with comment period, we are maintaining the APC assignment for HCPCS code C9747 in APC 5375. We note that for the CY 2021 update, the CPT Editorial Panel established CPT code 55880 (Ablation of malignant prostate tissue, transrectal, with high intensity—focused ultrasound (HIFU), including ultrasound guidance) to describe HIFU effective January 1, 2021. Therefore, we are deleting HCPCS code C9747 on December 31, 2020 because it will be replaced with CPT code 55880. The final CY 2021 payment rate for CPT code 55880 can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes

reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

b. Optilume Procedure—Optilume Drug Coated Balloon Catheter System (APC 5375)

For the July 2020 update, the CPT Editorial Panel established a new code, specifically, Category III CPT code 0619T (Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed), to describe the surgical procedure associated with the Optilume Drug Coated Balloon Catheter System used to treat benign prostate hyperplasia (BPH). We announced the APC assignment for CPT code 0619T in the July 2020 OPPS quarterly update CR (Transmittal 10207, Change Request 11814, dated July 2, 2020).

Specifically, we assigned CPT code 0619T to APC 5375 (Level 5 Urology and Related Services) with a payment rate of approximately $4,232 effective July 1, 2020 and also assigned the code a status indicator of ''J1'' (Hospital Part B services paid through a comprehensive APC). Based on input from our medical advisors and the nature of the procedure, we believed that the procedure described by CPT code 0619T was similar, based on clinical homogeneity and resource cost, to CPT code 52601 (Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)).

Comment: A commenter asserted that CPT code 0619T should be reassigned to APC 5376 (Level 6 Urology and Related Services). The commenter reported that the CPT code 0619T is more clinically similar to HCPCS C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) in terms of clinical characteristics, physician work/intraoperative intensity, and resource costs including both non-device related and device related costs. Furthermore, the commenter also indicated that CPT code 0619T has additional non-device costs, including transrectal ultrasound, fluoroscopy and use of a rectal steeper device. The commenter stated that CPT code 0619T has similar resource cost to HCPCS code C9740 in terms of its device and non-device cost.

Response: We appreciate the commenter's input on this subject and we understand that this is a new procedure without a predecessor code. Based on our evaluation, we do not agree that CPT code 0619T is similar to HCPCS code C9740. Based on the nature of the procedure and input from our medical advisors, we believe CPT code 0619T is more comparable to HCPCS code C9739 (Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants), and CPT 52601 (Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)), which are both currently assigned to APC 5375 (Level 5 Urology and Related Services). We believe the assignment of CPT code 0619T to APC 5375 and its device-offset of 31 percent is appropriate until CMS receives more cost data to support a reassignment to another APC or a different device offset adjustment.

In summary, after consideration of the comment, we are finalizing our proposal without modification to continue to assign CPT code 0619T to APC 5375 for CY 2021. The final CY 2021 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

30. Venous Mechanical Thrombectomy (APC 5193)

For CY 2020, CPT code 37187 (Percutaneous transluminal mechanical thrombectomy, vein(s), including intraprocedural pharmacological thrombolytic injections and fluoroscopic guidance) is assigned to APC 5192 (Level 2 Endovascular Procedures) with a payment of $4,953.91. For CY 2021, we proposed to reassign CPT code 37187 from APC 5192 to APC 5193 (Level 3 Endovascular Procedures) with a proposed payment of $10,222.32.

Comment: A commenter approved of our proposal to reassign CPT code 37187 to APC 5193 and requested that CMS finalize the proposal. The commenter noted that the geometric mean cost of CPT code 37187 is well aligned with APC 5193, and stated that the cost of the venous mechanical thrombectomy procedure is comparable to other clinically similar procedures within the APC.

Response: We appreciate the support for our proposal to reassign CPT code 37187 from APC 5192 to APC 5193. The claims data for the final rule, which is based on claims submitted between January 1, 2019, through December 31, 2019, processed through June 30, 2020, show that the geometric mean cost for CPT code 37187 is approximately $10,385, which is within the range of procedures of significant volume within APC 5193. Procedures with significant volume in APC 5193 range between $7,278 for CPT code 36905 and $13,492 for CPT code 37225. We believe that reassigning CPT code 37187 is appropriate based on its clinical homogeneity and similarity in resource costs to the other thrombectomy procedures (*e.g.,* 36905, 37225) assigned to APC 5193.

In summary, after consideration of the public comment, we are finalizing our proposal to assign CPT code 37187 to APC 5193 for CY 2021. The final CY 2021 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings 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. 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 42 CFR 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 42 CFR 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 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.

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).

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 7 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; and C1748-Endoscope, single-use (that is disposable), Upper GI, imaging/illumination device (insertable).

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 category for HCPCS code C1748 will end on June 30, 2023; and the pass-through payment status of the device categories for HCPCS codes C1824, C1982, C1839, C1734, and C2596 will end on December 31, 2022. Table 35 shows the expiration of transitional pass-through payments for these devices. All of these HCPCS codes will have pass-through payment status and will continue to receive pass-through payments in CY 2021.

Table 35: 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

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 2021 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 2021 OPPS/ASC proposed rule for a complete discussion of this pathway.

As specified in regulations at 42 CFR 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 a 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 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.

Comment: Some commenters requested that CMS waive the criteria for establishing new device categories specified at § 419.66(c)(1), which states 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, for devices that are granted a FDA Breakthrough Device designation. The commenters stated that these devices should automatically be considered not to be described by any of the existing (either currently active or expired) categories established for transitional device pass-through payments because the FDA Breakthrough Device designation implies that the device is a first of kind. These commenters noted that under the IPPS New Technology Add-on Payment (NTAP), devices granted a Breakthrough Device designation that have received FDA marketing authorization are considered new and not substantially similar to an existing technology for purposes of the NTAP.

Response: We continue to believe that it is necessary to evaluate whether a device that has been granted a FDA Breakthrough Device designation is already described by any of the current device pass-through categories or by any category previously in effect to ensure that no device is described by more than one category. We also remind stakeholders that the criteria for establishing a new device category described in the regulation at 42 CFR 419.66(c)(1) are unique to the OPPS device pass-through policy.

b. Applications Received for Device Pass-Through Payment for CY 2021

We received five complete applications by the March 1, 2020 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2021 OPPS/ASC proposed rule. We received one of the applications in the second quarter of 2019, two of the applications in the fourth quarter of 2019, and two of the applications in the first quarter of 2020. Two of the applications were approved for device pass-through payment during the quarterly review process: CUSTOM*FLEX*® ARTIFICIAL*IRIS* and EXALT™ Model D Single-Use Duodenoscope. CUSTOM*FLEX*® ARTIFICIAL*IRIS* received fast-track approval under the alternative pathway effective January 1, 2020. EXALT™ Model D Single-Use Duodenoscope received fast-track approval under the alternative pathway effective July 1, 2020. 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, CUSTOM*FLEX*® ARTIFICIAL*IRIS* and EXALT™ Model D Single-Use Duodenoscope are discussed below in section IV.2.b.1.

Applications received for the later deadlines for the remaining 2020 quarters (June 1, September 1, and December 1), if any, will be presented in the CY 2022 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, 2020 deadline is presented below.

1. Alternative Pathway Device Pass-Through Applications

We received three device pass-through applications by the March 2020 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 final rule with comment, under this alternative pathway, devices that are granted a 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 will need to meet the other requirements for pass-through payment status in our regulation at § 419.66.

(1) CUSTOM*FLEX*® ARTIFICIAL*IRIS*

VEO Ophthalmics submitted an application for a new device category for transitional pass-through payment status for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* by the June 2019 quarterly deadline. The CUSTOM*FLEX*® ARTIFICIAL*IRIS* device is described as a foldable iris prosthesis that is custom-made for each individual patient who requires one. The applicant stated that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* comes in two models-With Fiber or Fiber Free. The two models are identical in every respect except that the With Fiber model has a polyester meshwork layer embedded in it to provide adequate tear strength to withstand suturing.

The applicant provided that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is intended to serve as an artificial iris prosthesis, inserted at the time of cataract surgery or during a subsequent stand-alone procedure. The CUSTOM*FLEX*® ARTIFICIAL*IRIS* is indicated for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia. The conditions that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* treats are rare; congenital aniridia is present in approximately 1.8 in 100,000 live births (1 in 40,000 to 1 in 100,000),[6–2] congenital IridoCorneal Endothelial Syndrome (ICE) syndrome is even less common (incidence not available). Iris defects such as iatrogenic iridodialysis as a complication of cataract surgery has variable prevalence, ranging from 0–0.84 percent of surgeries,[3–8] and may

[6] Berlin HS, Ritch R. The treatment of glaucoma secondary to aniridia. Mt Sinai J Med. 1981;48:11.

[2] Nelson LB, Spaeth GL, Nowinski TS, et al. Aniridia. A review. Surv Ophthalmol. 1984; 28:621–642.

[3] Greenberg PB, Tseng VL, Wu WC, et.al. Prevalence and predictors of ocular complications associated with cataract surgery in United States veterans. Ophthalmology. 2011 Mar;118(3):507–14.

[4] Jaycock P, Johnston RL, Taylor H, et al., UK EPR User Group. The Cataract National Dataset electronic multi-centre audit of 55,567 operations: Updating benchmark standards of care in the United Kingdom and internationally. Eye (Lond). 2009;23:38–49.

[5] Lum F, Schein O, Schachat AP, et al. Initial two years of experience with the AAO National Eyecare Outcomes Network (NEON) cataract surgery database. Ophthalmology. 2000;107:691–697.

occur in approximately 0.2 percent of blunt orbital trauma.[9] Although rare, these conditions are cosmetically and functionally limiting. The applicant provided that in addition to a noticeably absent or irregular iris/pupil, affected patients frequently experience photophobia (light sensitivity) and glare as well as symptoms such as dry eye.[10] [11]

According to the applicant, currently available treatments for symptomatic glare, photophobia, and cosmesis are limited, and an FDA-approved, commercially available iris prosthesis fills a needed gap. Alternatives include tinted spectacles or contact lenses, iris reconstruction (for example, pupilloplasty or iridodialysis repair), and corneal tattooing.[10] Among these, tinted spectacles can provide some symptomatic relief, but the applicant stated that they do not address the underlying problem and cannot be used in all settings. Iris reconstruction requires that sufficient iris tissue be present. Tinted contact lenses and corneal tattooing are cosmetically not ideal and have an associated risk of corneal infection (corneal ulcer and infectious keratitis). According to the applicant, in addition, corneal tattooing has a risk of surface toxicity, anterior segment inflammation, and/or corneal epithelial defect. The only other artificial iris devices in the U.S. were previously available under FDA compassionate use exemption (Morcher 50F, 96F; Ophtec 311 aniridia lens).[10] However, these devices are no longer available following FDA approval of the CUSTOM*FLEX*® ARTIFICIAL*IRIS.*

With respect to the newness criterion at § 419.66(b)(1), the FDA designated the CUSTOM*FLEX*® ARTIFICIAL*IRIS* as a Breakthrough Device on December 21, 2017, and approved the premarket approval application (PMA) for CUSTOM*FLEX*® ARTIFICIAL*IRIS* (P170039) on May 30, 2018 for use in the treatment of full or partial aniridia resulting from congenital or acquired defects. The applicant provided that there was a roughly 3-month market delay after receipt of PMA approval while final labeling in its printed form was submitted to FDA and FDA completed its review and approval process. The applicant notes that commercial availability of the device commenced on September 12, 2018 after it received FDA approval for the final labeling. We received the application for a new device category for transitional pass-through payment status for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* on May 31, 2019, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the newness criterion.

Comment: Commenters claimed that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the newness criterion as described at § 419.66(b)(1).

Response: After consideration of the public comments and our review of the application, we agree that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the newness criterion as described at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the applicant stated that the device is implanted via injection through a 2.75–4 mm clear corneal incision. Depending on the site of implantation (capsular bag, ciliary sulcus, sutured to sclera), the device is cut (trephined) to the correct diameter. The device can also be sutured to an intraocular lens if an intraocular lens is also implanted at the time of surgery. The applicant further provided that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted. The applicant also claimed that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* 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 solicited public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the eligibility criteria at § 419.66(b).

Comment: Commenters believed that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the eligibility criteria as described at § 419.66(b).

Response: After consideration of the public comments we received and our review of the application, we agree that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the eligibility criteria as described 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. Upon review, it did not appear that there were any other existing pass-through payment categories that might apply to the CUSTOMFLEX® ARTIFICIAL*IRIS* and we solicited public comments on this issue.

Comment: Commenters claimed that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the criterion for establishing new device categories specified at § 419.66(c)(1).

Response: After consideration of the public comments we received, we have determined that there are no existing pass-through categories that appropriately describe the CUSTOMFLEX® ARTIFICIAL*IRIS* and we have determined the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the criterion for establishing new device categories specified at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. As stated in section IV.2.a above, devices that apply under the alternative pathway for devices that have a Breakthrough Device designation with a FDA marketing authorization are not subject to evaluation for substantial clinical improvement (84 FR 61295). The CUSTOM*FLEX*® ARTIFICIAL*IRIS* was designated as a Breakthrough Device by FDA on December 21, 2017.

We did not receive comments on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the second criterion for establishing a device category at § 419.66(c)(2)(i). Based on its Breakthrough Device designation, we

[6] Steinberg EP, Tielsch JM, Schein OD, et.al. National study of cataract surgery outcomes: Variation in 4-month postoperative outcomes as reflected in multiple outcomes measures Ophthalmology. 1994;101:1131–1140.

[7] Schein OD, Steinberg EP, Javitt JC, et al. Variation in cataract surgery practice and clinical outcomes. Ophthalmology. 1994;101:1142–1152.

[8] Powe NR, Schein OD, Gieser SC, et al. Cataract Patient Outcome Research Team Synthesis of the literature on visual acuity and complications following cataract extraction with intraocular lens implantation. Arch Ophthalmol, 1994;112:239–252.

[9] Kreidl KO, Kim DY, Mansour SE. Prevalence of significant intraocular sequelae in blunt orbital trauma. Am J Emerg Med. 2003 Nov;21(7):525–8.

[10] Weissbart SB, Ayres BD. Management of aniridia and iris defects: An update on iris prosthesis options. Curr Opin Ophthalmol. 2016 May;27(3):244–9.

[11] Lee HJ, Colby KA. A review of the clinical and genetic aspects of aniridia. Semin Ophthalmol. 2013 Sep-Nov;28(5–6):306–12.

have determined that CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets this 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 CUSTOM*FLEX*® ARTIFICIAL*IRIS* would be reported with CPT code 66999—Unlisted procedure, anterior segment of eye, which was assigned to APC 5491 (Level 1 Intraocular Procedures) for Calendar Year (CY) 2020. 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 5491, which had a CY 2019 payment rate of $1,917. 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 66999 had a device offset amount of $149.80 at the time the application was received. According to the applicant, the cost of the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is $7,700, for both the Fiber Free and with Fiber models.

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 $7,700 for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is 402 percent of the applicable APC payment amount for the service related to the category of devices of $1,917 (($7,700/$1,917) × 100 = 402 percent). Therefore, we stated in the CY 2021 OPPS/ASC proposed rule that we believe the CUSTOM*FLEX*® ARTIFICIAL*IRIS* 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 $7,700 for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is 5,140 percent of the cost of the device-related portion of the APC payment amount for the related service of $150 (($7,700/$150) × 100 = 5,140 percent). Therefore, we stated in the CY 2021 OPPS/ASC proposed rule that we believe that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* 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 $7,700 for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* and the portion of the APC payment amount for the device of $1,917 is 394 percent of the APC payment amount for the related service of $150 (($7,700 − $150)/$1,917) × 100 = 394 percent). Therefore, we stated in the CY 2021 OPPS/ASC proposed rule that we believe that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the third cost significance requirement.

We solicited public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the device pass-through payment criteria discussed in this section, including the cost criterion.

Comment: We received comments indicating that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the device pass-through payment criteria, including the cost criterion.

Response: After considering the public comments received and our review of the application, we have determined that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the device pass-through payment criteria, including the cost criterion.

As stated above, we received the application for the CUSTOMFLEX® ARTIFICIAL*IRIS* application by the June 1, 2019 quarterly deadline and preliminarily approved it for transitional pass-through payment under the alternative pathway for CY 2020, effective January 1, 2020. We solicited public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* should continue to receive transitional pass-through payment under the alternative pathway for devices that have FDA's Breakthrough Device designation and marketing authorization.

Comment: Commenters stated that CUSTOM*FLEX*® ARTIFICIAL*IRIS* should continue to receive transitional pass-through payment.

Response: After consideration of the public comments we received and our review of the device pass-through application, we have determined that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the requirements for device pass-through payment status described at § 419.66. As stated previously, devices that are granted a FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but must meet the other criteria for device pass-through status, which we believe CUSTOM*FLEX*® ARTIFICIAL*IRIS* does. Therefore, we are finalizing approval for device pass-through payment status for CUSTOM*FLEX*® ARTIFICIAL*IRIS* under the alternative pathway for devices that have a FDA Breakthrough Device designation and are FDA market authorized. For CY 2021, we will continue the device pass-through payment status for CUSTOM*FLEX*® ARTIFICIAL*IRIS.*

(2) EXALT™ Model D Single-Use Duodenoscope

Boston Scientific Corporation submitted an application before the March 2020 quarterly deadline for a new device category for transitional pass-through payment status for the EXALT™ Model D Single-Use Duodenoscope. The EXALT™ Model D Single-Use Duodenoscope is described as a sterile, single-use, flexible duodenoscope used to examine the duodenum and perform endoscopic retrograde cholangiopancreatography (ERCP) procedures by facilitating access to the pancreaticobiliary system. The applicant stated that it has designed the technology of the EXALT™ Model D Single-Use Duodenoscope to eliminate the risk of nosocomial infections due to improper reprocessing of a reusable duodenoscope. As stated above, the EXALT™ Model D Single-Use Duodenoscope is used during ERCP procedures that are performed to examine bile and pancreatic ducts. According to the applicant, the EXALT™ Model D Single-Use Duodenoscope enables passage and manipulation of accessory devices in the pancreaticobiliary system for diagnostic and therapeutic purposes, as necessary. During the ERCP procedure, the physician inserts the duodenoscope through the patient's mouth, passes the duodenoscope through the esophagus and stomach and enters into the first part of the small intestine (duodenum). The applicant stated that during ERCP a cannula is passed through the duodenoscope via a working channel and used to cannulate a small opening on the duodenal wall. Once that step is complete, the physician injects contrast while x-rays are taken to study the bile and/or pancreatic ducts. If the physician

identifies an area that warrants further investigation, accessory devices can be inserted through the working channel of the scope and into the pancreaticobiliary system for diagnosis or treatment. According to the applicant, after the conclusion of the procedure, the single-use EXALT™ Model D Single-Use Duodenoscope device has no further medical use and is fully disposable.

With respect to the newness criterion at § 419.66(b)(1), the FDA designated the EXALT™ Model D Single-Use Duodenoscope as a Breakthrough Device on November 19, 2019, and approved the premarket approval application (K193202) for EXALT™ Model D Single-Use Duodenoscope on December 13, 2019. We received the application for a new device category for transitional pass-through payment status for the EXALT™ Model D Single-Use Duodenoscope on January 17, 2020, which is within 3 years of the date of the initial FDA premarket approval. We solicited public comment on whether the EXALT™ Model D Single-Use Duodenoscope meets the newness criterion.

Comment: The manufacturer of EXALT™ Model D Single-Use Duodenoscope believes the device meets the eligibility criteria for device pass-through payment under the regulation at § 419.66, which includes the newness criterion, based on FDA Breakthrough Device designation it received on December 13, 2019 and the 510(k) premarket approval it received on November 19, 2019.

Response: We appreciate the commenter's input. After consideration of the public comment we received and based on the fact that the EXALT™ Model D Single-Use Duodenoscope application was received January 17, 2020, within 3 years of FDA premarket approval, which was on November 19, 2019, and FDA Breakthrough Device designation on December 13, 2019, we believe that the EXALT™ Model D Single-Use Duodenoscope meets the newness criterion.

With regard to the eligibility criterion at § 419.66(b)(3), according to the applicant, the EXALT™ Model D Single-Use Duodenoscope is integral to the ERCP service provided, is used for one patient only, and is surgically inserted as it is inserted through the patient's mouth, down the esophagus, into the stomach, and then into the first part of the small intestine. The applicant also stated that the EXALT™ Model D Single-Use Duodenoscope 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.

Comment: The manufacturer of EXALT™ Model D Single-Use Duodenoscope believed that the EXALT™ Model D Single-Use Duodenoscope met the eligibility criteria at § 419.66(b). They maintained that the EXALT™ Model D Single-Use Duodenoscope meets the criterion at § 419.66(b)(3) because it is integral to the ERCP service provided, is used for one patient only, and is surgically inserted through the patient's mouth, down the esophagus, into the stomach, and then into the first part of the small intestine. The commenter believes the device meets eligibility requirements at § 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.

Response: We appreciate the commenter's feedback. Based on the information we have received from the commenter and our review of the application, we have determined that EXALT™ Model D Single-Use Duodenoscope meets the eligibility criteria at § 419.66(b)(3) and (b)(4) because, as previously discussed, the device is integral to the service furnished, is used for one patient only, and is inserted through the patient's mouth, down the esophagus, into the stomach, and finally into the first part of the small intestine. It also 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.

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. With respect to the existence of a previous pass-through device category that describes EXALT™ Model D Single-Use Duodenoscope, the applicant suggested a category descriptor of ''Duodenoscope, single-use.'' The applicant also provided an existing device category ''C1749, Endoscope, retrograde imaging/illumination colonoscope device (implantable),'' for pass-through payment for another endoscope and explained why they believe the category descriptor is not applicable to EXALT™ Model D Single-Use Duodenoscope. The applicant stated that HCPCS C1749 does not appropriately describe the EXALT Model D, as C1749 is intended to describe endoscopic imaging devices that are inserted through a colonoscope and into the colon. The applicant argued that EXALT Model D is the first and only single-use duodenoscope through which devices can be passed, and it is utilized in ERCP procedures. The applicant further stated that the scope that is the subject of this request provides access to a different part of the anatomy, specifically, the pancreaticobiliary system and facilitates access for diagnostic and therapeutic purposes, as opposed to the devices described by C1749, which are endoscopic imaging devices that are inserted through a colonoscope and into the colon, providing access to a different part of the anatomy. Upon review, we agreed with the applicant that it does not appear that there are any other existing pass-through payment categories that might apply and we solicited public comment on this issue.

Comment: Several commenters stated they did not believe there is an existing pass-through payment category that describes the EXALT™ Model D Single-Use Duodenoscope. They commented that the existing device category that CMS identified does not adequately describe critical aspects of the device. The commenters also noted that existing category, C1749 Endoscope, retrograde imaging/illumination colonoscope device (implantable), does not appropriately describe single-use endoscopes that provide access to a different part of the anatomy, specifically the upper gastrointestinal (GI) tract.

Response: We appreciate the commenters' input. After consideration of the public comments we received, we agree there is no existing pass-through payment category that appropriately describes the EXALT™ Model D Single-Use Duodenoscope because it is a single use endoscope with internal channel that provides access to the duodenum and the hepatopancreatic duct. Based on this information, we have determined that the EXALT™ Model D Single-Use Duodenoscope meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part

compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. 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 EXALT™ Model D Single-Use Duodenoscope has a Breakthrough Device designation and marketing authorization from the FDA and therefore is not evaluated based on substantial clinical improvement.

We did not receive comments on whether EXALT™ Model D Single-Use Duodenoscope meets the second criterion for establishing a device category at § 419.66(c)(2). We have determined that the EXALT™ Model D Single-Use Duodenoscope meets this 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 EXALT™ Model D Single-Use Duodenoscope would be reported with CPT code 43274 which is associated with APC 5331 (Complex GI Procedures). 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. We used APC 5331 for our calculations, which had a CY 2020 payment rate of $4,780.30 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). CPT code 43274 had a device offset amount of $1,287.81 at the time the application was received. According to the applicant, the cost of the EXALT™ Model D Single-Use Duodenoscope is $2,930.

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 $2,930 for the EXALT™ Model D Single-Use Duodenoscope is 61 percent of the applicable APC payment amount for the service related to the category of devices of $4,780.30 ($2,930/$4,780.30 × 100 = 61.3 percent). Therefore, we believe the EXALT™ Model D Single-Use Duodenoscope meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,930 for the EXALT™ Model D Single-Use Duodenoscope is 228 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,287.81 ($2,930/$1,287.81) × 100 = 227.5 percent. Therefore, we believe that the EXALT™ Model D Single-Use Duodenoscope meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,930 for the EXALT™ Model D Single-Use Duodenoscope and the portion of the APC payment amount for the device of $1,287.81 is 34 percent of the APC payment amount for the related service of $4,780.30 (($2,930 − $1,287.81)/$4,780.30) × 100 = 34.4 percent). Therefore, we believe that the EXALT™ Model D Single-Use Duodenoscope meets the third cost significance requirement. We solicited public comment on whether the EXALT™ Model D Single-Use Duodenoscope meets the device pass-through payment criteria discussed in this section, including the cost criterion.

As specified above, the EXALT™ Model D Single-Use Duodenoscope application was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2020. We solicited public comment on whether the EXALT™ Model D Single-Use Duodenoscope should continue to receive transitional pass-through payment under the alternative pathway for devices that have a FDA Breakthrough Device designation and are FDA market authorized.

Comment: Several commenters, including the manufacturer of the EXALT™ Model D Single-Use Duodenoscope, believed that the device meets the cost criterion for device pass-through payment status. Some commenters recommended we not apply a device offset amount for EXALT™ Model D Single-Use Duodenoscope because they believed that single-use duodenscopes are not replacing devices that are packaged into the APC payment rate and thus, should not be subject to the device offset.

Response: We appreciate the commenters input. Section 1833(t)(6)(D)(ii) of the Act requires that the amount of payment for a pass-through device be the amount by which a hospital's charges, adjusted to cost, exceeds the portion of the otherwise applicable APC payment amount that the Secretary determines is associated with the device. The portion of the APC payment amount that we determine is associated with the cost of the pass-through device is referred to as the device offset. The device offset is used to reduce the otherwise applicable APC payment amount for the applicable pass-through device.

After further review, we agree with the commenters. We have determined that the costs associated with the EXALT™ Model D Single-Use Duodenoscope are not already reflected in the device portions of APCs 5303 (Level 3 Upper GI Procedures) or 5331 (Complex GI Procedures) because there were no single-use duodenoscopes on the market previously so no operating cost data associated with such devices could be included historical OPPS claims data. Therefore, we are not applying a device offset for the EXALT™ Model D Single-Use Duodenoscope.

After consideration of the public comments we received, we believe that EXALT™ Model D Single-Use Duodenoscope meets the cost criterion for device pass-through payment status.

For CY 2021, we will continue the device pass-through payment status for EXALT™ Model D Single-Use Duodenoscope. As stated previously, devices that are designated as Breakthrough Devices by the FDA are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but must meet the other criteria for device pass-through status, which we believe EXALT™ Model D Single-Use Duodenoscope does. Therefore, we are finalizing approval for

device pass-through payment status for EXALT™ Model D Single-Use Duodenoscope under the alternative pathway for devices that have FDA Breakthrough Device designation and FDA market authorization beginning CY 2021.

(3) BAROSTIM NEO™ System

CVRx, Inc. submitted an application for the BAROSTIM NEO™ System by the December 2019 quarterly deadline. The applicant provided that the BAROSTIM NEO™ is indicated for the treatment of symptoms of patients with advanced heart failure. The applicant asserted that the BAROSTIM therapy triggers the body's main cardiovascular reflex to regulate blood pressure and address the underlying causes of the progression of heart failure. According to the applicant, increased sympathetic and decreased parasympathetic activity contribute to heart failure (HF) symptoms and disease progression. Barostim's mechanism of action is stimulating the carotid baroreceptor which results in centrally mediated reduction of sympathetic and increase in parasympathetic activity. A single 2 mm coated electrode with a 7 mm silicone backer is sutured to the carotid artery to activate the baroreceptors. It is connected to an implantable pulse generator in the chest which provides control of baroreflex activation energy. The BAROSTIM NEO™ System uses CVRx patented BAROSTIM THERAPY™ technology to trigger the body's own natural systems (baroreflex) by electrically activating the carotid baroreceptors, the body's natural cardiovascular regulation sensors.

According to the applicant, in conditions such as hypertension and heart failure, it is believed the baroreceptors, the body's natural sensors, are not functioning properly and are not sending sufficient signals to the brain. This results in the brain sending signals to other parts of the body (heart, blood vessels, kidneys) to constrict the blood vessels, retain water and salt by the kidneys and increase stress-related hormones. The applicant provided that when the baroreceptors are activated by the BAROSTIM NEO™ system, signals are sent through neural pathways to the brain. In response, the brain works to counteract this stimulation by sending signals to other parts of the body (heart, blood vessels, and kidneys) that relax the blood vessels and inhibit the production of stress-related hormones. These changes act to reduce cardiac after-load and enable the heart to increase blood output, while maintaining or reducing its workload. Parameters are programmed into the Implantable Pulse Generator (IPG) using telemetry via a wireless external programming system. The applicant stated that the BAROSTIM NEO™ System is fully programmable to adjust the therapy to each patient's needs.

With respect to the newness criterion at § 419.66(b)(1), the FDA designated the BAROSTIM NEO™ System as a Breakthrough Device and approved the premarket approval application (P180050) on August 16, 2019 based on the improvement of symptoms of heart failure—quality of life, six-minute hall walk, and functional status—for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are New York Heart Association (NYHA) Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤35 percent, a NT-proBNP <1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines. We received the application for a new device category for transitional pass-through payment status for the BAROSTIM NEO™ on November 27, 2019, which is within 3 years of the date of the initial FDA premarketing approval. We solicited public comment on whether the BAROSTIM NEO™ meets the newness criterion.

Comment: The manufacturer stated that BAROSTIM NEO™ meets the newness criterion as described by § 419.66(b) because the FDA designated the BAROSTIM NEO™ System as a Breakthrough Device and approved the premarket application (P180050) on August 16, 2019 based on the improvement of symptoms of heart failure—quality of life, six-minute hall walk, and functional status—for patients who remain symptomatic despite treatment.

Response: We appreciate the commenter's input. After consideration of the public comments we received and because the BAROSTIM NEO™ application was received November 27, 2019 and received FDA premarketing approval on August 16, 2019 which is within 3 years, we agree that the BAROSTIM NEO™ meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of BAROSTIM NEO™ is integral to the service of providing baroreflex therapy, is used for one patient only, comes in contact with human skin and is surgically implanted or inserted. The applicant also claimed the BAROSTIM NEO™ 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 solicited public comments on whether the BAROSTIM NEO™ meets the eligibility criteria at § 419.66(b).

Comment: The manufacturer of BAROSTIM NEO™ felt that their device met the eligibility criteria at § 419.66(b) because it is used for one patient only, comes in contact with human skin and is surgically implanted or inserted. The applicant claimed the BAROSTIM NEO™ 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.

Response: Based on the information we have received and our review of the application, we agree with the commenter that the device is used for one patient only, comes in contact with human skin and is surgically implanted or inserted. We also agree with the commenter that BAROSTIM NEO™ 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. Based on this assessment we have determined that BAROSTIM NEO™ meets the eligibility criterion at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. With respect to the existence of a previous pass-through device category that described BAROSTIM NEO™, the applicant suggested a category descriptor of ''Generator, neurostimulator (implantable), non-rechargeable with carotid sinus stimulation lead.'' The applicant also provided a list of current and expired device categories for pass-through payment for other neurostimulation systems and their rationale for why they believed the category descriptors are not applicable to BAROSTIM NEO™.

The applicant stated that BAROSTIM NEO™ is not described by existing device category C1767, Generator, neurostimulator (implantable), non-

rechargeable. The applicant stated that similar to the traditional spinal cord stimulation (SCS) systems included in this category, the BAROSTIM NEO™ System is not rechargeable; however, it is the only system that works to deliver CVRx's proprietary baroreflex activation therapy (BAT). The applicant provided that BAT uses afferent signaling to the brain by stimulating the carotid artery to reduce the sympathetic signal and increase the parasympathetic signal. The applicant stated that this unique therapy works to rebalance the autonomic input to the heart to improve heart failure symptoms.

Additionally, the applicant stated that traditional devices provide pain relief by disrupting the pain signals traveling between the spinal cord's nervous system and the brain, but the BAROSTIM NEO System uses the generator to stimulate the baroreceptors in the carotid artery to treat the symptoms of patients with advanced heart failure. The applicant stated that the BAROSTIM NEO generator is unique in its capability to drive electricity up to 20 mA/100 Hz with sufficient battery capacity to provide the required therapy through the BAROSTIM NEO™ carotid sinus lead. The applicant described that the BAROSTIM NEO™ carotid sinus lead is sutured to the carotid wall, where the baroreceptors (stretch fibers) are located. Electrical current radiating from the carotid sinus lead activates the baroreceptors. When activated, the baroreceptors send afferent signals through the Carotid Sinus Nerve to the brain. The brain interprets these afferent signals and reacts by reducing the sympathetic tone and increasing the parasympathetic tone. The applicant stated that the BAROSTIM NEO™ System is the only device currently approved by FDA that leverages this mechanism of action to treat the symptoms of patients with advanced heart failure.

The applicant stated that BAROSTIM NEO™ is not described by existing device category C1823, Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads. They contended that existing device category C1823 is exclusively used to describe a complete system comprised of a generator implanted in the chest, a stimulation lead attached to the phrenic nerve and a sensing lead to control the function of the diaphragm for the treatment of moderate to severe central sleep apnea. The applicant also stated that the BAROSTIM NEO™ System utilizes a single stimulation lead positioned on the carotid artery to stimulate baroreceptors. The stimulation of the baroreceptors creates afferent nerve traffic through the Carotid Sinus Nerve, and results in the activation of the baroreflex. The applicant again stated that the BAROSTIM NEO™ System is the only device currently approved by FDA that leverages this mechanism of action to improve quality of life and functional status in heart failure.

The applicant also provided that BAROSTIM NEO™ is not described by existing device category C1778, Lead, neurostimulator (implantable). The applicant stated that leads used in traditional neurostimulation are implanted on nerves (for example, spinal cord, peripheral nerves). The applicant contended that in contrast, the BAROSTIM NEO carotid sinus lead is sutured onto the carotid artery and is the only lead that is designed to be secured on an arterial wall to stimulate sensors located inside the arterial wall (baroreceptors). The applicant provided that stimulation is delivered to the arterial wall, where the baroreceptors (stretch fibers) are located. The applicant stated that the BAROSTIM NEO™ generator is uniquely designed to send electric current via the BAROSTIM NEO™ carotid sinus lead and that the BAROSTIM NEO™ carotid sinus lead is uniquely designed to only interface with the BAROSTIM NEO generator. Again, the applicant provided that the BAROSTIM NEO™ System is the only device currently approved by FDA that leverages this mechanism of action to treat the symptoms of patients with advanced heart failure.

We stated in the CY 2021 OPPS/ASC proposed rule that we were concerned that the BAROSTIM NEO™ System may be appropriately described by existing pass-through payment categories. For example, we believed that the BAROSTIM NEO™ System may be appropriately described by C1767 as the BAROSTIM NEO™ device consists of a generator, a neurostimulator, and a lead. We solicited public comment on this issue.

Comment: The manufacturer of the device stated that it does not believe there is an existing pass-through payment category that describes the BAROSTIM NEO™ System, commenting that the existing device categories that CMS identified do not adequately describe critical aspects of the device. The manufacturer noted that existing categories, such as C1767, Generator, neurostimulator (implantable), non-rechargeable, C1823, Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads, and C1778, Lead, neurostimulator (implantable), do not appropriately describe systems that activate special receptors in the carotid artery known as baroreceptors, which are in a different anatomical location than nerves. The manufacturer stated that baroreceptors are sensory cells that respond to mechanical pressure. They have ion channels that open to allow ions to pass through when they are stretched. Baroreceptors are mechanosensitive ion channels, which according to the manufacturer, are functionally very different from the voltage gate ion channels of nerves. In addition, the manufacturer continued, BAROSTIM NEO stimulates baroreceptors deep within the arterial wall of the carotid sinus, as opposed to direct activation of the carotid sinus nerve. The manufacturer explained that the carotid sinus nerve contains afferent nerve fibers leading from baroreceptors, but also contains afferent nerve fibers leading from the chemoreceptors, which can cause unwanted side effects. The manufacturer stated that BAROSTIM NEO™ uses electricity to activate the baroreceptors and stimulate the baroreflex and does not directly stimulate neurons and therefore, is not appropriately described by existing categories.

Response: We appreciate the commenter's input. After consideration of the public comments we received, we agree that there is no existing pass-through payment category that appropriately describes BAROSTIM NEO™ because it is an implantable generator with surgically placed lead providing selective stimulation of carotid sinus baroreceptors and activation of baroreflex, which then stimulates the autonomic nervous system. Based on this information, we have determined that BAROSTIM NEO™ meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. As stated in section IV.2.a above, devices

that apply under the alternative pathway for devices with FDA premarketing approval and a Breakthrough Device designation are not subject to evaluation for substantial clinical improvement (84 FR 61295). The BAROSTIM NEO™ System has Breakthrough Device designation and FDA premarketing approval, and therefore is not evaluated based on substantial clinical improvement.

We did not receive comments on whether BAROSTIM NEO™ meets the second criterion for establishing a device category at § 419.66(c)(2). We have determined that the BAROSTIM NEO™ meets this 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 BAROSTIM NEO™ would be reported with CPT code 0266T, which they consider to be a total system code. CPT code 0266T is assigned to APC 5464 (Level 4 Neurostimulator and Related Procedures). 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 5464, which has a CY 2020 payment rate of $29,115.50. 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 0266T had a device offset amount of $24,253 at the time the application was received. According to the applicant, the cost of the BAROSTIM NEO™ is $35,000.

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 $35,000 for the BAROSTIM NEO™ is 120 percent of the applicable APC payment amount for the service related to the category of devices of $29,116 (($35,000/29,116) × 100 = 120.2 percent). Therefore, we believe the BAROSTIM NEO™ 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 $35,000 for the BAROSTIM NEO™ is 144 percent of the cost of the device-related portion of the APC payment amount for the related service of $24,253 (($35,000/$24,253) × 100 = 144.3 percent). Therefore, we believe that the BAROSTIM NEO™ 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 $35,000 for BAROSTIM NEO™ and the portion of the APC payment amount for the device of $24,253 is 37 percent of the APC payment amount for the related service of $29,116 (($35,000 − $24,253)/$29,116) × 100 = 36.9 percent). Therefore, we believe that the BAROSTIM NEO™ System meets the third cost significance requirement.

We solicited public comment on whether the BAROSTIM NEO™ System meets the device pass-through payment criteria discussed in this section, including the cost criterion.

Comment: The manufacturer of the BAROSTIM NEO™ System believed that the device meets the cost criterion for device pass-through payment status.

Response: We appreciate the manufacturer's input. After consideration of the public comments we received and our cost threshold calculations, we agree that BAROSTIM NEO™ meets the cost criterion for device pass-through payment status.

After consideration of the public comments we received and our review of the device pass-through application, we have determined that the BAROSTIM NEO™ qualifies for device pass-through payment. As stated previously, devices that receive FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but must meet the other criteria for device pass-through status, which we believe BAROSTIM NEO™ does. Therefore, we are finalizing approval for device pass-through payment status beginning CY 2021 for BAROSTIM NEO™ under the alternative pathway for devices that receive FDA Breakthrough Device designation and FDA premarket approval. Please refer to section IV.B.1.b of this final rule with comment for more information on the device offset for BAROSTIM NEO™ device.

2. Traditional Device Pass-Through Applications

(1) Hemospray® Endoscopic Hemostat

Cook Medical submitted an application for a new device category for transitional pass-through payment status for the Hemospray® Endoscopic Hemostat (Hemospray) for CY 2021. Hemospray® Endoscopic Hemostat is a prescription use device consisting of a hemostatic agent and a delivery system. The hemostatic agent is an inert, bentonite powder, naturally sourced from aluminum phyllosilicate clay, developed for endoscopic hemostasis. According to the applicant, Hemospray® is indicated by the FDA for hemostasis of nonvariceal gastrointestinal bleeding. Using an endoscope to access the gastrointestinal tract, the Hemospray delivery system is passed through the accessory channel of the endoscope and positioned just above the bleeding site without making contact with the GI tract wall. The Hemospray® powder is propelled through the application catheter, either a 7 or 10 French polyethylene catheter, by release of CO_2 from the cartridge located in the device handle and sprayed onto the bleeding site. Bentonite can absorb five to ten times its weight in water and swell up to 15 times its dry volume. Bentonite rapidly absorbs water and becomes cohesive to itself and adhesive to tissue, forming a physical barrier to aqueous fluid (for example, blood). Hemospray® is not absorbed by the body and does not require removal as it passes through the GI tract within 72 hours. Hemospray® is single-use and disposable.

With respect to the newness criterion at § 419.66(b)(1), the FDA granted a *de novo* request classifying the Hemospray® Endoscopic Hemostat (Hemospray®) as a Class II device under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act on May 7, 2018. We received the application for a new device category for transitional pass-through payment status for the Hemospray® Endoscopic Hemostat on December 2, 2019, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comments on whether Hemospray® meets the newness criterion.

Comment: The manufacturer of Hemospray® believed this device meets

the newness eligibility criteria for device pass-through payment under the regulation at § 419.66(b)(1) since Hemospray® was granted de novo marketing authorization and classified as a Class II device on May 7, 2018.

Response: We appreciate the commenter's input. After consideration of the public comments we received and based on the fact that the Hemospray® application was received on May 7, 2018, within 3 years of FDA approval, we agree that the Hemospray® System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Hemospray® is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. The applicant also claimed that Hemospray® 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 solicited public comments on whether Hemospray® meets the eligibility criteria at § 419.66(b).

Comment: Three commenters, including the manufacturer of Hemospray®, believed that the Hemospray® meets the eligibility criteria at § 419.66(b)(3) stating that Hemospray® is a prescription single use device consisting of a hemostatic agent and a delivery system that is integral to the service provided.

Response: We appreciate the commenters' input. Based on the public comments we have received and our review of the application, we have determined that Hemospray® meets the eligibility criterion at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We stated in the CY 2021 OPPS/ASC proposed rule that we have not identified an existing pass-through payment category that describes Hemospray®. We solicited public comment on whether Hemospray® meets the device category criterion.

Comment: Two commenters, including the manufacturer of the Hemospray®, indicated that there is not an existing pass-through payment category that describes the device.

Response: We appreciate the commenters' input. After consideration of the public comments we received, we continue to believe that there is not an existing pass-through payment category that describes Hemospray®, and therefore, Hemospray® meets the device category eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. The applicant stated that Hemospray® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant submitted studies that examined the impact of Hemospray® on endoscopic hemostasis outcomes, rebleeding occurrence, and mortality.

According to the applicant, Hemospray® is a topically applied mineral powder that offers a novel primary treatment option for endoscopic bleeding management, serves as an option for patients who fail conventional endoscopic treatments, and serves as an alternative to interventional radiology hemostasis (IRH) and surgery. Broadly, the applicant outlined two treatment areas in which it stated Hemospray® would provide a substantial clinical improvement: (1) As a primary treatment or a rescue treatment after the failure of a conventional method, and (2) in use for the treatment of malignant lesions. The applicant provided seven articles specifically for the purpose of addressing the substantial clinical improvement criterion.

The first article provided by the applicant was a prospective, single-armed, multicenter Phase 2 safety and efficacy study performed in France.[7] From March 2013 to January 2015, 64 endoscopists in 20 centers enrolled 202 patients in the study in which Hemospray® was used as either a first line treatment (46.5 percent) or salvage therapy (53.5 percent) following unsuccessful treatment with another method. The indication for Hemospray® as a first-line therapy or salvage therapy was at the discretion of the endoscopist. Of the 202 patients, the mean age was 68.9, 69.3 percent were male, and all patients were classified into four primary etiologic groups: Ulcers (37.1 percent), malignant lesions (30.2 percent), post-endoscopic bleeding (17.3 percent), and other (15.3 percent). Patients were further classified by the American Society of Anesthesiologist (ASA) physical status scores with 4.5 percent as a normal healthy patient, 24.3 percent as a patient with mild systemic disease, 46 percent as a patient with severe systemic disease, 22.8 percent as a patient with severe systemic disease that is a constant threat to life, and 2.5 percent as a moribund patient who is not expected to survive without an operation.[8] [9] Immediate hemostasis was achieved in 96.5 percent across all patients; among treatment subtypes, immediate hemostasis was achieved in 96.8 percent of first-line treated patients and 96.3 percent of salvage therapy patients. At day 30, the overall rebleeding was 33.5 percent of 185 patients with cumulative incidences of 41.4 percent for ulcers, 37.7 percent for malignant lesions, 17.6 percent for post-endoscopic bleedings, and 25 percent for others. When Hemospray® was used as a first-line treatment, rebleeding at day 30 occurred in 26.5 percent (22/83) of overall lesions, 30.8 percent of ulcers, 33.3 percent of malignant lesions, 13.6 percent of post-endoscopic bleedings, and 22.2 percent of other. When Hemospray® was used as a salvage therapy, rebleeding at day 30 occurred in 39.2 percent (40/102) of overall lesions, 43.9 percent of ulcers, 50.0 percent of malignant lesions, 25.0 percent of post-endoscopic bleedings, and 26.3 percent for others. According to the article, the favorable hemostatic results seen from Hemospray® are due to its threefold mechanism of action: Formation of a mechanical barrier; concentration of clotting factors at the bleeding site; and enhancement of clot formation.[10] No severe adverse events

[7] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: A multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[8] Ibid.

[9] ASA House of Delegates/Executive Committee. (2014, October 15). *ASA Physical Status Classification System*. Retrieved from American Society of Anesthesiologists: *https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system*.

[10] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal

were noted, however the authors note the potential for pain exists due to the use of carbon dioxide. Lastly, the authors stated that while Hemospray® was found to reduce the need for radiological embolization and surgery as salvage therapies, it was not found to be better than other hemostatic methods in terms of preventing rebleeding of ulcers.

The applicant provided a second article consisting of an abstract from another systematic review article.[11] The abstract purports to cover a review of prospective, retrospective, and randomized control trials evaluating Hemospray® as a rescue therapy. Eighty-five articles were initially identified and 23 were selected for review. Of those, 5 studies were selected which met the inclusion criteria of the analysis. The median age of patients was 69; 68 percent were male. The abstract concludes that when used as a rescue therapy after the failure of conventional endoscopic modalities in nonvariceal gastrointestinal bleeding, Hemospray® seems to have significantly higher rates of immediate hemostasis.

A third article provided by the applicant described a single-arm retrospective analytical study of 261 enrolled patients conducted at 21 hospitals in Spain.[12] The mean age was 67 years old, 69 percent of patients were male, and the overall technical success, defined as correct assembled and delivery of Hemospray® to a bleeding lesion, was 97.7 percent (95.1 percent–99.2 percent). The most common causes of bleeding in patients were peptic ulcer (28 percent), malignancy (18.4 percent), therapeutic endoscopy-related (17.6 percent), and surgical anastomosis (8.8 percent). Overall, 93.5 percent (89.5 percent to 96 percent) of procedures achieved hemostasis. Recurrent bleeding, defined as (1) a new episode of bleeding symptoms, (2) a decrease in hemoglobin of >2 g/dL within 48 hours of an index endoscopy or >3g/dL in 24 hours, or (3) direct visualization of active bleeding at the previously treated lesion on repeat endoscopy, had a cumulative incidence at 3 and 30 days of 16.1 percent (11.9 percent–21 percent) and 22.9 percent (17.8 percent–28.3 percent) respectively. The overall risk of Hemospray® failure at 3 and 30 days was 21.1 percent (16.4 percent–26.2 percent) and 27.4 percent (22.1 percent–32.9 percent) respectively with no statistically significant differences (p=0.07) between causes at 30 days (for example, peptic ulcer, malignancy, anastomosis, therapeutic endoscopy-related, and other causes). With the use of multivariate analysis, spurting bleeding vs. nonspurting bleeding (subdistribution hazard ratio [sHR] 1.97 (1.24–3.13)), hypotension vs. normotensive (sHR 2.14 (1.22–3.75)), and the use of vasoactive drugs (sHR 1.80 (1.10–2.95)) were independently associated with Hemospray® failure. The overall 30-day survival was 81.9 percent (76.5 percent–86.1 percent) with 46 patients dying during follow-up and 22 experiencing bleeding related deaths; twenty patients (7.6 percent) with intraprocedural hemostasis died before day 30. The authors indicated the majority of Hemospray® failures occurred within the first 3 days and the rate of immediate hemostasis was similar to literature reports of intraprocedural success rates of over 90 percent. The authors stated that the hemostatic powder of Hemospray® is eliminated from the GI tract as early as 24 hours after use, which could explain the wide ranging recurrent bleeding percentage. The authors reported that importantly, adverse events are rare, but cases of abdominal distension, visceral perforation, transient biliary obstruction, and splenic infarct have been reported; one patient involved in this study experienced an esophageal perforation without a definitive causal relationship.

A fourth article provided by the applicant described a single-arm multicenter prospective registry involving 314 patients in Europe which collected data on days 0, 1, 3, 7, 14, and 30 after endotherapy with Hemospray®.[13] The outcomes of interest in this study were immediate endoscopic hemostasis (observed cessation of bleeding within 5 minutes post Hemospray® application) with secondary outcomes of rebleeding immediately following treatment and during follow-up, 7 and 30 day all-cause mortality, and adverse events. The sample was 74 percent male with a median age of 71 with the most common pathologies of peptic ulcer (53 percent), malignancy (16 percent), post-endoscopic bleeding (16 percent), bleeding from severe inflammation (11 percent), esophageal variceal bleeding (2.5 percent), and cases with no obvious cause (1.6 percent). The median baseline Blatchford score (BS) and RS were 11 and 7 respectively. The BS ranges from 0 to 23 with higher scores indicating increasing risk for required endoscopic intervention and is based upon the blood urea nitrogen, hemoglobin, systolic blood pressure, pulse, presence of melena, syncope, hepatic disease, and/or cardiac failure.[14] The RS ranges from 0 to 11 with higher scores indicating worse potential outcomes and is based upon age, presence of shock, comorbidity, diagnosis, and endoscopic stigmata of recent hemorrhage.[15] Immediate hemostasis was achieved in 89.5 percent of patients following the use of Hemospray®; only the BS was found to have a positive correlation with treatment failure in multivariate analysis (OR 1.21 (1.10–1.34)). Rebleeding occurred in 10.3 percent of patients who achieved immediate hemostasis again with only the BS having a positive correlation with rebleeding (OR: 1.13 (1.03–1.25)). At 30 days, the all-cause mortality was 20.1 percent; 78 percent of these patients had achieved immediate endoscopic hemostasis and had a cause of death resulting from the progression of other comorbidities. A subgroup analysis of treatment type (monotherapy, combination therapy, and rescue therapy groups) was performed showing no statistically significant difference in immediate hemostasis across groups (92.4 percent, 88.7 percent, and 85.5 percent respectively). Higher all-cause mortality rates at 30 days were highest in the monotherapy group (25.4 percent, p=0.04) as compared to all other groups. According to the authors, in comparison to major recent studies, they were able to show lower rebleeding rates overall and in all subgroups despite the high-risk population.[16] The authors further note limitations in that the inclusion of patients was nonconsecutive and at the discretion of the endoscopist at the time of the endoscopy, which allows for the potential introduction of selection bias,

bleeding: A multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[11] Moole, V., Chatterjee, T., Saca, D., Uppu, A., Poosala, A., & Duvvuri, A. A Systematic review and meta-analysis: Analyzing the efficacy of hemostatic nanopowder (TC–325) as rescue therapy in patients with nonvariceal upper gastrointestinal bleeding. Gastroenterology 2019; 156(6), S–741

[12] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et al. Hemostatic spray TC–325 for GI bleeding in a nationwide study: Survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581–590.

[13] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[14] Saltzman, J. (2019, October). Approach to acute upper gastrointestinal bleeding in adults. (M. Feldman, Editor) Retrieved from UpToDate: *https://www.uptodate.com/contents/approach-to-acute-upper-gastrointestinal-bleeding-in-adults.*

[15] Ibid.

[16] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

which may have affected these study results.

The fourth article also described the utility of Hemospray® in the treatment of malignant lesions. According to the applicant, malignant lesions pose a significant clinical challenge as successful hemostasis rates are as low as 40 percent with high recurrent bleeding over 50 percent within 1 month following standard treatments.[17] [18] The applicant added that bleeding from tumors is often diffuse and consists of friable mucosa decreasing the utility of traditional treatments (for example, ligation, cautery). From the fourth article, the applicant noted that 50 patients were treated for malignant bleeding with an overall immediate hemostasis in 94 percent of patients.[19] Of the 50 patients, 33 were treated with Hemospray® alone, 11 were treated with Hemospray® as the final treatment, and 4 were treated with Hemospray® as a rescue therapy of which 100 percent, 84.6 percent and 75 percent experienced immediate hemostasis respectively.[20] Similarly, from the first discussed article, the applicant noted that among malignant bleeding patients, 95.1 percent achieved immediate hemostasis with lower rebleeding rates at 8 days when Hemospray® was used as a primary treatment compared to when used as a rescue therapy (17.1 percent vs. 46.7 percent respectively).[21] The applicant concluded that Hemospray® may provide an advantage as a primary treatment to patients with malignant bleeding.

The applicant provided a fifth article, which consisted of a journal pre-proof article detailing a 1:1 randomized control trial of 20 patients treated with Hemospray® versus the standard of care (for example, thermal and injection therapies) in the treatment of malignant gastrointestinal bleeding.[22] The goals of this pilot study were to determine the feasibility of a definitive trial. The primary outcome of the study was immediate hemostasis (absence of bleeding after 3 minutes) with secondary outcomes of recurrent bleeding at days 1, 3, 30, 90, and 180 and adverse events at days 1, 30, and 180. The mean age of patients was 67.2, 75 percent were male, and on average patients presented with 2.9 ± 1.7 comorbidities. All patients had active bleeding at endoscopy and the majority of patients had an ASA score of 2 (45 percent) or 3 (40 percent). Immediate hemostasis was achieved in 90 percent of Hemospray® patients and 40 percent of standard of care patients (5 injection alone, 3 thermal, 1 injection with clips, and 1 unknown). Of those patients in the control group, 83.3 percent crossed over to the Hemospray® treatment. One patient died while being treated with Hemospray® from exsanguination; post-mortem examination demonstrated that bleeding was caused by rupture of a malignant inferior mesenteric artery aneurysm. Overall, 86.7 percent of patients treated with Hemospray® initially or as crossover treatment achieved hemostasis. Recurrent bleeding was lower in the Hemospray® group (20 percent) as compared to the control group (60 percent) at 180 days. Forty percent of the treated group received blood transfusions as compared to 70 percent of the control group. The overall length of stay was 14.6 days among treated patients as compared to 9.4 in the control group. Mortality at 180 days was 80 percent in both the treated and control groups. The authors noted the potential for operator bias in the use of Hemospray® prior to switching to another method when persistent bleeding exists. Lastly, the authors noted that while they did not occur during this study, there are concerns around the risks of perforation, obstruction, and systemic embolization with the use of Hemospray®.

A sixth article provided by the applicant was a case-controlled study with 10 patients with active upper gastrointestinal bleeding from tumor compared with 10 conventional therapy patients selected as historical controls, matched by type of tumor.[23] The study evaluated efficacy for tumor-related bleeding and compared Hemospray® to conventional therapies, specifically examining 14-day rebleeding rates, lengths of hospital stay (LOS), and mortality rate at 30-day follow up. Historical controls were selected from patient medical records from 2010 to 2014. Among the patients who received Hemospray®, the 14-day rebleeding rate (10 percent vs. 30 percent; P=0.60) and the 30-day mortality rates (10 percent vs. 30 percent, P=0.7) were three times lower compared to the control group; neither rate was statistically significant. There was no difference in LOS between the Hemospray® and conventional therapy patients.

A seventh article provided by the applicant described a single-arm multicenter retrospective study from 2011 to 2016 involving 88 patients who bled as a result of either a primary GI tumor or metastases to the GI tract.[24] In this study the authors define immediate hemostasis as no further bleeding at least one minute after treatment with Hemospray®, and recurrent bleeding was suspected if one of seven criteria were met: (1) Hematemesis or bloody nasogastric tube >6 hours after endoscopy; (2) melena after normalization of stool color; (3) hematochezia after normalization of stool color or melena; (4) development of tachycardia or hypotension after >1 hour of vital sign stability without other cause; (5) decrease in hemoglobin level greater than or equal to 3 hours apart; (6) tachycardia or hypotension that does not resolve within 8 hours after index endoscopy; or (7) persistent decreasing hemoglobin of >3 g/dL in 24 hours associated with melena or hematochezia). The sample for this study consisted of 88 patients (with a mean age of 65 years old and 70.5 percent male) of which 33.3 percent possessed no co-morbid illness, and 25 percent were on current antiplatelet/anticoagulant medication. The mean BS was 8.7 plus or minus 3.7 with a range from 0 to 18. Overall, 72.7 percent of patients had a stage 4 adenocarcinoma, squamous cell carcinoma, or lymphoma. Immediate hemostasis was achieved in 97.7 percent of patients. Recurrent bleeding occurred in 13 of 86 (15 percent) and 1 of 53 (1.9 percent) at 3 and 30 days, respectively. A total of 25 patients (28.4 percent) died during the 30-day follow up period. Overall, 27.3 percent of patients re-bled within 30 days after treatment of which half were within 3 days. Using multivariate analysis, the authors found patients

[17] Kim YI, Choi IJ, Cho SJ, et al. Outcome of endoscopic therapy for cancer bleeding in patients with unresectable gastric cancer. J Gastroenterol Hepatol 2013;28:1489–95.

[18] Roberts SE, Button LA, Williams JG. Prognosis following upper gastrointestinal bleeding. PLoS One 2012;7:e49507.

[19] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[20] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[21] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: A multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[22] Chen Y–I, Wyse J, Lu Y, Martel M, Barkun AN, TC–325 hemostatic powder versus current standard of care in managing malignant GI bleeding: A pilot randomized clinical trial. Gastrointestinal Endoscopy (2019), doi: *https://doi.org/10.1016/j.gie.2019.08.005*.

[23] Pittayanon, R., Prueksapanich, P., & Rerknimitr, R. (2016). The efficacy of Hemospray in patients with upper gastrointestinal bleeding from tumor. Endoscopy international open, 4(09), E933–E936.

[24] Pittayanon R, Rerknimitr R, Barkun A. Prognostic factors affecting outcomes in patients with malignant GI bleeding treated with a novel endoscopically delivered hemostatic powder. Gastrointest Endosc 2018; 87:991–1002.

with good performance status, no end-stage cancer, or receiving any combination of definitive hemostasis treatment modalities had significantly greater survival. The authors acknowledged the recurrent bleeding rate post Hemospray® treatment at 30 days of 38 percent is comparable with that seen in sole conventional hemostatic techniques and state this implies that Hemospray® does not differ from conventional techniques and remains unsatisfactory.

Ultimately, the applicant concluded nonvariceal gastrointestinal bleeding is associated with significant morbidity and mortality in older patients with multiple co-morbid conditions. Inability to achieve hemostasis and early rebleeding are associated with increased cost and greater resource utilization. According to the applicant, patients with bleeding from malignant lesions have few options that can provide immediate hemostasis without further disrupting fragile mucosal tissue and worsening the active bleed. The applicant stated Hemospray® is an effective agent that provides immediate hemostasis in patients with GI bleeding as part of multimodality treatment, as well as when used as rescue therapy in patients who have failed more conventional endoscopic modalities. Furthermore, the applicant stated that in patients with malignant bleeding in the GI tract, Hemospray® provides a high rate of immediate hemostasis and fewer recurrent bleeding episodes, which, in combination with definitive cancer treatment, may lead to improvements in long term survival. Lastly, the applicant stated Hemospray® is an important new technology that permits immediate and long-term hemostasis in GI bleeding cases where standard of care treatment with clip ligation or cautery are not effective.

In the CY 2021 OPPS/ASC proposed rule, we noted that the majority of studies provided lacked a comparator when assessing the effectiveness of Hemospray®. Three of the articles provided were systematic reviews of the literature. While we found these articles helpful in establishing a background for the use of Hemospray®, we were concerned that they may not provide strong evidence of substantial clinical improvement. Four studies appeared to be single-armed studies assessing the efficacy of Hemospray® in the patient setting. In all of these articles, comparisons were made between Hemospray® and standard of care treatments; however, without the ability to control for factors such as study design, patient characteristics, etc., it is difficult to determine if any differences seen resulted from Hemospray® or confounding variables. Furthermore, within the retrospective and prospective studies lacking a control subset, some level of selection bias appeared to potentially be introduced in that providers may have been allowed to select the manner and order in which patients were treated, thereby potentially influencing outcomes seen in these studies.

Additionally, one randomized control trial provided by the applicant appeared to be in the process of peer-review and was not yet published. Furthermore, this article was written as a feasibility study for a potentially larger randomized control trial and contained a sample of only 20 patients. This small sample size left us concerned that the results were not representative of the larger Medicare population. Lastly, as described, we were concerned the control group could receive one of multiple treatments which lacked a clear designation methodology beyond physician choice. For instance, 50 percent of the control patients received injection therapy alone, which according to the literature provided by the applicant is not an acceptable treatment for endoscopic bleeding. Accordingly, it was not clear whether performance seen in the treated group as compared to the control group was due to Hemospray® itself or due to confounding factors.

Third, we stated in the CY 2021 OPPS/ASC proposed rule that we were concerned with the samples chosen in many of the studies presented. Firstly, the Medicare population is approximately 54 percent female and 46 percent male.[25] Many of the samples provided by the applicant were overwhelmingly male. Secondly, many of the studies provided were performed in Europe and other settings outside of the U.S. We were therefore concerned that the samples chosen within the literature provided may not represent the Medicare population.

Lastly, we were concerned about the potential for adverse events resulting from Hemospray®. It was unclear from the literature provided by the applicant what the likelihood of these events is and whether or not an evaluation for the safety of Hemospray® was performed. About one-third of the articles submitted specifically addressed adverse events with Hemospray®. However, the evaluation of adverse events was limited and most of the patients in the studies died of disease progression. A few of the provided articles mentioned the potential for severe adverse reactions (for example, abdominal distension, visceral perforation, biliary obstruction, splenic infarct). Specifically, one article[26] recorded adverse events related to Hemospray®, including abdominal distention and esophageal perforation.

According to information submitted by the applicant, Cook Medical had voluntarily recalled Hemospray® Endoscopic Hemostat due to complaints received that the handle and/or activation knob on the device in some cases had cracked or broken when the device was activated and in some cases had caused the carbon dioxide cartridge to exit the handle. The applicant stated that Cook Medical had received one report of a superficial laceration to the user's hand that had required basic first aid; however, there were no reports of laceration, infection, or permanent impairment of a body structure to users or to patients due to the carbon dioxide cartridge exiting the handle. The applicant stated that Cook Medical had initiated an investigation and would determine the appropriate corrective action(s) to prevent recurrence of this issue. According to the applicant, although the recall did restrict availability of the device, they wished to continue their application as they believed the use of Hemospray® significantly improves clinical outcomes for certain patient populations compared to currently available treatments.

Based upon the evidence presented, we solicited public comments on whether the Hemospray® Endoscopic Hemostat meets the substantial clinical improvement criterion.

Comment: The manufacturer responded to several statements regarding Hemospray® and substantial clinical improvement in the CY 2021 OPPS/ASC proposed rule, and asserted that Hemospray® meets the substantial clinical improvement criterion. The manufacturer agreed the data presented is primarily from single arm and retrospective studies and may suffer from selection bias. However, the manufacturer suggested that CMS should consider that Hemospray® is commonly used when the conventional standard of care, such as injection plus clips or cautery, is inadequate to treat patients undergoing an urgent catheter-based embolization or surgery. The manufacturer stated that the selection

[25] *https://www.cms.gov/files/document/2018-mdcr-enroll-ab-5.pdf.*

[26] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et al. Hemostatic spray TC–325 for GI bleeding in a nationwide study: Survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581–590.

bias is toward patients with the highest risk of morbidity or mortality and the high rate of successful treatment for those patients with Hemospray® represents substantial clinical improvement. They cited several studies that found that, after all other conventional treatments failed, there was overall treatment success in cases where Hemospray® was used.

In response to CMS' concerns about the unpublished randomized controlled trial presented, the manufacturer stated that the study has been published with no changes and noted that, despite the small sample size, they believe the results are representative of the general population with malignant gastrointestinal bleeding and consistent with other published retrospective studies.

The manufacturer stated that the research and studies for Hemospray® are largely international because Hemospray® was commercially available outside the U.S. for 5 to 7 years before the FDA awarded the product de Novo 510(k) status. They believed that this data is representative of the U.S. population, as the treatment strategy and patient outcomes are similar. The manufacturer acknowledged that study populations are predominantly male but noted that 60 percent of patients undergoing endoscopic control of bleeding are male, according to the 2016 Healthcare Cost and Utilization Project. The manufacturer mentioned that the mean age of study populations varied from 67–71 years, which is representative of the Medicare population.

Regarding the potential for adverse events, the manufacturer stated that FDA has determined the product is safe and effective for its intended use, has an acceptable risk/benefit ratio, and cleared Hemospray® to return to the market as of July 2020 after the issue was addressed. The manufacturer also mentioned that they understand the potential risks associated with Hemospray® and have clearly labeled the product, conducted physician training, diligently monitor reported complaints or complications, and will take appropriate steps to correct any future issues that arise.

Response: We appreciate the manufacturer's response to our questions regarding Hemospray®. After reviewing the information provided in the public comment, we agree with the applicant's statements that any potential bias introduced was toward the patients with the highest risk of negative outcomes and that this potential bias is no longer a concern. Regarding the applicant's comment on study samples, we agree with the applicant that these samples are adequately representative of the Medicare population. We also appreciate the comment response regarding the potential for adverse events and the update on the status of the Hemospray® voluntary recall. We will continue to monitor available data for Hemospray® in regard to any potential risk of adverse events.

As we noted in the FY 2021 IPPS final rule (85 FR 58672), while we acknowledge some of the data limitations, we believe that Hemospray® represents a substantial clinical improvement for the treatment of gastrointestinal bleeding for the following reasons. We believe that, given the results from the RCT trials and the single-armed studies, Hemospray® provides a treatment benefit for those with bleeding from gastrointestinal malignancies. We also see the clinical importance of Hemospray as an alternative to invasive treatments traditionally used as salvage therapy. Lastly, we note that Hemospray® provides treatment for bleeding, without requiring tissue trauma or precise targeting.

After consideration of the public comments we received, we have determined that Hemospray® 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 Hemospray® would be reported with HCPCS codes 43227, 43255, 44366, 44378, 44391, 45334, and 45382. 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 in the CY 2021 OPPS/ASC proposed rule, we used APC 5312, which had a CY 2020 payment rate of $1,004.10 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 45382 had a device offset amount of $33.54 at the time the application was received. According to the applicant, the cost of the Hemospray® Endoscopic Hemostat is $2,500.

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 $2,500 for Hemospray® was 249 percent of the applicable APC payment amount for the service related to the category of devices of $1004.10 (($2,500/$1,004.10) × 100 = 249 percent). Therefore, we stated in the CY 2021 OPPS/ASC proposed rule that we believe Hemospray® meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,500 for Hemospray® was 7,454 percent of the cost of the device-related portion of the APC payment amount for the related service of $33.54 (($2,500/$33.54) × 100 = 7,453.8 percent). Therefore, we stated in the CY 2021 OPPS/ASC proposed rule that we believe that Hemospray® meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,500 for Hemospray® and the portion of the APC payment amount for the device of $33.54 was 246 percent of the APC payment amount for the related service of $1004.10 t ((($2,500 − $33.54)/$1004.10) × 100 = 245.6 percent). Therefore, we stated in the CY 2021 OPPS/ASC proposed rule that we believe that Hemospray® meets the third cost significance requirement.

We solicited public comment on whether the Hemospray® Endoscopic Hemostat meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: Three commenters, including the manufacturer of the Hemospray®, believe that the device meets the cost criterion for device pass-through payment status.

Response: We appreciate the manufacturer's input. After consideration of the public comments we received and consideration of the

cost criterion, we have determined that Hemospray® meets the cost criterion for device pass-through payment status.

After consideration of the public comments we received, we are approving the Hemospray® for device pass-through payment status beginning in CY 2021.

(2) The SpineJack® Expansion Kit

Stryker, Inc., submitted an application for a new device category for transitional pass-through payment status for the SpineJack® Expansion Kit (hereinafter referred to as the SpineJack® system) by the March 2020 quarterly deadline. The applicant described the SpineJack® system as an implantable fracture reduction system, which is indicated for use in the reduction of painful osteoporotic vertebral compression fractures (VCFs) and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cement.

The applicant described the SpineJack® system as including two cylindrical implants constructed from Titanium-6-Aluminum-4-Vanadium (Ti6Al4V) with availability in three sizes: 4.2 mm (12.5 mm expanded), 5.0 mm (17 mm expanded) and 5.8 mm (20 mm expanded). The applicant explained implant size selection is based upon the internal cortical diameter of the pedicle. According to the SpineJack® system Instructions for Use, the use of two implants is recommended to treat a fractured VB. According to the applicant, multiple VBs can also be treated in the same operative procedure as required. Additionally, the applicant explained that titanium alloy allows for plastic deformation when it encounters the hard cortical bone of the endplate yet still provides the lift force required to restore midline VB height in the fractured vertebra. The applicant stated that the SpineJack® system notably contains a self-locking security mechanism that restricts further expansion of the device when extreme load forces are concentrated on the implant. As a result, the applicant stated that this feature significantly reduces the risk of vertebral endplate breakage while it further allows functional recovery of the injured disc.[27]

The applicant stated that the implants are then progressively expanded though actuation of an implant tube that pulls the two ends of the implant towards each other in situ to mechanically restore VB height. The applicant explained that the mechanical working system of the implant allows for progressive and controlled reduction of the vertebral fracture.[28] The applicant stated that when expanded, each SpineJack® implant exerts a lifting pressure on the fracture through a mechanism that may be likened to the action of a scissor car jack, and that the longitudinal compression on the implant causes it to open in a craniocaudal direction. The applicant explained that the implant is locked into the desired expanded position as determined and controlled by the treating physician.[29]

The applicant further explained that the expansion of the SpineJack® implants creates a preferential direction of flow for the bone cement, and once the desired expansion has been obtained, polymethylmethacrylate (PMMA) bone cement is deployed from the center of the implant into the VB. The applicant stated that when two implants are symmetrically positioned in the VB, this allows for a more homogenous spread of PMMA bone cement. The applicant stated that the interdigitation of bone cement creates a broad supporting ring under the endplate, which is essential to confer stability to the VB.

According to the applicant, osteoporosis is one of the most common bone diseases worldwide that disproportionately affects aging individuals. The applicant explained that in 2010, approximately 54 million Americans aged 50 years or older had osteoporosis or low bone mass,[30] which resulted in more than 2 million osteoporotic fragility fractures in that year alone.[31] The applicant stated it has been estimated that more than 700,000 VCFs occur each year in the United States (U.S.),[32] and of these VCFs, about 70,000 result in hospital admissions with an average length of stay of 8 days per patient.[33] Furthermore, the applicant noted that in the first year after a painful vertebral fracture, patients have been found to require primary care services at a rate 14 times greater than the general population.[34] The applicant explained that medical costs attributed to VCFs in the U.S. exceeded $1 billion in 2005 and are predicted to surpass $1.6 billion by 2025.[35]

The applicant explained that osteoporotic VCFs occur when the vertebral body (VB) of the spine collapses and can result in chronic disabling pain, excessive kyphosis, loss of functional capability, decreased physical activity, and reduced quality of life. The applicant stated that as the spinal deformity progresses, it reduces the volume of the thoracic and abdominal cavities, which may lead to crowding of internal organs. The applicant noted that the crowding of internal organs may cause impaired pulmonary function, abdominal protuberance, early satiety and weight loss. The applicant indicated that other complications may include bloating, distention, constipation, bowel obstruction, and respiratory disturbances such as pneumonia, atelectasis, reduced forced vital capacity and reduced forced expiratory volume in 1 second.

The applicant explained that the SpineJack® implants provide symmetric, broad load support for osteoporotic vertebral collapse, which is based upon precise placement of bilateral ''struts'' that are encased in PMMA bone cement, whereas BKP and vertebroplasty (VP) do not provide structural support via an implanted device. The applicant explained that the inflatable balloon tamps utilized in BKP are not made from titanium and are not a permanent implant. According to the applicant, the balloon tamps are constructed from thermoplastic polyurethane, which have limited load bearing capacity. The applicant noted that although the balloon tamps are expanded within the VB to create a cavity for bone cement, they do not remain in place and are removed before the procedure is completed. The applicant explained that partial lift to the VB is obtained during inflation, resulting in kyphotic deformity

[27] Vanni D et al. ''Third-generation percutaneous vertebral augmentation systems.'' *Journal of Spine Surgery.* 2016, vol 2(1), pp. 13–20.

[28] Vanni D., et al., ''Third-generation percutaneous vertebral augmentation systems,'' *J. Spine Surg.,* 2016, vol. 2(1) pp. 13–20.

[29] Noriega D. et al., ''Clinical Performance and Safety of 108 SpineJack Implantations: 1-Year Results of a Prospective Multicentre Single-Arm Registry Study,'' *BioMed Res. Int.,* 2015, vol. 173872.

[30] National Osteoporosis Foundation. (2019). What is osteoporosis and what causes it? Available from: *https://www.nof.org/patients/what-is-osteoporosis/.*

[31] King A and Fiorentino D. ''Medicare payment cuts for osteoporosis testing reduced use despite tests' benefit in reducing fractures.'' *Health Affairs (Millwood),* 2011, vol. 30(12), pp. 2362–2370.

[32] Riggs B and Melton L. ''The worldwide problem of osteoporosis: Insights afforded by epidemiology.'' *Bone,* 1995, vol. 17(Suppl 5), pp. 505–511.

[33] Siemionow K and Lieberman I. ''Vertebral augmentation in osteoporotic and osteolytic fractures: Current Opinion in Supportive and Palliative Care.'' 2009, vol. 3(3), pp. 219–225.

[34] Wong C and McGirt M. ''Vertebral compression fractures: A review of current management and multimodal therapy.'' *Journal of Multidisciplinary Healthcare,* 2013, vol 6, pp. 205–214.

[35] Burge R et al. ''Incidence and economic burden of osteoporosis-related fractures in the United States: 2005–2025.'' *Journal of Bone and Mineral Research.* 2007, vol 22(3), pp. 465–475.

correction and partial gains in anterior VB height restoration, but inflatable balloon tamps are deflated prior to removal so some of the VB height restoration obtained is lost upon removal of the bone tamps. According to the applicant, BKP utilizes the placement of PMMA bone cement to stabilize the fracture and does not include an implant that remains within the VB to maintain fracture reduction and midline VB height restoration.

The applicant stated that if VB collapse is >50 percent of the initial height, segmental instability will ensue. As a result, the applicant explained that adjacent levels of the VB must support the additional load and this increased strain on the adjacent levels may lead to additional VCFs. Furthermore, the applicant summarized that VCFs also lead to significant increases in morbidity and mortality risk among elderly patients, as evidenced by a 2015 study by Edidin et al., in which researchers investigated the morbidity and mortality of patients with a newly diagnosed VCF (n = 1,038,956) between 2005 to 2009 in the U.S. Medicare population. For the osteoporotic VCF subgroup, the adjusted 4-year mortality was 70 percent higher in the conservatively managed group than in the balloon kyphoplasty procedures (BKP)-treated group, and 17 percent lower in the BKP group than in the vertebroplasty (VP) group. According to the applicant, when evaluating treatment options for osteoporotic VCFs, one of the main goals of treatment is to restore the load bearing bone fracture to its normal height and stabilize the mechanics of the spine by transferring the adjacent level pressure loads across the entire fractured vertebra and in this way, the intraspinal disc pressure is restored and the risk of adjacent level fractures (ALFs) is reduced.

The applicant explained that treatment of osteoporotic VCFs in older adults most often begins with conservative care, which includes bed rest, back bracing, physical therapy and/or analgesic medications for pain control. According to the applicant, for those patients that do not respond to conservative treatment and continue to have inadequate pain relief or pain that substantially impacts quality of life, vertebral augmentation (VA) procedures may be indicated. The applicant explained that VP and BKP are two minimally invasive percutaneous VA procedures that are most often used in the treatment of osteoporotic VCFs, and another VA treatment option includes the use of a spiral coiled implant made from polyetheretherketone (PEEK), which is part of the Kiva® system.

According to the applicant, among the treatment options available, BKP is the most commonly performed procedure and the current gold standard of care for VA treatment. The applicant stated that it is estimated that approximately 73 percent of all vertebral augmentation procedures performed in the U.S. between 2005 and 2010 were BKP.[36] According to the applicant, the utilization of the Kiva® system is relatively low in the U.S. and volume information was not available in current market research data.[37]

The applicant stated that VA treatment with VP may alleviate pain, but it cannot restore VB height or correct spinal deformity. The applicant stated that BKP attempts to restore VB height, but the temporary correction obtained cannot be sustained over the long term. The applicant stated that the Kiva® implant attempts to mechanically restore VB height, but it has not demonstrated superiority to BKP for this clinical outcome.[38]

The applicant provided additional detail comparing the construction and mechanism of action for other VA treatments, provided below. According to the applicant the Kiva® system is constructed of a nitinol coil and PEEK–OPTIMA sheath, with sizes including a 4-loop implant (12 mm expanded) and a 5-loop implant (15 mm expanded), and unlike the SpineJack® system, is not made of titanium and does not include a locking scissor jack design. The applicant stated that the specific mechanism of action for the Kiva® system is different from the SpineJack® system. The applicant explained that during the procedure that involves implanting the Kiva® system, nitinol coils are inserted into the VB to form a cylindrical columnar cavity. The applicant stated that the PEEK–OPTIMA is then placed over the nitinol coil. The applicant explained that the nitinol coil is removed from the VB and the PEEK material is filled with PMMA bone cement. The applicant stated that the deployment of 5 coils equates to a maximum height of 15 mm. The applicant stated that the lifting direction of the Kiva implant is caudate and unidirectional. According to the applicant, in the KAST (Kiva Safety and Effectiveness Trial) pivotal study, it was reported that osteoporotic VCF patients treated with the Kiva® system had an average of 2.6 coils deployed.[39] Additionally, in a biomechanical comparison conducted for the Kiva® system and BKP using a loading cycle of 200–500 Newtons in osteoporotic human cadaver spine segments filled with bone cement, there were no statistically significant differences observed between the two procedures for VB height restoration, stiffness at high or low loads, or displacement under compression.[40]

The applicant summarized the differences and similarities of the SpineJack®, BKP, and PEEK coiled implant as follows: (1) With respect to construction, SpineJack® is made of Titanium-6-Aluminum-4-Vanadium compared to thermoplastic polyurethanes for BKP and nitinol and PEEK for the PEEK coiled implant; (2) with respect to mechanism of action, the SpineJack® uses a locking scissor jack encapsulated in PMMA bone cement compared to hydrodynamic cavity creation and PMMA cavity filler for BKP and coil cavity creation and PEEK implant filled with PMMA bone cement for the PEEK coiled implant; (3) with respect to plastic deformation, SpineJack® and BKP allow for plastic deformation while the PEEK coiled implant does not; (4) with respect to craniocaudal expansion, SpineJack® allows for craniocaudal expansion, whereas BKP and the PEEK coiled implant do not; (5) with respect to bilateral load support, SpineJack® provides bilateral load support whereas BKP and the PEEK coiled implant do not; and (6) with respect to lift pressure of >500 N, SpineJack® provides lift pressure of >500 N whereas BKP and the PEEK coiled implant do not. The applicant summarized that the SpineJack® system is uniquely constructed and utilizes a different mechanism of action than BKP, which is the gold standard of treatment for osteoporotic VCFs, and that the construction and mechanism of action of the SpineJack® system is further differentiated when compared with the PEEK coiled implant.

With respect to the newness criterion, the SpineJack® Expansion Kit received FDA 510(k) clearance on August 30, 2018, based on a determination of substantial equivalence to a legally

[36] Goz V et al. ''Vertebroplasty and kyphoplasty: National outcomes and trends in utilization from 2005 through 2010.'' *The Spine Journal.* 2015, vol. 15(5), pp. 959–965.

[37] Lin M. ''Minimally invasive vertebral compression fracture treatments. *Medtech 360, Market Insights, Millennium Research Group.* 2019.

[38] Ibid.

[39] Tutton S et al. KAST Study: The Kiva system as a vertebral augmentation treatment—a safety and effectiveness trial: A randomized, noninferiority trial comparing the Kiva system with balloon kyphoplasty in treatment of osteoporotic vertebral compression fractures. *Spine.* 2015; 40(12):865–875.

[40] Wilson D et al. An ex vivo biomechanical comparison of a novel vertebral compression fracture treatment system to kyphoplasty. *Clinical Biomechanics.* 2012; 27(4):346–353.

marketed predicate device. The applicant explained that although the SpineJack® Expansion Kit received FDA 510(k) clearance on August 30, 2018, due to the time required to prepare for supply and distribution channels, it was not available on the U.S. market until October 2018. As we discussed previously, the SpineJack® Expansion Kit is indicated for use in the reduction of painful osteoporotic VCFs and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cements. We received the application for a new device category for transitional pass-through payment status for the SpineJack® Expansion Kit on February 4, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comments on whether the SpineJack® Expansion Kit meets the newness criterion.

Comment: The applicant reaffirmed that the SpineJack® system meets the newness criteria as it received FDA 510(k) clearance on August 30, 2018 and was commercially available in the United States on October 11, 2018.

Response: We appreciate the commenter's input. After consideration of the public comments we received and based on the fact that the SpineJack® Expansion Kit application was received within 3 years of FDA approval, we have determined that the SpineJack® Expansion Kit meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the SpineJack® Expansion Kit is integral to the service of reducing painful osteoporotic vertebral compression fractures (VCFs), 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 SpineJack® system is designed to be implanted into a collapsed vertebral body (VB) via a percutaneous transpedicular approach under fluoroscopic guidance. According to the applicant, the implants remain within the VB with the delivered bone cement. The applicant also claimed the SpineJack® Expansion Kit 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 solicited public comments on whether the SpineJack® Expansion Kit meets the eligibility criteria at § 419.66(b).

Comment: The applicant stated that the SpineJack® system meets each of the device eligibility requirements at § 419.66(b)(3) for transitional pass-through payment under the OPPS as it is integral to a service provided, and is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered nor is it a material or supply furnished incident to a service.

Response: We appreciate the comment's input. Based on the information we have received and our review of the application, we have determined that the SpineJack® system meets the eligibility criteria at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant describes the SpineJack® Expansion Kit as an implantable fracture reduction system used to treat vertebral compression fractures (VCFs). The applicant reported that it does not believe that the SpineJack® Expansion Kit is described by an existing category and requested category descriptor ''Vertebral body height restoration device, scissor jack (implantable).'' We identified one existing pass-through payment categories that may be applicable to SpineJack® Expansion Kit. The SpineJack® Expansion Kit may be described by HCPCS code C1821 (interspinous process distraction device (implantable)). We solicited public comments on this issue.

Comment: In response to CMS' comment about whether SpineJack® is described by an existing category, the applicant stated that the SpineJack® system and implantable interspinous process distraction devices are vastly different medical devices that are distinguished by several attributes. According to the applicant, where the SpineJack® system involves the insertion of two bilateral expandable titanium implants into the vertebral body within the anterior portion of the spinal column, the interspinous spacer uses a single non-expandable device that is implanted between the spinous processes of two adjacent veterbral bodies in the posterior portion of the spinal column. The applicant further noted that the SpineJack® system differs from interspinous spacers in terms of the FDA submission type, the intended use, the mechanism of action, and whether bone cement is used as a method of fixation. The applicant reaffirmed their belief that the SpineJack® system meets the requirement at § 419.66(c)(1) that the device is not appropriately described by any of the existing categories or by any category previously in effect.

Response: We appreciate the additional information provided by the applicant. After consideration of the public comments we received, we believe there is no existing pass-through device category that appropriately describes the SpineJack® system, due to the many differences which exist between the predicate device and HCPCS code C1821—interspinous process distraction device (implantable). Based on this information, we believe that the SpineJack® system meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. With respect to the substantial clinical improvement criterion, the applicant submitted 8 studies and 19 other references to support assertions that the treatment of osteoporotic vertebral compression fracture (VCF) patients with the SpineJack® system represents a substantial clinical improvement over existing technologies because clinical research supports that it reduces future interventions, hospitalizations, and physician visits through a decrease in adjacent level fractures (ALFs), which the applicant stated are clinically significant adverse events associated with osteoporotic VCF. The applicant also stated that treatment with the SpineJack® system greatly reduces pain scores and pain medication use when compared to BKP, which the applicant stated is the current gold standard in vertebral augmentation (VA) treatment.

The applicant explained that the SpineJack® system has been available for the treatment of patients with osteoporotic VCFs for over 10 years in Europe. The applicant explained that, as

a result, the SpineJack® implant has been extensively studied, and claims from smaller studies are supported by the results from a recent, larger prospective, randomized study known as the SAKOS (SpineJack® versus Kyphoplasty in Osteoporotic Patients) study. The applicant cited the SAKOS study [41] in support of multiple substantial clinical improvement claims: Reduction in adjacent level fractures, superiority in mid-vertebral body height restoration, and pain relief. The applicant explained that the SAKOS study was the pivotal trial conducted in support of the FDA 510(k) clearance for the SpineJack® system and that the intent of the study was to compare the safety and effectiveness of the SpineJack® system with the KyphX Xpander Inflatable Bone Tamp (BKP) for treatment of patients with painful osteoporotic VCFs in order to establish a non-inferiority finding for use of the SpineJack® system versus balloon kyphoplasty procedure (BKP).

The SAKOS study is a prospective, international, randomized, non-inferiority study comparing a titanium implantable vertebral augmentation device (TIVAD), the SpineJack® system, versus BKP in the reduction of vertebral compression fractures with a 12-month follow-up. The primary endpoint was a 12-month responder rate based on a composite of three components: (1) Reduction in VCF fracture-related pain at 12 months from baseline by >20 mm as measured by a 100-mm Visual Analog Scale (VAS) measure; (2) maintenance or functional improvement of the Oswestry Disability Index (ODI) score at 12 months from baseline; and (3) absence of device-related adverse events or symptomatic cement extravasation requiring surgical reintervention or retreatment at the index level. If the primary composite endpoint was successful, a fourth component (absence of ALF) was added to the three primary components for further analysis. If the analysis of this additional composite endpoint was successful, then midline target height restoration at 6 and 12 months was assessed. According to the applicant, freedom from ALFs and midline VB height restoration were two additional superiority measures that were tested. According to the SAKOS study, secondary clinical outcomes included changes from baseline in back pain intensity, ODI score, EuroQol 5-domain (EQ–5D) index score (to evaluate quality of life), EQ–VAS score, ambulatory status, analgesic consumption, and length of hospital stay. Radiographic endpoints included restoration of vertebral body height (mm), and Cobb angle at each follow-up visit. Adverse events (AEs) were recorded throughout the study period. The applicant explained that researchers did not blind the treating physicians or patients, so each group was aware of the treatment allocation prior to the procedure; however, the three independent radiologists that performed the radiographic reviews were blinded to the personal data of the patients, study timepoints, and results of the study.

The SAKOS study recruited patients from 13 hospitals across 5 European countries and randomized 152 patients with osteoporotic vertebral compression fractures (OVCFs) (1:1) to either SpineJack® or BKP procedures. Specifically, patients were considered eligible for inclusion if they met a number of criteria, including: (1) At least 50 years of age; (2) had radiographic evidence of one or two painful VCF between T7 and L4, aged less than 3 months, due to osteoporosis; (3) fracture(s) that showed loss of height in the anterior, middle, or posterior third of the VB ≥15 percent but ≤40 percent; and (4) patient failed conservative medical therapy, defined as either having a VAS back pain score of ≥50 mm at 6 weeks after initiation of fracture care or a VAS pain score of ≥70 percent mm at 2 weeks after initiation of fracture care. Eleven of the originally recruited patients were subsequently excluded from surgery (9 randomized to SpineJack® and 2 to BKP). A total of 141 patients underwent surgery, and 126 patients completed the 12-month follow-up period (61 TIVAD and 65 BKP). The applicant contended that despite the SAKOS study being completed outside the U.S., results are applicable to the Medicare patient population, noting that 82 percent (116 of 141) of the patients in the SAKOS trial that received treatment (SpineJack® system or BKP) were age 65 or older. The applicant explained further that the FDA evaluated the applicability of the SAKOS clinical data to the U.S. population and FDA concluded that although the SAKOS study was performed in Europe, the final study demographics were very similar to what has been reported in the literature for U.S.-based studies of BKP. The applicant also explained that FDA determined that the data was acceptable for the SpineJack® system 510(k) clearance, including two clinical superiority claims versus BKP.

The SAKOS study reported that analysis on the intent to treat population using the observed case method resulted in a 12-month responder rate of 89.8 percent and 87.3 percent, for SpineJack® and BKP respectively (p=0.0016). The additional composite endpoint analyzed in observed cases resulted in a higher responder rate for SpineJack® compared to BKP at both 6 months (88.1 percent vs. 60.9 percent; p<0.0001) and 12 months (79.7 percent vs. 59.3 percent; p<0.0001). Midline VB height restoration, tested for superiority using a *t* test with one-sided 2.5 percent alpha in the ITT population, was greater with SpineJack® than BKP at 6 months (1.14 ± 2.61 mm vs 0.31 ± 2.22 mm; p=0.0246) and at 12 months (1.31 ± 2.58 mm vs. 0.10 ± 2.23 mm; p=0.0035), with similar results in the per protocol (PP) population.

Also, according to the SAKOS study, decrease in pain intensity versus baseline was more pronounced in the SpineJack® group compared to the BKP group at 1 month (p=0.029) and 6 months (p=0.021). At 12 months, the difference in pain intensity was no longer statistically significant between the groups, and pain intensity at 5 days post-surgery was not statistically different between the groups. The SAKOS study publication also reported that at each timepoint, the percentage of patients with reduction in pain intensity >20 mm was ≥90 percent in the SpineJack® group and ≥80 percent in the BKP group, with a statistically significant difference in favor of SpineJack® at 1-month post-procedure (93.8 percent vs 81.4 percent; p=0.03). The study also reported: (1) No statistically significant difference in disability (ODI score) between groups during the follow-up period, although there was a numerically greater improvement in the SpineJack® group at most time points; (2) at each time point, the percentage of patients with maintenance or improvement in functional capacity was at or close to 100 percent; and (3) in both groups, a clear and progressive improvement in quality of life was observed throughout the 1-year follow-up period without any statistically significant between-group differences.

In the SAKOS study, both groups had similar proportions of VCFs with cement extravasation outside the treated VB (47.3 percent for TIVAD, 41.0 percent for BKP; p=0.436). No symptoms of cement leakage were reported. The SAKOS study also reported that the BKP group had a rate

[41] Noriega, D., et al., ''A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures (SAKOS study),'' *The Spine Journal,* 2019, vol. 19(11), pp. 1782–1795.

of adjacent fractures more than double the SpineJack® group (27.3 percent vs. 12.9 percent; p=0.043). The SAKOS study also reported that the BKP group had a rate of non-adjacent subsequent thoracic fractures nearly 3 times higher than the SpineJack® group (21.9 percent vs. 7.4 percent) (a p-value was not reported for this result). The most common AEs reported over the study period were back pain (11.8 percent with SpineJack®, 9.6 percent with BKP), new lumbar vertebral fractures (11.8 percent with SpineJack®, 12.3 percent with BKP), and new thoracic vertebral fractures (7.4 percent with SpineJack®, 21.9 percent with BKP). The most frequent SAEs were lumbar vertebral fractures (8.8 percent with SpineJack®; 6.8 percent with BKP) and thoracic vertebral fractures (5.9 percent with SpineJack®, 9.6 percent with BKP). We also note that the length of hospital stay (in days) for osteoporotic VCF patients treated in the SAKOS trial was 3.8 ± 3.6 days for the SpineJack® group and 3.3 ± 2.4 days for the BKP group (p=0.926, Wilcoxon test).

The applicant also submitted additional studies, which are described in more detail in this section, related to the applicant's specific assertions regarding substantial clinical improvement.

As stated previously, the applicant stated that the SpineJack® system represents a substantial clinical improvement over existing technologies because it will reduce future interventions, hospitalizations, and physician visits through a decrease in ALFs. The applicant explained that ALFs are considered clinically significant adverse events associated with osteoporotic VCFs, citing studies by Lindsay et al.[42] and Ross et al.[43] The applicant explained that these studies reported, respectively, that having one or more VCFs (irrespective of bone density) led to a 5-fold increase in the patient's risk of developing another vertebral fracture, and the presence of two or more VCFs at baseline increased the risk of ALF by 12-fold. The applicant stated that analysis of the additional composite endpoint in the SAKOS study demonstrated statistical superiority of the SpineJack® system over BKP (p<0.0001) for freedom from ALFs at both 6 months (88.1 percent vs. 60.9 percent) and 12 months (79.7 percent vs. 59.3 percent) post-procedure. The applicant noted that the results were similar on both the intent to treat and PP patient populations. In addition, the applicant stated the SpineJack® system represents a substantial clinical improvement because in the SAKOS study, compared to patients treated with the SpineJack® system, BKP-treated patients had more than double the rate of ALFs (27.3 percent vs. 12.9 percent; p=0.043) and almost triple the rate of non-adjacent thoracic VCFs (21.9 percent vs. 7.4 percent).

The applicant also stated superiority with respect to mid-vertebral body height restoration with the SpineJack® system. The applicant explained that historical treatments of osteoporotic VCFs have focused on anterior VB height restoration and kyphotic Cobb angle correction; however, research indicates that the restoration of middle VB height may be as important as Cobb angle correction in the prevention of ALFs.[44] According to the applicant, the depression of the mid-vertebral endplate leads to decreased mechanics of the spinal column by transferring the person's weight to the anterior wall of the level adjacent to the fracture, and as a result the anterior wall is the most common location for ALFs. The applicant further stated that by restoring the entire fracture, including mid-VB height, the vertebral disc above the superior vertebral endplate is re-pressurized and transfers the load evenly, preventing ALFs.[45] The applicant stated that the SpineJack® system showed superiority over BKP with regard to midline VB height restoration at both 6 and 12 months, pointing to the SAKOS study results in the intent to treat population at 6 months (1.14 ± 2.61 mm vs 0.31 ± 2.22 mm; p=0.0246) and 12 months (1.31 ± 2.58 mm vs. 0.10 ± 2.23 mm; p=0.0035) post-procedure. The applicant noted that similar results were also observed in the PP population (134 patients in the intent-to-treat population without any major protocol deviations).

The applicant also provided two prospective studies, a retrospective study, and two cadaveric studies in support of its assertions regarding superior VB height restoration. The applicant stated that in a prospective comparative study by Noriega D., et al.,[46] VB height restoration outcomes utilizing the SpineJack® system were durable out to 3 years. This study was a safety and clinical performance pilot that randomized 30 patients with painful osteoporotic vertebral compression fractures to SpineJack® (n=15) or BKP (n=15).[47] Twenty-eight patients completed the 3-year study (14 in each group). The clinical endpoints of analgesic consumption, back pain intensity, ODI, and quality of life were recorded preoperatively and through 36-months post-surgery.[48] Spine X-rays were also taken 48 hours prior to the procedure and at 5 days, 6, 12, and 36 months post-surgery.[49] The applicant explained that over the 3-year follow-up period, VB height restoration and kyphosis correction was better compared to BKP, specifically that VB height restoration and kyphotic correction was still evident at 36 months with a greater mean correction of anterior VB height (10 ± 13 percent vs 2 ± 8 percent for BKP, p=0.007) and midline VB height (10 ± 11 percent vs 3 ± 7 percent for BKP, p=0.034), while there was a larger correction of the VB angle (− 4.97° ± 5.06° vs 0.42° ± 3.43°; p=0.003) for the SpineJack® group. The applicant stated that this study shows superiority with regards to VB height restoration.

The applicant stated that Arabmotlagh M., et al., also supported superiority with regard to VB height restoration. Arabmotlagh M., et al. reported an observational case series (with no comparison group) of SpineJack®. They enrolled 42 patients with osteoporotic vertebral compression fracture of the thoracolumbar, who were considered for kyphoplasty, 31 of whom completed the clinical and radiological evaluations up to 12 months after the procedure.[50] According to materials provided by the applicant, the purpose of the study was to evaluate the efficacy of kyphoplasty with the SpineJack® system to correct the kyphotic deformity and to analyze parameters affecting the restoration and maintenance of spinal alignment. The

[42] Lindsay R. et al., ''Risk of new vertebral fracture in the year following a fracture,'' *Journal of the American Medical Association,* 2001, vol. 285(3), pp. 320–323.

[43] Ross P. et al., Pre-existing fractures and bone mass predict vertebral fracture incidence in women. *Annals of Internal Medicine.* 1991, vol. 114(11), pp. 919–923.

[44] Lin J et al. Better height restoration, greater kyphosis correction, and fewer refractures of cemented vertebrae by using an intravertebral reduction device: A 1-year follow-up study. *World Neurosurgery.* 2016; 90:391–396.

[45] Tzermiadianos M., et al., ''Altered disc pressure profile after an osteoporotic vertebral fracture is a risk factor for adjacent vertebral body fracture,'' *European Spine Journal,* 2008, vol. 17(11), pp. 1522–1530.

[46] Noriega D., et al., ''Long-term safety and clinical performance of kyphoplasty and SpineJack procedures in the treatment of osteoporotic vertebral compression fractures: a pilot, monocentric, investigator-initiated study,'' *Osteoporosis International,* 2019, vol. 30, pp. 637–645.

[47] Ibid.

[48] Ibid.

[49] Ibid.

[50] Arabmotlagh M., et al., ''Radiological Evaluation of Kyphoplasty With an Intravertebral Expander After Osteoporotic Vertebral Fracture,'' *Journal of Orthopaedic Research,* 2018. Doi: 10.1002.jor.24180.

applicant explained that the mean VB height calculated prior to fracture was 2.8 cm (standard deviation (SD) of 0.47), which decreased to 1.5 cm (SD of 0.59) after the fracture. According to the applicant, following the procedure performed with the SpineJack® device, the VB height significantly increased to 1.9 cm (SD of 0.64; p<0.01), but was reduced to 1.8 cm (SD of 0.61; p<0.01) at 12 months post-procedure. We note that according to Arabmotlagh M., et al., these results were specifically for mean anterior VB height. The study does not appear to report results for midline VB height.[51] The applicant also stated that the mean kyphotic angle (KA) calculated prior to fracture was -1° (SD of 5.8), which increased to 13.4° (SD of 8.1) after the fracture. The applicant also stated that following the procedure performed with the SpineJack® device, KA significantly decreased to 10.8° (SD of 9.1; p<0.01); however, KA correction was lost at 12 months post-procedure with an increase to 13.3° (SD of 9.5; p<0.01).

The applicant provided a Lin et al., retrospective study of 75 patients that compared radiologic and clinical outcomes of kyphoplasty with the SpineJack® system to vertebroplasty (VP) in treating osteoporotic vertebral compression fractures to support its assertions regarding superiority with regard to midline VB height restoration.[52] The applicant stated that the radiologic outcomes from this study were: (1) The mean KA and mean KA restoration were more efficient after SpineJack® than VP at all time points (up to 1 year), except for mean KA observed postoperatively at 1 week; and (2) the mean middle VB heights and mean VB height restoration were more favorable after SpineJack® than VP.[53] We note that this study did not compare the SpineJack® system to BKP, which the applicant stated is the gold-standard in vertebral augmentation.

In the two cadaveric studies, Kruger A., et al. (2013) and Kruger A., et al. (2015), wedge compression fractures were created in human cadaveric vertebrae by a material testing machine and the axial load was increased until the height of the anterior edge of the VB was reduced by 40 percent.[54] The VBs were fixed in a clamp and loaded with 100 N in a custom made device. In Kruger A., et al. (2013), vertebral heights were measured at the anterior wall as well as in the center of the vertebral bodies in the medial sagittal plane in 36 human cadaveric vertebrae pre- and post-fracture as well as after treatment and loading in (27 vertebrae were treated with SpineJack® with different cement volumes (maximum, intermediate, and no cement), and 9 vertebrae were treated with BKP). In Kruger A., et al. (2015), anterior, central, and posterior height as well as the Beck index were measured in 24 vertebral bodies pre-fracture and post-fracture as well as after treatment (12 treated with SpineJack® and twelve treated with BKP). The applicant stated that Kruger A., et al. (2013) showed superiority on VB height restoration and height maintenance, and summarized that: (1) Height restoration was significantly better for the SpineJack® group compared to BKP; (2) height maintenance was dependent on the cement volume used; and (3) the group with the SpineJack® without cement nevertheless showed better results in height maintenance, yet the statistical significance could not be demonstrated.[55] The applicant stated that Kruger A., et al. (2015) showed superiority on VB height restoration, because the height restoration was significantly better in the SpineJack® group compared with the BKP group. The applicant explained that the clinical implications include a better restoration of the sagittal balance of the spine and a reduction of the kyphotic deformity, which may relate to clinical outcome and the biological healing process.[56]

The applicant also stated that use of the SpineJack® system represents a substantial clinical improvement with respect to pain relief. According to the applicant, pain is the first and most prominent symptom associated with osteoporotic VCFs, which drives many elderly patients to seek hospital treatment and negatively impacts on their quality of life. The applicant provided the SAKOS randomized controlled study, a prospective consecutive observational study, and a retrospective case series to support its assertions regarding pain relief with the SpineJack® system. The applicant cited the SAKOS trial for statistically significant greater pain relief achieved at 1 month and 6 months after surgery with the SpineJack® system. The applicant summarized that in the SAKOS trial: (1) Progressive improvement in pain relief was observed over the follow-up period in the SpineJack® system group only; (2) the decrease in pain intensity versus baseline was more pronounced in the SpineJack® system group compared to the BKP group at 1 month (p=0.029) and 6 months (p=0.021); and (3) at each time point, the percentage of patients with reduced pain intensity >20 mm was ≥90 percent in the SpineJack® system group and ≥80 percent in the BKP group, with a statistically significant difference in favor of the SpineJack® system at 1 month post-procedure (93.8 percent vs. 81.5 percent; p=0.030). The applicant also noted that although continued pain score improvements were seen out to 1 year for patients treated with the SpineJack® system, the difference between the treatment groups did not meet statistical significance (p=0.061). The applicant also explained that in the SAKOS study, at 5 days after surgery, there were significantly fewer patients taking central analgesic agent medications in the SpineJack® implant-treated group as compared to those in the BKP-treated group (SJ 7.4 percent vs. BKP 21.9 percent, p=0.015). According to the applicant, central analgesic agents included medications such as non-steroidal anti-inflammatory drugs (NSAIDS), salicylates, or opioid analgesics.

The applicant also cited a prospective consecutive observational study by Noriega D., et al. for statistically significant pain relief immediately after surgery and at both 6 and 12 months. Noriega D., et al. was a European multicenter, single-arm registry study that aimed to confirm the safety and clinical performance of the SpineJack® system for the treatment of vertebral compression fractures of traumatic origin (no comparison procedure).[57] The study enrolled 103 patients (median age: 61.6 years) with 108 VCFs due to trauma (n=81), or traumatic VCF with associated osteoporosis (n=22) who had a SpineJack® procedure. Twenty-three patients withdrew from the study before

[51] Arabmotlagh M., et al., ''Radiological Evaluation of Kyphoplasty With an Intravertebral Expander After Osteoporotic Vertebral Fracture,'' *Journal of Orthopaedic Research,* 2018. Doi: 10.1002.jor.24180.

[52] Lin J., et al., ''Better Height Restoration, Greater Kyphosis Correction, and Fewer Refractures of Cemented Vertebrae by Using an Intravertebral Reduction Device: A 1-Year Follow-up Study,'' *World Neurosurg.* 2016, vol. 60, pp. 391–396.

[53] Ibid.

[54] Kruger A., et al., ''Height restoration and maintenance after treating unstable osteoporotic vertebral compression fractures by cement augmentation is dependent on the cement volume used,'' *Clinical Biomechanics,* 2013, vol. 28, pp. 725–730; and Kruger A., et al., ''Height restoration of osteoporotic vertebral compression fractures using different intervertebral reduction devices: A cadaveric study,'' *The Spine Journal,* 2015, vol. 15, pp. 1092–1098.

[55] Ibid.

[56] Ibid.

[57] Noriega D., et al., ''Clinical performance and safety of 108 SpineJack implantations: 1-year results of a prospective multicentre single arm registry study.'' *BioMed Research International.* 2015, 173872.

the 12-month visit. The study reported a significant improvement in back pain at 48 hours after SpineJack® procedure, with the mean VAS pain score decreasing from 6.6 ± 2.6 cm at baseline to 1.4 ± 1.3 cm (mean change: −5.2 ± 2.7 cm; p<0.001) (median relative decrease in pain intensity of 81.5 percent) for the total study population. Noriega D., et al. also reported that the improvement was maintained over the 12-month follow-up period and similar results were observed with both pure traumatic VCF and traumatic VCF in patients with osteoporosis. The traumatic VCF with osteoporosis sub-group had a mean change of −5.5 (SD=1.9) (median relative change of 81.0 percent) (p<0.001) at 48 hours post-surgery (n=22), and −5.7 (SD=2.3) mean change (90.3 percent median relative change) (p<0.001) at 12 months (n=16). The applicant stated that this study supported a claim of statistically significant pain relief immediately after surgery and at both 6 and 12 months. The applicant summarized that (1) pain relief and improvements in pain scores were statistically significant immediately after treatment (48–72 hours) and at 6 and 12 months following surgery (p<0.001); and (2) the mean improvement between baseline and at 48–72 hours after the procedure (n=31) was −4.6 (2.6) (p<0.001), while the mean improvement between baseline and at the 12-month follow-up (n=22) was −6.0 (3.4) (p<0.001). We note that Noriega D., et al. did not report results for 6 months (although it does include results for 3 months versus baseline) and does not include the results of mean improvement stated by the applicant.[58] It is also unclear if the applicant intended to rely on the overall results of the study or the subgroup of traumatic VCF with osteoporosis.

The applicant also cited a retrospective case series, Renaud C., et al., for statistically significant pain relief after surgery with the SpineJack® system. Renaud C., et al., included 77 patients with a mean age of 60.9 years and 83 VCFs (51 due to trauma and 32 to osteoporosis) treated with 164 SpineJack® devices (no comparison procedure).[59] The applicant summarized that: (1) Pain relief was statistically significant (p<0.001), with a pain score decrease from 7.9 pre-operatively to 1.8 at 1 month after the procedure; (2) the pain score improvement was 77 percent at hospital discharge and gradually increased to 86 percent after 1 year following surgery; and (3) the study outcomes demonstrated that the SpineJack® system provided both immediate and long-lasting pain relief.

As we stated in the CY 2021 OPPS/ASC proposed rule (85 FR 48861), the results of the SAKOS trial did not appear to have been corroborated in any other randomized controlled study. Additionally, although the applicant stated that BKP is the gold standard in VA, there appeared to be a lack of data comparing the SpineJack® system to other existing technology, such as the PEEK coiled implant (Kiva® system), particularly since the PEEK coiled system was considered the predicate device for the SpineJack 510(k). Furthermore, there appeared to be a lack of data comparing the SpineJack® system to conservative medical therapy. We noted that there was an active study posted on *clinicaltrials.gov* comparing SpineJack® system to conservative orthopedic management consisting of brace and pain medication in acute stable traumatic vertebral fractures in subjects aged 18 to 60 years old. The *clinicaltrials.gov* entry indicated that findings should be forthcoming in 2020. Additionally, we noted that the recent systematic reviews of the management of vertebral compression fracture (Buchbinder et al. for Cochrane (2018), Ebeling et al. (2019) for the American Society for Bone and Mineral Research (ASBMR)), did not support vertebral augmentation procedures due to lack of evidence compared to conservative medical management.[60] The ASBMR recommended more rigorous study of treatment options including ''larger sample sizes, inclusion of a placebo control and more data on serious AEs (adverse events).''

We solicited public comment on whether the SpineJack® system meets the substantial clinical improvement criterion.

Comment: Many commenters expressed their support for approval of the SpineJack® system for device pass-through status. Many of these commenters shared their academic knowledge of and first-hand clinical experience with vertebral augmentation procedures, including claims of familiarity and expertise with the use of the Kiva® system, BKP and the SpineJack® system. According to many of these commenters, the SpineJack® system provides a significant benefit beyond that which is achieved by other vertebral augmentation technology. Many commenters also indicated that the price compared to the reimbursement rate has been an impediment to use of the SpineJack® system in some cases. Finally, several of these commenters expressed their belief that the SpineJack® system may reduce costs to hospitals and the U.S. health system overall by preventing the onset of additional adjacent fractures in patients.

The applicant and multiple commenters disagreed with CMS' concern that recent systematic reviews of the management of vertebral compression fracture do not support vertebral augmentation procedures according to the ASBMR, which also suggested more rigorous study of treatment options. The applicant stated that the latest clinical evidence and a policy statement from the International Society for the Advancement of Spine Surgery (ISASS) provide robust support for the use of vertebral augmentation (VA) over non-surgical management (NSM) in the treatment of osteoporotic vertebral compression fractures. Another commenter disagreed with CMS' interpretation of the ASBMR report and emphasized that the study found kyphoplasty was associated with significantly more reduction in pain, more reduction in RMDQ scale, and improvement in quality of life as compared to nonsurgical management; the commenter concluded that it is not accurate to group kyphoplasty with vertebroplasty data.

The applicant referenced a systematic review and meta-analysis of 25 prospective studies, which found that patients treated with balloon kyphoplasty and vertebroplasty had greater pain reduction that those treated with non-surgical management. Further, the applicant stated that the most compelling evidence for the use of vertebral augmentation in the treatment of osteoporotic VCF patients comes from the recently published Local Coverage Determination (LCD) on Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture by the seven regional MACs, which currently appear in either a proposed or final state.

The applicant and commenters also responded to CMS' concern that the

[58] Ibid.

[59] Renaud C., ''Treatment of vertebral compression fractures with the cranio-caudal expandable implant SpineJack: Technical note and outcomes in 77 consecutive patients.'' *Orthopaedics & Traumatology: Surgery & Research,* 2015, vol. 101, pp. 857–859.

[60] Buchbinder R., Johnston R.V., Rischin K.J., Homik J., Jones C.A., Golmohammadi K., Kallmes D.F., ''Percutaneous vertebroplasty for osteoporotic vertebral compression fracture,'' *Cochrane Database Syst Rev.* 2018 Apr 4 and Nov 6. PMID: 29618171; Ebeling P.R., Akesson K., Bauer D.C., Buchbinder R., Eastell R., Fink H.A., Giangregorio L., Guanabens N., Kado D., Kallmes D., Katzman W., Rodriguez A., Wermers R., Wilson H.A., Bouxsein M.L., ''The Efficacy and Safety of Vertebral Augmentation: A Second ASBMR Task Force Report.'' *J Bone Miner Res.,* 2019, vol. 34(1), pp. 3–21.

SAKOS trial results do not appear to be corroborated in any other randomized controlled study. Commenters stated it is unfair of CMS to require results from multiple randomized control trials (RCTs) because these studies take a large amount of time and resources to conduct, which is at odds with the characteristics inherent in applicants for device pass-through payment status given the newness criterion requiring FDA approval within three years of application. The applicant stated that multiple RCTs are often not conducted to corroborate level one evidence that has been published in journals. They added that there are a minimum of 16 journal articles that highlight the clinical benefit that the SpineJack® system provides to patients.

In response to CMS' concern that SpineJack® was not compared to the PEEK coiled implant, the applicant and multiple commenters stated that the PEEK coiled system has not demonstrated clinical superiority to BKP, which is the gold standard treatment for osteoporotic VCFs. Commenters added that the PEEK coiled implants are not widely used in the United States because of the very limited scope of use, the high price, and the difficulty of use as compared to other procedures.

In response to CMS' concern that the SpineJack® system was not compared to conservative medical therapy, many commenters and the applicant stated that this comparison would be inappropriate primarily because of the large body of research showing improvements for patients who receive treatment for VCFs with VA as opposed to NSM. One commenter stated that there is a subset of patients who suffer compression fractures for which no vertebral augmentation is advised but these patients would not currently receive balloon kyphoplasty nor would they likely receive treatment with the SpineJack® system. The applicant stated that there is clinical evidence showing improved outcomes for patients with VCFs treated with BKP as compared to NSM. The applicant concluded that based upon the body of evidence available, the use of NSM as a comparator treatment to the SpineJack® system for a new clinical study would not be in the best interest of osteoporotic VCF patients, primarily due to the increased risk of morbidity and mortality that has been reported in this patient population, particularly among the elderly. Lastly the applicant stated that the SpineJack® system is not indicated for use in the treatment of traumatic vertebral fractures in the United States.

In regard to CMS' statement that a study by Lin et al. did not compare the SpineJack® system to BKP, the applicant agreed and added that the publication provides further support of the claim for superior mid-vertebral body height restoration with the SpineJack® system as compared to other treatment options such as vertebroplasty, which the applicant asserted continue to be widely performed in Medicare patients.

In regard to CMS' statement that findings from the Arabmotlagh M. et al. study did not report results for midline VB height, the applicant stated that the publication shows that it is possible to achieve anterior VB height restoration with the SpineJack® system in addition to midline VB height restoration demonstrated in the SAKOS trial.

In response to CMS' assertion that the Noriega et al. article did not report results for six months and does not include results of mean improvement as stated by the applicant, the applicant stated that they would like to correct an error in their application attachment for the 2015 Noriega et al. publication. The data presented in their application reflects findings from another citation [61] in which the overall improvements in visual analog scale back pain scores were statistically significant at multiple time points.

Lastly, the applicant supplied minor corrections regarding the SAKOS study results. Specifically the applicant stated that for the midline VB height restoration reported at 12 months post-procedure for the SpineJack® system compared to BKP in the SAKOS trial, an error in the standard deviation value for the BKP data is reported in the CY 2021 OPPS/ASC proposed rule. The applicant stated that this value should be revised to 2.34 mm rather than the 2.23 mm reported previously.

One commenter, a manufacturer of BKP implants, criticized the evidence the applicant submitted to support its position that the SpineJack® system meets the substantial clinical improvement criterion. The commenter emphasized that although the applicant cited the SAKOS study as the basis for concluding that the SpineJack® system meets the substantial clinical improvement criterion, the SAKOS study compared the SpineJack® system to older BKP technology (KyphX), rather than to the most current BKP technology available at the time of the study (Xpander II and Express II). According to the commenter, these newer generation balloons have been available since 2011, generate lift force in excess of 1200 Newtons, and are the only BKP products indicated for the cement resistance technique, whereby one bone tamp is left in place during cement injection and curing to maximize height restoration in a collapsed vertebral body. The commenter stated that BKP does offer craniocaudal expansion while creating a void for safer cement fill. Furthermore, with respect to bilateral load support, according to the commenter, BKP has been offered since 1998 as a bilateral procedure option to maximize lift potential and reduce stress exerted on endplates. The commenter went on to explain that BKP provides bilateral symmetric load support to fractured endplates by providing a larger surface area when restoring height. The commenter suggested that if the SAKOS study had compared the SpineJack® system to these second-generation BKP implants, then the SpineJack® system might not have demonstrated superior performance on secondary outcome measures.

The commenter also offered several additional criticisms of the SAKOS study. The commenter pointed out that the SAKOS study design did not involve an even distribution of the spine levels treated across study arms, and that it is possible that a difference in the levels treated could have contributed to the reduction of ALFs in the SpineJack® system group. The commenter asserted that the vertebral levels T11–L1 are commonly known for higher number of fractures, and that these spinal segments had 14 more levels treated with BKP than with the SpineJack® system in the SAKOS study. According to the commenter, further analysis would be needed to determine if the location of fractures had an effect on the occurrence of ALFs between the two study arms in SAKOS. The commenter also pointed out that it was unclear whether there was any difference in the two treatment groups' bone density metrics, as this was not disclosed in the SAKOS study.

The commenter went on to emphasize that the clinical comparison in the SAKOS study demonstrated the SpineJack® system was non-inferior to BKP at the time of the primary endpoint (12 months); however, there was no significant difference between groups in pain intensity visual analog scale (VAS) score at the final time point, and no difference in Oswestry Disability Index (ODI) or the EQ–5D health status questionnaire at any time point during the study. The commenter acknowledged that SAKOS

[61] Noriega D et al. Long-term safety and clinical performance of kyphoplasty and SpineJack procedures in the treatment of osteoporotic vertebral compression fractures: A pilot, monocentric, investigator-initiated study. Osteoporosis International. 2019; 30:637–645.

demonstrated superiority for the SpineJack® system for mid-vertebral height restoration, but emphasized that measures of anterior height, posterior height, and cobb angle showed no difference across the study arms, within the secondary endpoints. The commenter also observed that the SAKOS study showed a similar number of adverse events between study arms, with the SpineJack® system population seeing a higher percentage of serious adverse events.

Finally, the commenter disputed the applicant's assertion that vertebral augmentation treatment with vertebroplasty may alleviate pain, but cannot restore vertebral body height or correct spinal deformity. The commenter likewise disputed the applicant's assertion that BKP attempts to restore vertebral body height, but the temporary correction obtained cannot be sustained over the long-term. In countering the applicant's assertions, the commenter referenced three published articles with empirical evidence regarding the impact of BKP on kyphotic angle and VB height restoration.[62] [63] [64] Lastly the commenter stated that any mortality benefits have only been studies for BKP and vertebroplasty and not for SpineJack®. According to the commenter, it is therefore not appropriate to use this information to demonstrate the mortality benefits from using the SpineJack® technology.

Response: We appreciate all the comments we received related to the SpineJack® system, and we have taken them into consideration in making our determination, including the applicant's submission of additional information to address the concerns presented in the CY 2021 OPPS/ASC proposed rule and the comments expressing concerns with the design and results of the SAKOS study.

After consideration of the public comments received, we believe that commenters have addressed our concerns regarding whether the SpineJack® system meets the substantial clinical improvement criterion and that the SpineJack® system represents a substantial clinical improvement over existing technologies based on the data received from commenters. The data provided from the commenters with clinical experience with vertebral augmentation procedures and the SpineJack® system, which included improved pain, VB height restoration and ALF outcomes for patients with osteoporotic VCFs when compared with existing treatments, demonstrates substantial clinical improvement.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the SpineJack® system would be reported with CPT code 22513, which is assigned to APC 5114 (Level 4 Musculoskeletal Procedures). 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 5114, which has a CY 2019 payment rate of $5,891.95. 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 22513 had a device offset amount of $1,127 at the time the application was received. According to the applicant, the cost of the SpineJack® system is $5,623.

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 $5,622.64 for the SpineJack® system is 94 percent of the applicable APC payment amount for the service related to the category of devices of SpineJack® system (($5,622.64/$5,981.28) × 100 = 94 percent). Therefore, we believe the SpineJack® system meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $5,622.64 for the SpineJack® system is 499 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,126.87(($5,622.64/$1,126.87) × 100 = 499 percent). Therefore, we believe that the SpineJack® 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 $5,622.64 for the SpineJack® system and the portion of the APC payment amount for the device of $1,126.87 is 75 percent of the APC payment amount for the related service of $5,987.28 (($5,622.64 − $1,126.87)/$5,981.28) = 75.2 percent). Therefore, we believe that the SpineJack® Expansion Kit meets the third cost significance requirement.

We solicited public comment on whether the SpineJack® Expansion Kit meets the device pass-through payment criteria discussed in this section, including the cost criterion.

Comment: The applicant agreed with CMS' conclusion that the SpineJack® system meets all three of the cost significance requirements for establishing a device pass-through category as described in § 419.66(d).

Response: We appreciate the applicant's input.

After consideration of the public comments we received, we have determined that the SpineJack® Expansion Kit qualifies for device pass-through payment status and we are approving the application for device pass-through payment status for the SpineJack® Expansion Kit beginning in CY 2021.

3. Technical Clarification to the Alternative Pathway to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion for Certain Transformative New Devices

As described previously, in the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that receive Food and Drug Administration (FDA) marketing authorization and are granted a Breakthrough Device designation (84 FR 61295 through 61297). 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 purposes of determining device pass-through payment status, but will need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Similarly, in the FY 2020 IPPS/LTCH PPS final rule, we finalized an alternative pathway for new

[62] Van Meirhaeghe JV, et al. 2013; 38(12): 971–983.

[63] Dohm M, et al. 2014. (24 Months), Am J Neuroradiol. 2014;35:2227–2236.

[64] Bozkurt M, et al. 2014. Asian Spine J. 2014; 8(1):27–34.

technology add-on payments for certain transformative new devices. Under the existing regulations at § 412.87(c), to be eligible for approval for IPPS new technology add-on payments under this alternative pathway, the device must be part of the FDA's Breakthrough Devices Program and have received FDA marketing authorization.

We have received questions from the public regarding CMS's intent with respect to the ''marketing authorization'' required for purposes of approval under the alternative pathway for certain transformative new devices at § 412.87(c). Some of the public appear to assert that so long as a technology has received marketing authorization for any indication, even if that indication differs from the indication for which the technology was designated by FDA as part of the Breakthrough Devices Program, the technology would meet the marketing authorization requirement at § 412.87(c). Because of this potential confusion, we clarified in the FY 2021 IPPS/LTCH PPS proposed rule that an applicant cannot combine a marketing authorization for an indication that differs from the technology's indication under the Breakthrough Device Program, and for which the applicant is seeking to qualify for the new technology add-on payment, for purposes of approval under the alternative pathway for certain transformative devices (85 FR 32692).

We clarified in the CY 2021 OPPS/ASC proposed rule that the same policy applies for purposes of the OPPS alternative pathway policy. Specifically, we clarified that under the OPPS, in order to be eligible for the alternative pathway, the device must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation and we are making a conforming change to the regulations at § 419.66(c)(2). We also noted that the transitional pass-through payment application for the device must be received within 2 to 3 years of the initial FDA marketing authorization (or a verifiable market delay) for the device for the indication covered by the Breakthrough Devices Program designation.

In summary, in the CY 2021 OPPS/ASC proposed rule, we proposed to amend the regulations in § 419.66(c)(2)(ii) to state that ''A new medical device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.''

We did not receive any comments regarding the technical clarification outlined in the CY 2021 OPPS/ASC proposed rule that in order to be eligible for the alternative pathway to the OPPS device pass-through substantial clinical improvement criterion, the device must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. Therefore we are finalizing our proposal to amend the regulations in § 419.66(c)(2)(ii) to provide that ''a new medical device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.''

4. Comment Solicitation on Continuing To Provide Separate Payment in CYs 2022 and Future Years for Devices With OPPS Device Pass-Through Payment Status During the COVID–19 Public Health Emergency (PHE)

In the CY 2021 OPPS/ASC proposed rule, we solicited comments on whether we should adjust future payments for devices currently eligible to receive transitional pass-through payments that may have been impacted by the PHE, and if so, how we should implement that adjustment and for how long the adjustment should apply. On January 31, 2020, HHS Secretary Azar determined that a PHE exists retroactive to January 27, 2020 [65] 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.[66] On March 13, 2020, the President of the United States declared that the COVID–19 outbreak in the U.S. constitutes a national emergency,[67] retroactive to March 1, 2020. Due to the PHE, we received multiple inquiries from stakeholders regarding potential adjustments to the pass-through payment for devices with OPPS transitional pass-through payment status that may be impacted by the PHE. According to stakeholders, healthcare resources have been triaged to assist in the COVID–19 pandemic response effort, which has reduced utilization for devices receiving transitional pass-through payment, particularly for devices used in services that could be considered elective. Stakeholders cited the CMS recommendations issued on March 18, 2020 to postpone elective surgeries due to the COVID–19 PHE.[68] Stakeholders claim that devices on pass-through status are frequently used during such elective procedures, and that CMS's ability to calculate appropriate payment for services that include these devices once the devices transition off of pass-through status could be hindered by a reduction in claims being submitted with these devices during the PHE.

Transitional pass-through payment for devices is described in section 1833(t)(6) of the Act. It is intended as an interim measure to allow for adequate payment of new innovative technology while we collect the necessary data to incorporate the costs for these items into the procedure APC rate (66 FR 55861). As previously stated, transitional pass-through payments for devices can be made for a period of at least 2 years, but not more than 3 years, beginning on the first date on which pass-through payment was made for the device.

In response to stakeholder concerns regarding reduced utilization of procedures that include pass-through devices during the PHE, we specifically requested public comment on utilizing 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 these devices in order to account for the period of time that utilization for the devices was reduced due to the PHE. Any rulemaking on this issue in response to this comment solicitation would be included in the CY 2022 OPPS/ASC proposed rule and would consider the impact of the PHE on devices with OPPS device pass-through payment status during the PHE. Note that OPPS device pass-through payment status generally lasts 3 years, and none of the devices with less than 3 years of pass-through payment status at the start of the PHE have pass-through payment status set to end before December 31, 2021.

The following is summary of the comments we received and our responses to those comments.

Comment: Several commenters submitted comments in support of CMS' comment solicitation on continuing to provide separate payment in CYs 2022 and future years for devices with OPPS device pass-through payment status during the COVID–19 Public Health Emergency (PHE). All commenters who supported CMS' comment solicitation stated that the COVID–19 PHE has

[65] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[66] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx.*

[67] *https://www.whitehouse.gov/presidentialactions/proclamation-declaring-nationalemergency-concerning-novel-coronavirus-diseasecovid-19-outbreak/.*

[68] *https://www.cms.gov/newsroom/press-releases/cms-releases-recommendations-adult-elective-surgeries-non-essential-medical-surgical-and-dental.*

negatively affected items currently receiving pass-through payment. Two commenters stated that CMS has the authority to make an equitable adjustment to provide additional time for items to receive pass-through payments to account for reduced utilization during the PHE. Multiple commenters stated that the pass-through payment extension should be equal to the duration of the PHE with one commenter adding that it should start immediately after the later of the expiration of the item's pass-through status or the expiration of the emergency period. One commenter stated that CMS should provide, specific to each pass-through item, an adjustment to begin on January 1, 2021, and provide for a period of continued pass-through payment, rounded up to the nearest quarter, for which the item's pass-through period coincided with the PHE. Lastly, one commenter stated that CMS should allow pass-through periods for devices, drugs or biologicals adversely impacted by the PHE to be extended, if any extension does not apply to devices, drugs or biologicals that already had 3 years or more of pass-through status when the PHE began. One applicant, as well as offering support for this proposal, added a request that CMS share the operational details of its policy by the end of CY 2020 rather than waiting for the CY 2022 rulemaking cycle to facilitate planning.

Response: We appreciate the commenters' support and will take the information submitted into consideration for future rulemaking.

Comment: Some commenters stated that CMS should not limit the extension of pass-through payments to devices, but should also extend pass-through payments for drugs. One commenter stated that drugs should be subject to this policy because, like pass-through devices, the commenter believed pass-through drugs likely had reduced utilization from the PHE. A second commenter stated that there is no principled reason to limit any COVID–19 related pass-through adjustment to devices only; adding that it is a basic principle of administrative law that agencies must treat ''similarly situated'' entities ''similarly'' and there is no logical basis for treating pass-through devices used in outpatient settings differently than pass-through drugs used in outpatient settings. Two commenters stated that CMS should extend the pass-through period to radiopharmaceuticals in addition to medical devices, stating that the COVID–19 PHE has negatively affected their utilization as it has for devices.

One commenter, who supported an extension for pass-through devices, stated that most drugs, biologicals, and biosimilar biological products continue to be separately paid after their pass-through period expires such that prior year claims data do not impact their treatment under OPPS. For such products, the commenter stated that it would not be necessary or appropriate to use the equitable adjustment authority to adjust payment. A second commenter recommended that the products that received extended pass-through payments under section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018, should not receive an additional extension of pass-through status due to the PHE as these products have already had more than the required 3 years of pass-through payments. The commenter added that extending pass-through payments for these products would needlessly increase cost to taxpayers and would be contradictory to the administration's efforts to reduce the cost of prescription drugs.

Response: We did not solicit comments on extending pass-through payments for drugs, however, we will consider the commenters' points for potential future rulemaking.

We thank the commenters for their submissions and will consider their input when determining whether a change is warranted in response to the PHE as we develop the 2022 OPPS/ASC proposed rule.

B. Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs and is discussed in detail in section IV.B.4. of the CY 2021 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). 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, the device-intensive methodology 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 APCs 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 APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.B.1.b. of the CY 2021 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 the CY 2021 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 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not either of the following:

(a) Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

(b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the

HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation or insertion of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have 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.

In response to stakeholder requests for additional detail on our device-intensive methodology, we have updated our claims accounting narrative with a description of our device offset percentage calculation. Our claims accounting narrative for the CY 2021 OPPS/ASC final rule can be found under supporting documentation on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

For CY 2021, we did not propose any changes to our device-intensive policy.

Comment: A number of commenters and the Advisory Panel on Hospital Outpatient Payment (HOP Panel) recommended that CMS consider lowering the device-intensive threshold from 30 percent to 25 percent to avoid excessive payment gaps when device costs do not reach the device-intensive threshold and thereby do not ''carry over'' device costs from the hospital outpatient setting to the ASC setting.

Response: We thank the commenters and the HOP Panel for their recommendation. While payment rates under the ASC payment system for a particular procedure may be subject to fluctuation if device-intensive status varies for the procedure on a year-to-year basis, we believe that the potential payment gaps that commenters note will exist for any threshold value. Further, as discussed in section XIII.G.2.a. of this final rule with comment, our established policy under the ASC payment system is to scale prospective ASC relative payment weights by comparing total payment using current year ASC scaled relative payment weights with the total payment using the prospective ASC relative payment weights, holding ASC utilization, the ASC conversion factor, and the mix of services constant from the claims year. Lowering the device-intensive threshold assigns a greater amount of device costs, which are held constant between the OPPS and ASC payment system, into the prospective year. This would put additional downward pressure on the ASC weight scalar and reduce the non-device portion of ASC payment rates for most surgical procedures. Additionally, a reduction in the device-intensive threshold to 25 percent would also be accompanied with a reduction in the default device offset percentage, from 31 percent to 26 percent. A reduction in the default device offset percentage would reduce the device portion for covered surgical procedures with device offset amounts established at the existing default offset percentage of 31 percent. In light of these concerns, we are not accepting the recommendation to lower the device-intensive threshold at this time.

Comment: Some commenters recommended that the device offset percentage for 0424T (Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)) be reevaluated. Commenters contend that a 99.99 percent device offset percentage appears to be erroneous and would eliminate transitional pass-through device payments for the associated device C1823 (Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads). Commenters recommended

device offset percentages of 37.76 percent which excludes the costs associated with C1823, or 74.96 percent which includes the costs associated with C1823.

Response: In reviewing our device cost calculations, we discovered an oversight related to the cost of certain devices approved for transitional pass-through payment status. Currently, our ratesetting process excludes the cost of pass-through devices from being packaged into the major procedure until those devices no longer have pass-through status. However, our device cost calculation process in developing the offsets incorporated the cost of some devices currently receiving pass-through payment status. Because the costs of these devices are not included in developing the geometric mean cost of the procedure and therefore the APC payment rate, the costs associated with these pass-through devices should not be included in a procedure's device offset percentage. For this CY 2021 OPPS/ASC final rule with comment period, we have removed the pass-through device costs at issue from the calculation of the device offsets. We have also included these changes in our claims accounting narrative for the CY 2021 OPPS/ASC final rule which can be found under supporting documentation on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

The change in device cost calculation from the proposed and final rule only impacted the device offset percentage associated with CPT code 0424T. Specifically, the updated calculations using final rule claims data show a device offset percentage of 27.10 percent after removing the cost of pass-through devices. Therefore, for CY 2021, we are finalizing a device offset percentage of 27.10 percent for CPT code 0424T.

Comment: Commenters contended that CPT codes 22857 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar), 66174 (Transluminal dilation of aqueous outflow canal; without retention of device or stent), and 55880 (Ablation of malignant prostate tissue, transrectal, with high intensity—focused ultrasound (HIFU), including ultrasound guidance) should be designated as device-intensive under the OPPS and ASC payment systems.

Response: Using the updated final rule claims data, we have determined that the device offset percentages for CPT codes 22857 and 66174 are not above the 30-percent device-intensive threshold and, therefore, these procedures are not eligible to be assigned device-intensive status. Additionally, while we do not have claims data for CPT code 55880, we have determined that the device offset percentage of C9747, the predecessor code to CPT code 55880, is also not above the 30-percent threshold based on CY 2019 claims and, therefore, CPT code 55880 is also not eligible to be assigned device-intensive status.

Comment: Commenters requested that we designate CPT code 50590 (Lithotripsy, extracorporeal shock wave) device-intensive status, or establish alternative device-intensive criteria so that the costs of capital equipment, specifically, the lithotripter, associated with CPT code 50590 would allow this procedure to receive a device-intensive designation. The commenter suggested alternative criteria that would include that: (1) The procedure cannot be performed without the equipment/device; (2) the equipment/device is typically obtained on an ''as-needed'' basis rather than purchased or leased by the entity providing the care; (3) the fair-market lease or rental cost in an HOPD or ASC setting is not materially different for either site of service; (4) the fair-market lease or rental cost of the equipment precludes performing the service at an appropriate margin in an ASC setting; and (5) the procedure is most appropriately done on an ambulatory basis for the majority of patients.

Response: Using the updated claims data for this CY 2021 OPPS/ASC final rule with comment period, we have determined that the device offset percentage for CPT code 50590 is not above the 30-percent threshold and, therefore, this procedure is not eligible to be assigned device-intensive status.

We also do not believe changes to our device-intensive criteria are necessary. We believe the existing criteria are adequate to differentiate implantable and insertable device costs from non-invasive equipment costs and other procedure-related costs. We also note that the operating resource costs associated with CPT code 50590 are captured in the geometric mean cost of the procedure used to develop the ASC relative weights, as well as the ASC payment rate. While we acknowledge that the reliance on OPPS scaled relative weights to develop the ASC payment rate may not necessarily capture the geometric mean cost of procedures with significant capital equipment costs in the ASC setting, we are not finalizing any changes to our ASC ratesetting methodology at this time.

Comment: One commenter requested that we finalize our device-intensive designation for CPT code 0275T (Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (e.g., fluoroscopic, ct), single or multiple levels, unilateral or bilateral; lumbar) but only determine the device offset percentage based on claims with a reported device code.

Response: We appreciate the commenter's recommendation; however, we do not believe it would be appropriate to exclude claims data that would otherwise be available from our ratesetting process for the purposes of modifying the final device offset percentage for 0275T in particular. We are finalizing our proposal to assign device-intensive status to CPT code 0275T with a device offset percentage of 34.16 percent, as determined based on the final rule claims data.

Comment: Some commenters recommended that we assign CPT code 0404T (Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency) device-intensive status. Commenters argue that the device was not commercially available until late 2019, which they believed explains the lack of claims data and device cost information.

Response: We agree with the commenters. While CPT code 0404T was established in 2016, which predates our policy of applying a default device offset percentage for new procedures, we have yet to receive claims information for this procedure that would allow us to determine any associated device costs. We also thank the commenters for their submission of device pricing information. After reviewing the pricing information provided by commenters, we believe a default device offset percentage of 31 percent appropriately reflects the device costs for these procedures for CY 2021.

Comment: One commenter recommended that we assign 0632T (Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance) device-intensive status.

Response: As discussed in section III.D of this CY 2021 OPPS/ASC final rule with comment period, we are finalizing our proposal to assign SI=E1 ''Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)'' to CPT code 0632T. This

procedure is not payable under the OPPS beginning in CY 2021, and therefore we are not assigning device-intensive status to 0632T at this time.

Comment: Some commenters suggested that CMS only adjust the non-device portion of the payment by the wage index, consistent with the Agency's policy for separately payable drugs and biologicals.

Response: While we did not make such a proposal in this year's proposed rule, we will take this comment into consideration for future rulemaking. We note that such a policy would increase payments to providers with a wage index value of less than 1 and be offset by a budget neutral decrease in payments to other providers.

As discussed in section IV.A. of this final rule with comment period, we are approving the BAROSTIM NEO™ system for transitional pass-through device payment status. The applicant has stated that the BAROSTIM NEO™ would be reported with CPT code 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)). There have been no device costs reported for CPT code 0266T in CY 2019 claims or in previous calendar years. Therefore, for purposes of applying a device offset percentage for transitional pass-through device payments for CPT code 0266T, we are assigning a device offset percentage to 0266T in CY 2021 based on the clinically-similar procedure 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)). Based on our review of CY 2019 claims data, CPT code 0268T has a device offset percentage of 95.74 percent. Therefore, for CY 2021, we are assigning device-intensive status to CPT code 0266T with a device offset percentage of 95.74 percent.

The full listing of the final CY 2021 device-intensive procedures can be found in Addendum P to the CY 2021 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website).

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 did not propose any changes to this policy for CY 2021.

Comment: Some commenters requested that CMS restore the device-to-procedure and procedure-to-device edits.

Response: As we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66794), we continue to believe that the elimination of device-to-procedure edits and procedure-to-device edits is appropriate due to the experience hospitals now have in coding and reporting these claims fully. More specifically, for the most costly devices, we believe the C–APCs reliably reflect the cost of the device if charges for the device are included anywhere on the claim. We note that, under our current policy, hospitals are still expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. We also note that, as with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

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. Although 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, we inadvertently did not make conforming changes to the regulation text. In particular, we did not change our regulation at 42 CFR 419.45(b)(1) and (2), which describes the amount of the reduction in the APC payment in situations where the beneficiary receives an implanted device that is replaced without cost to the provider or the beneficiary or where the provider receives a full or partial credit for the cost of a replaced device and which continues to state that the amount of the reduction is the device offset amount. Therefore, in the CY 2021 OPPS/ASC proposed rule, we proposed to change our regulation at § 419.45(b)(1) and (2) to conform with the policy we adopted in CY 2014. In particular, we proposed revising our regulations at § 419.45(b)(1) to state that, for situations in which a beneficiary has received an implanted device that is replaced without cost to the provider or the beneficiary, or where the provider receives full credit for the cost of a replaced device, the amount of reduction to the APC payment is calculated by reducing the APC payment amount by the lesser of the amount of the credit or the device offset amount that would otherwise apply if the procedure assigned to the APC had transitional pass-through status under § 419.66. Additionally, we proposed to revise our regulation at § 419.45(b)(2) to state that, for situations in which the provider receives partial credit for the cost of a replaced device, but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the replacement device being implanted, the amount of the reduction to the APC payment is calculated by reducing the APC payment amount by the lesser of the amount of the credit or the device offset amount that would otherwise apply if the procedure assigned to the APC had transitional-pass through status under § 419.66. The proposed revisions to § 419.45(b)(1) and (2) appear in section XXVII. of the CY 2021 OPPS/ASC proposed rule.

We did not receive any comments on our proposal and are finalizing, without modification, our revisions to § 419.45(b)(1) and (2).

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. The CY 2018 final rule geometric mean cost for the procedure described by CPT code 0308T (based on 19 claims containing the device HCPCS C-code, in accordance with the device-intensive edit policy) was $21,302, and the median cost was $19,521. The final CY 2018 payment rate (calculated using the median cost) was $17,560.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58951), for CY 2019, we continued with 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 based on calculations using the median cost instead of the geometric mean cost. For more information on the specific policy for assignment of low-volume device-intensive procedures for CY 2019, we refer readers to section III.D.13. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58917 through 58918).

For CY 2020, we finalized our policy to continue 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 using the median cost instead of the geometric mean cost. In CY 2020, this policy applied to CPT code 0308T which we assigned to APC 5495 (Level 5 Intraocular Procedures) in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61301).

For CY 2021, we proposed to continue our current 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 using the median cost instead of the geometric mean cost. For CY 2021, this policy would not apply to any procedure. As discussed in section III.D.3. of the CY 2021 OPPS/ASC proposed rule, we received no claims data with CPT code 0308T, which we previously assigned as a low-volume device-intensive procedure for CY 2017 through CY 2020. As such, we proposed to assign 0308T a payment weight based on the most recently available data, from the CY 2020 OPPS final rule, and therefore proposed to assign CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures). Additionally, in the absence of CY 2019 claims data for the CY 2021 OPPS/ASC proposed rule, we proposed to use the most recently available data, from the CY 2020 OPPS final rule, to establish the device offset percentage for 0308T. Therefore, the proposed CY 2021 device offset percentage for CPT code 0308T was based on the CY 2020 OPPS final rule device offset percentage of 82.21 percent for CPT code 0308T. For more discussion on the proposed APC assignment and proposed payment rate for CPT code 0308T, see CY 2021 OPPS/ASC proposed rule (85 FR 48840).

Comment: One commenter supported our proposed device offset percentage for CPT code 0308T.

Response: We thank the commenter for their support.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to use the CY 2020 median cost in determining the OPPS and ASC relative payment weights for 0308T and to assign the CY 2020 OPPS final rule device offset percentage of 82.21 percent as the CY 2021 device offset for CPT code 0308T. For more discussion on the APC assignment and payment rate for CPT code 0308T, please see section III.D of this CY 2021 OPPS/ASC final rule with comment period.

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

A. 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 this final rule with comment period, we use the term ''biological'' because this is the term that appears in section 1861(t) of the Act. A ''biological'' as used in this final rule with comment period 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 product as a hospital outpatient service under Medicare Part B. Proposed CY 2021 pass-through drugs and biologicals and their designated APCs were 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 product 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 product'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.

Comment: One commenter commended CMS for continuing the policy to provide for quarterly expiration of pass-through payment status, which allows a pass-through period that is as close to a full three years as possible.

Response: We thank the commenter for their input and support of this policy change, which was adopted in the CY 2017 OPPS/ASC final rule (81 FR 79654 through 79655).

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2020

There are 29 drugs and biologicals whose pass-through payment status will expire during CY 2020 as listed in Table 36. Most of these drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2017 through December 31, 2020. However, there are two groups of drugs and biologicals included in Table 36 whose total period of OPPS pass-through payment is greater than 3 years. The first group are five drugs and biologicals that have already had 3 years of pass-through payment status but for which pass-through payment status was extended for an additional 2 years from October 1, 2018 until September 30, 2020 under section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141). The drugs covered by this provision include: HCPCS code A9586 (Florbetapir f18, diagnostic, per study dose, up to 10 millicuries); HCPCS code J1097 (Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml); HCPCS code Q4195 (Puraply, per square centimeter); HCPCS code Q4196 (Puraply am, per square centimeter); and HCPCS code Q9950 (Injection, sulfur hexafluoride lipid microspheres, per ml). The second group are two diagnostic radiopharmaceuticals: HCPCS code Q9982 (Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries) and HCPCS code Q9983 (Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries) whose pass-through payment status was extended for an additional 9 months from January 1, 2020 to September 30, 2020 under Division N, Title I, Subtitle A, Section 107(a) of the Further Consolidated Appropriations Act of 2020, which amended section 1833(t)(6) of the Social Security Act and added a new section 1833(t)(6)(J) to the Act.

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 was proposed to be $130 for CY 2021), as discussed further in section V.B.2. of the CY 2021 OPPS/ASC 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 relative ASP-based payment amount (which was proposed at ASP+6 percent for non-340B drugs for CY 2021, as discussed further in section V.B.3. of the CY 2021 OPPS/ASC proposed rule).

We did not receive any public comments regarding our proposals. Therefore, we are adopting these proposals as final for CY 2021 without modification. The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B of the CY 2021 OPPS/ASC final rule (which is available via the internet on the CMS website).

BILLING CODE 4120–01–P

TABLE 36.--DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL EXPIRE BETWEEN MARCH 31, 2020 AND DECEMBER 31, 2020

CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017	03/31/2020
J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017	03/31/2020
J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017	03/31/2020
J3358	Ustekinumab, for intravenous injection, 1 mg	G	9487	04/01/2017	03/31/2020
J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	G	1862	04/01/2017	03/31/2020
J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017	03/31/2020
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2018	03/31/2020
J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017	06/30/2020
J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017	06/30/2020
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018	09/30/2020
J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	G	9324	10/01/2018	09/30/2020
J1301	Injection, edaravone, 1 mg	G	9493	10/01/2017	09/30/2020

CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017	09/30/2020
J2797	Injection, rolapitant, 0.5 mg	E1	9464	04/01/2018	09/30/2020
J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017	09/30/2020
J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017	09/30/2020
Q4195	Puraply, per square centimeter	G	9175	01/01/2019	09/30/2020
Q4196	Puraply am, per square centimeter	G	9176	01/01/2019	09/30/2020
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018	09/30/2020
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459	01/01/2020	09/30/2020
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458	01/01/2020	09/30/2020
J0567	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018	12/31/2020
J0599	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units	G	9015	01/01/2018	12/31/2020
J1628	Injection, guselkumab, 1 mg	G	9029	01/01/2018	12/31/2020
J3316	Injection, triptorelin, extended-release, 3.75 mg	G	9016	01/01/2018	12/31/2020
J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301	01/01/2018	12/31/2020
J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018	12/31/2020
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018	12/31/2020
J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018	12/31/2020

BILLING CODE 4120–01–C

4. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in CY 2021

We proposed to end pass-through payment status in CY 2021 for 25 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status between April 1, 2018 and January 1, 2019, are listed in Table 37. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2021, are assigned status indicator ''G'' in Addenda A and B to the CY 2021 OPPS/ASC 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 CY 2021, we

proposed 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 2021. We proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2021 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which was proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which was 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 proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2021 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 the CY 2021 OPPS/ASC proposed rule. We proposed 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 proposed to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2021 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 2021, consistent with our CY 2020 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed 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 2021, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which was proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of the proposed rule), the equivalent payment provided to pass-through payment 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 the proposed rule. If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We did not receive any public comments regarding our proposals. Therefore, we are adopting these proposals as final for CY 2021 without modification. The drugs and biologicals for which pass-through payment status will expire between March 31, 2021 and December 31, 2021 are shown in Table 37.

BILLING CODE 4120–01–P

TABLE 37: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING DURING CY 2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9462	C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018	03/31/2021
J0185	J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	03/31/2021
J0517	J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018	03/31/2021
J3304	J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	03/31/2021
J7203	J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	04/01/2018	03/31/2021
J7318	J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	9174	04/01/2018	03/31/2021
J9311	J9311	lnjection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	03/31/2021
Q2041	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	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	Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	03/31/2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9513	A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018	06/30/2021
J3398	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	07/01/2018	06/30/2021
J7170	J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018	06/30/2021
J9057	J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	06/30/2021
Q9991	Q9991	Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg	G	9073	07/01/2018	06/30/2021
Q9992	Q9992	Injection, buprenorphine extended-release (sublocade), greater than 100 mg	G	9239	07/01/2018	06/30/2021
J1454	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	09/30/2021
Q5105	Q5105	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018	09/30/2021
Q5106	Q5106	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018	09/30/2021
A9590	A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9339	01/01/2019	12/31/2021
J0222	J0222	Injection, Patisiran, 0.1 mg	G	9180	01/01/2019	12/31/2021
J0291	J0291	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2021
J1943	J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2021
J2798	J2798	Injection, risperidone, (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2021
J9204	J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021

5. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Continuing in CY 2021

We proposed to continue pass-through payment status in CY 2021 for 46 drugs and note that 22 additional drugs were granted pass-through status since publication of the proposed rule. Thus, for CY 2021, there are 68 drugs and biologicals with pass-through status. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2019 and January 1, 2021, are listed in Table 38. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will continue after December 31, 2021, were assigned status indicator ''G'' in Addenda A and B to the CY 2021 OPPS/ASC 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 CY 2021, we proposed 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 2021. We proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2021 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which was proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which was 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 proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2021 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6. of the CY 2021 OPPS/ASC proposed rule. We proposed 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 proposed to continue to update pass-through payment rates on a quarterly basis on our website during CY 2021 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 2021, consistent with our CY 2020 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed 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 2021, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which was proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of the proposed rule), the equivalent payment provided to pass-through payment 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 the proposed rule. If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We did not receive any public comments regarding our proposals. Therefore, we are adopting these proposals for CY 2021 without modification. The drugs and biologicals that have pass-through payment status expire after December 31, 2021 are shown in Table 38.

TABLE 38: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS CONTINUING THROUGH CY 2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 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
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

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
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
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	9342	04/01/2020	03/31/2023
C9057	J1201	Injection, cetirizine hydrochloride, 1 mg	G	9344	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	C9059	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
C9061	C9061	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
C9063	C9063	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9122	C9122	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
Q5116	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	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

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
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
N/A	C9068	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9383	01/01/2021	12/31/2023
N/A	C9069	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384	01/01/2021	12/31/2023
N/A	C9070	Injection, tafasitamab-cxix, 2 mg	G	9385	01/01/2021	12/31/2023
N/A	C9071	Injection, viltolarsen, 10 mg	G	9386	01/01/2021	12/31/2023
N/A	C9072	Injection, immune globulin (Asceniv), 500 mg	G	9392	01/01/2021	12/31/2023
N/A	C9073	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

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

Under the regulations 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 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 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 2021, as we did in CY 2020, we proposed 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 39.

TABLE 39: APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2021

CY 2021 APC	CY 2021 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 proposed 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.

Comment: One commenter requested that CMS release a copy of the APC offset file with future OPPS/ASC proposed rules to enable the public to

calculate the percentage of APC payment associated with packaged drug costs using APC offset data for the upcoming calendar year.

Response: We thank the commenter for their suggestion, and we will consider addressing this request in future rulemaking.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. 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 2020 (84 FR 61312 through 61313).

Following the CY 2007 methodology, for this CY 2021 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 2021 and rounded the resulting dollar amount ($130.95) 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 2021 OPPS/ASC proposed rule, based on these calculations using the CY 2007 OPPS methodology, we proposed a packaging threshold for CY 2021 of $130.

Comment: One commenter expressed their support for maintaining the drug packaging threshold for CY 2021 at $130. The commenter believes, however, that the drug packaging threshold has been increasing faster than payment increases under the OPPS. The commenter would like us to research if the drug packaging threshold should be lowered in future years.

Response: We appreciate the commenter's support of the drug packaging threshold level of $130. We also thank the commenter for their suggestion to consider reducing the drug packaging threshold in future years and will consider it for future rulemaking.

After consideration of the public comment, we are implementing our proposal without modification to have a drug packaging threshold for CY 2021 of $130.

b. 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 2021 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 before January 1, 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 proposed to continue to package in CY 2021: 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 2021, 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 proposed for separately payable drugs and biologicals (other than 340B drugs) for CY 2021, as discussed in more detail in section V.B.2.b. of the proposed rule) to calculate the CY 2021 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2019 (data that were used for payment purposes in the physician's office setting, effective April 1, 2020) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2021, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2019 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 were 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, 2020. 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 proposed 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 2020 HCPCS codes that we display in Addendum B to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website) for proposed payment in CY 2021.

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 2021 OPPS/ASC proposed rule, we proposed to use ASP data from the fourth quarter of CY 2019, 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, 2020, along with updated hospital claims data from CY 2019. We note that we also

proposed to use these data for budget neutrality estimates and impact analyses for this CY 2021 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for this final rule with comment period will be based on ASP data from the third quarter of CY 2020. 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, 2020. These payment rates would then be updated in the January 2021 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2021. 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 updated cost report information available for the CY 2021 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 2021 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2020. 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 2021, 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 2020 and that are proposed for separate payment in CY 2021, and that then have per day costs equal to or less than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would continue to receive separate payment in CY 2021.
- HCPCS codes for drugs and biologicals that were packaged in CY 2020 and that are proposed for separate payment in CY 2021, and that then have per day costs equal to or less than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would remain packaged in CY 2021.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2021 but that then have per-day costs greater than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would receive separate payment in CY 2021.

We did not receive any public comments on our proposal to recalculate the mean unit cost for items that do not currently have an ASP-based payment rate from all of the CY 2019 claims data and updated cost report information available for this CY 2021 final rule with comment period to determine their final per day cost. We also did not receive any public comments on our proposal to continue to follow the established policies, initially adopted for the CY 2005 OPPS (69 FR 65780), when the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the final rule with comment period. Therefore, for CY 2021, we are finalizing these two proposals without modification.

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).

Comment: One commenter requested that we develop a policy to provide separate payment for drugs that are administered at the time of ophthalmic surgery and have an FDA-approved indication to treat or prevent post-operative issues.

Response: A surgical procedure episode consists of both pre-operative and post-operative care in addition to the surgical procedure itself. If a drug used to address a post-operative concern, such as pain management, is billed together with a surgical procedure, we assume that the pain management drug was given as a part of the overall surgical procedure, and based on our policy, it is required to be packaged.

Comment: One commenter recommended that CMS continue to apply radiolabeled product edits to the nuclear medicine procedures to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future. The commenter was concerned that many providers performing nuclear medicine procedures are not including the cost of diagnostic radiopharmaceuticals used

for the procedures in their claims submissions. The commenter believes this lack of drug cost reporting could be causing the cost of nuclear medicine procedures to be underreported and therefore request that the radiolabeled product edits be reinstated.

Response: We appreciated the commenter's feedback; however, we do not plan to reinstate the radiolabeled product edits to nuclear medicine procedures, which required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure for payment to be made under the OPPS. As previously discussed in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61314), the edits were in place between CY 2008 and CY 2014 (78 FR 75033). We believe the period of time in which the edits were in place was sufficient for hospitals to gain experience reporting procedures involving radiolabeled products and to become accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those radiolabeled products. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

Comment: The HOP Panel and several commenters requested that diagnostic radiopharmaceuticals be paid separately in all cases, not just when the drugs have pass-through payment status. One commenter suggested payment based upon ASP, WAC, AWP, or mean unit cost data derived from hospital claims. Some commenters mentioned that pass-through payment status helps the diffusion of new diagnostic radiopharmaceuticals into the market, but is not enough to make up for what the commenters believe is inadequate payment after pass-through status expires. Commenters opposed incorporating the cost of the drug into the associated APC, and provided evidence showing procedures in which diagnostic radiopharmaceuticals are considered to be a surgical supply, which the commenter believed are often paid at a lower rate than the payment rate for the diagnostic radiopharmaceutical itself when the drug had pass-through payment status. Additionally, commenters proposed alternative payment methodologies such as subjecting diagnostic radiopharmaceuticals to the drug packaging threshold, creating separate APC payments for diagnostic radiopharmaceuticals that cost more than $500, or using ASP, WAC, or AWP to account for packaged radiopharmaceutical costs.

Response: We thank commenters for their suggestions. Commenters made many of these suggestions and we addressed them in previous rules, including the CY 2019 OPPS/ASC final rule (83 FR 58955 through 58966) and the CY 2020 OPPS/ASC final rule (84 FR 61314 through 61315). We continue to believe that diagnostic radiopharmaceuticals are an integral component of many nuclear medicine and imaging procedures and charges associated with them should be reported on hospital claims to the extent they are used. Therefore, the payment for the radiopharmaceuticals is reflected within the payment for the primary procedure. In response to the comment regarding the proposed cost of the packaged procedure in CY 2021 being substantially lower than the payment rate of the radiopharmaceutical when it was on pass-through payment status plus the payment rate of the procedure associated with the radiopharmaceutical, we note that rates are established in a manner that uses the geometric mean of reported costs to furnish the procedure based on data submitted to CMS from all hospitals paid under the OPPS to set the payment rate for the service. Accordingly, the costs that are calculated by Medicare reflect the average costs of items and services that are packaged into a primary procedure and will not necessarily equal the sum of the cost of the primary procedure and the average sales price of the specific items and services used in the procedure in each case. Furthermore, the costs will be based on the reported costs submitted to Medicare by the hospitals and not the list price established by the manufacturer. Claims data that include the radiopharmaceutical packaged with the associated procedure reflect the combined cost of the procedure and the radiopharmaceutical used in the procedure. Additionally, we do not believe it is appropriate to create a new packaging threshold specifically for diagnostic radiopharmaceuticals as such a threshold would not align with our overall packaging policy and commenters have submitted only limited data to support a specific threshold. With respect to the request that we create a new APC for each radiopharmaceutical product, we do not believe it is appropriate to create unique APCs for diagnostic radiopharmaceuticals. Diagnostic radiopharmaceuticals function as supplies during a diagnostic test or procedure and following our longstanding packaging policy, these items are packaged under the OPPS. Packaging supports our goal of making OPPS payments consistent with those of a prospective payment system, which packages costs into a single aggregate payment for a service, encounter, or episode of care. Furthermore, diagnostic radiopharmaceuticals function as supplies that enable the provision of an independent service, and are not themselves the primary therapeutic modality, and therefore, we do not believe they warrant separate payment through creation of a unique APC at this time. We welcome ongoing dialogue with stakeholders regarding suggestions for payment changes for consideration for future rulemaking.

After consideration of the public comments we received, we are finalizing our proposals without modification regarding products that are packaged consistent with the policies in 42 CFR 419.2(b).

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 proposed 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 2021.

For CY 2021, 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 2021 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 2021 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 2021 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 2018 was displayed in Table 25 of the CY 2021 OPPS/ASC proposed rule (82 FR 48879).

We did not receive any public comments on this proposal. Therefore, for CY 2021, we are finalizing our proposal, without modification, 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. The packaging status of each drug and biological HCPCS code to which this methodology applies in CY 2021 is displayed in Table 40.

BILLING CODE 4120–01–P

TABLE 40: HCPCS CODES TO WHICH THE CY 2021 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2021 HCPCS Code	CY 2021 Long Descriptor	CY 2021 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

CY 2021 HCPCS Code	CY 2021 Long Descriptor	CY 2021 Status Indicator (SI)
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
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.[69]

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 the CY 2021 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 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 2020.

b. Proposed CY 2021 Payment Policy

For CY 2021, we proposed 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 proposed to pay for separately payable nonpass-through drugs acquired with a 340B discount at a net rate of ASP minus 28.7 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), the CY 2019 OPPS/ASC final rule with comment period (83 FR 58979 through 58981), and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321 through 61327) 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). In the CY 2020 OPPS/ASC final rule with comment period, 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). For CY 2021, we proposed to continue to utilize a 3-percent add-on instead of a 6-percent add-on for WAC-based drugs 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 proposed to apply this provision to non-SCOD separately payable drugs. Because we proposed to establish the average price for a WAC-based drug under section 1847A of the Act as WAC+3 percent instead of WAC+6 percent, we believe it is appropriate to price separately payable WAC-based drugs at the same amount under the OPPS. We proposed 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 net rate of WAC minus 28.7 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 proposed 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 the CY 2021 OPPS/ASC proposed rule (available via the internet on the CMS website), which illustrate the proposed CY 2021 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, 2020, or WAC, AWP, or mean unit cost from CY 2019 claims data and updated cost report information available for the proposed rule. In general, these published payment rates are not the same as the actual January 2021 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2021 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2020 (July 1, 2020 through September 30, 2020) will be used to set the payment rates that are released for

[69] 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.*

the quarter beginning in January 2021 near the end of December 2020. 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 2020 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 2021, 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 2020 ASP data) that do not have ASP information available for the quarter beginning in January 2021. 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 were not for January 2021 payment purposes and are only illustrative of the CY 2021 OPPS payment methodology using the most recently available information at the time of issuance of the proposed rule.

Comment: Multiple commenters expressed their support for paying for separately payable drugs and biologicals at ASP plus 6 percent. The commenters believe this policy is consistent with statute and Congressional intent, and generates more predictable payment for providers than previous payment methodologies for drugs and biologicals. The commenters believe the ASP plus 6 percent payment policy ensures equivalent payment for drugs and biologicals between the outpatient hospital setting and the physician office, which encourages Medicare beneficiaries to receive care in the most clinically appropriate setting.

Response: We appreciate the commenters' support for our policy.

Comment: One commenter requested that an add-on percentage of greater than 6 percent of ASP be paid for separately payable radiopharmaceuticals to reflect higher overhead and handling costs for these products.

Response: The add-on percentage of 6 percent is generally viewed as reflecting the overhead and handling cost of most drugs, radiopharmaceuticals, and biologicals that are separately payable in the OPPS even though the overhead and handling costs for individual products may be higher or lower than 6 percent of the ASP. It is not practical to calculate the overhead and handling costs for each drug and radiopharmaceutical. We believe that the add-on percentage of 6 percent is appropriate for separately payable radiopharmaceuticals.

After considering the public comments we received, we are finalizing our proposals related to payment for specified covered outpatient drugs (SCODs) and other separately payable drugs and biologicals without modification.

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 CY 2021, we proposed 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 proposed to continue our current policy for paying for nonpass-through biosimilars acquired under the 340B program, except that we proposed to pay for these biosimilars at the biosimilar's ASP minus 28.7 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 28.7 percent of the reference product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. ASP minus 28.7 percent reflects the proposed net payment rate. However, in this final rule, as discussed in section V.B.6, we are not adopting our proposal to pay for drugs acquired under the 340B program at ASP minus 28.7 percent but instead are continuing to pay for 340B drugs under the OPPS at ASP minus 22.5 percent in the OPPS. Accordingly, we are also continuing our policy to pay for biosimilars acquired through the 340B program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP.

Comment: Multiple commenters supported our proposal to continue our policy from CY 2018 to make biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

Response: We appreciate the commenters' support of this established policy.

Comment: Multiple commenters supported our proposal to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 28.7 percent of the biosimilar's ASP in accordance with section 1833(t)(14)(A)(iii)(II) of the Act.

Response: We appreciate the commenters' support. Please see section V.B.6 of this final rule with comment period for a discussion of payment for biosimilars acquired under the 340B program. As noted above, we are not finalizing our proposal to pay for 340B drugs or biologicals at a net rate of ASP minus 28.7 percent.

Comment: One commenter did not support our proposal to continue our CY 2018 policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. The commenter believes biosimilars are not new or innovative drugs or biologicals because they believe the reference product is the only new and innovative product. Therefore, the commenter stated that biosimilars should not be considered for pass-through payment status at all. Additionally, the commenter stated that there should be a ''level playing field'' between biosimilars and their reference products in order to increase competition and reduce costs for beneficiaries. The commenter does not believe it is fair for biosimilars of a reference product to be receiving pass-through payment of ASP+6 percent of the reference product's ASP. The commenter pointed out that when the reference product is no longer eligible for pass-through payment, if it is acquired under the 340B program, hospitals would be paid for the product at ASP minus 22.5 percent. The commenter believes that this difference in the payment rates for biosimilars and their reference products could potentially lead to increased Medicare spending on biosimilars as providers utilize biosimilars instead of the biosimilars' reference products because of the higher payment rates for biosimilars in these circumstances.

Response: As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58977), we continue to believe that eligibility for pass-through payment status reflects the unique, complex nature of biosimilars and is important as biosimilars become established in the market, just as it is for all other new drugs and biologicals. In terms of the potential increased payment for biosimilars under our policy to allow biosimilars to be eligible for pass-through status, overall increased competition due to the presence of more biosimilars on the market as a result of this policy is expected to drive payments down for both Medicare and for beneficiaries over time, even if there may be increased spending on biosimilars in the short term.

Comment: Several commenters recommended that CMS provide additional support for biosimilars in the form of beneficial payment policies. Some of these recommendations included a delayed effective date for the 340B payment reduction; a smaller reduction in payment for biosimilars acquired under the 340B program; an add-on based on the reference product's ASP when the biosimilar is subject to the 340B payment reduction; increased payment for biosimilars in general; and biosimilar value-based models.

Response: We thank the commenters for their feedback. However, we maintain that our proposed payment policy for biosimilars adequately supports these products by permitting both reference products and their associated biosimilars to receive the same percentage add-on amount, which is calculated based on the ASP of the reference product, regardless of the biosimilar's ASP. Similarly, for products acquired under the 340B program, we note that CMS pays for nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP rather than ASP minus 22.5 percent of the reference product's ASP. If the payment reduction were based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, it would result in a more significant payment decrease than if the 22.5 percent were calculated based on the biosimilar's ASP. Please see section V.B.6 for a discussion of payment for biosimilars acquired under 340B. Biosimilars will be treated the same as other separately payable drugs and cannot be excluded from the 340B discount once their pass-through period has ended. We do not believe that additional add-on payments for biosimilars obtained under the 340B program are necessary to encourage their utilization. We note value-based models are outside of the scope of this rule.

For CY 2021, after consideration of the public comments we received, we are finalizing our proposed payment policy for biosimilar products, without modification, to continue the policy established in 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. We are also finalizing our alternative proposal to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. Our final policy regarding the payment rate for drugs and biologicals that are acquired under the 340B program is described in section V.B.6 of this final rule with comment period.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2021, we proposed 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 2021. Therefore, we proposed for CY 2021 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 proposed 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 2021 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals were included in Addenda A and B to the CY 2021 OPPS/ASC proposed rule (which are available via the internet on the CMS website).

Comment: One commenter supported the continuation of this policy to provide a predicable payment methodology and avoid the payment swings that occurred prior to adoption of the statutory default rate.

Response: We thank the commenter for their support.

We did not receive any additional public comments on this proposal. Therefore, we are finalizing our proposal, without modification, to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent. We are also finalizing our proposal to continue 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. The CY 2021 final payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website).

4. Payment for Blood Clotting Factors

For CY 2020, 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 (83 FR 58979). That is, for CY 2020, 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 2020 updated furnishing fee was $0.226 per unit.

For CY 2021, we proposed 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 for 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 proposed 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 proposed 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.

We did not receive any public comments on our proposal. Therefore, we are finalizing our proposal, without modification, 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 2021, we proposed to continue to use the same payment policy as in CY 2020 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 2021 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 the CY 2021 OPPS/ASC proposed rule, which is available via the internet on the CMS website.

We did not receive any comments on our proposal. Therefore, we are finalizing our CY 2021 proposal without modification, including our proposal to assign drug or biological products status indicator ''K'' and pay for them separately for the remainder of CY 2021 if pricing information becomes available. The CY 2021 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 final rule with comment period, which is available via the internet on the CMS website.

6. CY 2021 OPPS Payment Methodology for 340B Purchased Drugs

a. Overview and Background

Section Overview

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 lacked the authority to bring the default rate in line with average acquisition cost unless the Secretary obtained survey data from hospitals on their acquisition costs. HHS disagreed with that ruling and appealed the decision. HHS meanwhile gathered the relevant survey data from 340B hospitals. As described in detail below, those survey data confirmed that the ASP minus 22.5 percent rate does not underpay 340B hospitals, and the survey data could support an even lower payment rate. The following sections expand upon the points discussed in this overview.

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. 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.[70] 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.[71] 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.[72] 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,'' [73] 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.'' [74] *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.'' [75]

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 judgement in this matter. Nonetheless, before the D.C. Circuit upheld our authority to pay ASP minus 22.5 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 is 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.[76] 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.

We noted that under current law, any changes to the OPPS must be budget neutral, and reversal of the payment adjustment for 340B drugs, which raised rates for non-drug items and services by an estimated $1.6 billion for 2018 alone, could have a significant economic impact on the approximately 3,900 facilities that are paid for outpatient items and services covered under the OPPS. In addition, we stated that any remedy that increases payments to 340B hospitals could significantly affect beneficiary cost-sharing. The items and services that could be affected by the remedy were provided to millions of Medicare beneficiaries, who, by law, are required to pay cost-sharing for most items and services, which is usually 20 percent of the total Medicare payment rate. Accordingly, we solicited comments on how to formulate an appropriate remedy in the event of an unfavorable decision on appeal. Those comments are summarized in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61323 through 61327).

b. Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Outpatient Drugs (SCODs)

As discussed in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61326), we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for the fourth quarter of CY 2018 and the first quarter of CY 2019. We noted that the 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 in the event of an adverse decision on appeal in the pending litigation. We stated that we believed it was prudent to use the Secretary's existing authority to collect survey data to set OPPS payment rates for drugs acquired under the 340B Program at rates based on hospitals' costs to acquire such drugs. We also stated that we believe it is appropriate for the Medicare program to pay for SCODs purchased under the 340B program at a rate that approximates what hospitals actually pay to acquire the drugs, and we believe it is inappropriate for Medicare to subsidize other programs through Medicare payments for separately payable drugs. We stated that this approach would ensure that the Medicare program uses Medicare trust fund dollars prudently, while maintaining beneficiary access to these drugs and allowing beneficiary cost-sharing to be based on the amounts hospitals actually pay to acquire the drugs.

Section 1833(t)(14)(D)(i)(I) of the Act required the Comptroller General of the United States to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each SCOD and, not later than April 1, 2005, to furnish data from such surveys to the Secretary for purposes of setting payment rates under the OPPS for SCODs for 2006. The Comptroller General was then required to make recommendations to the Secretary under section 1833(t)(14)(D)(i)(II) of the Act regarding the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii). Clause (ii) of section 1833(t)(14)(D) of the Act provides that the Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for SCODs for use in setting payment rates under subparagraph (A) of section 1833(t)(14).

[70] *American Hosp. Ass'n, et al.* v. *Azar, et al.,* No. 1:18-cv-2084 (D.D.C. Dec. 27, 2018).

[71] *Id.* at 35 (quoting *Amgen, Inc.* v. *Smith,* 357 F.3d 103, 112 (D.C. Cir. 2004) (citations omitted)).

[72] *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.

[73] *Id.* at 13.

[74] *Id.* at 19.

[75] *Id.* (citing Declaration of Elizabeth Richter).

[76] *See American Hosp. Assoc.* v. *Azar,* 348 F. Supp. 3d 62, 82 (D.D.C. 2018).

In response to the requirements at section 1833(t)(14)(D)(i)(I) and (II) of the Act, the Government Accountability Office (GAO) surveyed hospitals and prepared a report that included its recommendations for the Secretary regarding the frequency and methodology for subsequent surveys.[77] While GAO recognized that collecting accurate and current drug price data was important to ensure the agency does not pay too much or too little for drugs, GAO's 2006 report recommended that CMS conduct a streamlined hospital survey once or twice per decade because of the significant operational difficulties and burden that such a survey would place on hospitals and CMS.[78] In response to questions about whether the data undercounted rebates, GAO acknowledged that their data did not include drug rebates or 340B rebates as part of its calculation.[79] In the CY 2006 OPPS final rule, we explained that the data collected by the GAO was ultimately not used to set payment rates, in part because the data did not fully account for rebates from manufacturers or other price concessions or payments from group purchasing organizations made to hospitals (70 FR 68640). Instead, we adopted a policy to pay hospitals at ASP+6 percent because we believed ASP+6 percent was a reasonable level of payment for both the hospital acquisition and pharmacy overhead cost of drugs and biologicals (70 FR 68642).

Between 2006 and 2017, we have generally paid for separately payable drugs for which ASP data is available at ASP plus 6 percent. Beginning in 2018, we adopted the current policy to pay for 340B-acquired drugs at ASP minus 22.5 percent to better align Medicare payment with acquisition costs for 340B-acquired drugs. The Medicare Payment Advisory Commission (MedPAC) has consistently stated that Medicare should institute policies that improve the program's value to beneficiaries and taxpayers. For example, in its March 2019 Report to the Congress, MedPAC noted that outpatient payments increased in part due to rapid growth in Part B drug spending. MedPAC stated this rapid growth in OPPS specifically, was ''largely driven by the substantial margins for drugs obtained through the 340B Drug Pricing Program.'' [80] While we continue to believe that ASP plus 6 percent represents a reasonable proxy for Part B drug acquisition costs for most hospitals, we do not believe the same is true for hospitals that acquire Part B drugs under the 340B program since such hospitals are able to purchase drugs at deeply discounted 340B ceiling prices, or at even lower ''sub-ceiling'' prices. For this reason, we concluded that it was appropriate to survey 340B hospitals to gather drug acquisition cost data for drugs acquired under the 340B program to allow us to pay hospitals for these drugs at amounts that approximate the hospitals' acquisition costs.

Population of Surveyed Hospitals

Because of our longstanding belief that ASP plus 6 percent is a reasonable proxy for hospital acquisition costs and overhead for separately payable drugs, we did not believe it was necessary or appropriate to burden hospitals that are not eligible to acquire drugs under the 340B program with a drug acquisition cost survey where we have a proxy for hospital acquisition costs for those drugs. ASP data does not, however, include 340B drug prices. (CY 2011 OPPS/ASC final rule with comment period (75 FR 71800, 71960)). When GAO surveyed hospitals in 2005, it found that the survey ''created a considerable burden for hospitals as the data suppliers and considerable costs for GAO as the data collector,'' and recommended that CMS survey hospitals only once or twice per decade to ''occasionally validat[e] CMS's proxy for SCODs' average acquisition costs—the [ASP] data that manufacturers report.'' GAO Report to Congress: *Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS,* 4 (April 2006). Section 1833(t)(14)(D)(ii) requires the Secretary, in conducting periodic subsequent surveys, to take into account GAO's recommendations on the frequency and methodology of subsequent surveys. We considered GAO's conclusion that the 2005 survey created ''considerable burden'' for hospitals and, thus, only surveyed 340B hospitals given our belief that the current payment rate for non-340B hospitals continues to be an appropriate rate. For the same reason, we also limited the data we requested from 340B hospitals to acquisition costs for 340B-acquired drugs, rather than for drugs purchased outside the 340B program for 340B participating hospitals. We note that section 1833(t)(14)(D)(ii) refers to use of surveys conducted by the Secretary to determine the hospital acquisition costs for SCODs in setting payment rates under subparagraph (A). Therefore, we stated that we believed it is appropriate to read the two provisions together to permit the Secretary to survey 340B hospitals only, and formulate a 340B payment policy for this hospital group that is distinct from the payment policy for non-340B hospitals.

Survey Methodology

Under the authority at section 1833(t)(14)(D)(ii) to conduct periodic subsequent surveys to determine hospital acquisition costs, we administered the survey to 1,422 340B covered entity hospitals between April 24 and May 15, 2020. We requested that all hospitals that participated in the 340B program, including rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals (which are currently exempt from the Medicare 340B payment rate adjustment), supply their average acquisition cost for each SCOD purchased under the 340B program during the last quarter of CY 2018 (October 1, 2018 through December 31, 2018) and/or the first quarter of 2019 (January 1, 2019 through March 31, 2019), which could be the 340B ceiling price, a 340B sub-ceiling price, or another amount, depending on the discounts the hospital received when it acquired a particular drug. The ceiling price is the maximum amount covered entities may permissibly be required to pay for a drug under section 340B(a)(1) of the Public Health Service Act, so we would not expect any 340B hospital to have acquisition costs for any 340B-acquired drug that are greater than the ceiling price. For this reason, where the acquisition price for a particular drug was not available or not submitted in response to the survey, we stated that we would use the 340B ceiling price for that drug as a proxy for the hospitals' acquisition cost in order to produce the most conservative drug discount when data was missing or not submitted.

We incorporated valuable input from stakeholders on the development and construction of the 340B acquisition cost survey. We collected the stakeholders' input in two rounds of public comment through the survey Paperwork Reduction Act (PRA) submission process. We published the initial 340B drug hospital acquisition cost survey proposal in the **Federal Register** (84 FR 51590) for a 60-day public comment period that began September 30, 2019 and ended November 29, 2019. After incorporating comments from the 60-day public comment period, we released a revised 340B acquisition cost survey proposal in the **Federal Register** (85 FR 7306) for a

[77] *https://www.gao.gov/new.items/d06372.pdf.*

[78] *Id.* at 18.

[79] *https://www.gao.gov/new.items/d06372.pdf* (Appendix I: Purchase Price for Drug SCODs).

[80] *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0.*

30-day public comment period from February 7, 2020 to March 9, 2020.

After incorporating the stakeholders' comments and suggestions from the second public comment period, OMB approved CMS' survey design (OMB control number 0938–1374, expires 10/31/2021), and CMS released the 340B acquisition cost survey to the relevant 340B hospitals under the OPPS. As mentioned earlier in this section, the survey was open from April 24, 2020, to May 15, 2020. The survey sample was 100 percent of the potential respondent universe, or all hospitals that acquired drugs under the 340B Program and were paid under OPPS in the fourth quarter of 2018 and/or the first quarter of 2019. We provided respondents with two options to complete the survey: The Detailed Survey and the Quick Survey.

Respondents that selected the Detailed Survey provided acquisition costs for each individual SCOD. We requested that these respondents report the net acquisition cost for each SCOD that they acquired under the 340B program (that is, the sub-ceiling price after all applicable discounts). We stated that if the acquisition cost for the SCOD was unknown, the respondent may leave the field blank and we would use the 340B ceiling price as a proxy for the acquisition cost for that drug. In the survey instructions, we stated that acquisition cost for purposes of the survey meant the price that the hospitals paid upon receiving the product, including, but not limited to, prices paid for 340B drugs purchased via a replenishment model under the 340B program, or under penny pricing. We explained that applicable discounts are any discounts below the discounted ceiling price. We also made clear that for purposes of the survey the 340B drug acquisition cost should be reported regardless of whether the drug was dispensed at all, or whether the drug was dispensed in multiple settings. We only requested the acquisition cost of the drugs acquired under the 340B program during the specified timeframes: The fourth quarter of 2018 and/or the first quarter of 2019. We also stated that acquisition costs for drugs acquired by 340B hospitals outside of the 340B program should not be submitted in response to the survey.

The Quick Survey option allowed the hospital to indicate that it preferred that CMS utilize the 340B ceiling prices obtained from (HRSA) as reflective of their hospital acquisition costs. Additionally, we stated that in instances where the acquisition price for a particular drug is not available or submitted in response to the survey, we would use the 340B ceiling price for that drug as a proxy for the hospitals' acquisition cost because the price for a drug acquired under the 340B program cannot be higher than the 340B ceiling price by statute. Finally, we noted that where a hospital did not affirmatively respond to the Detailed or Quick Survey within the open period of response, we would use the 340B ceiling prices in lieu of their responses because the ceiling price represents the highest possible price that a 340B hospital could permissibly be required to pay for a 340B-acquired drug.

c. Analysis of Hospital Acquisition Cost Survey Data for 340B Drugs

The results of the survey, which closed on May 15, 2020 were as follows: Seven percent (n=100) of surveyed hospitals affirmatively responded via the Detailed Survey option; 55 percent (n=780) of surveyed hospitals affirmatively responded via the Quick Survey option; and the remaining 38 percent (n=542) of surveyed hospitals did not respond affirmatively to either survey option. As previously noted, we applied 340B ceiling prices for hospitals that did not affirmatively respond to the survey; such action may skew the survey results towards the *minimum* average discount (that is, the ceiling price) that a 340B hospital would receive on a drug.

We also examined the hospital characteristics of those hospitals that submitted either a Detailed or Quick Survey to the general 340B survey population. The characteristics we analyzed included hospital bed count, teaching hospital status, hospital type, and geographic classification as a rural or urban hospital. Our findings showed that the hospital survey respondents, including respondents to both the Quick and Detailed surveys, were generally similar to the hospital characteristics of the aggregate 340B survey population.

d. Proposed Payment Policy for Drugs Acquired Under the 340B Program for CY 2021

(1) Grouping Hospitals by 340B Covered Entity Status

Section 1833(t)(14)(A)(iii)(I) authorizes the Secretary to set the amount of payment for SCODs at an amount equal to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D). In the CY 2021 OPPS/ASC proposed rule, we stated that we were exercising the authority to vary the amount of payment for the group of hospitals that is enrolled in the 340B program because their drug acquisition costs vary significantly from those not enrolled in that program. Section 1833(t)(14)(A)(iii) of the Act allows the Secretary to exercise discretion to vary payment by hospital group, ''as defined by the Secretary based on the volume of covered OPD services or other relevant characteristics.'' We stated that we believe that it is within the Secretary's authority to distinguish between hospital groups based on whether or not they are covered entities under section 340B(a)(4) of the PHSA that are eligible to receive drugs and biologicals at discounted rates under the 340B program. We also stated that we believe that the significant drug acquisition cost discounts that 340B covered entity hospitals receive enable these hospitals to acquire drugs at much lower costs than non-340B hospitals incur for the same drugs. Accordingly, we explained that we believe it is appropriate to use 340B covered entity status as a relevant characteristic to group hospitals for purposes of payment based on average acquisition cost under section 1833(t)(14)(A)(iii)(I).

(2) Applying a Single Reduction Amount to ASP for 340B-Acquired Drugs

Section 1833(t)(14)(A)(iii)(I) provides that the payment amount for a SCOD for a year is equal to the average acquisition cost for the drug ''as determined by the Secretary taking into account'' the survey data collected under subparagraph (D). As we explained in the CY 2021 OPPS/ASC proposed rule (85 FR 48886), we interpret the reference to acquisition costs being ''determined'' by the Secretary, ''taking into account'' survey data, to give us discretion to determine the appropriate payment rate based on data collected from the hospital acquisition cost survey for 340B drugs. We proposed to apply a single discount factor to ASP for drugs acquired by 340B hospitals in lieu of calculating individual acquisition cost amounts for 340B-acquired drugs. We note that 340B ceiling prices are protected from disclosure both because the prices themselves are sensitive, and because they could potentially be used to reverse-engineer average manufacturer prices, which are protected under section 1927(b)(3)(D) of the Act. We also pledged confidentiality of individual responses regarding acquisition prices for each SCOD to the extent required by law. Given that the survey data is heavily weighted towards

340B ceiling prices (because 340B ceiling prices were used for any SCODs within the Detailed Survey for which a hospital did not provide responses, for hospitals that selected the Quick Survey option, and for hospitals that did not affirmatively respond), and since ceiling prices are protected by law from public disclosure, we instead proposed to establish one aggregate discount amount relative to ASP for SCODs acquired under the 340B program rather than proposing drug-specific prices, which could reveal sensitive or protected pricing information.

(3) Methodology To Calculate ASP Reduction Amount Based on Survey Data

As we explained in the CY 2021 OPPS/ASC proposed rule and as described in detail in the following sections, we analyzed the survey results and applied various statistical methodologies to determine an appropriate average or typical amount by which to reduce ASP that would approximate hospital acquisition costs for 340B drugs and biologicals. In fairness to hospitals, we generally chose methodologies that yield the most conservative reduction to ASP when establishing the payment rate, and thus would be most generous to hospitals. This includes the use of 340B ceiling prices, which must be kept confidential, where applicable in the survey results. Based on our analysis of the available information, we estimated that the typical acquisition cost for 340B drugs for hospitals paid under the OPPS is ASP minus 34.7 percent.

We explained in the proposed rule that we determined the average discount of 34.7 percent by assessing a number of factors including: Multiple measures of central tendencies (arithmetic mean, median, geometric mean); the effect of including penny priced drugs; mapping of multi-source NDCs to a single HCPCS code; weighting values by volume/utilization; and applying trimming methodologies to remove anomalous or outlier data. The analysis of each of these variables is discussed in the next section.

(a) Selecting an Averaging Methodology

When determining the appropriate average reduction amount relative to ASP for 340B drugs, we assessed multiple measures of central tendencies, including the arithmetic mean, median, and geometric mean, on the typical 340B discount based on drug acquisition cost survey data. Based upon the cumulative data from the Detailed Survey option, the Quick Survey option, and imputed responses for hospitals that did not affirmatively respond, we analyzed the effects of each averaging method, combining the data from all three sources in both survey quarters (fourth quarter 2018 and first quarter 2019). Using the raw data without accounting for outliers, we explained in the proposed rule that we determined that the arithmetic mean would result in an average discount from ASP of approximately 66.3 percent; the median would result in an average discount from ASP of approximately 70.4 percent, and the geometric mean would result in an average discount from ASP of approximately 58.3 percent.

Under the OPPS, we generally calculate resource costs for a given service using the geometric mean. The geometric mean minimizes the effects of the outliers without ignoring them. Minimizing outliers is consistent with our methodology to estimate an average or typical 340B discount that is representative across all 340B SCODs. Therefore, we proposed to utilize the geometric mean discount to ASP from both survey quarters—2018 Q4 and 2019 Q1—as a component of our overall analysis of the survey data. Without any further adjustments, we explained that applying the geometric mean to the survey results would result in an average drug acquisition cost estimate of ASP minus 58.3 percent for 340B-acquired drugs.

(b) Volume Weighting Survey Data

While we realize the geometric mean minimizes the effects of some outliers, it does not take into consideration several other important factors. Notably, we explained in the proposed rule that we believe that in calculating the average discount that 340B drugs receive relative to ASP, we should take into account how often those drugs were billed by all hospitals under the OPPS for 2018 and 2019, to give a better reflection of each drug's overall utilization under the OPPS. Therefore, we volume-weighted the drug discounts determined from the survey to mirror the drug utilization in the OPPS. That is, drugs that were commonly used were assigned a higher weight while those less commonly used were assigned a lower weight. We explained that we incorporated volume weighting into our analysis by assessing the utilization rate of each individual drug (using its HCPCS code) under the OPPS for CY 2018 and CY 2019. Specifically, we calculated the average discount by taking the utilization of each drug under the OPPS into account to arrive at a case-weighted average for each HCPCS code. For example, a highly utilized HCPCS code for an oncology drug would be weighted higher than a drug for snake anti-venom that has relatively low utilization in the OPPS. In the proposed rule, we stated that the data for CY 2018 Q4 was volume weighted based upon OPPS utilization during CY 2018 as determined using OPPS claims data. The data for CY 2019 Q1 was volume weighted based upon OPPS utilization during CY 2019 as determined using OPPS claims data. As we explained in the proposed rule, this resulted in a change in the geometric mean to an average discount of 58.0 percent from 58.3 percent non-weighted.

(c) Addressing HCPCS Codes With Multiple NDCs

In addition, we stated in the proposed rule that a small portion of the SCODs that were subject to the 340B drug acquisition cost survey contain multiple NDCs that map to a single HCPCS code. This is because these drugs are multiple source drugs, meaning that they were manufactured by different entities and have varying package sizes or strengths, and thus, multiple different NDCs for the same drug. For payment purposes under the OPPS, we pay for drug products based on the drug's HCPCS code, regardless of which NDC is used. Hospitals that completed the Detailed Survey option were instructed to report their average acquisition costs for each drug during the surveyed quarters per HCPCS code. However, for those hospitals that opted for the Quick Survey option or that did not affirmatively respond, we were unable to determine which combination of NDCs mapped to the HCPCS codes these entities would have used during the given quarters. Therefore, we analyzed the effects of averaging all of the NDCs' acquisition costs for a given HCPCS code when determining the average discount, as well as selecting the NDC with the highest acquisition cost for a given HCPCS code and using that NDC's acquisition cost amount to determine the average discount. When we calculated the average discount using an average of the acquisition costs for all of the NDCs assigned to the HCPCS code, the average volume weighted geometric mean discount off of ASP is 58.0 percent. The 58.0 percent was calculated by taking all of the various NDCs (across various manufacturers, package sizes, and strengths) for the same drug and averaging the unit costs together in order to arrive at a single amount for each HCPCS code for a drug. When we calculated the average discount using the highest acquisition cost NDC for each HCPCS code for a

drug, the average volume weighted geometric mean discount from ASP is 47.0 percent. This was achieved by analyzing all of the various NDCs (across various manufacturers, package sizes, and strengths) assigned to the HCPCS code for the same drug and selecting the NDC that has the highest unit cost in order to arrive at a single cost for each HCPCS code. Consistent with the general principle of choosing the methodological approach that is most generous to hospitals, we proposed to use the highest acquisition cost NDC for each HCPCS code for a drug to determine the average 340B discount.

(d) Addressing Penny Pricing in the Survey Data

As part of our analysis of the survey data, we examined the effect of including ''penny priced'' drugs on the average discount off of ASP. The 340B ceiling price is statutorily defined as the Average Manufacturer Price (AMP) reduced by the rebate percentage, which is commonly referred to as the Unit Rebate Amount (URA).[81] The calculation of the 340B ceiling price is defined in section 340B(a)(1) of the PHSA. Penny pricing occurs when, under section 1927(c)(2)(A) of the Social Security Act, the AMP increases at a rate faster than inflation, in which case the manufacturer is required to pay an additional rebate amount, which is reflected in an increased URA and could result in a 340B ceiling price of zero. However, as HRSA noted in the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation Final Rule (82 FR 1210), although infrequent, there are instances when the 340B ceiling price is zero. HRSA did not believe that it is consistent with the statutory scheme to set the price at zero. In this circumstance, HRSA required that manufacturers charge $0.01 for the drug, which they believed best effectuates the statutory scheme by requiring a payment.[82] We proposed to exclude penny priced drugs to remove outliers that may distort the average discount in order to provide the most conservative estimate of the average 340B discount from ASP.

In the proposed rule, we acknowledged that penny pricing of drugs is not intended to be permanent and, by its very nature, is dynamic, meaning the select group of drugs to which penny pricing applies could vary from quarter to quarter. We analyzed the inclusion and exclusion of penny pricing on the overall average discount of 340B drugs compared to ASP. As expected, we found that excluding penny pricing provides a much more conservative estimate of the average 340B discount from ASP relative to including penny pricing. When we excluded penny pricing, the geometric mean volume weighted average discount, using the highest NDC for a drug's HCPCS code, decreased to 40.9 percent from 47.0 percent. We observed penny pricing in less than 10 percent of the drugs surveyed. Because penny pricing is dynamic and the drugs to which it applies may vary from quarter to quarter, we believe it is appropriate to exclude penny pricing from our survey analysis, although we acknowledge that penny pricing, when it does apply, represents the acquisition cost for the drug to which it applies.

We stated in the proposed rule that we were concerned that including a discount of a penny priced drug from the two quarters surveyed may inappropriately increase the average discount, where the drug may not have been priced based on penny pricing in following or preceding quarters. However, it also is the case that a drug could have penny pricing for any given quarter and it could be appropriate to include penny priced drugs in the calculation of the average acquisition cost because in such cases, penny prices do represent the maximum (ceiling) price the 340B hospital would pay for that drug. Nonetheless, in order to provide for a more conservative discount estimate, we proposed to exclude penny priced drugs from our analysis, but solicited public comment on whether such a policy accurately represents 340B drug acquisition costs.

(e) Addressing Outliers

In response to the Detailed Survey, hospitals provided some drug acquisition cost data that exceeded 340B ceiling prices, and in some cases even exceeded the ASP or ASP+6 percent payment rate for certain drugs. As previously noted, covered entities cannot be required to pay more than the ceiling price to acquire a drug under the 340B program. Therefore, we attributed any Detailed Survey acquisition cost data greater than the ceiling price to potential data entry error; for instance, miscalculation or incorrect decimal point placement. However, because hospitals may have been overcharged for their drug acquisition costs and could have accurately reported acquisition costs greater than the HRSA ceiling price, we did not eliminate these data from our calculations. Instead, consistent with our standard methodology for processing extreme outliers under the OPPS, we excluded responses for any SCODs that were three standard deviations from the geometric mean. We believe applying a three standard deviation limit to the reported acquisition data is appropriate because it removes outliers from both the high and low reported values. In addition, applying a three standard deviations limit may be more representative of the respondents' acquisition cost, even though it may not eliminate some data values that are above the ceiling price. While this approach means that some values above the ceiling price will be included in our data analysis, we did not propose to trim them because we proposed to apply a standard trimming methodology. The cumulative application of this trimming methodology, along with other methodologies applied to the survey data described above, results in an average acquisition cost for drugs that hospitals acquire under the 340B program of ASP minus 34.7 percent. For the reasons previously discussed, we proposed to exclude survey data from the Detailed Survey that is more than three standard deviations from the mean. We note that we also explored capping any survey submissions received at the 340B ceiling price, as no covered entity can be required to pay more than the ceiling price. This approach, holding all other methodological approaches constant, would have resulted in an average acquisition cost of ASP minus 41.5 percent for drugs acquired under the 340B program.

Table 41, *Aggregate 340B Drug Program Cost Savings Percentage Relative to ASP,* shows the aggregate 340B drug program discount percentage relative to ASP using several different statistical measures. In this table, we outlined some additional figures following a similar path as described above. For example, we arrived at the 33.8 percent figure in Table 41 under median, and penny pricing excluded, by initially choosing the median as the averaging methodology, and then performing trimming methodologies as described above, which include volume weighting by HCPCS code, using the highest NDC per HCPCS code, and using only data within three standard deviations of the median. This would have resulted in a final proposed discount of 33.8 percent. While this final discount appears more generous to hospitals than our proposal, we do not believe it would be appropriate. Specifically, we believe using the

[81] *https://www.hrsa.gov/opa/updates/2015/may.html.*

[82] *https://www.govinfo.gov/content/pkg/FR-2017-01-05/pdf/2016-31935.pdf.*

geometric mean as outlined in the methodology above is the most generous methodology for establishing a final discount amount that also maintains accuracy and consistency with past OPPS practices. As described previously, under the OPPS, we generally calculate resource costs for a given service using the geometric mean. The geometric mean minimizes the effects of the outliers without ignoring them. As an additional example, under the arithmetic mean methodology with penny pricing included in Table 41, the final discount was determined to be 23.1 percent. We arrived at this figure of 23.1 percent by initially choosing the arithmetic mean as the averaging methodology, and then performing trimming methodologies as described above, with the exception of including penny prices in this figure. Similar to the discussion above regarding the use of the median, we do not think utilizing the arithmetic mean would be appropriate or consistent with the averaging methodologies historically used under the OPPS. The arithmetic mean could easily skew towards outlier data and anomalous data not captured by previously described trimming methodologies. Additionally, with this 23.1 percent figure, while penny pricing is a valid maximum (that is, ceiling) price for drugs to which it applies, as noted above we believed it was appropriate to exclude penny priced drugs for purposes of our proposal.

We explained in the CY 2021 OPPS/ASC proposed rule that we believe the manner in which we arrived at the proposed payment amount of ASP minus 34.7 percent for 340B-acquired drugs is an appropriate and accurate method of determining the average discount or typical discount. We also noted that we believe it is reflective of stakeholder's actual acquisition costs, and is as generous as possible without compromising accuracy. We explained that we believe the geometric mean is the most appropriate averaging methodology as it mitigates the effects of outliers relative to the arithmetic mean and median and is consistent with OPPS payment methodologies. Although ceiling prices are protected by statute and the respondents to the survey were given a pledge of confidentiality, we also emphasized that we were exploring and previously sought comment on the possibility of providing microdata to qualified researchers through their restricted access infrastructure, in accordance with best practices for transparency.

Table 41: AGGREGATE 340B DRUG PROGRAM COST SAVINGS PERCENTAGE RELATIVE TO ASP*

	Weighted by HCPCS Volume, Highest NDC per HCPCS used, and only Data with 3 Standard Deviations of the Mean					
	With Penny Pricing Included			With Penny Pricing Excluded		
	Arithmetic Mean	Median	Geometric Mean	Arithmetic Mean	Median	Geometric Mean
Average 2018Q4-2019Q1	23.1%	39.6%	39.4%	20.3%	33.8%	34.7%

* Based on Combined Survey Data.

(4) Determining an Add-on Payment for 340B Drugs

Under the OPPS, Medicare pays for separately payable drugs at rates that approximate their acquisition costs, such as at ASP or WAC. These drugs typically also receive an add-on payment. Under the OPPS, section 1833(t)(14)(E) authorizes, but does not require, the Secretary to make an adjustment to payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs.

In the MedPAC report from 2005,[83] MedPAC recommended that the Secretary:

- Establish separate, budget neutral payments to cover the costs that hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals;
- define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs;
- instruct hospitals to submit charges for those APCs; and
- base payment rates for the handling fee APCs on submitted charges, reduced to costs.

Because we took a conservative approach in estimating the average acquisition costs for 340B-acquired drugs, we stated in the proposed rule that we did not believe that it was imperative to establish an add-on for overhead and handling as we believe that such a conservative estimate may already account for the costs of overhead and handling. In addition, our current 340B drug payment policy under the OPPS pays separately payable drugs at ASP minus 22.5 percent with no add-on payment because this payment rate represents the minimum average discount that a 340B entity would receive on a drug. We emphasized that we believe hospitals receive a significant margin on 340B drugs under our current policy, so an additional add-on payment is not necessary. Nonetheless, under the methodology in section 1847A, we explained that the Part B payments for separately payable drugs and biologicals furnished by practitioners and certain suppliers generally include an add-on set at 6 percent of the ASP for the specific drug. As discussed in the CY 2019 Physician Fee Schedule final rule with comment period (83 FR 59661–59662), the 6 percent add-on is widely believed to include services associated with drug acquisition that are not separately paid for, such as handling, storage, and other overhead. We noted

[83] *http://medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.*

that we realize that the acquisition costs for drugs acquired under the 340B program are significantly lower than for those drugs purchased outside of the 340B program, so we did not find it appropriate to base the add-on for 340B drugs on the 340B acquisition cost as previously discussed. However, we explained that we believe that it is reasonable to assume that a given drug will have similar overhead and other administrative costs regardless of whether the drug was purchased under the 340B Program or a by non-340B entity. Additionally, we stated that utilizing a drug add-on will ensure a level of payment parity with the add-on that applies to Part B drugs outside of the 340B program.

Therefore, for CY 2021 and subsequent years, we proposed to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent. Under this payment methodology, we explained that each drug would receive the same add-on payment regardless of whether it is paid at the 340B rate or at the traditional ASP rate for drugs not purchased under the 340B program. We noted that this add-on percentage would be more generous to hospitals than adding 6 percent of the reduced 340B rate. As an example, assuming a non-340B drug is paid its ASP of $1,000 and $60 for the 6 percent add-on, the 340B rate would be $653 ($1,000—$347) plus $60 or $713 total, instead of $653 plus $39.18 (6 percent of the reduced rate of $653) which would equal $39.18 or $692.18 total. We proposed that this payment methodology would be our Medicare payment policy for 340B-acquired drugs going forward for CY 2021 and subsequent years.

(5) 340B Payment Policy for Drugs for Which ASP Is Unavailable

As we clarified in the CY 2019 OPPS/ASC proposed rule, the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and 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. We proposed the 340B payment adjustment for WAC-priced drugs would mirror that of ASP payment with payment being WAC minus 34.7 percent plus 6 percent of the drug's WAC, except for when WAC plus 3 percent policy applies under 1847A(c)(4) and as discussed in V.B.2.b., for which we would propose a payment rate of WAC minus 34.7 percent plus 3 percent of the drug's WAC. Previously, AWP-priced drugs have had a payment rate of 69.46 percent of AWP when the 340B payment adjustment is applied. The 69.46 percent of AWP was calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we applied the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which is similar to either ASP minus 22.5 percent or WAC minus 22.5 percent. Similarly, for CY 2021, we proposed to pay for drugs paid at AWP under the 340B program at 95 percent AWP first reduced by 6 percent to generate a value that is similar to ASP or WAC with no percentage mark up. Then we proposed to apply the net 28.7 percent reduction resulting in a payment rate of 63.90 percent of AWP.

(6) 340B Payment Policy Exemptions

In the CY 2018 OPPS/ASC proposed rule, we sought public comment on whether, due to access to care issues, certain groups of hospitals, such as those with special adjustments under the OPPS (for example, children's hospitals or PPS-exempt cancer hospitals) should be excepted from a policy to adjust OPPS payments for drugs acquired under the 340B program. Specifically, in accordance with section 1833(t)(7)(D)(ii) of the Act, we make transitional outpatient payments (TOPs) to both children's and PPS-exempt cancer hospitals. This means that these hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive 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. Accordingly, if we were to reduce drug payments to these hospitals on a per claim basis, it is very likely that the reduction in payment would be paid back to these hospitals at cost report settlement, given the TOPs structure. We believed further study on the effect of the 340B drug payment policy was warranted for classes of hospitals that receive statutory payment adjustments under the OPPS. Accordingly, we stated that we continued to believe it is appropriate to exempt children's and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology.

In addition to the children's and PPS-exempt cancer hospitals, Medicare has long recognized the particularly unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act gave 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, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006.

For CY 2021 and subsequent years, similar to previous years, we proposed that rural sole community hospitals (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals would be excepted from the 340B payment adjustment and that these hospitals continue to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent. We may revisit our policy to exempt rural SCHs, as well as other the hospital types that are exempt from the 340B drug payment reduction, in future rulemaking.

As discussed in section V.B.2.c. of the CY 2019 OPPS/ASC proposed rule, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP. Similarly, for CY 2021, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at the biosimlar's ASP minus the net payment discount reduction, 34.7 percent plus an add-on of 6 percent, of the biosimilar's ASP, for a net payment rate of the biosimilar's ASP minus 28.7 percent of the biosimilar's ASP.

Summary of Proposed Policy

In summary, we proposed for CY 2021 and subsequent years to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent using the authority under section 1833(t)(14)(A)(iii)(I) of the Act.

This proposal included our previously discussed methodology used to arrive at the 34.7 percent average discount that we proposed to apply to all drugs acquired under the 340B program. This methodology included using the geometric mean of the survey data, volume weighting the average based upon utilization of the drug in the OPPS, using the highest priced NDC when multiple NDCs are available for a single HCPCS code, eliminating penny pricing from the average, and eliminating any data outside of 3 standard deviations from the mean when calculating the average discount of 34.7 percent. We explained in the proposed rule that our intent was that, if finalized, this payment methodology would apply beginning on January 1, 2021 and any changes to this permanent payment policy would be required to be adopted through notice and comment rulemaking. We also proposed that Rural SCHs, PPS-exempt cancer hospitals and children's hospitals would be exempted from the 340B payment policy for CY 2021 and subsequent years. Finally, we proposed in the alternative to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs as we prevailed on appeal to the D.C. Circuit in the litigation.

For the reasons discussed below, we are finalizing our alternative proposal to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs. However, we also summarize and respond below to the comments we received on our proposal to pay for 340B-acquired drugs at a net rate of ASP minus 28.7 percent based on survey data.

Comments Regarding 340B Survey Methodology and Implementation

Comment: Several commenters contended that CMS' plan to collect acquisition cost data from 340B hospitals only, and not from other providers that are paid under the OPPS, but that do not participate in the 340B program, violates section 1833(t)(14)(D)(iii) of the Act. Specifically, they stated that although the Medicare statute allows for a survey of hospitals based on drug acquisition costs, the statute does not allow the Secretary to use subclause (I) of section 1833(t)(14)(A)(iii) to target a subset of hospitals for the survey and subclause (II) of section 1833(t)(14)(A)(iii) for other non-340B hospitals. While commenters agreed that the Secretary has authority under section 1833(t)(14)(A)(iii)(I) to set payment rates that vary by hospital group based on relevant hospital characteristics such as volume of outpatient services, they maintained that the Secretary is not permitted to survey only one group of hospitals for acquisition costs for purposes of setting the payment rates under the OPPS. Furthermore, commenters stated that section 1833(t)(14)(D)(iii) requires that surveys conducted by the Secretary ''shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug (SCODs).'' Commenters continued to state that because the survey had what they contended was a low response rate, they believed CMS was unable to gain enough data to yield a statistically significant estimate of average hospital acquisition cost for each specified covered outpatient drug. Additionally, some of these commenters contended that the acquisition data collected in response to the survey only included data from the fourth quarter of 2018 and the first quarter of 2019, and that this was an inadequate sample due to yearly fluctuations in drug pricing.

Response: We disagree with the commenters' assertion that the manner in which we collected drug and biological acquisition cost data from 340B hospitals is inconsistent with the statute, as well as the commenters' interpretation of section 1833(t)(14)(D)(iii) that the survey of hospital acquisition costs for SCODs must be administered to all hospitals or all hospital types. Section 1833(t)(14)(D)(iii) does not require the Secretary to survey all hospitals, it requires Medicare to have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each SCOD. The statute does not prescribe how we develop the sampling methodology. Surveying 340B hospitals, for which average sales price (ASP) data does not serve as a reliable proxy for their acquisition costs, is necessary to accurately determine payment amounts for drugs acquired under the 340B program. However, we do not believe it is necessary to survey non-340B hospitals because our ASP data includes drug acquisition costs from these hospitals, which are an adequate proxy of the average drug acquisition costs of such providers. Surveying non-340B hospitals would unnecessarily burden such hospitals, for which we already have an adequate proxy for drug acquisition costs.

Unlike the reasonable proxy that exists for average acquisition drug costs for non-340B enrolled hospitals (that is, ASP data), the significant drug acquisition cost discounts that 340B participating hospitals receive are much greater than those received by hospitals not participating in the 340B program; accordingly, 340B enrollment status is a relevant characteristic for drug acquisition costs. The statutory provision at issue—section 1833(t)(14)(A)(iii)(I)—explicitly states that the average acquisition cost for a drug for a year ''at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics).'' We believe it is within the Secretary's discretion under section 1833(t)(14)(A)(iii)(I) to choose to distinguish between hospital groups based on whether or not they are covered entities eligible to receive drugs and biologicals at discounted rates under the 340B program. We also note that section 1833(t)(14)(D)(ii) refers to use of the hospital acquisition costs for SCODs in setting payment rates under subparagraph (A) of section 1833(t)(14), and therefore, we believe it is appropriate to read the two provisions together to permit the Secretary to survey 340B hospitals only. Conversely, no provision compels the Secretary to impose an unnecessary survey burden on non-340B hospitals, for which we have an adequate proxy for average acquisition drug costs. As previously stated, we believe the sampling timeframe is appropriate due to the numerous factors taken into consideration to provide a conservative estimate as well as the proposed application of the ASP reduction, which was proposed as a single reduction amount applied to each drug's ASP.

Comment: Some commenters had concerns with the survey response rate. Commenters stated that only providing approximately 3 weeks to complete the survey during the initial stages of the PHE was concerning. Commenters believed this was why CMS received what they contended was a low response rate of 62 percent (7 percent Detailed Surveys and 55 percent Quick Surveys). Several commenters who completed the Quick Survey noted in their comments that they chose this method due to it being the least burdensome option, and that ceiling prices were not necessarily reflective of their acquisition costs. For these reasons, commenters felt it would be inappropriate for CMS to base OPPS payment for 340B drugs on these survey results.

Response: We thank commenters for their feedback. We respectfully disagree with commenters' assertion that CMS received an inadequate response rate on

which to base OPPS payment for 340B-acquired drugs. As commenters noted, a combined 62 percent of the 340B participating providers responded to the survey through a Detailed or Quick Survey submission. For the remaining 38 percent of non-affirmative responders, we noted in the survey instructions that we would utilize 340B ceiling prices as proxies for the hospitals' highest possible acquisition costs. We believe the 340B ceiling price is a fair proxy for the hospitals' acquisition costs because hospitals cannot be required to pay more than the 340B ceiling price (and, in fact, often pay much less) for a 340B drug. Therefore, we explained in the proposed rule that we believed using the 340B ceiling price was the most conservative, and yet appropriate, way to calculate the discount for the 38 percent of non-affirmative responders.

Comment: Commenters were generally supportive of CMS' application of a 6 percent add-on based upon the product's ASP as part of our proposal to pay for 340B-acquired drugs under the OPPS based on survey data. Commenters did not find it appropriate to base payment on ASP minus 34.7 percent, which would not include a 6 percent add-on, and instead supported a payment amount of ASP minus 28.7 percent, which includes the 6 percent add-on. Commenters believed this add-on was necessary, and they felt it would be appropriate for the same drug to receive the same add-on payment regardless of whether it was purchased through the 340B program or at the current policy of ASP minus 22.5 percent.

Response: We thank the commenters for their support on this proposal. We still do not believe that it is imperative to establish an add-on for overhead and handling, as we believe that our conservative estimate of average acquisition costs may already account for the costs of overhead and handling. However, as explained further below, we are not finalizing our proposal to pay for 340B-acquired drugs based on hospital survey data at ASP minus 28.7 percent, which we proposed would include a 6 percent add-on. Nonetheless, we will consider this information for potential future rulemaking.

Comment: Commenters generally did not agree that our proposed methodology, including our use of 340B ceiling prices for Quick Survey respondents and as a proxy for non-affirmative responses, together with a 6 percent add-on, as well as the manner in which we calculated the proposed discount, yielded a conservative estimate of hospitals' costs to acquire 340B drugs. Commenters often stated that CMS should also take into consideration the costs that 340B entities incur to maintain their status and comply with 340B program requirements. Commenters contended that 340B program compliance costs are quite considerable and that CMS should consider these administrative costs in determining an OPPS payment rate for 340B-acquired drugs.

Response: As outlined in the section above, *Methodology to Calculate ASP Reduction Amount Based on Survey Data,* CMS considered numerous factors in order to calculate what we believe was a conservative discount amount. Section 1833(t)(14)(A)(iii)(I) authorizes the Secretary to set the amount of payment for SCODs at an amount equal to the average acquisition cost for the drug for that year, but the statute does not mention covering 340B program compliance cost. Accordingly, we do not believe it is necessary to provide additional payment for costs that commenters state they must pay in order to remain compliant with the 340B program. We reiterate that we do not believe CMS payment is required for these costs as Medicare payments for drugs are not intended to cross-subsidize other programs. Nonetheless, we believe that such a conservative estimate and the add-on of 6 percent of the product's ASP would already allow for a significant margin to offset these costs.

Comment: Commenters stated that not every entity is able to purchase all drugs at the 340B ceiling price and that some drugs must be purchased under WAC-based pricing. Furthermore, stakeholders contended that their systems are limited in determining which drugs were purchased at the 340B price and thus were limited in their ability to assign the ''JG'' modifier. Therefore, commenters stated they applied the ''JG'' modifier to all of their purchased drugs, even if the drug was purchased under WAC-based pricing. Commenters stated that WAC-based pricing is significantly higher than 340B pricing; 30 to 90 percent greater according to one stakeholder. Additionally, commenters believed using ceiling prices as proxies was a flawed methodology as these data do not come directly from those being surveyed, even if they are the highest prices hospitals can pay to acquire these drugs.

Response: The ceiling price is the maximum amount covered entities may permissibly be required to pay for a drug under section 340B(a)(1) of the Public Health Service Act, so we would not expect a 340B hospital to have acquisition costs for any drug that is acquired through the 340B program that are greater than the ceiling price. For this reason, where the acquisition price for a particular drug was not available or submitted in response to the survey, we stated that we would use the 340B ceiling price for that drug as a proxy for the hospital's acquisition cost in order to produce a conservative drug discount estimate when data was missing or not submitted. We believed using ceiling prices as proxies was the most appropriate option when drug acquisition cost information was not available, because this price represents the most conservative discount that a 340B entity could have received. In addition, while some commenters expressed generalized disagreement with our proposed approach, we did not receive any comments demonstrating that 340B hospitals pay more than the ceiling price for a particular drug, or that 340B hospitals pay more than ASP minus 28.7 for a particular drug when acquired under the 340B program at their negotiated 340B price. Thus, similar to our policy of paying ASP minus 22.5 percent, this proposed approach of paying ASP minus 28.7 percent appears to be in line with hospital acquisition costs for such drugs, which is reinforced by the fact that we did not receive public comments demonstrating that 340B hospitals pay more for particular drugs acquired under the 340B program. However, because we are not finalizing our proposal to pay for 340B drugs based on hospital survey data for CY 2021, we will take these comments into account for potential future rulemaking.

Additionally, the payment rate of ASP minus 22.5 percent only applies to drugs acquired under the 340B program and therefore, the ''JG'' modifier should only be appended to claim lines for these drugs. Hospitals should not append the ''JG'' modifier for drugs for which the hospital paid an amount based on WAC where the drug was not acquired under the 340B program.

Comment: Commenters generally did not make specific recommendations about CMS' methodology for calculating the reduction that would be applied to ASP for 340B-acquired drugs. Rather, most commenters expressed opposition to the policy in general. However, several commenters expressed support for CMS' exclusion of penny pricing in our calculation of the proposed payment rate. Additionally, several commenters encouraged CMS to eliminate any drugs with inflationary penalties, as the commenters believed these penalties are unevenly distributed among drugs and

among hospitals and may skew our data if included. Additionally, some commenters were not supportive of CMS' volume weighting methodology. Commenters stated that taking into account how often those drugs were billed by all hospitals under the OPPS for 2018 and 2019 was inappropriate as 340B utilization may differ from all OPPS hospital utilization.

Response: We thank commenters for their input on our proposal. We believe the methodology for developing the proposed payment adjustment appropriately provided for a conservative estimate for the ASP reduction. At this time, we do not believe it would be appropriate to eliminate all drugs with inflationary penalties; however, we will take this point into consideration for future potential rulemaking. Additionally, as outlined in our summary above, our volume weighting methodology took into account how often drugs were billed by all hospitals under the OPPS for 2018 and 2019, to better reflect each drug's overall utilization under the OPPS. We calculated the average discount by taking the utilization of each drug under the OPPS into account to arrive at a case-weighted average for each HCPCS code. Therefore, we volume-weighted the drug discounts determined from the survey to mirror the drug utilization in the OPPS. We note that the 340B hospitals drug utilization pattern did not vary significantly from the overall OPPS utilization. Therefore, drugs that were commonly used were assigned a higher weight while those less commonly used were assigned a lower weight. For example, a highly utilized HCPCS code for an oncology drug would be weighted higher than that of a drug for snake anti-venom that has a relative low utilization in the OPPS. We incorporated volume weighting into our analysis by assessing the utilization rate of each individual drug (using its HCPCS code) under the OPPS for CY 2018 and CY 2019. For the purposes of creating an average discount, we believe this is the most appropriate methodology. Nonetheless, we will consider these comments for potential future rulemaking.

Comment: Several commenters asked for the release of data that CMS used in order to calculate the 340B payment reduction. Commenters expressed a desire to replicate CMS' calculations based on the data submitted in response to the 340B Drug Acquisition Cost Survey.

Response: We do not intend to release an individual hospitals' SCOD acquisition cost data to the public. During the Paperwork Reduction Act process for the 340B survey, we pledged to maintain the confidentiality of individual responses that include acquisition prices for each SCOD to the extent required by law. However, we stated we would make average acquisition prices reported for SCODs across all hospitals surveyed public. We believe the confidentiality of drug prices applies to individual drugs purchased by individual hospitals, which we have no intent to make public. Additionally, this confidentiality extends to the ceiling prices used in the survey. Therefore, we are unable to publicly disclose the ceiling prices for the same reason. As we stated in the proposed rule, we are exploring the possibility of providing microdata to qualified researchers through their restricted access infrastructure, in accordance with best practices for transparency. We will continue to explore if there is an appropriate method in which to release microdata to qualified researchers.

e. Alternative Proposal To Continue Policy To Pay ASP Minus 22.5 Percent

Previously, 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 continue to believe that ASP minus 22.5 percent is an appropriate payment rate for 340B-acquired drugs under the authority of 1833(t)(14)(A)(iii)(II) for the reasons we stated when we adopted this policy in CY 2018 (82 FR 59216). 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 believe maintaining the current payment policy of paying ASP minus 22.5 percent for 340B drugs is 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. 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 note that any changes to the current 340B payment policy would be adopted through public notice and comment rulemaking.

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 stakeholders' concerns. As described above, the utilization of the survey data is complex, and 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 appreciate the feedback from commenters and will continue to assess it 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) in future years.

Comments on Maintaining Current 340B Payment Reduction of ASP Minus 22.5 Percent

Comment: A few commenters voiced their support for the current OPPS payment policy for 340B-acquired drugs. These commenters generally believed that approximating payment based on acquisition costs is appropriate; however, they also recommended reform to the 340B program itself.

Response: We thank the commenters for their support of our 340B payment policies. We note that comments related to reform of the 340B program are out of scope for purposes of this final rule, and we also note that the 340B program is administered by the Health Resources and Services Administration, not CMS; however, we thank commenters for their input.

Comment: Many commenters did not support CMS finalizing the proposal to pay a net payment rate of ASP minus 28.7 percent for 340B-acquired drugs. These commenters stated that they opposed any reduction in payment for 340B drugs in general, but preferred the proposal to maintain ASP minus 22.5 percent if CMS continued to adjust payment for 340B drugs. Commenters stated that the profits derived from participation in the 340B program allowed them to deliver charity or uncompensated care to their patients. Commenters detailed a wide variety of programs that they fund with profits

from the 340B program, and stated they may not be able to continue these programs without profits from Medicare payments for 340B-acquired drugs. Many commenters stated that the current 340B payment rate has hurt hospitals financially and undermined hospitals' ability to provide safety-net care to their low-income patients, thereby threatening the patients' access to care. They stated that any policy proposal to reduce payment for 340B-acquired drugs was contrary to the congressional intent for the 340B program. Commenters asserted that CMS should pay hospitals participating in the 340B program the statutory default payment amount of ASP plus 6 percent.

Response: We note that we have not seen evidence that the current OPPS 340B drug payment policy has limited patient access to 340B drugs. Further, Medicare payments for drugs are not intended to cross-subsidize other programs. As noted in the CY 2018 OPPS/ASC final rule with comment period, we continue to believe that ASP minus 22.5 percent for drugs acquired through the 340B Program represents the average minimum discount that 340B enrolled hospitals receive. Additionally, as discussed throughout this section, the proposed payment reduction based on the survey data was calculated in a conservative manner. We disagree with commenters that the OPPS 340B payment policy has had a negative impact on Medicare patients and are not aware of any access issues related to the implementation of this policy. Further, we note that under the current policy, Medicare patients who receive 340B drugs for which the Medicare program paid ASP minus 22.5 percent have much lower cost sharing than if these beneficiaries received 340B drugs for which the Medicare program paid ASP+6 percent. As a result, we continue to believe that ASP minus 22.5 percent is a reasonable payment rate for these drugs. We note that the 340B drug payment policy is consistent with our authority under the statute, as confirmed by the D.C. Circuit's decision. As explained further below, we are finalizing our proposal to continue our current policy of generally paying under the OPPS for 340B-acquired drugs at ASP minus 22.5 percent.

Comment: We received several comments regarding OPPS payment for biosimilars acquired under the 340B program. Commenters suggested a variety of modified payment methodologies for biosimilars. Some commenters believed biosimilars should be excluded from the adjustment for 340B-acquired drugs altogether, and some commenters stated if CMS moves forward with the net reduction of ASP minus 28.7 percent, the agency should maintain the reduction for biosimilars at ASP minus 22.5 percent. Additionally, several commenters suggested the add-on payment of 6 percent should be based on the reference product's ASP when calculating the net payment rate for biosimilars under the survey methodology. Finally, some commenters had concerns that new biosimilars on pass-through status would have a competitive advantage over its reference product.

Response: We are finalizing our alternate proposal to continue paying for 340B-acquired drugs under the OPPS at a rate of ASP − 22.5 percent, and thus we do not believe any changes to our biosimilar policy are necessary for CY 2021. We believe the continuation of our current biosimilar policy will allow for appropriate payment and access to these important treatments. Regarding comments related to biosimilars and the perceived competitive advantage, we do not believe that the temporary payments provided by pass-through status will create the substantial competitive advantage that commenters described. We also note we are continuing the policy from previous years regarding biosimilars and 340B payment, under which we will pay ASP minus 22.5 percent of the biosimilar's ASP. We thank the commenters for the comments regarding biosimilar add-on payment under the survey methodology (ASP minus a net 28.7 percent), and we will take these comments into consideration for potential future rulemaking. Please see section V.B.2.C. for additional discussion regarding biosimilars and section V.A.1. for additional discussion on drug pass-through payments.

Comment: Many commenters opposed both the CY 2021 proposal to pay for drugs acquired under the 340B program at the net payment rate of ASP minus 28.7 percent, as well as the alternative proposal of continuing the current 340B program payment reduction of ASP minus 22.5 percent. These commenters urged CMS to withdraw its proposed policy and contended that the policy was an unlawful application of the CMS' authority.

Commenters also stated that reducing payment for drugs acquired through the 340B Program does not help reduce high drug costs. Many commenters opposed the current 340B policy and argued that it takes away resources designated for safety net hospitals to subsidize non-340B hospitals because the payment reduction is budget neutral. The commenters requested that CMS end its policy of paying for drugs obtained through the 340B program at ASP minus 22.5 percent and restore the statutory default payment rate of ASP plus 6 percent.

Response: We respectfully disagree with the commenters' assertions that our 340B drug payment policy is illegal or an unlawful application of the law. It is also beyond the scope of the CY 2021 rulemaking, nor is it the intent of the 340B payment policy to address all aspects of a larger drug pricing issue. We disagree with commenters that the OPPS 340B payment policy has taken away resources designated for safety net hospitals, and we are not aware of any access to care issues related to the implementation of this policy. As discussed in this section of the CY 2021 final rule with comment period, the D.C. Circuit has confirmed that our 340B drug payment policy is within our authority in section 1833(t)(14) of the Act. Thus, we are finalizing our alternate proposal, without modification, to continue to pay ASP minus 22.5 percent for 340B-acquired drugs, including when furnished in nonexcepted off-campus PBDs paid under the PFS. Our final policy continues the 340B Program policies that were implemented in CY 2018 with the exception of the way we are 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 continues 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.

Furthermore, although we are finalizing our alternate proposal, without modification, to pay ASP minus 22.5 percent for 340B-acquired drugs, we believe our proposal to pay for 340B-acquired drugs at ASP minus 34.7 percent based on hospital survey data, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent could be within the Secretary's authority under section 1833(t)(14). The 340B payment rate proposal of ASP minus 28.7 percent was based on drug acquisition cost data derived from the CMS 2020 Hospital Acquisition Cost Survey for 340B-Acquired SCODs, authorized under subclause 1833(t)(14)(D). Specifically, we applied the statutory authority under section 1833(t)(14)(A)(iii)(I) to collect 340B drug acquisition cost data and limited our survey to the 340B hospital groups. A more detailed discussion of the CMS 2020 Hospital Acquisition Cost Survey methodology is included earlier in this section. Although we are continuing the current 340B payment

policy, we will continue to consider the 340B drug payment rate of under the ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent in potential future rulemaking.

Comment: Several commenters stated that CMS has not provided sufficient analysis for the continuation of the 340B payment policy, believing that CMS has not considered changes in utilization and volume for hospitals that are actively participating in the 340B program since the policy was initially proposed in 2017. They further noted that CMS has not analyzed the impact of the prior year reimbursement changes for drugs acquired under the 340B program for the affected hospitals. They also contended that CMS has not provided evidence that the payment policy remains budget neutral by recalculating the policy's impact to make sure the conversion factor is properly adjusted.

Response: In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we implemented the 340B drug payment policy 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. This adjustment changed the payment rate from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent for drugs subject to this policy. In that rule, 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. We believe the current 340B drug payment policy reflects the average minimum discount that 340B participating hospitals receive for drugs acquired under the 340B Program and we believe it is inappropriate for Medicare to subsidize other programs through Medicare payments for separately payable drugs. While commenters remarked on the continuation of this policy since CY 2018, the commenters did not provide us with any evidence that ASP minus 22.5 percent is no longer a conservative estimate of their drug acquisition costs. Moreover, we note that the data collected in our 2020 Hospital Acquisition Cost Survey for 340B-acquired SCODs found the average 340B program drug discount to be 34.7 percent. Additionally, in the CY 2021 OPPS/ASC proposed rule (85 FR 48890), we proposed that we could continue the current Medicare 340B payment policy of ASP minus 22.5 percent as an alternative, as the D.C. Circuit concluded that this policy was a reasonable application of the Secretary's statutory authority under 1833(t)(14)(A)(iii)(II) of the Act.

With respect to OPPS budget neutrality and the conversion factor, OPPS budget neutrality is generally developed on a prospective basis by isolating the effect of any changes in payment policy or data under the prospective OPPS with all other factors held constant. We note that since the CY 2018 implementation of the 340B drug payment policy in which we developed a budget neutrality adjustment for the policy, the adjusted percentage payment has remained at ASP minus 22.5 percent. As a result, while some of the claims may change based on drug payment and billing, as indicated by the ''JG'' modifier, these drugs, including their utilization and expected payments, would be included as part of the broader budget neutrality adjustments, but collectively they would not have a separate budget neutrality adjustment specifically for the 340B drug payment policy. We note that in rulemaking where we proposed to establish or modify the adjustment, we have included in the impact analysis the estimated effects on different categories of providers based on the policy. Finally, we note that we monitor the payment and utilization patterns associated with this adjustment and for drug spending more broadly, and will continue to do so.

Comment: Several commenters expressed confusion as to whether our proposed policy would affect drugs purchased at their retail pharmacies or whether this payment reduction applied to Federally Qualified Health Centers (FQHCs).

Response: The 340B payment policy originally adopted in the CY 2018 OPPS/ASC final rule with comment period and continued in subsequent years applies to certain hospitals paid under the OPPS. 340B payment policy exceptions under the OPPS include rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals. FQHCs and retail pharmacies are not paid under the OPPS, and therefore are not affected by this policy.

Comment: As previously discussed, several commenters recommended CMS avoid any further action on a 340B payment reduction until the issue is settled in the courts. Commenters noted that although CMS prevailed in the D.C. Circuit, a petition for a rehearing was filed on September 14, 2020. Commenters believed CMS should wait until this decision has been finalized by the courts before moving forward with a continuation of the 340B payment reduction.

Response: On October 16, 2020, the D.C. Circuit denied the appellees' petition for rehearing en banc. We believe our 340B drug payment policy is within the Secretary's statutory authority at 1833(t)(14)(A)(iii)(II) of the Act, which was confirmed by the D.C. Circuit. Thus, we are finalizing our alternate proposal, without modification, to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs.

Comment: Several commenters requested that we make our 340B policy exemptions permanent. Additionally, commenters asked CMS to extend the exemption to urban SCHs, Medicare Dependent Hospitals, and Rural Referral Centers.

Response: We thank commenters for their recommendations. At this time, we do not believe it is appropriate to revise our policy on 340B policy exemptions and we believe we should maintain our current policy. Nonetheless, we will take these comments into consideration for future rulemaking.

Summary of Finalized Policy

We are finalizing our alternate proposal, without modification, to continue our current policy 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. Our finalized policy continues the 340B Program policies that were implemented in CY 2018 with the exception of the way we are 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 continuing the 340B payment adjustment for WAC-priced drugs, which is WAC minus 22.5 percent. 340B-acquired drugs that are priced using AWP will continue to be paid an adjusted amount of 69.46 percent of AWP.

Additionally, we are finalizing our proposal to continue to exempt rural sole community hospitals (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment. These hospitals must 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. Finally, we are continuing to require hospitals to use of 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 note that any future changes to our policy regarding payment for 340B drugs will be adopted through notice and comment rulemaking.

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 2020, the payment rate for APC 5053 (Level 3 Skin Procedures) was $497.02, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,622.74, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $2,766.13. This information also is available in Addenda A and B of the CY 2020 OPPS/ASC final rule with comment period, correction notice (which is available via the internet on the CMS website).

We have continued the high cost/low cost categories policy since CY 2014, and we proposed to continue it for CY 2021. Under this 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 (84 FR 61327 through 61328).

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 approximately $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 does 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.

b. Discussion of CY 2019 and CY 2020 Comment Solicitations for Episode-Based Payment for Graft Skin Substitute Procedures

The methodology that commenters discussed most in response to our comment solicitation in CY 2019 and that stakeholders raised in subsequent meetings we have had with the wound care community has been a lump-sum ''episode-based'' payment for a wound care episode. Commenters that supported an episode-based payment believe that it would allow health care professionals to choose the best skin substitute to treat a patient's wound and would give providers flexibility with the treatments they administer. These commenters also believe an episode-based payment helps to reduce incentives for providers to use excessive applications of skin substitute products or use higher cost products to generate more payment for the services they furnish. In addition, they believe that episode-based payment could help with innovations with skin substitutes by encouraging the development of products that require fewer applications. These commenters noted that episode-based payment would make wound care payment more predictable for hospitals and provide incentives to manage the cost of care that they furnish. Finally, commenters that supported an episode-based payment believe that workable quality metrics can be developed to monitor the quality of care administered under the payment methodology and limit excessive applications of skin substitutes.

However, many commenters opposed establishing an episode-based payment. One of the main concerns of commenters who opposed episode-based payment was that wound care is too complex and variable to be covered through such a payment methodology. These commenters stated that every patient and every wound is different; therefore, it would be very challenging to establish a standard episode length for coverage. They noted that it would be too difficult to risk-stratify and specialty-adjust an episode-based payment, given the diversity of patients receiving wound care and their providers who administer treatment, as well as the variety of pathologies covered in treatment. Also, these commenters questioned how episodes would be defined for patients when they are having multiple wounds treated at one time or have another wound develop while the original wound was receiving treatment. These commenters expressed concerns that episode-based payment would be burdensome both operationally and administratively for providers. They believe that CMS will need to create a large number of new APCs and HCPCS codes to account for all of the patient situations that would be covered with an episode-based payment, which would increase provider burden. Finally, these commenters had concerns about the impact of episode-based payment on the usage of higher cost skin substitute products. They believe that a single payment could discourage the use of higher-cost products because of the large variability in the cost of skin substitute products, which could limit innovations for skin substitute products.

The wide array of views on episode-based payment for skin substitute products and the unforeseen issues that may arise from the implementation of such a policy encouraged us to continue to study the issues associated with episode-based payment. Therefore, we sought further comments from stakeholders and other interested parties regarding skin substitute payment policies that could be applied in future years to address concerns about excessive utilization and spending on skin substitute products, while avoiding administrative issues such as establishing additional HCPCS codes to describe different treatment situations.

One possible policy construct that we sought comments on was whether to establish a payment period for skin substitute application services (CPT codes 15271 through 15278 and HCPCS codes C5271 through C5278) between 4 weeks and 12 weeks. Under this option, we could also assign CPT codes 15271, 15273, 15275, and 15277, and HCPCS codes C5271, C5273, C5275, and C5277 to comprehensive APCs with the option for a complexity adjustment that would allow for an increase in the standard APC payment for more resource-intensive cases. Our research has found that most wound care episodes require one to three skin substitute applications. Those cases would likely receive the standard APC payment for the comprehensive procedure. Then the complexity adjustment could be applied for the relatively small number of cases that require more intensive treatments.

Several commenters were in favor of establishing a comprehensive APC with either an option for a complexity adjustment or outlier payments to pay for higher cost skin substitute application procedures. The commenters supported the idea of having a traditional comprehensive APC payment for standard wound care cases with a complexity adjustment or outlier payment to handle complicated or costly cases. However, they also expressed concerns about how many payment levels would be available in the skin substitute procedures APC group since a complexity adjustment can only be used if there is an existing higher-paying APC to which the service receiving the complexity adjustment may be assigned. A couple of commenters wanted more opportunities for services to receive a complexity adjustment through using clusters of procedure codes that reflect the full range of wound care services a beneficiary receives instead of using code pairs to determine if a complexity adjustment should apply. Other commenters suggested that episodic

payments be risk-adjusted to account for clinical conditions and co-morbidities of beneficiaries with outlier payments and that complexity adjustments be linked to beneficiaries with more comorbidities.

Some commenters opposed the idea of a complexity adjustment for skin substitute application procedures. The commenters stated there was not enough detail in the comment solicitation to understand how a complexity adjustment would work with an episodic payment arrangement. Commenters also expressed concerns that payment rates for comprehensive APCs may not be representative of the wound care services that would be paid within those APCs. One commenter stated that payment policy is not the right way to resolve issues with the over-utilization and inappropriate use of skin substitutes because they are concerned that major changes in payment methodology, such as episodic payment, could lead to serious issues with the care beneficiaries receive. In recent meetings, stakeholders have expressed concerns that establishing a comprehensive APC for graft skin substitute procedures could lead to other unrelated wound care services such as hyperbaric oxygen treatments being bundled into those procedures. Some stakeholders have provided suggestions to provide additional payment for the treatment of complicated wounds, similar to a complexity adjustment, without bundling unrelated wound care services.

The additional comments we received in CY 2020 related to including a complexity adjustment with an episode-based payment, along with the comments we received on episode-based payment in general from the CY 2019 comment solicitation, show that there are many issues that continue to require study for this payment methodology. In addition, we also need more time to assess the benefits and drawbacks of episode-based payment compared to other possible options to change the payment methodology for graft skin substitute procedures. Therefore, in the CY 2021 OPPS/ASC proposed rule, we stated that will continue our review of the feasibility of using episode-based payment for graft skin substitute procedures, and we did not propose any episode-based payment for these procedures.

Comment: Several commenters expressed either their support for or their concerns about establishing episode-based payment for graft skin substitute procedures. Commenters made many suggestions about how a payment episode should be constructed and which services should be included or excluded from a payment episode.

Response: We appreciate the feedback we received from the commenters. We will continue to study issues related to changing the methodology for paying for skin substitute products and procedures for possible future rulemaking.

c. Discussion of CY 2019 and CY 2020 Comment Solicitations To Have a Single Payment Category for Graft Skin Substitute Procedures

Another policy option on which we solicited comments in CY 2019 and CY 2020 was 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. Under this option, the only available procedure codes to bill for graft skin substitute procedures would be CPT codes 15271 through 15278. HCPCS codes C5271 through C5278 would be eliminated. Providers would bill CPT codes 15271 through 15278 without having to consider either the MUC or PDC of the graft skin substitute product used in the procedure. There would be only one APC for the graft skin substitute application procedures described by CPT codes 15271 (Skin sub graft trnk/arm/leg), 15273 (Skin sub grft t/arm/lg child), 15275 (Skin sub graft face/nk/hf/g), and 15277 (Skin sub grft f/n/hf/g child). The payment rate would be based on the geometric mean cost of all graft skin substitute procedures for a given CPT code that are paid through the OPPS. For example, under the current skin substitute payment policy, there are two procedure codes (CPT code 15271 and HCPCS code C5271) that are reported for the procedure described as ''*application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area*''.

Commenters who supported this option believed it would remove the incentives for manufacturers to develop and providers to use high cost skin substitute products and would lead to the use of lower cost, quality products. Commenters noted that lower Medicare payments for graft skin substitute procedures would lead to lower copayments for beneficiaries. In addition, commenters believe a single payment category would reduce incentives to apply skin substitute products in excessive amounts. Commenters and stakeholders also believe a single payment category is clinically justified because they stated that many studies have shown that no one skin substitute product is superior to another. Supporters of a single payment category believed it would simplify coding for providers and reduce administrative burden. Finally, some stakeholders believed that a single payment category policy could serve as a transitional payment policy for graft skin substitute products while we continue to study the feasibility of establishing an episode-based payment for skin substitutes.

Most commenters and stakeholders were opposed to a single payment category for skin substitute products. Commenters and stakeholders stated that the large difference in resource costs between higher cost and lower cost skin substitute products would provide an incentive for hospitals to use the most inexpensive products, which would hurt both product innovation and the quality of care beneficiaries receive. Commenters and stakeholders were concerned that a single payment category would encourage providers to choose financial benefit over clinical efficacy when determining which skin substitute products to use.

These commenters and stakeholders also stated that a single payment category would increase incentives for providers to use cheaper products that require more applications to generate more revenue and emphasize volume over value. A couple of commenters believed that overall Medicare spending on skin substitutes would be higher with a single payment category than under the current payment methodology, which has separate payment for higher cost and lower cost skin substitutes. The reason spending would increase according to the commenters is that overpayment for low cost skin substitutes by Medicare would exceed the savings Medicare would receive on reduced payments for higher cost skin substitutes.

Further, commenters and stakeholders stated that a single payment rate would lead to too much heterogeneity in the products receiving payment through the skin substitute application procedures. That is, the same payment rate would apply to skin substitute products whether they cost less than $10 per cm^2 or over $200 per cm^2 and regardless of the type of wound they treat. Commenters and stakeholders would prefer to have multiple payment categories where the payment rate is more reflective of the cost of the product. Commenters and stakeholders believe that a single payment category would discourage providers from treating more complicated wounds and wounds larger than 100 cm^2.

The responses to the comment solicitation indicated that a single payment category could potentially reduce the cost of wound care services for graft skin substitute procedures for both beneficiaries and Medicare. In addition, a single payment category may help reduce administrative burden for providers. Conversely, we are cognizant of other commenters' concerns that a single payment category may hinder innovation of new graft skin substitute products and cause some products that are currently well-utilized to leave the market. Nonetheless, we are persuaded that a single payment category could potentially provide a more equitable payment for many products used with graft skin substitute procedures, while recognizing that procedures performed with expensive skin substitute products would likely receive substantially lower payment.

We believe some of the concerns that commenters who oppose a single payment category for skin substitute products raised might be mitigated if stakeholders have a period of time to adjust to the changes inherent in establishing a single payment category. Accordingly in CY 2020, we solicited public comments that provide additional information about how commenters believe we should transition from the current low cost/high cost payment methodology to a single payment category.

Such suggestions to facilitate the payment transition from a low cost/high cost payment methodology to a single payment category methodology included—

- Delaying implementation of a single category payment for 1 or 2 years after the payment methodology is adopted; and
- Gradually lowering the MUC and PDC thresholds over 2 or more years to add more graft skin substitute procedures into the current high cost group until all graft skin substitute procedures are assigned to the high cost group and it becomes a single payment category.

Those commenters in favor of a single payment category did not see a need for a transition period or wanted only a one-year transition period. Conversely, those commenters opposed to a single payment category either mentioned the idea of a transition period or wanted it to last multiple years, with one commenter suggesting a transition period of four years. In the end, having a transition period before establishing a single payment category did not affect the views of commenters who were initially opposed to establishing a single payment category, as they continued to oppose this policy option.

Based on the comments received regarding establishing a single payment category for graft skin substitute procedures, we stated that we need more time to consider the trade-offs between the potential benefits of a single category against the potential substantial drawbacks. We also need to consider the merits of this policy option compared to episode-based payment for graft skin substitute procedures. Therefore, we did not propose a single payment category for graft skin substitute procedures for CY 2021 in the CY 2021 OPPS/ASC proposed rule.

Comment: Several commenters expressed either their support or their concerns about a single payment category for graft skin substitute procedures. Commenters provided their views on whether a single payment category encourages value and cost savings for graft skin substitute procedures, or if a single payment category would discourage providers from using higher-cost skin substitute products that may have better clinical results for patients.

Response: We appreciate the feedback we received from the commenters. We will continue to study issues related to changing the methodology for paying for skin substitute products.

d. Packaged Skin Substitutes for CY 2021

For CY 2021, consistent with our policy since CY 2016, we proposed 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 final CY 2021 MUC threshold is $48 per cm^2 (rounded to the nearest $1) (proposed at $47 per cm^2) and the final CY 2021 PDC threshold is $949 (rounded to the nearest $1) (proposed at $936). We also proposed to clarify 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 the CY 2021 OPPS/ASC proposed rule. We also want to clarify that the availability of a HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2021, as we did for CY 2020, we proposed to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, we proposed 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 2021, we proposed that any skin substitute product that was assigned to the high cost group in CY 2020 would be assigned to the high cost group for CY 2021, regardless of whether it exceeds or falls below the CY 2021 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 CY 2021, we proposed to continue to assign skin substitutes with pass-through payment status to the high cost category. We proposed 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 proposed 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 proposed to use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. We proposed 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 the CY 2021 OPPS/ASC 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 2021 MUC and PDC thresholds. 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). Table 42 displays the final CY 2021 cost category assignment for each skin substitute product.

Comment: One commenter did not support our proposal to assign graft skin substitute products to a high cost or a low cost group based on if the MUC or PDC of a product exceeds a weighted average of either the MUC or PDC of all graft skin substitute products. The commenter believes the current two-tier system provides incentives for providers to use higher-cost graft skin substitute products instead of lower-cost products that have similar efficacy to the higher-cost products.

Response: As we explained in the CY 2014 OPPS/ASC final rule (78 FR 74933), the graft skin substitute procedures described by CPT codes 15271 through 15278 are clinically homogeneous, but there is a large amount of resource heterogeneity between different skin substitute products with the cost per cm^2 ranging from under $10 per cm^2 to over $200 per cm^2. We believe establishing high cost and low cost groups for skin substitutes makes the payment for these products more homogeneous and reduces the risk of excessive overpayment or underpayment to a provider when a skin substitute product is used.

Comment: Multiple commenters supported our proposal to continue to assign skin substitutes to the low cost or high cost group. Commenters also supported our proposal that any skin substitute product that was assigned to the high cost group in CY 2020 would be assigned to the high cost group for CY 2021, regardless of whether it exceeds or falls below the CY 2021 MUC or PDC threshold.

Response: We appreciate the support of the commenters for our proposals.

Comment: One commenter requested that CMS be more transparent when presenting the data regarding whether individual graft skin substitute products are assigned to either the high cost or low cost group. The commenter requested that we share more of the process details for determining high cost and low cost assignments and provide the calculation processes and formulas used to make the determinations.

Response: We already provide the information that the commenter seeks. In the CY 2021 OPPS/ASC final rule (85 FR 48891) and in previous OPPS proposed and final rules, we discuss in detail how both the MUC and PDC thresholds are calculated and which pricing data are used to determine if a graft skin substitute product is assigned to the high cost or low cost group. We provide drug cost statistics data on our website, which include cost data for all the graft skin substitute products that are used to calculate the overall MUC and PDC cost group thresholds. Links to the drug cost statistics data may be found on the same web page that has links to the OPPS preamble, OPPS claims accounting narrative, OPPS addenda, and other data related to the OPPS/ASC final rule.

Comment: One commenter requested that HCPCS code Q4235 (Amniorepair or altiply, per square centimeter) be assigned to the high cost skin substitute group based on either WAC plus 3 percent or 95 percent of AWP pricing data, which the commenter believed would demonstrate that the cost of these products exceeds the MUC threshold.

Response: The commenter did not provide the required information to make a determination on assignment to the high cost skin substitute group in time. Therefore, HCPCS code Q4235 will continue to be assigned to the low cost skin substitute group in this final rule.

Comment: Individual commenters have requested that the HCPCS codes Q4205 (Membrane graft or membrane wrap, per square centimeter), Q4222 (Progenamatrix, per square centimeter), Q4226 (MyOwn skin, includes harvesting and preparation procedures, per square centimeter), Q4227 (Amniocore, per square centimeter), and Q4232 (Corplex, per square centimeter) be assigned to the high cost skin substitute group based on either WAC plus 3 percent or 95 percent of AWP pricing data, which the commenters believed would demonstrate that the cost of these products exceeds the MUC threshold.

Response: HCPCS codes Q4205 and Q4226 were assigned to the high cost group starting in October 2020. We also note that we are assigning HCPCS codes Q4222, Q4227, and Q4232 to the high cost group starting on January 1, 2021.

Comment: Individual commenters have requested that HCPCS codes Q4206 (Fluid flow or fluid gf, 1 cc) and Q4231 (Corplex p, per cc) be assigned to the high cost skin substitute group based on either WAC plus 3 percent or 95 percent of AWP pricing data, which the commenters believed would demonstrate that the cost of these products exceeds the MUC threshold.

Response: HCPCS codes Q4206 and Q4231 are not graft skin substitute products. Therefore, these products cannot be assigned to either the high cost or low cost skin substitute group.

Comment: One commenter, the manufacturer, has requested that HCPCS codes Q4122 (Dermacell, per square centimeter) and Q4150 (Allowrap ds or dry, per square centimeter) continue to be assigned to the high-cost skin substitute group.

Response: HCPCS codes Q4122 and Q4150 were both assigned to the high-cost group in CY 2020 and also were proposed to be assigned to the high-cost group for CY 2021. Per our proposal, a skin substitute that has been proposed in the high-cost group in a proposed rule will remain in the high-cost group in the final rule. Also, any skin substitute assigned to the high-cost group in CY 2020 will continue to be assigned to the high-cost group in CY 2021 even if the MUC and PDC for the skin substitute product is below the overall MUC and PDC thresholds for all skin substitute products. Accordingly, we are finalizing our proposal to assign HCPCS codes Q4122 and Q4150 to the high-cost group in CY 2021.

After consideration of the public comments we received, we are finalizing our proposal to assign a 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, unless the product was assigned to the high cost group in CY 2020, in which case we would assign the product to the high cost group for CY 2021, regardless of whether it exceeds the CY 2021 MUC or PDC threshold. We are also finalizing our proposal to assign to the high cost group any skin substitute product that exceeds the CY 2021 MUC or PDC thresholds and assign to the low cost group any skin substitute product that does not exceed the CY 2021 MUC or PDC thresholds and was not assigned to the high cost group in CY 2020. We are finalizing our proposal to continue to use payment methodologies, including ASP+6 percent and 95 percent of AWP, for skin substitute products that have pricing information but do not have claims data to determine if their costs exceed the CY 2021 MUC. In addition, we are finalizing our proposal to continue to use WAC+3 percent instead of WAC+6 percent for skin substitute products that do not have ASP pricing information or claims data to determine if those products' costs exceed the CY 2021 MUC. We also are finalizing our proposal to retain our established policy to assign new skin substitute products with pricing information to the low cost group. Table 42 below includes the final CY 2021 cost category assignment for each skin substitute product.

BILLING CODE 4120–01–P

TABLE 42: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2021

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Final CY 2021 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

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Final CY 2021 High/Low Cost Assignment
Q4123	Alloskin	High	High
Q4124	Oasis tri-layer wound matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High
Q4127	Talymed	High	High*
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	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 ecm px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High*

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Final CY 2021 High/Low Cost Assignment
Q4158	Kerecis omega3, per sq cm	High	High*
Q4159	Affinity 1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per square centimeter	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	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Transcyte, per sq centimeter	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 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Final CY 2021 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	Low
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
Q4222	Progenamatrix, per sq cm	Low	Low
Q4226	Myown harv prep proc sq cm	High	High

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Final CY 2021 High/Low Cost Assignment
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 2021, but are assigned to the high cost group because they were assigned to the high cost group in CY 2020.

BILLING CODE 4120–01–C

e. Synthetic Skin Graft Sheet Products To Be Reported With Graft Skin Substitute Procedure Codes

The CY 2014 OPPS/ASC final rule with comment period describes skin substitute products as ''. . . a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers . . . [T]hese products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action that stimulate the host to regenerate lost tissue.'' (78 FR 74930 through 74931) The CY 2014 final rule also described skin substitutes as ''. . . a class of products that we treat as biologicals . . .'' and mentioned that prior to CY 2014, skin substitutes were separately paid in the OPPS as if they were biologicals according to the ASP methodology (78 FR 74930 through 74931).

The 2014 rule did not specifically mention whether synthetic products could be considered to be skin substitute products in the same manner as biological products, because there were no synthetic products at that time that were identified as skin substitute products. Then in 2018, a manufacturer made a request that an entirely synthetic product that it claimed is used in the same manner as biological skin substitutes, receive a HCPCS code that would allow the product to be billed with graft skin substitute procedure codes, including CPT codes 15271 through 15278 and C5271 through C5278, starting in 2019. Initially, the

synthetic product was not described as a graft skin substitute product. However, we now believe that both biological and synthetic products could be considered to be skin substitutes for Medicare payment purposes.

This view is supported by a paper referenced in a report we cited in the CY 2014 OPPS/ASC final rule with comment period titled ''Skin Substitutes for Treating Chronic Wounds Technology Assessment Report at ES–2'', which is available on the AHRQ website at: *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/skinsubs/HCPR0610_skinsubst-final.pdf*. That paper, titled ''Regenerative medicine in dermatology: biomaterials, tissue engineering, stem cells, gene transfer and beyond'' by Dieckmann et al.,[84] states that skin substitutes should be divided into two broad categories: biomaterial and cellular. The paper explains that ''. . . biomaterial skin substitutes do not contain cells (acellular) and are derived from natural or synthetic sources . . .''[85] The paper continues by describing biomaterial skin substitutes further: ''Synthetic sources include various degradable polymers such as polylactide and polyglycolide. Whether natural or synthetic, the biomaterial provides an extracellular matrix that allows for infiltration of surrounding cells.''[86] The paper by Dieckmann et al. indicates that skin substitute products may be synthetic products as well as biological products.

Therefore, for CY 2021 we proposed to include synthetic products in addition to biological products in our description of skin substitutes. Our new description would define skin substitutes as a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers. We also proposed to retain the additional description of skin substitute products from the CY 2014 OPPS final rule which states ''. . . that skin substitute products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue . . .'' (78 FR 74930 through 74931).

Comment: Two commenters requested that CMS no longer use the term ''skin substitutes'' to describe products that do not function like human skin that is grafted onto a wound and are not substitutes for skin grafts, but do aid in wound healing by stimulating the patient to regenerate lost tissue. Instead, the commenters request that we use the term ''cellular and/or tissue based products for skin wounds'' that is abbreviated ''CTPs''. The commenters believe the term ''skin substitute'' is a misleading and clinically incorrect term that does not accurately describe all of the products that are considered to be cellular and tissue based products to treat skin wounds. Also, one of the commenters notes that the FDA discourages the use of the term ''skin substitute'' and that an international standards organization, the American Society for Testing and Materials (ASTM), has adopted the ''CTPs'' terminology as well. Finally, the commenter claims the ''CTPs'' terminology is used by physicians and clinicians throughout the wound care community.

Response: We appreciate the suggestion by the commenters, but we do not believe it is appropriate at this time to end our use of the term ''skin substitute.'' Notably, the CPT and HCPCS codes used to report graft procedures using cellular and tissue based products to heal skin wounds, CPT codes 15271 through 15278 and HCPCS codes C5271 through C5278, use the term ''skin substitute'' in the descriptor. We feel that we should use terminology that reflects the service descriptors that are reported in the OPPS. Also, the term ''skin substitute'' is well-understood by providers and industry stakeholders, even if it is not the most precise terminology to describe cellular and tissue based products to heal skin wounds. Finally, we did not propose to change the terminology used to describe products that do not function like human skin that is grafted onto a wound and are not substitutes for skin grafts, but do aid in wound healing by stimulating the patient to regenerate lost tissue. While we are not changing the use of the term ''skin substitute'', we appreciate the information from commenters.

Comment: A commenter expressed concern about our proposed definition of synthetic skin substitutes. The commenter believes it is possible under our proposal that bandages and standard dressings could be defined as skin substitutes. The commenter does support Medicare coverage of synthetic skin substitutes, but would like us to modify our proposal to prevent products that would normally be described as medical supplies to be defined as skin substitutes.

Response: The descriptor for HCPCS code C1849 (Skin substitute, synthetic, resorbable, per square centimeter) includes the term ''resorbable'', which means the graft skin substitute product must be able to be absorbed by the body. Bandages and standard dressings are not resorbable products and are removed and replaced on a regular basis while treating a wound. We find it highly unlikely that a bandage or standard dressing would be used for a graft skin substitute procedure. However to make it clear, we will modify our definition of a synthetic graft skin substitute product to exclude bandages and standard dressings.

Comment: Multiple commenters agreed with CMS that synthetic graft skin substitute products should receive payment under the OPPS, even if the commenters did not support our methodology for the payment of graft skin substitute products.

Response: We appreciate commenters' support for our proposal to pay for synthetic graft skin substitute products under the OPPS.

Comment: Several commenters requested that we establish product-specific HCPCS codes for synthetic graft skin substitute products. Most of the same commenters also requested that we delete HCPCS code C1849, but there was one commenter who supported both product-specific HCPCS codes and continuing to have HCPCS code C1849 be packaged in the OPPS. The primary reason commenters want product-specific codes for synthetic graft skin substitute is they feel that synthetic products should be assigned to either the high cost or low cost skin substitute group based on the cost of each individual product in a similar manner to biological skin substitute products. Commenters feel that because multiple synthetic graft skin substitute products can be assigned to HCPCS code C1849, there may be some synthetic products that should be in the low cost skin substitute group that will receive payment in the high cost skin substitute group if HCPCS code C1849 is assigned to the high cost group. Commenters also are concerned about the opposite situation, in which high cost synthetic products would potentially be underpaid if HCPCS code C1849 is assigned to the low cost skin substitute group. Commenters believed the only resolution to these issues with HCPCS code C1849 is to delete the code so there are not cases of synthetic products being either overpaid or underpaid.

[84] Dieckmann C, Renner R, Milkova L, et al. Regenerative medicine in dermatology: Biomaterials, tissue engineering, stem cells, gene transfer and beyond. Exp Dermatol 2010 Aug;19(8):697–706.

[85] Ibid, Dieckmann C, Renner R, Milkova L, et al.

[86] Ibid, Dieckmann C, Renner R, Milkova L, et al.

Commenters also expressed concerns about using a C-code to report synthetic graft skin substitute codes in Medicare. One commenter noted that the use of a C-code meant that synthetic graft skin substitute products would only be in a payable status under the OPPS, and cannot be reported for graft skin substitute application services provided in the physician office setting. Two commenters thought that a C-code might confuse providers by unintentionally implying that HCPCS code C1849 has pass-through status under the OPPS, even though HCPCS code C1849 does not have pass-through status. Another commenter had concerns that there would be a less rigorous process to determine that a graft skin substitute product can be reported with HCPCS code C1849 than the process CMS uses to assign biological skin substitute products to product-specific HCPCS codes. Finally, two commenters asked for more transparency from CMS regarding the reasons for the creation of HCPCS code C1849.

Response: HCPCS code C1849 was established in response to the need to pay for graft skin substitute application services performed with synthetic graft skin substitute products in the OPPS in a manner comparable to how we pay for graft skin substitute application services performed with biological graft skin substitute products. As mentioned earlier in this section, when we established our policy in the CY 2014 OPPS final rule to package graft skin substitute products into their associated application procedures (78 FR 74930 through 74931), we did not specifically mention whether synthetic products could be considered skin substitute products in the same manner as biological products. The reason for this was that there were no synthetic products at that time that were identified as skin substitute products.

We note that unless a graft skin substitute product has pass-through status, graft skin substitute products are not paid separately under unique HCPCS or CPT codes in OPPS. However, in CY 2018, a manufacturer requested that CMS develop methodologies to allow synthetic graft skin substitute products to receive payment in the outpatient hospital setting and in the physician office setting. After extensive review, we decided against establishing a product-specific HCPCS code for the synthetic graft skin substitute product. Instead, CMS decided to assign the synthetic product in CY 2019 to HCPCS codes A6460 and A6461, which were newly created HCPCS codes to report synthetic, resorbable wound dressings. HCPCS codes A6460 and A6461 are packaged under the OPPS and cannot be assigned to either the high cost or low cost skin substitute group. This meant that graft skin substitute products could not be billed with CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278, even though synthetic graft skin substitute products and biological graft skin substitute products perform the same function and have similar efficacy.

Because all skin substitutes, except those with pass-through status, are packaged under the OPPS, we explored solutions that would permit synthetic skin substitute products to be billed with either CPT codes 15271 through 15278 or HCPCS codes C5271 though C5278. We decided to create HCPCS code C1849 to describe any synthetic graft skin substitute product, and we revised the payment logic for the graft skin substitute application procedure codes to allow HCPCS code C1849 to be billed with those procedures. So far, we have identified one synthetic graft skin substitute product that is described by HCPCS code C1849. Even though there are no OPPS claims data for the synthetic product, the manufacturer of the product was able to produce pricing data for the product. Using our alternative methodology to assign products to the high cost skin substitute group through WAC or AWP pricing that exceeds the MUC threshold, the data showed that the synthetic product would be assigned to the high cost group. As more synthetic graft skin substitute products are identified as being described by HCPCS code C1849, we will average the pricing data from the various products to determine an amount for the products described by HCPCS code C1849 to compare against the MUC threshold. This comparison will determine if HCPCS code C1849 should be assigned to the high cost or low cost skin substitute category.

Regarding other comments about HCPCS code C1849, it is correct that HCPCS C-codes are only payable under the OPPS and not under the PFS. We also note that while the process may be different to receive payment for synthetic graft skin substitute products reporting HCPCS code C1849 than for a new product-specific HCPCS code for a biological skin substitute product, synthetic graft skin substitute products must be described by C1849 to be eligible for payment in the OPPS. Like any other claim paid in the OPPS, claims reporting C1849 also are subject to medical review to ensure that providers are appropriately billing for synthetic, resorbable graft skin substitute products. Finally, we disagree with the commenters who feel that assigning a HCPCS C-code to report synthetic graft skin substitute products may confuse providers who may think synthetic products are receiving pass-through payment. We note that for several years a biological graft skin substitute product, Integra meshed bilayer wound matrix, has been assigned to HCPCS code C9363, and providers are well aware the product is packaged under the OPPS and does not have pass-through status.

Comment: Several commenters stated that if HCPCS code C1849 is not either modified or deleted, then the HCPCS code should be assigned to the low cost skin substitute group by default, similar to how we pay for HCPCS code Q4100 (Skin substitute, not otherwise specified), which is used to report multiple biological skin substitute products that do not have product-specific HCPCS codes. Commenters are concerned that synthetic graft skin substitute products that should receive payment through the low cost skin substitute group would instead receive payment in the high cost skin substitute group and increase overall graft skin substitute costs for Medicare. In addition, two commenters expressed concern about the assignment of HCPCS code C1849 to the high cost skin substitute group because the commenters believed it was an automatic assignment that was not based on OPPS claims data or product pricing data.

Response: We are currently aware of one synthetic graft skin substitute product that is described by HCPCS code C1849. As we mentioned earlier, the manufacturer provided pricing data that showed the cost of the product is above the MUC threshold for graft skin substitute products and therefore HCPCS code C1849 should be assigned to the high cost skin substitute group. We note that we used pricing data to assign HCPCS code C1849 to the high cost group, and the assignment of HCPCS code C1849 to the high cost skin substitute group was not automatic. As more synthetic graft skin substitute products are identified, we will use their pricing data to calculate an average price for the products described by HCPCS code C1849 and compare that average price to the overall MUC threshold to determine whether HCPCS code C1849 should be assigned to the high cost or low cost skin substitute group. We are not in favor of a default assignment of HCPCS code C1849 to the low cost skin substitute group. Instead, we want to rely on pricing data and, when available, claims data to determine the appropriate skin

substitute cost group for HCPCS code C1849. If most of the products described by HCPCS code C1849 have pricing or cost that qualify the products to be assigned to the high cost group, then the HCPCS code should be assigned to the high cost skin substitute group as that group best reflects the costs of the products described by HCPCS code C1849.

Comment: One commenter was concerned that the establishment of a single HCPCS code to describe all synthetic graft skin substitute products is a substantial step towards the establishment of a single category payment system for both synthetic and biological graft skin substitute products.

Response: The creation of HCPCS code C1849 and the scope of its descriptor was not an attempt to promote one of the several payment methodologies discussed in the CY 2019 and CY 2020 comment solicitations regarding alternative payment methodologies for graft skin substitute products over the other payment methodologies. This is made clear by the fact that there are over 100 biological graft skin substitute products with their own product-specific HCPCS codes as compared to one identified synthetic graft skin substitute product. As explained previously, HCPCS code C1849 was created to provide a way for synthetic skin substitute products that have similar function and efficacy to biological skin substitute products to receive comparable payment under the OPPS.

Comment: Multiple commenters expressed their support for our proposal without any suggested changes.

Response: We appreciate the commenters' support for our proposal. After reviewing the public comments, we have decided to implement our proposal for CY 2021 with modification to include synthetic products, in addition to biological products, in our description of skin substitutes. Our new description defines skin substitutes as a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers. We will retain the additional description of skin substitute products from the CY 2014 OPPS final rule which states that ''skin substitute products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue'' (78 FR 74930 through 74931). Finally, we note that our definition of skin substitutes does not include bandages or standard dressings and therefore, these items cannot be assigned to either the high cost or low cost skin substitute groups or be reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278.

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 2021 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 2021. 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 2020 or beginning in CY 2021. The sum of the proposed CY 2021 pass-through spending estimates for these two groups of device categories equaled the proposed total CY 2021 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 proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2021, we also proposed 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 2021 for this group of items was $473.4 million, as discussed below, because we proposed that most non pass-through separately payable drugs and biologicals would be paid under the CY 2021 OPPS at ASP+6 percent with the exception of 340B-acquired separately payable drugs, which are paid at ASP minus 22.5

percent, but for which we proposed to pay a net rate of ASP minus 28.7 percent, and because we proposed to pay for CY 2021 pass-through payment drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of this CY 2021 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 and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section V.B.1.c. of this CY 2021 OPPS/ASC proposed rule. We proposed that all of these policy-packaged drugs and biologicals with pass-through payment status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2020. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2021 was not $0, as discussed below. In section V.A.6. of the CY 2021 OPPS/ASC proposed rule, we discussed our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we proposed 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 proposed 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 2021. 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 2020 or beginning in CY 2021. The sum of the CY 2021 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2021 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Estimate of Pass-Through Spending

In the CY 2021 OPPS/ASC proposed rule, we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2021, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2020 (84 FR 61336 through 61337).

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 2021, there are four active categories for CY 2021. The active categories are described by HCPCS codes C1734, C1824, C1982, and C2596. Based on the information from the device manufacturers, we proposed estimates that C1824 will cost $46 million in pass-through expenditures in CY 2021, C1982 will cost $116.3 million in pass-through expenditures in CY 2021, C2596 will cost $11.3 million in pass-through expenditures in CY 2021, and C1734 will cost $37.2 million in pass-through expenditures in CY 2021. Therefore, we proposed an estimate for the first group of devices of $210.8 million. We did not receive any public comments on the proposal. Therefore, we are finalizing the proposed estimate for the first group of devices of $210.8 million for CY 2021.

In estimating our proposed CY 2021 pass-through spending for device categories in the second group, we included: Device categories that we knew at the time of the development of the proposed rule will be newly eligible for pass-through payment in CY 2021; additional device categories that we estimated could be approved for pass-through status after the development of the proposed rule and before January 1, 2021; and contingent projections for new device categories established in the second through fourth quarters of CY 2021. For CY 2021, we proposed 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 2021 pass-through spending for this second group of device categories is $99 million.

We did not receive any public comments on this proposal. As stated earlier in this final rule with comment period, we are approving five devices for pass-through payment status in the CY 2021 rulemaking cycle: Barostim NEO® System, Hemospray® Endoscopic Hemostat, EXALT™ Model D Single-Use Duodenoscope, The SpineJack® Expansion Kit, and Customflex® Artificial Iris. The manufacturers of these systems provided utilization and cost data that indicate the spending for the devices would be approximately $4 million for Barostim NEO® System, $40 million for Hemospray® Endoscopic Hemostat, $40 million for EXALT™ Model D Single-Use Duodenoscope, $14 million for SpineJack® Expansion Kit, and $600 thousand for Customflex® Artificial Iris. Therefore, we are finalizing an estimate of $99 million for this second group of devices for CY 2021.

To estimate proposed CY 2021 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 2021, we proposed to use the most recent Medicare hospital outpatient claims data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals to project the CY 2021 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 2021, 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 currently pay ASP minus 22.5 percent but for which we proposed to pay a net rate of ASP minus 28.7 percent or in the alternative, to continue our current policy of paying ASP minus 22.5 percent. Therefore, the payment rate difference between the pass-through

payment amount and the non pass-through payment amount is $473.4 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 2021 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 2021 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 2021.

We did not receive any public comments on our proposal. Using our methodology for this final rule with comment period, we calculated a CY 2021 spending estimate for this first group of drugs and biologicals of approximately $449.5 million based on our decision to finalize our alternative proposal to maintain our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs.

To estimate proposed CY 2021 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 final rule were newly eligible for pass-through payment in CY 2021, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the final rule and before January 1, 2021 and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2021), we proposed 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 2021 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2021 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 did not receive any public comments on our proposal. Therefore, for CY 2021, we are continuing to use the general methodology described above. For this final rule with comment period, we calculated a CY 2021 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 2021 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2021 would be approximately $769.3 million (approximately $309.8 million for device categories and approximately $459.5 million for drugs and biologicals) which represents 0.92 percent of total projected OPPS payments for CY 2021 (approximately $84 billion). Therefore, we estimate that pass-through spending in CY 2021 will not amount to 2.0 percent of total projected OPPS CY 2021 program spending.

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

For CY 2021, we proposed 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 proposed to continue our payment policy for critical care services for CY 2020. 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 the CY 2021 OPPS/ASC proposed rule, we solicited public comment on any changes to these codes that we should consider for future rulemaking cycles. We encouraged commenters to provide the data and analysis necessary to justify any suggested changes.

The following is a summary of the comments we received and our responses to those comments.

Comment: We received comments suggesting that CMS develop a set of national guidelines for coding hospital emergency department (ED) visits. One commenter cited the June 2019 Medicare Payment Advisory Commission (MedPAC) ''Report to the Congress: Medicare and the Health Care Delivery System,'' which recommended that the Secretary develop and implement a set of national guidelines for coding hospital ED visits under the OPPS by 2022. In this report, MedPAC indicated that national guidelines are necessary in order to improve the accuracy of Medicare payments for ED visits and to regain a distribution of coding frequency that is approximately normal, meaning Level 3 ED visits being the most frequently coded level and Levels 1 and 5 the least frequently coded. MedPAC found that hospitals' coding of ED visits has steadily shifted from the lower levels to the higher levels, and they estimated that 20 to 25 percent of the growth in Medicare spending on ED visits was due to these visits being coded to higher levels. Commenters felt that ''standardized, national guidelines are necessary in order to ensure coding consistency and data comparability across hospitals and to improve payment accuracy.'' Another commenter stated that absent such standards, payers are creating their own criteria and are downgrading higher-level ED evaluation and management services, resulting in a loss of resources and increased administrative burden.

Response: We thank the commenters for their suggestions. As we noted in the CY 2008 OPPS/ASC final rule (72 FR 66579) we understand the interest in promulgating national guidelines but we continue to believe that it is unlikely that national guidelines could apply to the reporting of all ED visits. We may revisit this topic in the future as necessary.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), we adopted a method to control unnecessary increases in the volume of covered outpatient department services under section 1833(t)(2)(F) of the Act by utilizing a Medicare Physician Fee Schedule (PFS)-equivalent payment rate for the hospital outpatient clinic visit (HCPCS code G0463) when it is furnished by excepted off-campus provider-based departments (PBDs). As discussed in section X.D of that proposed rule and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58818 through 59179), CY 2020 was the second year of the 2-year transition for this policy and, beginning in CY 2020, these departments are paid the site-specific PFS rate for the clinic visit service. We note that on September 1, 2019, the United States District Court for the District of Columbia (the district court) entered an order vacating the portion of the CY 2019 OPPS/ASC final

rule with comment period that adopted the volume control method for clinic visit services furnished by nonexcepted off-campus PBDs and remanded the matter to the Secretary for further proceedings consistent with the district court's opinion.[87] In the CY 2020 OPPS/ASC final rule with comment period, we acknowledged that the district court vacated the volume control policy for CY 2019 and we stated that we were working to ensure affected 2019 claims for clinic visits were paid consistent with the court's order. We also stated that we did not believe it was appropriate at that time to make a change to the second year of the 2-year phase-in of the clinic visit policy. We explained that we still had appeal rights, and were evaluating the rulings and considering whether to appeal from the final judgment. On July 17, 2020, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) ruled in favor of CMS, holding that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. For a full discussion of this policy, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

As detailed later in this section, after consideration of public comments, we are continuing the clinic visit payment policy as adopted in CY 2019 rulemaking. We will continue to take information submitted by the commenters into consideration for future analysis.

The following is a summary of the comments we received and our responses to those comments.

Comment: We received comments supporting CMS' efforts to continue implementing its method to control for unnecessary increases in the volume of outpatient services. Commenters expressed their support for site-neutral payment policies in excepted and non-excepted off-campus PBDs that promote greater payment alignment between physicians and hospitals. One commenter noted, ''Over the last decade, our nation has seen a trend of formerly independent physician practices becoming affiliated with major hospital systems.[88] This movement is part of a larger trend of consolidation among health systems and physicians where health systems are able to use their market power to leverage higher prices for all consumers.[89] The purchasing of physician practices by hospital systems has resulted in costs shifting to outpatient facilities where the costs of care are substantially higher. The drive toward higher-cost hospital-based outpatient services has had a direct negative financial impact on Medicare beneficiaries and overall Medicare expenditures. Medicare beneficiaries pay higher copays at hospital outpatient departments (HOPDs) than they do in physician offices, and HOPDs are paid more than twice as much as physicians are paid under the Medicare physician fee schedule for the same service, thereby contributing to excess Medicare expenditures.'' One commenter recommended CMS continue implementing site-neutral payments not just for off-campus PBDs but also for on-campus PBDs, and freestanding and non-freestanding emergency departments.

Response: We appreciate the commenters' support. As we noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143), ''[a] large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the shift of services from (lower cost) physician offices to (higher cost) HOPDs.'' We continue to believe that these shifts in the sites of service are unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting due to payment incentives. In addition to the concern that the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, we remain concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in physician offices. We continue to believe that our method will address the concerns as described in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005).

Comment: We received numerous comments outlining concerns we contemplated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005) and in the CY 2020 OPPS/ASC (84 FR 61142) final rule with comment period. Commenters' expressed that the payment cut for hospital outpatient clinic visits threatens access to care, especially in rural and other vulnerable communities, and that CMS has undermined the clear congressional intent of Section 603 of the Bipartisan Budget Act of 2015 and exceeded its legal authority.

Many commenters asserted that the clinic visit policy is an ''adjustment'' subject to budget neutrality. Commenters expressed concern that we did not create sufficient data analytics to support our policy rationales. Commenters stated that there are several factors in the Medicare program (and outside of hospital control) that could influence more services moving to the hospital outpatient setting, including the hospital readmissions reduction program, hospital value-based purchasing, and the 2-midnight rule. Commenters further stated that care provided at PBDs is held to higher quality standards and thus cannot be directly compared to care provided at physician offices.

Commenters reiterated their comments from the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005) that, relative to patients seen in physician offices, patients seen in HOPDs:

- Have more severe chronic conditions;
- Have higher prior utilization of hospitals and EDs;
- Are more likely to live in low-income areas;
- Are 1.8 times more likely to be dually eligible for Medicare and Medicaid;
- Are 1.4 times more likely to be nonwhite;
- Are 1.6 times more likely to be under age 65 and disabled; and
- Are 1.1 times more likely to be over 85 years old.

Response: We continue to believe that section 1833(t)(2)(F) of the Act gives the Secretary authority to develop a method for controlling unnecessary increases in the volume of covered OPD services, including a method that controls unnecessary volume increases by removing a payment differential that is driving a site-of-service decision, and as a result, is unnecessarily increasing service volume.[90] We also continue to believe shifts in the sites of service described in CY 2019 OPPS/ASC final rule with comment period (83 FR

[87] *American Hospital Ass'n, et al.* v. *Azar,* No. 1:18–cv–02841–RMC (D.D.C. Sept. 17, 2019).

[88] Jeff Lagasse, ''Hospitals acquired 5,000 physician practices in a single year,'' Healthcare Finance, March 15, 2018, *https://www.healthcarefinancenews.com/news/hospitals-acquired-5000-physician-practices-single-year.*

[89] Bela Gorman, Don Gorman, Jennifer Smagula, John D. Freedman, Gabriella Lockhart, Rik Ganguly, Alyssa Ursillo, Paul Crespi, and David Kadish, Why Are Hospital Prices Different? An Examination of New York Hospital Reimbursement, New York: New York State Health Foundation, December 2016, *https://nyshealthfoundation.org/wp-content/uploads/2017/11/an-examination-of-new-york-hospital-reimbursement-dec-2016.pdf.*

[90] Available at: *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

59011) are inherently unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting due to the payment incentives created by the difference in payment amounts. While HOPDs may serve unique patient populations and provide services to medically complex beneficiaries, we have not received data from commenters that demonstrates the need for higher payment for clinic visits furnished in excepted off-campus PBDs. As we asserted in the 2019 OPPS/ASC final rule with comment period (83 FR 59011), the fact that the commenters did not supply new or additional data supporting these assertions suggests that the payment differential is likely the main driver for unnecessary volume increases in outpatient department services, particularly clinic visits.

As we noted in the CY 2019 OPPS/ASC final rule comment period (83 FR 59013), we maintain that while section 1833(t)(9)(B) of the Act does require that certain changes made under the OPPS be made in a budget neutral manner, this provision does not apply to the volume control method under section 1833(t)(2)(F) of the Act. Further, as we stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143), we believe that implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the volume within the OPPS system in the aggregate.

On July 17, 2020, the D.C. Circuit ruled in favor of CMS, holding that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service.[91] The D.C. Circuit concluded that CMS reasonably read subparagraph (2)(F) to allow a service-specific, non-budget-neutral payment reduction in the circumstances presented in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013).[92] On October 16, 2020, appellees' petition for panel rehearing and petition for rehearing en banc were denied.

Comment: We received comments asserting that our site-neutral policies are based on the flawed assumption that Medicare PFS payment rates are sustainable rates for physicians.

Response: As we noted in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142), Medicare payment rates under the PFS for services furnished by physicians and other suppliers are determined as required by the PFS statute, and the rates for individual services are determined based on the resources involved in furnishing these services relative to other services paid under the PFS. To the extent that commenters believe that the PFS rate for a particular service is misvalued relative to other PFS services, we encourage commenters to nominate the service for review as a potentially misvalued service under the PFS.

Comment: Many commenters referenced the ongoing litigation (described earlier in this section). They noted that the American Hospital Association (AHA) is seeking a rehearing by the full D.C. Circuit of the recent decision overturning the district court's ruling in favor of AHA. Several commenters stated that while this issue remains under consideration by the D.C. Circuit, CMS should delay continuing the policy in CY 2021. Some commenters requested that CMS restore the higher payment rates for off-campus HOPDs. Commenters also requested that CMS make remedial payments to hospitals for underpayments in 2019 and 2020. One commenter stated that CMS should not seek recoupment of previously adjusted claims, given hospitals' current financial situations as a result of the ongoing COVID–19 pandemic. They noted that CMS and HHS have sought opportunities to support hospitals throughout the pandemic and one simple way to do so would be to refrain from recouping prior repayments made to hospitals in response to the district court's decision.

Response: As noted earlier in this section, on July 17, 2020, the D.C. Circuit ruled in favor of CMS, holding that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. On October 16, 2020, the D.C. Circuit denied the appellees' petitions for a panel rehearing or a rehearing en banc. The appellees have 90 days from the date of the orders denying their petitions to ask the United States Supreme Court to review the case. We are still considering how we may address any over or underpayments for 2019 claims.

Comment: Many commenters characterized the reductions to hospital payments for clinic visits as excessive and harmful, especially during the COVID–19 PHE. One commenter noted that ''Continuing to impose a 60% cut on clinic visit services in 2021, on top of the dire financial impacts on U.S. hospitals and health systems due to COVID–19, would greatly endanger the critical role that HOPDs play in their communities, including providing convenient access to care for the most vulnerable and medically complex beneficiaries.'' Another commenter asked CMS to reconsider its current policy and exempt Medicare-Dependent Hospitals, Small Rural Hospitals, Sole Community Hospitals (urban and rural) and Rural Referral Centers from all applications of the PFS relativity adjuster.

Response: We share commenter's concerns about the financial difficulties brought on by the COVID–19 PHE. We have taken a variety of actions to support hospitals so they can more effectively respond to the COVID–19 PHE, including waiving the provider-based rules and permitting on-campus and excepted off-campus provider-based departments to temporarily relocate and continue to be paid under the OPPS if they submit a temporary extraordinary relocation exception request to their Regional Office. Additionally, we provided for a 2-year phase-in of this policy to help to mitigate the immediate financial impact on providers.

We share the commenters' concerns about access to care, especially in rural areas where access issues may be more pronounced than in other areas of the country. Medicare has long recognized the unique needs of rural communities and the financial challenges rural providers face. Across the various Medicare payment systems, CMS has implemented a number of special payment provisions for rural providers to maintain access and ensure beneficiaries in rural areas receive high quality care. Under the OPPS, section 1833(t)(13) of the Act gives the Secretary 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 sole community hospitals. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural sole community hospitals of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006. We will continue to monitor trends for any access to care issues and may consider exemptions from the clinic visit policy for future rulemaking.

[91] *Am. Hosp. Ass'n* v. *Azar,* 964 F.3d 1230, 1244–45 (D.C. Cir. July 17, 2020).

[92] *Id.*

After consideration of public comments we received, we are continuing the clinic visit payment policy for CY 2021 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 2021 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 2021) for the clinic visit service in CY 2021. Considering the effects of estimated changes in enrollment, utilization, and case-mix, this policy results in an estimated CY 2021 savings of approximately $430 million, with approximately $340 million of the savings accruing to Medicare, and approximately $90 million saved by Medicare beneficiaries in the form of reduced copayments, when compared to estimated expenditures if the policy were not applied. We will continue to monitor the effect of this change in Medicare payment policy, including the volume of these types of OPD services. We also will continue to evaluate this policy as necessary in response to the ongoing litigation.

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 the CY 2021 OPPS/ASC 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.

B. PHP APC Update for CY 2021

1. PHP APC Geometric Mean Per Diem Costs

In summary, for CY 2021, we are finalizing our proposal to use the CY 2021 CMHC geometric mean per diem cost calculated in accordance with our existing methodology, using the most recent updated claims and cost data, as the basis for developing the CY 2021 CMHC APC per diem rate. We are also finalizing our proposal for CY 2021 to use the CY 2021 hospital-based geometric mean per diem cost calculated in accordance with our existing methodology, using the most recent updated claims and cost data.

In the CY 2021 OPPS/ASC proposed rule, we proposed to use geometric mean per diem cost for CMHCs and hospital-based PHPs, calculated in accordance with our existing methodology as the basis for calculating the APC per diem rates for CMHCs and hospital-based PHPs respectively, but with a cost floor applicable for each APC. We proposed to use the cost floors calculated last year for CY 2020 ratesetting; that is, a cost floor of $121.62 for CMHCs and a cost floor of $222.76 for hospital-based PHPs. Following this methodology, we proposed to use a cost floor value of $121.62 for CMHCs as the basis for developing the CY 2021 CMHC APC per diem rate. We proposed to use the CY 2021 hospital-based PHP geometric mean per diem cost of $243.94, calculated in accordance with our existing methodology for hospital-based PHPs, as the basis for developing the CY 2021 hospital-based APC per diem rate.

Using the most recent updated claims and cost data as proposed, the final CMHC geometric mean per diem cost is $136.14 and the final hospital-based PHP geometric mean per diem cost is $253.76. The final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs are significantly higher than each proposed floor, therefore a floor is not necessary at this time and we are not finalizing the proposed cost floors in this CY 2021 OPPS/ASC final rule with comment period at this time.

Lastly, we are finalizing our proposal 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 policies are discussed in more detail below.

2. Development of the PHP APC Geometric Mean Per Diem Costs

In preparation for CY 2021, 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. The CMHC or hospital-based PHP APC per diem costs are the provider-type specific costs derived from the most recent claims and cost data. 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 CY 2021 OPPS/ASC final rule with comment period.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this CY 2021 OPPS/ASC final rule, prior to calculating the proposed geometric mean per diem cost for CMHC APC 5853, we prepared 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 was 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 excluded 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 2021 ratesetting, 2 CMHCs had geometric mean costs per day below the trim's lower limit of $33.81 or had geometric mean costs per day above the trim's upper limit of $519.84. Therefore, we excluded these 2 CMHCs from ratesetting because of the ±2 standard deviation trim.

In accordance with our PHP ratesetting methodology (80 FR 70465), we also removed service days with no wage index values, because we used the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation. For this CY 2021 OPPS/ASC final rule ratesetting, no CMHC was missing wage index data for all of its service days and, therefore, no CMHC was excluded. We also excluded providers without any days containing 3 or more units of PHP-allowable services. One provider was 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 greater than one to the statewide hospital CCR (80 FR 70457). For this CY 2021 OPPS/ASC final rule ratesetting, there were no CMHCs that showed CCRs greater than one. Therefore, it was not necessary to default any CMHC to its statewide hospital CCR for ratesetting.

In summary, these data preparation steps did not adjust the CCR for any CMHCs with a CCR greater than one during our ratesetting process. We excluded 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. We did not exclude any other CMHCs for any other trims or exclusions or for other missing data. There were 439 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 10,495 CMHC claims in our CY 2021 final 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) to calculate a CMHC APC geometric mean per diem cost.[93] The calculated CY 2021 geometric mean per diem cost for all CMHCs for providing three or more services per day (CMHC APC 5853) is $136.14, an increase from $121.62 calculated last year for CY 2020 ratesetting (84 FR 61347).

In the CY 2021 proposed rule (85 FR 48902) the CY 2021 calculated CMHC APC was $104.00, which we were concerned would not support ongoing access to PHPs in CMHCs. Therefore, we proposed to extend for CY 2021 and subsequent years the cost floor established in the prior year (84 FR 61339 through 61344). Because the final calculated CMHC geometric mean per diem cost for this final rule with comment period is substantially higher than the cost floor, we believe that the final calculated geometric mean per diem cost for CMHCs will effectively support access to partial hospitalization services and PHPs, and therefore the data no longer supports the need to finalize a cost floor at this time.

The CMHC APC 5853 is described as providing three or more partial hospitalization services per day (81 FR 79680), and 85.7 percent of CMHC paid days in CY 2019 were for providing four or more services per day. To be eligible for a PHP, a patient must need at least 20 hours of therapeutic services per week, as evidenced in the patient's plan of care (42 CFR 410.43(c)(1)). To meet those patient needs, most PHP provider paid days are for providing four or more services per day (we refer readers to Table 45—Percentage of PHP Days by Service Unit Frequency of this final rule with comment period). Therefore, the higher calculated geometric mean per diem cost of $136.14 is in line with our expectations, since the CMHC APC 5853 is actually heavily weighted to the cost of providing four or more services. For context, the per diem costs for CMHC APC 5853 have been calculated as $124.92, $143.22, and $121.62 for CY 2017 (81 FR 79691), CY 2018 (82 FR 59378), and CY 2019 (83 FR 58991), respectively.

In our analysis for the CY 2021 proposed rule, we found that six providers, collectively representing 39.7 percent of all CMHC days, reported lower costs per day than those reported for the CY 2020 final rule ratesetting. These six providers heavily influenced the calculated geometric mean per diem cost for CY 2021. Because these providers had a high number of paid PHP days, and because the CMHC data set was so small (n=38), these providers had a significant influence on the calculated CY 2021 CMHC APC geometric mean per diem cost. Based on updated cost and claims data for this final rule, the geometric mean costs for three of these six providers (collectively representing 15.7 percent of all CMHC days) increased substantially along with the geometric mean costs of a fourth provider, such that the final calculated geometric mean per diem cost for all CMHCs increased to $136.14.

For the CY 2021 OPPS/ASC proposed rule, in crafting our proposal, we also considered a 3-year collective PHP geometric mean per diem cost for each provider type calculated using the cost data from the three most recent years, that is the final cost data from CY 2017 and CY 2018, along with the latest available cost data from CY 2019. We also considered a 4-year collective PHP geometric mean per diem cost for each provider type calculated using the cost data from the four most recent years, which is the final cost data from CY 2016, CY 2017, and CY 2018, along with the latest available cost data from CY 2019. We did not ultimately propose either of these methodologies, and we did not receive any comments on these methodologies. Further discussion of these alternatives that we considered is found in the CY 2021 OPPS/ASC proposed rule (85 FR 48904).

In summary, we are finalizing our proposal to use the current year's CMHC APC geometric mean per diem cost (in this case, the CY 2021 CMHC APC geometric mean per diem cost), calculated in accordance with our existing methodology. Since the final calculated CMHC geometric mean per diem cost for this final rule with comment period is substantially higher than the cost floor, we believe that the final calculated geometric mean per diem cost for CMHCs will effectively support access to partial hospitalization services and PHPs, and therefore the data no longer supports the need to finalize a cost floor at this time. We refer readers to section XXIV. of this CY 2021 OPPS/ASC final rule with comment period for payment impacts, which are budget neutral.

We received 8 comments that addressed CMHC ratesetting, which are summarized as follows:

Comment: Nearly all commenters supported our proposed increase to the CMHC payment rate and the efforts by CMS to mitigate fluctuations in CMHC payments and help protect beneficiary access to PHP services. However, several commenters expressed concern that despite the modest, occasional rate increases proposed and finalized in recent years, the results of the proposed PHP ratesetting methodology are contrary to CMS's efforts to protect access. One commenter suggested that CMS consider incorporating an annual adjustment to the cost floor in order to ensure that it reflects updated cost information and continues to help minimize the impact of significant changes in the median costs. Five commenters stated that the current payment methodology has resulted in reductions in provider access rather than protection of access. Several commenters expressed concern about the decline in the number of CMHCs and the effect that further declines would have on beneficiary access to care. These commenters suggested that declining PHP payment rates have been the cause of the decline in the number of CMHCs. One commenter stated that decreased access to CMHC PHP services could force beneficiaries to use more costly hospital-based PHPs, with higher beneficiary co-payments, or lead to increased use of inpatient psychiatric resources. This commenter stated that the data used for CMHC ratesetting are

[93] 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 from the OPSF (or statewide CCR, where the overall CCR was greater than 1) 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.

skewed, the calculations are incorrect, and the proposed low payment rates would result in the remaining CMHCs closing. This commenter noted that setting CMHCs' payment rates based on a small number of CMHCs does not reflect the actual cost of providing these services and expressed concern that by using the mean or median costs, more CMHCs would close.

Response: We thank the commenters for their support, and we also share the commenters' concerns about the decline in the number of PHPs, particularly at CMHCs, and the effect on access. However, it does not directly follow that declining per diem payment rates alone have caused the decline in the number of PHPs. As we have noted in prior rulemaking (76 FR 74350 and 79 FR 66906), the closure of PHPs may be due to a number of reasons, such as business management or marketing decisions, competition, oversaturation of certain geographic areas, and federal and state fraud and abuse efforts, among others. Our goal is to ensure accurate and reasonable payment rates for PHP services that protect access to both provider types, so beneficiaries have choices regarding where to receive treatment. We want to ensure that CMHCs remain a viable option as providers of mental health care in the beneficiary's own community. Also, beneficiaries receiving care at a CMHC instead of a hospital-based PHP may incur lower beneficiary copayments. However, we disagree with the assertion that the CMHC data are skewed and that the calculations are incorrect. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70456 to 70459), we implemented a ±2 standard deviation trim on CMHC costs per day to remove aberrant data that could skew costs up or down inappropriately. We recognize that with a small number of providers, such as the 37 CMHCs used for this final rule rate setting, the calculations can be influenced by large providers, however it is important to note that the influence these providers have is appropriate and proportional to their share of PHP days furnished. In this CY 2021 final rule ratesetting, as discussed previously in this section, updated data from three large providers reflected a significant increase in geometric mean per diem costs. Due to the large share of PHP days that these providers furnished, their increased per diem costs influenced the overall CMHC geometric mean per diem cost calculation.

We also recognize that as the number of providers decreases, the ratesetting calculations can be more strongly influenced by the costs of large providers. We are regularly evaluating our rate setting methodology to ensure that it is as accurate as possible, and captures provider cost data fully. However, our rate setting methodology must comply with requirements at sections 1833(t)(2) and 1833(t)(9) of the Act, and 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, Part 2, available on the CMS website at *https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/PaperBased-Manuals.html*. 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 are confident that the per diem costs we calculate follow the methodology discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 to 70466) and in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79691). Those costs are geometric mean per diem costs, rather than arithmetic mean or median per diem costs; in the CY 2013 OPPS final rule (77 FR 68409), we discussed the advantages of using geometric means rather than medians to calculate PHP costs, and noted that the geometric mean more accurately captures the full range of service costs (including outliers) than the median cost and promotes more stability in the payment system. In summary, we believe that providing payment that is based upon actual provider-reported costs supports access to PHP services and does not lead to provider closures; however, as we noted above, we rely on providers to accurately report their costs in a timely and complete manner.

For CY 2021, after reviewing comments and updated cost and claims data, we are finalizing the CY 2021 CMHC geometric mean per diem cost as $136.14, which is above the proposed cost floor amount and based on updated cost and claims data. We believe this calculated geometric mean per diem cost will support access to PHP services. Therefore at this time, we are not finalizing our proposal to extend the cost floor for CY 2021 or subsequent years. Given the higher than expected calculated CMHC geometric mean per diem cost due to updated data, we do not believe our proposal for a cost floor is necessary for CY 2021 and do not believe it is appropriate to apply this cost floor for subsequent years; in response to the concerns raised by several commenters, we will continue to evaluate the effects of our policies and analyze the latest available cost and claims data to look for ways to further mitigate payment fluctuations and protect beneficiary access to PHP services. We appreciate the commenters' suggestions, and will take them into consideration as we explore future policies. We also refer readers to section VII.B.2.b of this final rule with comment period for a similar comment and response related to hospital-based PHPs.

Comment: Three commenters highlighted the importance of PHP services in the current environment and noted that the need for mental health services in general has increased.

Response: We appreciate the work PHPs do to care for a particularly vulnerable population with serious mental illnesses, and we recognize the particular importance of these programs in the current environment. We believe it is crucial to ensure that providers receive accurate payment in order to provide these necessary services to the PHP population. Based on the latest data, the geometric mean per diem cost for CMHCs is significantly higher than the cost floor that we proposed for CY 2021, and therefore the data does not support finalizing floor at this time in this CY 2021 OPPS/ASC final rule. As noted above, we will continue to look for ways to further mitigate payment fluctuations and protect beneficiary access to PHP services.

Comment: One commenter requested that CMS take into account for future rulemaking the effects that the COVID–19 PHE and the subsequent conversion to virtual care may have on PHP services and the payment methodology for such services.

Response: We appreciate the commenter's suggestion and will take this into consideration as we explore policy options for appropriately strengthening the PHP benefit and increasing access to the valuable services provided by CMHCs as well as by hospital-based PHPs. As part of that process, we regularly review our methodology to ensure that it is appropriately capturing the cost of care reported by providers and will give particular attention to effects of the ongoing COVID–19 PHE.

Comment: One commenter stated that CMHCs incur extra costs to meet the CMHC conditions of participation (CoPs) and have experienced an increase in bad debt expense.

Response: Most (if not all) of the costs associated with adhering to CoPs should be captured in the cost report data used in ratesetting and, therefore, are accounted for when computing the geometric mean per diem costs. Finally, the statutory reduction to bad debt reimbursement was a result of provisions of section 3201 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96). The reduction to bad debt reimbursement impacted all providers eligible to receive bad debt reimbursement, as discussed in the CY 2013 End-Stage Renal Disease final rule (77 FR 67518). Medicare currently reimburses bad debt for eligible providers at 65 percent of such debt. Because this percentage was enacted by Congress, CMS does not have the authority to change the percentage. In contrast to the Medicare bad debt reimbursement policy, private sector insurers typically do not reimburse providers for any amounts of enrollees' unpaid deductibles or coinsurance. In light of budgetary constraints and the steady increase in bad debt claims over the years, a reduction in bad debt reimbursement is necessary to protect the Medicare Trust Fund and preserve beneficiary access to care without imposing an undue burden on hospitals.

Comment: One commenter recommended that CMS pay CMHCs the same rate as hospital-based PHPs, since these two provider types provide the same services and have the same qualified clinical staff. This commenter objected to CMS' continuing use of the single-tier payment system for CMHCs, stating that it adversely affects the quality and intensity of PHP services.

Response: The OPPS pays for outpatient services, including partial hospitalization services, based on the costs of providing services using provider data from claims and cost reports, in accordance with statute. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In addition, by statute at Section 1833(t)(2)(C) of the Act, we are required to use data on claims and most recent available cost reports to establish relative payment weights for covered OPD services. Therefore, we calculate a CMHC APC rate based on costs, which providers supply on their cost reports. While CMHCs and hospital-based CMHCs provide the same clinical services, their resource use differs, because these two provider types have different cost structures. In this final rule and in prior rulemaking, commenters and CMS have noted that hospitals tend to have higher costs than CMHCs, particularly higher overhead (83 FR 58986, 82 FR 59377, and 81 FR 79686 to 79687). We see this difference in cost structures reflected when we calculate the geometric mean cost per day for CMHCs versus for hospital-based PHPs, where CMHC costs per day are consistently lower than hospital-based PHP costs per day. For example, for this CY 2021 OPPS/ASC final rule with comment, the calculated geometric mean costs for providing PHP services were $136.14 per day for CMHCs, but were $253.76 per day for hospital-based PHPs. Therefore, we do not believe it is appropriate to pay CMHCs the same APC rate as hospital-based PHPs. 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, Part 2, available on the CMS website at *https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/PaperBased-Manuals.html*.

We believe our policy to replace the existing Level 1 and Level 2 PHP APCs for both provider types with a single PHP APC, by provider type, is supported by the statute and regulations and will continue to pay for partial hospitalization services appropriately based upon actual provider costs (81 FR 79683). Regarding the commenter's concern about the small number of providers and the use of a single-tier payment system, we refer the commenter to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79682 through 79685), where we discussed our rationale for implementing the single-tier payment system for CMHCs. A key reason behind implementing the single tier for CMHCs was to reduce cost fluctuations and bring more stability to CMHC APC rates, especially given the small number of providers (81 FR 79683). We also noted that the costs of providing a Level 1 CMHC day were nearly the same as the cost of providing a Level 2 CMHC day (81 FR 79684). In accordance with the regulations at 42 CFR 419.31, we could not justify continuing to separate these services into two APCs, but combined clinically similar services with similar resource use into a single APC (81 FR 79683 to 79684).

We do not believe the intensity of PHP services provided in hospitals and in CMHCs has been affected by using a single-tier payment system. Based on the utilization data found in Table 45 of this final rule with comment period, the percentage of paid PHP days which have only three services has been relatively stable over time and has remained consistent for hospital-based PHPs. Even though we identified an increase in 3-service days for CMHCs in 2019, as we note in section VIII.B.3.b of this final rule with comment period, we also identified a noticeable increase in days with 5 or more services. We will continue to monitor the percentage of 3-service days and will also monitor the provision of 20 hours per week of PHP services, to ensure there are no unintended consequences of a single-tier payment system on PHP intensity. We are unable to determine the effects of the single-tier payment on CMHC quality, because there are no quality measures for CMHCs, nor is quality reporting required of CMHCs. However, we do not believe that a single-tier payment system would affect the quality of care provided in a CMHC.

Comment: One commenter suggested that CMS use value-based purchasing for paying CMHCs instead of a cost-based system stating that rewarding providers for higher-quality care, as measured by selected standards is a better way to improve the quality of any service. Other commenters recommended that CMS reconsider its policy positions on PHP services and look for ways to rebuild these services, suggesting that CMS base PHP reimbursement on incentives determined by documented productivity results. These commenters suggested we consider Measurement-based Care and Patient Satisfaction.

Response: We believe ''measurement-based care'' that the commenters cited refers to administering a standardized instrument to measure some aspect of patient symptoms when he or she begins and ends receiving PHP services. This type of measure could inform clinical decision-making and quality improvement activities at minimum, but results could theoretically be used to adjust payment. We also believe that the commenters are asking if CMS could administer patient satisfaction surveys and then reward high-performing PHPs. We responded to a similar public comment in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462) and refer readers to a summary of that comment and our response. Currently, there is no statutory language authorizing incentive payment methodology based on productivity results, patient satisfaction, or value-based purchasing for CMHCs or for outpatient hospital-based PHPs. To reiterate, sections 1833(t)(2) and 1833(t)(9) of the Act set forth the

requirements for establishing and adjusting OPPS payment rates, which are based on costs, and which include PHP payment rates. We note that section 1833(t)(17) of the Act authorizes the Hospital Outpatient Quality Reporting (OQR) Program, which applies a payment reduction to subsection (d) hospitals that fail to meet program requirements. In the CY 2015 OPPS/ASC proposed rule (79 FR 41040), we considered future inclusion of, and requested comments on, the following quality measures addressing PHP issues that would apply in the hospital outpatient setting: (1) 30-Day Readmission; (2) Group Therapy; and (3) No Individual Therapy. We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66957 through 66958) for a more detailed discussion of PHP measures considered for inclusion in the Hospital OQR Program in future years, and of the comments received as a result of the solicitation. CMS also adopted the OAS CAHPS survey in the Hospital OQR Program, beginning with CY 2020 payment determination (2018 data collection) (82 FR 52572 through 52573); however, implementation was delayed until further action in future rulemaking to ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; reaffirm the reliability of national implementation of OAS CAHPS Survey data; and appropriately account for the burden associated with administering the survey in the outpatient setting of care.

However, the Hospital OQR Program does not apply to CMHCs, and there are no quality measures applied to CMHCs.

After careful consideration of the comments and updated data, we are finalizing our proposal to use the CY 2021 CMHC APC geometric mean per diem cost calculated in accordance with our existing methodology. Because the final calculated CMHC geometric mean per diem cost for this final rule with comment period is substantially higher than the cost floor, we believe that the final calculated geometric mean per diem cost for CMHCs will effectively support access to partial hospitalization services and PHPs. Therefore, the data no longer supports the need to finalize a cost floor at this time. In response to the concerns raised by several commenters, we will continue to look for ways to further mitigate payment fluctuations and protect beneficiary access to PHP services. The final CY 2021 CMHC geometric mean per diem cost is $136.14.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this CY 2021 final 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. The CY 2019 PHP claims included data for 449 hospital-based PHP providers for our calculations in this CY 2021 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 this CCR greater than 5 trim removed affected service days from one hospital-based PHP provider from our final 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 final 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. In addition, 6 hospital-based PHP providers were defaulted to their overall hospital ancillary CCRs due to outlier cost center CCR values.

After completing these data preparation steps, we calculated the final CY 2021 geometric mean per diem cost for hospital-based PHP APC 5863 for hospital-based partial hospitalization services 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).[94] The calculated CY 2021 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 $253.76, which is an increase of 8.7 percent from $233.52 calculated last year for CY 2020 ratesetting (84 FR 61344 through 61348). We believe that a hospital-based PHP APC geometric mean per diem cost of $253.76 best supports ongoing access to hospital-based PHPs.

In the proposed rule (85 FR 48902) we stated that we believe access is better supported when the geometric mean per diem cost does not fluctuate greatly. In addition, while the hospital-based PHP APC 5863 is described as providing payment for the cost of three or more services per day (81 FR 79680), 89.1 percent of hospital-based PHP paid service days in CY 2019 were for providing four or more services per day. To be eligible for a PHP, a patient must need at least 20 hours of therapeutic services per week, as evidenced in the patient's plan of care (42 CFR 410.43(c)(1)). To meet those patient needs, most PHP paid service days provide four or more services (we refer readers to Table 45—Percentage of PHP Days by Service Unit Frequency in this final rule). Therefore, the hospital-based PHP APC 5863 is actually heavily weighted to the cost of providing four or more services. The per diem costs for hospital-based PHP APC 5863 have been

[94] 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.

calculated as $213.14, $208.09, and $222.76 for CY 2017 (81 FR 79691), CY 2018 (82 FR 59378), and CY 2019 (83 FR 58991), respectively.

As we noted for CMHCs above, we likewise do not believe that it is likely that the cost of providing hospital-based PHP services would suddenly decline when costs generally increase over time. In order to address concerns about potential fluctuations, which we believed could be influenced by data from a small number of providers with low service costs per day, we proposed to use the CY 2021 hospital-based PHP APC geometric mean per diem cost, calculated in accordance with our existing methodology, but with a cost floor equal to the floor for hospital-based providers of $222.76 calculated last year for CY 2020 ratesetting (84 FR 61344 through 61345), as the basis for developing the CY 2021 hospital-based PHP APC per diem rate. As part of this proposal, we proposed that we would use the most recent updated claims and cost data to calculate CY 2021 geometric mean per diem costs, just as we did for CMHCs. We further proposed that the established hospital-based geometric mean per diem cost floor of $222.76 be extended to CY 2021 and subsequent years and that if the calculated geometric mean per diem cost for a given year is below the floor, then the geometric mean per diem cost that would be used for ratesetting in that year would be equal to the geometric mean per diem cost floor of $222.76. We stated we believed using the CY 2020 hospital-based PHP per diem cost floor as the floor for CY 2021 is appropriate because it is based on very recent hospital-based PHP claims and cost data and would help to protect provider access by preventing wide fluctuation in the per diem costs for hospital-based APC 5863.

While the proposed cost floor would protect hospital-based PHPs if the CY 2021 calculated hospital-based PHP APC geometric mean per diem cost were less than $222.76, the calculated hospital-based PHP geometric mean per diem cost of $243.94 was greater than the floor, and therefore, we proposed this calculated CY 2021 cost for hospital-based PHPs.

For the CY 2021 proposed rule, we also considered a 3-year collective PHP geometric mean per diem cost for each provider type calculated using the cost data from the three most recent years, that is, the final cost data from CY 2017 and CY 2018, along with the latest available cost data from CY 2019. We also considered a 4-year collective PHP geometric mean per diem cost for each provider type calculated using the cost data from the four most recent years, which is the final cost data from CY 2016, CY 2017, and CY 2018, along with the latest available cost data from CY 2019. We did not ultimately propose either of these methodologies, and we did not receive any comments on these methodologies. Further discussion of these alternatives is found in the CY 2021 OPPS proposed rule (85 FR 48904).

In summary, we are finalizing our proposal to use the most recent updated claims and cost data to calculate CY 2021 geometric mean per diem costs, just as we are for CMHCs in the section above. Because the final calculated CY 2021 hospital-based PHP APC geometric mean per diem cost is significantly higher than the proposed floor, we believe that the final calculated geometric mean per diem cost for hospital-based PHPs will effectively support access to partial hospitalization services. The data no longer supports the need to finalize a cost floor at this time, and therefore, we are not finalizing our proposal to extend the established hospital-based geometric mean per diem cost floor of $222.76 to CY 2021 and subsequent years. The final CY 2021 hospital-based PHP geometric mean per diem cost is $253.76. We refer readers to section XXIV of this CY 2021 OPPS/ASC final rule with comment period for a discussion of payment impacts and the budget neutrality adjustment for OPPS rates.

We received 8 comments that addressed hospital-based PHP ratesetting, which are summarized as follows:

Comment: Nearly all commenters supported our proposed increase to the hospital-based PHP payment rate and the efforts by CMS to mitigate fluctuations in hospital-based PHP payments and help protect beneficiary access to PHP services. However, several commenters expressed concern that despite the modest, occasional rate increases proposed and finalized in recent years, the results of the proposed PHP ratesetting methodology are contrary to CMS's efforts to protect access. Several commenters expressed concern about the decline in the number of hospital-based PHPs and the effect that further declines would have on beneficiary access to care. Five of these commenters stated that the current payment methodology has resulted in reductions in provider access rather than protection of access. One commenter suggested that CMS consider incorporating an annual adjustment to the cost floor in order to ensure that it reflects updated cost information and continues to help minimize the impact of significant changes in the median costs.

Response: We thank the commenters for their support, and we also share the commenters' concerns about the decline in the number of PHPs and the effect on access. However, as we stated above, it does not directly follow that declining per diem payment rates alone have caused the decline in the number of PHPs. As we have noted in prior rulemaking (76 FR 74350 and 79 FR 66906), the closure of PHPs may be due to a number of reasons, such as business management or marketing decisions, competition, oversaturation of certain geographic areas, and federal and state fraud and abuse efforts, among others. Our goal is to ensure accurate and reasonable payment rates for PHP services that protect access to both provider types, so beneficiaries have choices regarding where to receive treatment. After reviewing comments and updated costs, for CY 2021, we are finalizing the CY 2021 hospital-based PHP geometric mean per diem cost as $253.76, which is above the cost floor amount and based on updated cost and claims data. We believe this calculated geometric mean per diem cost will support access to hospital-based PHP services. At this time we are not finalizing our proposal to extend the cost floor for CY 2021 or subsequent years. Given the hospital-based PHP geometric mean per diem cost is $253.76, which is above the cost floor, we do not believe our proposal for a cost floor is necessary for CY 2021 and do not believe it is appropriate to apply this cost floor for subsequent years; in response to the concerns raised by several commenters, we will continue evaluate the effects of our policies and analyze the latest available cost and claims data to look for ways to further mitigate payment fluctuations and protect beneficiary access to PHP services. We appreciate the commenters' suggestions, and will take them into consideration as we explore future policies.

We also recognize that as the number of providers decreases, the relative share of PHP days furnished by large providers can increase, such that large providers' costs more strongly influence the ratesetting calculations. We are regularly evaluating our rate setting methodology to ensure that it is as accurate as possible, that it captures provider cost data fully, and that it protects access to PHP services. However, our rate setting methodology must comply with requirements at sections 1833(t)(2) and 1833(t)(9) of the Act, and depends heavily on provider-

reported costs. We strongly encourage hospitals to review cost reporting instructions to be sure they are reporting their costs correctly. These instructions are available in chapter 40 of the Provider Reimbursement Manual, Part 2, available on the CMS website at *https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/PaperBased-Manuals.html*. We also refer readers to section VIII.B.2.a. for a similar comment and response related to CMHCs.

Comment: Three commenters highlighted the importance of PHP services in the current environment and noted that the need for mental health services in general has increased.

Response: We appreciate the work PHPs do to care for a particularly vulnerable population with serious mental illnesses and believe that having PHPs available to beneficiaries helps prevent patient recidivism and inpatient psychiatric admissions, and we recognize the particular importance of these programs in the current environment. We believe it is crucial to ensure that providers receive accurate payment in order to provide these necessary services to the PHP population. Based on the latest data, the geometric mean per diem cost for hospital-based PHPs is significantly higher than the cost floor that we proposed for CY 2021, and therefore the data does not support finalizing floor at this time in this CY 2021 OPPS/ASC final rule.

Comment: One commenter requested that CMS to take into account for future rulemaking the effects that the COVID–19 PHE and the subsequent conversion to virtual care may have on PHP services and the payment methodology for such services.

Response: As mentioned earlier, we will continue to explore policy options for strengthening the PHP benefit and increasing access to the valuable services provided by CMHCs as well as by hospital-based PHPs with particular attention to effects of this PHE. As part of that process, we regularly review our methodology to ensure that it is appropriately capturing the cost of care reported by providers.

Comment: One commenter suggested that CMS use value-based purchasing for paying hospital-based PHPs instead of a cost-based system stating that rewarding providers for higher-quality care, as measured by selected standards is a better way to improve the quality of any service. Other commenters recommended that CMS reconsider its policy positions on PHP services and look for ways to rebuild these services, suggesting that CMS base PHP reimbursement on incentives determined by documented productivity results. These commenters suggested we consider Measurement-based Care and Patient Satisfaction.

Response: We believe ''measurement-based care'' that the commenters cited refers to administering a standardized instrument to measure some aspect of patient symptoms when he or she begins and ends receiving PHP services. This type of measure could inform clinical decision-making and quality improvement activities at minimum, but results could theoretically be used to adjust payment. We also believe that the commenters are asking if CMS could administer patient satisfaction surveys and then reward high-performing PHPs. We responded to a similar public comment in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462) and refer readers to a summary of that comment and our response. Currently, there is no statutory language authorizing incentive payment methodology based on productivity results, patient satisfaction, or value-based purchasing for CMHCs or for outpatient hospital-based PHPs. To reiterate, sections 1833(t)(2) and 1833(t)(9) of the Act set forth the requirements for establishing and adjusting OPPS payment rates, which are based on costs, and which include PHP payment rates. We note that section 1833(t)(17) of the Act authorizes the Hospital OQR Program, which applies a payment reduction to subsection (d) hospitals that fail to meet program requirements. In the CY 2015 OPPS/ASC proposed rule (79 FR 41040), we considered future inclusion of, and requested comments on, the following quality measures addressing PHP issues that would apply in the hospital outpatient setting: (1) 30-Day Readmission; (2) Group Therapy; and (3) No Individual Therapy. We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66957 through 66958) for a more detailed discussion of PHP measures considered for inclusion in the Hospital OQR Program in future years, and of the comments received as a result of the solicitation. CMS also adopted the OAS CAHPS survey in the Hospital OQR Program, beginning with CY 2020 payment determination (2018 data collection) (82 FR 52572 through 52573); however, implementation was delayed until further action in future rulemaking to ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; reaffirm the reliability of national implementation of OAS CAHPS Survey data; and appropriately account for the burden associated with administering the survey in the outpatient setting of care.

After careful consideration of all the comments on the proposed rule and updated data, we used the most recent updated claims and cost data to calculate CY 2021 geometric mean per diem costs in this CY 2021 OPPS/ASC final rule with comment period. The final calculated geometric mean per diem costs for CY 2021 are substantially higher than the proposed cost floors for both CMHCs and hospital-based PHPs. We believe that the final calculated geometric mean per diem costs for CMHCs and hospital-based PHPs will effectively protect access to partial hospitalization services. Therefore, the data no longer supports the need to finalize either the proposed CMHC or hospital-based PHP cost floor at this time. In response to the concerns raised by several commenters, we will continue to look for ways to further mitigate payment fluctuations and protect beneficiary access to PHP services. The final CY 2021 hospital-based PHP geometric mean per diem cost is $253.76.

The final CY 2021 PHP geometric mean per diem costs are shown in Table 43 and are used to derive the final CY 2021 PHP APC per diem rates for CMHCs and hospital-based PHPs. The final CY 2021 PHP APC per diem rates are included in Addendum A to the CY 2021 OPPS/ASC 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*).[95]

[95] As discussed in section XX. of this CY 2021 OPPS/ASC final 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 the CY 2021 OPPS/ASC 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/*

Continued

TABLE 43: CY 2021 PHP APC Geometric Mean Per Diem Costs

CY 2020 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

3. PHP Service Utilization Updates

a. Provision of Individual Therapy

In the CY 2016 OPPS/ASC final rule with comment period (81 FR 79684 through 79685), we expressed concern over the low frequency of individual therapy provided to beneficiaries. The CY 2019 claims data used for the CY 2021 OPPS/ASC proposed rule revealed some changes in the provision of individual therapy compared to CY 2015, CY 2016, CY 2017, and CY 2018 claims data as shown in the Table 44.

TABLE 44: Provision of Individual Therapy, By Provider Type and Claims Year

	Percent of Individual Therapy on Days with 3 Services Only	Percent of Individual Therapy on Days with Four or More Services
CMHCs		
CY 2015 Claims	7.9%	4.4%
CY 2016 Claims	8.5%	5.0%
CY 2017 Claims	4.0%	4.3%
CY 2018 Claims	2.3%	4.5%
CY 2019 Claims	1.1%	4.8%
Hospital-based PHPs		
CY 2015 Claims	4.0%	6.2%
CY 2016 Claims	4.7%	5.8%
CY 2017 Claims	3.9%	5.1%
CY 2018 Claims	3.8%	5.7%
CY 2019 Claims	3.7%	5.7%

As shown in Table 44, the CY 2019 claims show that CMHCs have slightly increased the provision of individual therapy on days with four or more services, compared to CY 2018 claims. However, on CMHC days with three services, the provision of individual therapy decreased sharply from the prior year CY 2018. This appears to follow a downward trend which started in CY 2016 and has continued through CY 2019. In comparing CY 2018 to CY 2019, we see that for CMHCs the provision of 3-service days also sharply increased (this increase is shown in Table 45 in subsection b). The net effect of these two changes is that for all CMHC days with three or more services, the provision of individual therapy decreased from 4.4 percent in CY 2018 to 4.2 percent in CY 2019. We are concerned by this decrease in the provision of individual therapy among CMHCs from CY 2018, and will continue to monitor this trend. As we stated in the CY 2017 final rule with comment period (81 FR 79684 through 79685), the PHP is intensive in nature, and we believe that appropriate treatment for PHP patients includes individual therapy. We continue to encourage providers to examine their provision of individual therapy to PHP patients to ensure that patients are receiving all of the services that they may need.

For hospital-based providers, the CY 2019 claims show that the provision of individual therapy has slightly decreased on days with only 3 services and remained the same on days with four or more services. These very small decreases correspond with a modest increase of less than one tenth of one percent in the provision of individual therapy on all days with three or more services, comparable with fluctuations in prior years.

b. Provision of 3-Service Days

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59378), we stated that we are aware that our single-tier payment policy may influence a change in service provision because providers are able to obtain payment that is heavily weighted to the cost of providing four or more services when they provide only 3 services. We indicated that we are interested in ensuring that providers furnish an appropriate number of services to beneficiaries enrolled in PHPs. Therefore, with the CY 2017 implementation of CMHC APC 5853 and hospital-based PHP APC 5863 for

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

providing 3 or more PHP services per day, we are continuing to monitor utilization of days with only 3 PHP services.

For the CY 2021 OPPS/ASC proposed rule, we used the CY 2019 claims data. Table 45 shows the utilization findings based on the 2019 claims data.

TABLE 45: Percentage of PHP Days by Service Unit Frequency

	CY 2016	CY 2017*	CY 2018*	CY 2019*
CMHCs:				
Percent of Days with three services	4.8%	5.6%	6.9%	14.3%
Percent of Days with four services	70.3%	74.0%	71.2%	60.0%
Percent of Days with five or more services	24.9%	20.5%	21.9%	25.7%
Hospital-based PHPs:				
Percent of Days with three services	10.9%	9.8%	12.0%	10.9%
Percent of Days with four services	64.9%	56.4%	64.0%	65.8%
Percent of Days with five or more services	24.1%	33.9%	24.0%	23.4%

*May not sum to 100 percent by provider type due to rounding.

As shown in Table 45, the CY 2019 claims data used for proposed rule show that for CMHCs, utilization of 3 service days is increasing compared to the 3 prior claim years, whereas it is decreasing for hospital-based providers. Compared to CY 2018, in CY 2019 hospital-based PHPs provided fewer days with three services only, more days with four services only, and fewer days with five or more services. Compared to CY 2018, in CY 2019 CMHCs provided substantially more days with three services, fewer days with four services, and more days with five or more services.

The CY 2017 data were the first year of claims data to reflect the change to the single-tier PHP APCs. Since that time, we have observed a steady increase in the percentage of CMHC days with three services only. We are concerned by this increase, because as noted below, the intent of the PHP is for three-service days to be the exception, rather than the norm. As we noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79685), we will continue to monitor the provision of days with only three services, particularly now that the single-tier PHP APCs 5853 and 5863 are established for providing three or more services per day for CMHCs and hospital-based PHPs, respectively.

It is important to reiterate our expectation that days with only three services are meant to be an exception and not the typical PHP day. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68694), we clearly stated that we consider the acceptable minimum units of PHP services required in a PHP day to be 3 and explained that it was never our intention that three units of service represent the number of services to be provided in a typical PHP day. PHP is furnished in lieu of inpatient psychiatric hospitalization and is intended to be more intensive than a half-day program. We further indicated that a typical PHP day should generally consist of 5 to 6 units of service (73 FR 68689). We explained that days with only three units of services may be appropriate to bill in certain limited circumstances, such as when a patient might need to leave early for a medical appointment and, therefore, would be unable to complete a full day of PHP treatment. At that time, we noted that if a PHP were to only provide days with three services, it would be difficult for patients to meet the eligibility requirement in 42 CFR 410.43(c)(1) that patients must require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care (73 FR 68689).

The following is summary of the comments we received and our responses to those comments.

Comment: Four commenters noted that the data in Table 45 (Table 30 of the CY 2021 OPPS/ASC proposed rule) demonstrate commitment by PHPs to comply with and exceed the 20-hour rule. These commenters noted that the vast majority of claim days for CMHCs and hospital-based PHPs have 4 or more services provided. The commenters noted that PHPs are voluntary, and that they cannot force patients to attend every day. They also noted that the typical patient profile includes behaviors that work against attendance and full daily participation. In addition, the commenters wrote that there are other challenges to providing 20 hours of services per week that are beyond providers' control, such as holidays, weather, and other medical appointments.

Response: We appreciate that most PHP days include 4 or more services being provided. The updated data for this final rule with comment period showed an uptick in the percentage of 3-service days among CMHCs, but we also note that there is an increase in the percentage of days with 5 or more services. We will continue to monitor the data over time. The ''20-hour rule'' the commenters mentioned is from our regulations at 42 CFR 410.43(c) (discussed at 73 FR 68694 to 68695), which require that eligible PHP patients need at least 20 hours of therapeutic services per week, as evidenced in their plan of care. PHPs are intended to be intensive programs that are provided in lieu of inpatient hospitalization. We appreciate the efforts providers have

made to increase beneficiary attendance, and also recognize the provider concerns about circumstances beyond their control which can affect the number of hours of services provided each week. We did not make any proposals related to the 20-hour requirement, and are continuing to monitor the claims data regarding the hours per week of services provided, sending providers informational messaging without affecting payment.

C. Outlier Policy for CMHCs

For CY 2021, we proposed 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 2021 OPPS/ASC final rule with comment period for our general policies for hospital outpatient outlier payments.

We did not receive any public comments on our proposal, and are finalizing it as proposed.

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 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996). 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. We proposed to continue to calculate the CMHC outlier percentage according to previously established policies, and we did not propose any changes to our current methodology for calculating the CMHC outlier percentage for CY 2021. To calculate the CMHC outlier percentage, we followed three steps:

- *Step 1:* We multiplied 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 estimated CMHC outlier payments by taking each provider's estimated costs (based on their allowable charges multiplied by the provider's CCR) minus each provider's estimated CMHC outlier multiplier threshold (we refer readers to section VIII.C.3. of the CY 2021 OPPS/ASC 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 exceeded the threshold, we multiplied that excess by 50 percent, as described in section VIII.C.3. of the CY 2021 OPPS/ASC 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 the CY 2021 OPPS/ASC 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 summed 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 determined 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).

In CY 2019, we designated approximately 0.01 percent of that estimated 1.0 percent hospital outpatient outlier threshold for CMHCs (83 FR 58996), based on this methodology. For CY 2021, we proposed to continue to use the same methodology as CY 2020. Therefore, based on our CY 2021 payment estimates, CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2021, excluding outlier payments. We proposed 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.

We did not receive any public comments on this proposal, and are finalizing our proposal as proposed.

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) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351). For CY 2021, we proposed 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 2021, 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))].

We did not receive any public comments on this proposal, and are finalizing our proposal as proposed.

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 proposed to continue these policies for partial hospitalization services provided through PHPs for CY 2021. 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*).

We did not receive any public comments on this proposal, and are finalizing our proposal as proposed.

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.

For CY 2021, we proposed to continue to apply the 8 percent CMHC outlier payment cap to the CMHC's total per diem payments. We did not receive any public comments on this proposal, and are finalizing our proposal as proposed.

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). We proposed to continue this policy for CY 2021. We did not receive any public comments on this proposal, and are finalizing our proposal as proposed.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

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 longstanding policies for identifying services that are typically provided only in an inpatient setting (referred to as the inpatient only (IPO) list) and, therefore, that will not be paid by Medicare under the OPPS, as well as the criteria we use to review the IPO list each year to determine whether or not any services should be removed from the list. The complete list of codes that describe services that will be paid by Medicare in CY 2021 as inpatient only services is included as Addendum E to this CY 2021 OPPS/ASC proposed rule, which is available via the internet on the CMS website.[96]

B. Proposed Changes to the Inpatient Only (IPO) List

1. Methodology for Identifying Appropriate Changes to IPO List

Currently, there are approximately 1,740 services on the IPO list. Under our current policy, we annually review the IPO list to identify any services that should be removed from or added to the list based on the most recent data and medical evidence available. We have established five criteria to determine whether a procedure should be removed from the IPO list (65 FR 18455). As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we utilize these criteria when reviewing services to determine whether

[96] Note, the IPO list is proposed to be eliminated beginning in CY 2021, with all services being removed from the list over the course of a three-year transition period. The CY 2020 IPO List can be found here: Hospital Outpatient PPS, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.*

or not they 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 note that a procedure is not required to meet all of the established criteria to be removed from the IPO list. The criteria include 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.

2. CY 2021 Proposal To Eliminate the IPO List

The IPO List was established with the implementation of the OPPS in the CY 2000 OPPS/ASC final rule with comment period (65 FR 18455). Using the authority under section 1833(t)(1)(B)(i) of the Act, the IPO List was created to identify services that require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient who would require the surgery and, therefore, the service would not be paid by Medicare under the OPPS. For example, the list includes certain surgically invasive services on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies.

Since the IPO list was established in 2000, we have stated that regardless of how a procedure is classified for purposes of payment, we expect that in every case the surgeon and the hospital will assess the risk of a procedure or service to the individual patient, taking site of service into account, and will act in that patient's best interests (65 FR 18456). We have reiterated this sentiment in rulemaking several times over the years, including in our discussion of the removal of total knee arthroplasty (TKA) from the IPO list in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59383) and most recently when we discussed removing total hip arthroplasty (THA) from the IPO List in the CY 2020 OPPS/ASC final rule with comment period, where we stated that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary (84 FR 61354).

In previous years, we received several comments from stakeholders who believe that we should eliminate the IPO list entirely and instead defer to the clinical judgment of physicians for decisions regarding site of service. For example, in the CY 2000 final rule with comment period, in response to the establishment of the IPO list, commenters stated that they believed CMS was making decisions, such as the appropriate site of service for a particular medical procedure, that should be left to the discretion of surgeons and their patients (65 FR 18455, 18442). In the CY 2012 OPPS/ASC final rule with comment period, a number of commenters suggested that regulations should not supersede the physician's level of knowledge and assessment of the patient's condition, and that the physician can appropriately determine whether a procedure can be performed in a hospital outpatient setting (76 FR 74354). In the CY 2014 rulemaking, we again noted that some commenters requested that the IPO list be eliminated in its entirety (78 FR 75055). Stakeholders have also commented that the exclusion of services from payment under the OPPS is unnecessary and could have an adverse effect on advances in surgical care (65 FR 18442). Furthermore, some stakeholders have suggested that when a service is removed from the IPO list, it creates an expectation among hospitals that the service must be furnished in the outpatient setting, regardless of the clinical judgment of the physician or needs of the patient.

Other stakeholders have supported maintaining the IPO list and consider it an important tool to indicate which services are appropriate to furnish in the outpatient setting and to ensure that Medicare beneficiaries receive quality care. They have agreed that many of the procedures that we designated as ''inpatient only'' are currently performed appropriately and safely only in the inpatient setting (65 FR 18442). Commenters have expressed concerns that without the IPO list, patient safety and care quality could decline, and have noted the potential for surgical complications in response to allowing specific procedures to be paid under the OPPS when performed in the outpatient setting for the Medicare population, such as TKA and THA.

Stakeholders have also supported the use of the IPO list because services included on the IPO list are an exception to the 2-midnight rule and as such are considered appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay and therefore are not subject to medical review by Beneficiary and Family-Centered Care-Quality Improvement Organizations (BFCC–QIOs) for ''patient status'' (that is, site-of-service). We note that in the CY 2020 OPPS/ASC final rule with comment period, we finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities for 2 calendar years following their removal from the IPO list. For CY 2021 and subsequent years, we proposed to continue this 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to Recovery Audit Contractors (RACs), and RAC reviews for ''patient status'' for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. We also sought comment on whether a 2-year exemption continues to be appropriate, or if a longer or shorter period may be more warranted. For more information on these policies please refer to section X.B of the CY 2021 OPPS/ASC proposed rule.

While we agreed with commenters in previous rulemakings that the IPO list was necessary, we stated there are many surgical procedures that cannot be safely performed on a typical Medicare beneficiary in the hospital outpatient setting, and that it would be inappropriate for us to establish payment rates for those services under the OPPS (78 FR 75055). However, recently we have reconsidered the various stakeholder comments requesting that we eliminate the IPO list and reevaluated the need for CMS to restrict payment for certain procedures in the hospital outpatient setting. For the proposed rule, we concluded that we no longer believed there was a need for the IPO list in order to identify services that require inpatient care. Instead, we agreed with past commenters that the physician should use his or her 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 believed

that this change would ensure maximum availability of services to beneficiaries in the outpatient setting.

We also believed that since the IPO list was established, there have been significant developments in the practice of medicine that have allowed numerous services to be provided safely and effectively in the outpatient setting. We acknowledged in the CY 2000 OPPS/ASC final rule with comment period that we believed that emerging new technologies and innovative medical practice were blurring the difference between the need for inpatient care and the sufficiency of outpatient care for many services (65 FR 18456). We also stated in the CY 2001 OPPS/ASC interim final rule with comment period that, over time, given advances in technology and surgical technique, many of the procedures that were on the IPO list at the time may eventually be performed safely in a hospital outpatient setting and that we would continue to evaluate services to determine whether they should be removed from the IPO list (65 FR 67826). Specifically, we stated that insofar as advances in medical practice mitigate concerns about these services being furnished on an outpatient basis, we would be prepared to remove them from the IPO list and provide for payment under the OPPS (65 FR 67826). Since that time, there have been many new technologies and advances in surgical techniques and surgical care protocols, including the use of minimally invasive surgical procedures such as laparoscopy, improved perioperative anesthesia, expedited rehabilitation protocols, as well as significant enhancements to postoperative processes, such as improvements in pain management, that have reduced the inpatient length of stay and the need for postoperative care following a surgical service. In consideration of these advancements, we have removed services from the IPO list that were previously considered to require inpatient care, including TKA in CY 2018 (82 FR 59385) and THA in CY 2020 (84 FR 61355). 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. Therefore, we believed that the IPO list was no longer necessary to identify services that require inpatient care.

In the CY 2021 OPPS/ASC proposed rule, we acknowledged the seriousness of the concerns regarding patient safety and quality of care that various stakeholders have expressed regarding removing procedures from the IPO list or eliminating the IPO list altogether. However, we stated that we believe that the evolving nature of the practice of medicine, which has allowed more procedures to be performed on an outpatient basis with a shorter recovery time, in addition to physician judgment, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings, even in the absence of the IPO list. In the past, we stated that although hospitals must meet minimum safety standards through accreditation or state survey and certification of compliance with the CoPs that ensure a hospital is generally safe and an appropriate environment for providing care, we were concerned that those measures did not determine whether a particular service could be safely provided in the outpatient setting to beneficiaries (76 FR 74355). However, the CoPs are regulations that are focused on protecting the health and safety of all patients receiving services from Medicare enrolled providers. The CoPs are the baseline health and safety requirements for Medicare certification. Accrediting organizations and states and localities, through their licensure authorities, may have more specific and stringent requirements. Often professional organizations or other nonprofit organizations give additional guidance to health care providers to improve patient safety and quality of care. We note that the CoPs already require hospitals to be in compliance with applicable Federal laws related to the health and safety of patients (42 CFR 482.11) Additionally, there are numerous provisions in the hospital CoPs at 42 CFR part 482 that provide extensive patient safeguards and that provide enough flexibility to ensure that hospitals can follow nationally recognized standards of practice and of care, where they are applicable, and can adapt if those standards change over time through innovative new practices.

Additionally, as indicated in the 2020 Quality Strategy,[97] CMS has also continued to develop safety measures and tools, like the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey and the CMS' case management system, to help determine the safety and quality of the performance of procedures in the outpatient setting and to address concerns about the safety and quality of more varied, complex procedures performed in the outpatient setting. We stated in the CY 2021 OPPS/ASC proposed rule that we believe that the aforementioned federally established CoPs, the CMS Quality Strategy and state and local safety requirements help ensure important patient safeguards for all patients, including Medicare beneficiaries. Further, although we believe it was important to pause certain medical contractor reviews for patient status to allow providers time to adjust to the proposed changes to the IPO list, we note that the BFCC–QIO program's beneficiary case review contractors routinely address, and will continue to address any beneficiary quality of care complaints that include concerns about treatment as a hospital inpatient or outpatient, not receiving expected services, early discharge, and discharge planning. CMS' case management system currently allows QIOs and CMS to monitor the frequency and status of beneficiary quality of care complaints and other beneficiary appeals by topic, provider type, and geographic area. These numbers are compiled by the BFCC–QIO national coordinating and oversight review contractor and reported to the QIOs and CMS leadership on a weekly basis for monitoring purposes. As previously noted, although we proposed to continue a 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to Recovery Audit Contractors (RACs), and RAC reviews for ''patient status'' for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021, BFCC–QIOs will continue to conduct initial medical reviews for both the medical necessity of the services, the medical necessity of the site of service, and will also continue to be permitted and expected to deny claims if the service itself is determined not to be reasonable and medically necessary as noted in the CY 2020 OPPS/ASC final rule (84 FR 61365). Therefore, given CMS' 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 stated that we believe that quality of care was unlikely to be negatively affected by the elimination of the IPO list. However, we also requested that commenters submit evidence on what effect, if any, they believe eliminating the IPO list would have on the quality of care.

[97] Speech: Remarks by CMS Administrator Seema Verma at the 2020 CMS Quality Conference, *https://www.cms.gov/newsroom/press-releases/speech-remarks-cms-administrator-seema-verma-2020-cms-quality-conference.*

Furthermore, we explained that some stakeholders had previously shared concerns with us that removing procedures from the IPO list and allowing them to be paid under the OPPS when performed in the outpatient setting might result in an increased financial burden for beneficiaries for certain complex services. Under current law, the OPPS cost-sharing for a service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. However, this cap applies to individual services, so if a Medicare beneficiary receives multiple separately payable OPPS services, it is possible that the aggregate cost-sharing for a beneficiary may be higher for services provided in the outpatient setting than it would be had the services been furnished during an inpatient stay. We emphasized in the CY 2021 OPPS/ASC proposed rule that services included on the IPO list tend to be surgical procedures that would typically be the focus of the hospital outpatient stay and would likely be assigned to a comprehensive APC (C–APC) when they are removed from the IPO list. As such, these services would likely be considered a single episode of care with one payment rate and one copayment amount instead of multiple copayments for each individual service. In most instances, we expect that beneficiaries will not be responsible for multiple copayments for individual ancillary services associated with services removed from the IPO list, since because of their assignment to C–APCs, the inpatient deductible cap will apply to the entire hospital claim which is paid as a comprehensive service or procedure. In the event there are separately payable OPPS services included on a claim with a service assigned to a C–APC, our previously mentioned policy remains applicable, which is that the OPPS cost-sharing for an individual service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. For further information regarding beneficiary copayments, please refer to section II.I.1. of the CY 2021 OPPS/ASC proposed rule.

After careful consideration of the need for the IPO list and taking into account the feedback that we have received since the OPPS was implemented, we stated in the CY 2021 OPPS/ASC proposed rule that we believe that instead of maintaining a list of services that typically require inpatient care and are not paid under the OPPS, physicians should continue to use their clinical knowledge and judgment to appropriately determine whether a procedure can be performed in a hospital outpatient setting or whether inpatient care is required for the beneficiary based on the beneficiary's specific needs and preferences, subject to the general coverage rules requiring that any procedure be reasonable and necessary, and that payment should be made pursuant to the otherwise applicable payment policies. We also stated that we believe that developments in surgical technique and technological advances in the delivery of services may obviate the need for the IPO list. Finally, we also stated that we believe physician judgment, state and local regulations, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and other CMS quality and monitoring initiatives would continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings in the absence of the IPO list. Therefore, we proposed to eliminate the IPO list over a transitional period beginning in CY 2021. We also stated that while we believe that the list could be eliminated in its entirety at this point, as explained in further detail below, we proposed a transitional period.

Given the significant number of services on the list and that they would be newly priced under the OPPS, we recognized that stakeholders may need time to adjust to the removal of procedures from the list. Providers may need time to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the inpatient prospective payment system or outpatient prospective payment system. Therefore, we proposed to transition services off the IPO list over a 3-year period, with the list completely eliminated by 2024. In accordance with this proposal, we proposed to amend 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024.

For CY 2021, we proposed that musculoskeletal services would be the first group of services that would be removed from the IPO list. We stated that we believe it is appropriate to remove this group of services first for several reasons. In recent years, due to new technologies and advances in surgical care protocols, expedited rehabilitation protocols, and significant enhancements to 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' historical requests for removals were for musculoskeletal services. We also recognized that there is already a set of comprehensive APCs for musculoskeletal services for payment in the outpatient setting, which facilitates the removal of these types of services 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, these APCs generally describe appropriate ranges and placements for these musculoskeletal codes being proposed for removal in CY 2021, which will allow for appropriate payment. We identified 266 musculoskeletal services that we proposed to remove from the IPO list for CY 2021.

Comment: Numerous commenters, including some medical specialty societies, health systems, and individual physicians, supported our proposal to eliminate the IPO list and defer to physicians' judgment on site of service decisions. These commenters stated that CMS' efforts to remove regulatory barriers would provide patients with more choices for where to receive affordable care. The commenters also believed the proposed change could potentially decrease overall healthcare costs and improve clinical outcomes for patients. These commenters stated that there is no clinical difference between a surgery performed in an inpatient setting and an outpatient setting, and that eliminating the IPO list would create more flexibility for physicians and beneficiaries.

Response: We thank the commenters for their support.

Comment: Many commenters, including hospital associations, health systems, medical specialty societies and professional organizations, and advocacy groups opposed the elimination of the IPO list due to patient safety concerns, stating that the IPO list serves as an important programmatic safeguard and maintains a common standard in the Medicare program. These commenters stated that the high-risk, invasive procedures that require post-operative monitoring that are currently included on the IPO list

would not be safe to perform on Medicare beneficiaries in the outpatient setting. These commenters also stated that CMS should retain its current process for evaluating and removing procedures from the IPO list through rulemaking. Alternatively, several commenters requested that instead of eliminating the IPO list, CMS maintain the list specifically for a smaller number of procedures that are complex, surgically invasive, and should never be performed in the outpatient setting. Other commenters requested that specific CPT codes proposed to be removed from the IPO list for CY 2021 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).

Response: We acknowledge the commenters' important concerns regarding the elimination of the IPO list and the potential for safety risks for Medicare beneficiaries. We continue to believe that physicians can and should use their clinical knowledge and judgment to appropriately determine whether a procedure can be performed in a hospital outpatient setting or whether inpatient care is required for the beneficiary based on the beneficiary's specific needs and preferences, subject to the general coverage rules requiring that any procedure be reasonable and necessary, and that payment should be made pursuant to the otherwise applicable payment policies. We believe that patient safety and quality of care will be safeguarded by the physician's assessment of the risk of a procedure or service to the individual beneficiary and their selection of the most appropriate setting of care based on this risk in addition to state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs. In addition, as we have stated in previous rulemaking, the removal of a service from the IPO list does not require the service to be performed only on an outpatient basis. Rather, it allows for payment under the OPPS when the service is performed on a registered hospital outpatient (82 FR 59384; 84 FR 61354). Services that are removed from the IPO list can and are performed on individuals who are admitted as inpatients (as well as individuals who are registered hospital outpatients). We also continue to believe that there have been significant developments in the practice of medicine that have allowed numerous services to now be provided safely and effectively in the outpatient setting. Therefore, at this time, we do not believe it is necessary for CMS to maintain a list of services that typically require inpatient care and are not paid under the OPPS nor do we currently believe that it is necessary to require specific HCPCS codes to remain payable only when furnished in the inpatient setting.

Comment: We received comments from physicians and medical specialty societies who stated that, while they agreed that physicians should be the primary arbiters regarding the clinically appropriate site of service for a procedure, a physician's medical judgment is not always paramount in this decision-making. These commenters noted that when procedures are removed from the IPO list, many hospitals and commercial payors make rules establishing outpatient status as the assumed baseline site of service for these procedures, regardless of patient characteristics or the physician's clinical assessment. Commenters noted various reasons for this action on the part of hospitals and commercial payors, including concerns regarding the application of the 2-midnight benchmark to services that are removed from the IPO list and the potential for claim denials if this benchmark is not met and/or excessive administrative burden to support the case-by-case exception to the 2-midnight rule, misinterpretation of CMS' rulemaking guidance, or the desire to have the procedure performed in a lower cost setting. According to commenters, physicians must, at times, convince a hospital or payor that a particular patient should receive a given procedure in an inpatient setting due to patient safety concerns. Commenters requested that CMS issue clear guidance that encourages consideration of and deference to the judgment of the physician, professional societies, and hospital associations regarding the procedures that are appropriate to be performed in the HOPD.

Response: CMS has repeatedly recognized that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and on the general coverage rules requiring that any procedure be reasonable and necessary. We continue to believe that deference should be given to physicians and medical professionals in these determinations. In accordance with section 1801 of the Act, CMS does not control or supervise the practice of medicine or the manner in which medical services are provided. We also reiterate that we do not require services that are no longer included on the IPO list to be performed solely in the outpatient setting and that following elimination of the IPO list, services that were previously identified as inpatient-only can continue to be performed in the inpatient setting. It is not CMS' policy to require services that are removed from the IPO list to only be performed in the outpatient setting. Instead, we aim to offer providers enhanced flexibility and choice in determining the safest, most efficient setting of care for Medicare beneficiaries, whether that is the inpatient or outpatient setting. It is a misinterpretation of CMS payment policy for providers to create policies or guidelines that establish the outpatient setting as the baseline or default site of service for a procedure based on its removal from the IPO list or the elimination of the IPO list. As stated in previous rulemaking, services that are no longer included on the IPO list are payable in either the inpatient or outpatient setting subject to the general coverage rules requiring that any procedure be reasonable and necessary, and payment should be made pursuant to the otherwise applicable payment policies (84 FR 61354; 82 FR 59384; 81 FR 79697).

As discussed in detail in previous rulemaking (84 FR 61363 through 61365) as well as in section X.B. of this final rule with comment period, the 2-midnight benchmark, which provides that an inpatient admission is considered reasonable and necessary for purposes of Medicare Part A payment when the physician expects the patient to require hospital care that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation, is applicable to services that have been removed from the IPO list. Additionally, as we have detailed in previous rulemaking (80 FR 70538 through 70549), we allow for case-by-case exceptions to the 2-midnight benchmark, whereby Medicare Part A payment may be made for inpatient admissions where the admitting physician does not expect the patient to require hospital care spanning 2 midnights, if the documentation in the medical record supports the physician's

determination that the patient nonetheless requires inpatient hospital care. We acknowledge commenters' concerns regarding the application of the 2-midnight benchmark to services that are removed from the IPO list. While services removed from the IPO list are no longer subject to the blanket IPO list exception from the 2-midnight rule at 42 CFR 412.3(d)(2), such services may be payable under Part A pursuant to either the 2-midnight benchmark at § 412.3(d)(1) or the case-by-case exception at § 412.3(d)(3). In addition, beginning in CY 2020, we have allowed an exemption from certain medical review activities related to the 2-midnight rule for procedures that have been recently removed from the IPO list. Specifically, while inpatient claims for procedures that have been removed from the IPO list may be reviewed by the BFCC–QIOs for purposes of providing education to practitioners and providers on compliance with the 2-midnight rule, those claims identified as noncompliant will not be denied for such noncompliance within the first 2 calendar years of their removal from the IPO list. Additionally, 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 are these procedures reviewed by RACs for ''patient status.'' As discussed further in section X.B of this final rule, for CY 2021, we are finalizing a proposal to extend the medical review exemption period indefinitely for a service newly removed from the IPO list beginning in CY 2021, until there is data indicating that the procedure removed is more commonly performed in the outpatient setting than in the inpatient setting. We believe this exemption from certain medical review activities in combination with the fact that many inpatient admissions for procedures formerly on the IPO list are likely to meet either the 2-midnight benchmark or the case-by-case exception to that benchmark mitigates the concerns regarding denial of payment under Medicare Part A for procedures no longer included on the IPO list. Lastly, with regard to the behavior of commercial insurance providers and site selection for outpatient services, while we believe that these comments are outside the scope of the proposed rule, we note that commercial providers establish their own rules regarding payment for services.

Comment: Several commenters requested that if the proposal to eliminate the IPO list is finalized, CMS provide baseline criteria or guidance for providers to consider when determining which services would be appropriate to furnish in the outpatient setting based upon peer-reviewed evidence, patient factors including age, co-morbidities, social determinants, and other factors relevant to positive patient outcomes. Commenters urged CMS to develop national guidelines outlining beneficiaries who are appropriate candidates for the inpatient vs outpatient setting, particularly for services that generally have a short length of stay (*i.e.* do not meet the 2-midnight benchmark).

Response: We again emphasize that the decision about the most appropriate care setting for a given surgical procedure is a complex medical judgment and we believe this decision should be based on the beneficiary's individual clinical needs and on the general coverage rules requiring that any procedure be reasonable and necessary. However, we understand that with over 1,700 services currently included on the IPO list, the elimination of the list over the three-year period will vastly increase the number of services that are newly payable in the outpatient setting. It will take time for clinical staff and providers to gain experience furnishing these services to the appropriate Medicare beneficiaries in the HOPD in order to develop comprehensive patient selection criteria and other protocols to identify whether a beneficiary can safely have these procedures performed in the outpatient setting. We agree with the commenters that, in the near term, in light of the elimination of the IPO list over a three-year period, physicians and providers could benefit from having access to general considerations for physicians regarding the types of services that may continue to be more appropriately performed in the inpatient setting for Medicare beneficiaries. Therefore, in the future, we plan to provide information on appropriate site of service selection to support physicians' decision-making. We note that these considerations will be for informational or educational purposes only and will not supersede physicians' medical judgment about whether a procedure should be performed in the inpatient or outpatient hospital setting.

Comment: Some commenters also noted the potential for negative financial impacts for both providers and beneficiaries with the elimination of the IPO list. Commenters stated that beneficiaries who require more than one outpatient hospital procedure delivered in separate episodes of care could be subject to multiple co-payments that may, when combined, exceed the inpatient deductible. Other commenters, particularly hospital associations and health systems, stated that a shift in site of service from the inpatient setting to the outpatient setting for numerous procedures could be financially disadvantageous for providers because the patients who would continue to receive these services as inpatients would likely be the more complex cases and more costly to treat. These commenters stated that this financial impact would be particularly significant in light of the COVID–19 pandemic.

Response: As stated in the CY 2021 OPPS/ASC proposed rule (85 FR 48911), services included on the IPO list tend to be surgical procedures that, if performed on an outpatient basis, would typically be the focus of the hospital outpatient stay and would likely be assigned to a comprehensive APC (C–APC) when they are removed from the IPO list. As such, these services would likely be considered a single episode of care with one payment rate and one copayment amount. In most instances, we expect that beneficiaries will not be responsible for multiple copayments for individual ancillary services associated with services removed from the IPO list, because the primary service will be assigned to a C–APC and the inpatient deductible cap will apply to the entire hospital claim, which is paid as a comprehensive service. All 298 services that are being removed from the IPO list beginning in CY 2021 are assigned status indicator ''J1'' and will receive payment through C–APCs, except for 34 services that are assigned status indicator ''N'', which indicates that payment for the service is packaged into payment for other services and there is no separate APC payment, and two services assigned status indicator ''Q1'' which indicates conditionally packaged payment. CPT code 44314 (Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)), is the only code to be removed from the IPO list that is assigned status indicator ''T'', indicating that it is a separately paid procedure. The vast majority of the procedures being removed from the IPO list for CY 2021 are assigned to C–APCs or packaged into payment for other services, which will result in beneficiaries paying one copayment amount. Therefore, we do not believe that beneficiaries will be significantly impacted through increased cost sharing for services that were on the IPO list and are furnished in the hospital outpatient department setting.

In the event there are separately payable OPPS services included on a claim with a service assigned to a C–APC, our previously mentioned policy

remains applicable; that is, the OPPS cost-sharing for an individual service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. For further information regarding beneficiary copayments, please refer to section II.I.1. of this final rule.

With regard to stakeholder concerns about providers experiencing negative financial effects because of services transitioning from the inpatient setting to the lower cost outpatient setting, we understand the numerous challenges that providers are facing due to the COVID–19 public health emergency. We reiterate that providers retain the flexibility to provide services that are no longer included on the IPO list in the inpatient setting and that these services will remain payable under Medicare Part A when appropriate in accordance with the 2-midnight rule and general coverage rules. We also refer readers to the discussion of exemption from certain medical review activities for services removed from the IPO list in section X.B. of this final rule with comment period. Similar to other services that have been removed from the IPO list in previous years, we expect that the volume of services currently being performed in the inpatient setting that can be appropriately performed in the outpatient setting will gradually shift as physicians and providers gain experience furnishing these services to the appropriate Medicare beneficiaries in the HOPD. Therefore, we do not expect that providers will experience a significant financial impact due to the elimination of the IPO list.

Comment: Commenters expressed concerns regarding the proposed APC assignments for procedures proposed to be removed from the IPO list and stated that CMS did not provide sufficient detail as to how the proposed APC placements were determined. Some commenters also believed that the proposed APC payments did not adequately reflect the costs associated with providing the procedure in the outpatient setting and that there was a significant differential between MS–DRG payment and APC payment for some procedures. One commenter also disagreed with the proposed APC assignment of APC 5115 (Level 5 Musculoskeletal Procedures) for the following HCPCS codes: 27702 (Arthroplasty, ankle; with implant (total ankle)), 27703 (Arthroplasty; revision, total ankle), 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (*e.g.,* total shoulder))) and 23473 (Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component), stating that the geometric mean costs of these procedures is more similar to the geometric mean costs of procedures assigned to APC 5116 (Level 6 Musculoskeletal Procedures). The commenter noted the assignment of HCPCS code 27702 to APC 5115 would have created a 2 times rule violation within this APC based on geometric mean costs; however, the procedure did not have enough claims volume to be considered a significant procedure and therefore was not considered in the evaluation of 2 times rule violations. The commenter requested that all these procedures be assigned to C–APC 5116 for CY 2021.

Response: We assign services payable under the OPPS, including services removed from the IPO list, to APCs based on their similarity to other codes within the APC in terms of clinical characteristics and resource use. Based on the claims data currently available for procedures removed from the IPO list and the clinical characteristics of the procedures, we believe that the 266 musculoskeletal procedures being removed from the IPO list for CY 2021, including HCPCS codes 27702, 27703, 23472, and 23473, are appropriately assigned to the C–APCs identified in Table 48—Services Removed from the Inpatient Only (IPO) List for CY 2021. We will continue to monitor these procedures and claims data as they become available to determine if assignment to other APCs is appropriate. We refer readers to Section III.D.17 of this final rule with comment period for a discussion of the musculoskeletal procedure APC series (APCs 5111 through 5116).

Comment: Commenters raised concerns about the effect of the elimination of the IPO list on the target pricing of payment models administered by the Center for Medicare and Medicaid Innovation (CMS Innovation Center), such as the Bundled Payments for Care Initiatives, the Bundled Payments for Care Initiatives (BPCI) Advanced Model, and the Comprehensive Care for Joint Replacement Model and requested that CMS ensure that any changes to the IPO list do not unfairly penalize model participants.

Response: As we have stated in previous rulemaking (82 FR 59384 and 84 FR 61355) when commenters raised similar concerns when total knee arthroplasty and total hip arthroplasty were removed from the IPO list, the CMS Innovation Center will monitor the overall volume and complexity of cases performed in hospital outpatient departments to determine whether any future refinements to the CJR, BPCI, and BPCI Advanced Models are warranted. The Innovation Center may consider making future changes to these models to address the elimination of the IPO list and subsequent performance of procedures previously identified as inpatient-only in the outpatient hospital setting.

Comment: Commenters also raised concerns about the impact of this policy on the 3-day stay requirement for skilled nursing facility care. By statute, beneficiaries must have a prior inpatient hospital stay of no fewer than three consecutive days to be eligible for Medicare coverage of inpatient SNF care. Specifically, commenters stated that the elimination of the IPO list may have a significant impact on Medicare beneficiaries' ability to obtain a three day inpatient stay to qualify for SNF care.

Response: We reiterate that removal of procedures from the IPO list does not require the procedures to be performed only on an outpatient basis. Removal of procedures from the IPO list allows for payment of the procedure in either the inpatient setting or the outpatient setting. A prior 3-day inpatient hospital stay remains a statutory requirement for SNF coverage. However, as stated in the CY 2018 final rule with comment period (82 FR 59384), in our discussion of the removal of TKA from the IPO list, we would expect that Medicare beneficiaries who are identified as appropriate candidates to receive a surgical procedure in the outpatient setting instead of being admitted as an inpatient, would not be expected to require SNF care following surgery. Instead, we expect that many of these beneficiaries would be appropriate for discharge to home (with outpatient therapy) or home health care.

Comment: Commenters noted that there are anesthesia codes related to some of the musculoskeletal procedures proposed to be removed from the IPO list for CY 2021 that were not proposed to be removed from the list. These commenters requested that these related anesthesia services also be removed from the IPO list for CY 2021. In addition to these requests, at the August 31, 2020 meeting, the Advisory Panel on Hospital Outpatient Payment (HOP Panel) recommended that we remove the 16 additional procedures in Table 47 from the IPO list and assign these procedures to C–APCs.

Response: We appreciate the comments. We reviewed the IPO list for CPT codes describing anesthesia services that are related to the musculoskeletal procedures that we have proposed to remove from the IPO

list beginning in CY 2021. After our analysis, we agree with the commenters that the anesthesia codes that are billed with services that were proposed to be removed from the IPO list for CY 2021 should also be removed from the IPO list for CY 2021. Therefore, we are removing the 16 anesthesia codes from the IPO list for CY 2021.

We also accept the HOP panel recommendation to remove 16 additional procedures from the IPO list. The anesthesia services are included in Table 46 below. The CPT codes recommended for removal from the IPO list by the HOP panel are included in Table 47 below. We refer readers to Table 48 for the final list of all procedures we are removing from the IPO list for CY 2021.

BILLING CODE 4120–01–P

TABLE 46. – Anesthesia Services Removed from IPO List Beginning in CY 2021

CPT Code	Long Descriptor	CY 2021 OPPS Status Indicator
00192	Anesthesia for procedures on facial bones or skull; radical surgery (including prognathism)	N
00474	Anesthesia for partial rib resection; radical procedures (eg, pectus excavatum)	N
00604	Anesthesia for procedures on cervical spine and cord; procedures with patient in the sitting position	N
00904	Anesthesia for; radical perineal procedure	N
01140	Anesthesia for interpelviabdominal (hindquarter) amputation	N
01150	Anesthesia for radical procedures for tumor of pelvis, except hindquarter amputation	N
01212	Anesthesia for open procedures involving hip joint; hip disarticulation	N
01232	Anesthesia for open procedures involving upper two-thirds of femur; amputation	N
01234	Anesthesia for open procedures involving upper two-thirds of femur; radical resection	N
01274	Anesthesia for procedures involving arteries of upper leg, including bypass graft; femoral artery embolectomy	N
01404	Anesthesia for open or surgical arthroscopic procedures on knee joint; disarticulation at knee	N
01486	Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement	N
01634	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; shoulder disarticulation	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
01638	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement	N
01756	Anesthesia for open or surgical arthroscopic procedures of the elbow; radical procedures	N

TABLE 47. – HOP Panel-Recommended Procedures Removed from the IPO List Beginning in CY 2021

CPT Code	Long Descriptor	Related Services	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral	35321	J1	5184
35800	Exploration for postoperative hemorrhage, thrombosis or infection; neck	35800	J1	5184
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation)	37183	J1	5193
37617	Ligation, major artery (eg, post-traumatic, rupture); abdomen	37615	J1	5183
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	38571	J1	5362
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	43830	J1	5331
44300	Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression) (separate procedure)	43246	J1	5302
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)	44340	T	5055
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)	47536	J1	5341
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	47533	J1	5341
44602	Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation	43870	J1	5303
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	44950	J1	5341

49255	Omentectomy, epiploectomy, resection of omentum (separate procedure)	44950	J1	5341
51840	Anterior vesicourethropexy, or urethropexy (eg, marshall-marchetti-krantz, burch); simple	51845	J1	5341
56630	Vulvectomy, radical, partial;	57530	J1	5415
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	93581	J1	5194

BILLING CODE 4120–01–C

3. Comment Solicitation on Order of Removal of Additional Clinical Families From the IPO List During the Transition To Complete Elimination of the IPO List

As stated above, we proposed to eliminate the current IPO list of 1,740 services, starting with the 266 musculoskeletal-related services, which were listed in Table 31 of the CY 2021 OPPS/ASC proposed rule (85 FR 48912). We requested comments from the public on whether three years was an appropriate time frame for the transition, whether there are other services that would be ideal candidates for removal from the IPO list in the near term given known technological advancements and other advances in care, and the order of removal of additional clinical families and/or specific services for each of the CY 2022 and CY 2023 rulemakings until the IPO list is completely eliminated. Additionally, we sought comment on whether we should restructure or create any new APCs to allow for OPPS payment for services that are removed from the IPO list. We also solicited public comments on whether any of the musculoskeletal codes proposed for removal from the IPO list for CY 2021 may meet the criteria to be added to the ASC Covered Procedures List. We refer readers to section XIII.C.1.c. of the CY 2021 OPPS/ASC proposed rule for a complete discussion of the ASC Covered Procedures List.

Comment: Several commenters, including several hospital associations, medical specialty societies, and MedPAC requested we delay the elimination of the IPO list until a comprehensive evaluation of the procedures on the list has occurred. They felt a more thorough review of the services proposed for removal is appropriate due to the large number of services on the IPO list across a range of medical specialties. Commenters suggested various time frames for eliminating the IPO list that ranged from three years to seven years. Several hospital associations recommended we delay eliminating the list until we address patient safety concerns and provide national guidelines outlining patients who are appropriate candidates for care in the inpatient hospital versus outpatient hospital setting. One commenter 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 procedures. Some hospital systems also requested a delay, noting that the timing of the proposed change is particularly difficult in light of the COVID–19 pandemic.

Response: We thank commenters for their feedback. However, we do not believe it is necessary to delay eliminating the IPO list over the course of a three-year transition beginning in CY 2021. We are finalizing a three-year transition for removing procedures from the IPO list and enabling them to be paid under the OPPS, with the list eliminated in its entirety by 2024. In the CY 2021 OPPS/ASC proposed rule (85 FR 48911), we proposed to eliminate the IPO list over 3 years to provide a gradual transition that gives the public the opportunity to comment on the sequence in which services should be removed from the IPO list. In addition, as we previously discussed in the CY 2021 OPPS/ASC proposed rule (85 FR 48911), we recognized that stakeholders would need time to adjust to the significant number of services removed from the IPO list and newly priced under the OPPS. We believe that longer transition periods would prevent providers who are ready to perform services in the outpatient department from doing so, and it is equally important to note that providers are not required to perform services in the outpatient department as services are eliminated from the IPO list if they are not ready. While we still believe that 3 years will offer providers an adequate time period to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid when furnished in both the inpatient hospital and outpatient hospital settings, we also realize that providers will have varying time frames for completing the transition.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48909 through 48912) we discussed patient safety concerns stakeholders expressed regarding removing procedures from the IPO list or eliminating the IPO list. We continue to believe that the evolving nature of the practice of medicine, which has allowed more procedures to be performed on an outpatient basis with a shorter recovery time, in addition to physician judgment, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings, even in the absence of the IPO list (85 FR 48910). In prior rulemaking, we have

stated that regardless of how a procedure is classified for purposes of payment, we expect that in every case the surgeon and the hospital will assess the risk of a procedure or service to the individual patient, taking site of service into account, and will act in that patient's best interests (65 FR 18456). As we transition procedures off of the IPO list, we will continue to actively monitor for impacts on patient safety and quality through analyzing claims and other relevant data; throughout this transition, CMS will take necessary steps to address any changes in patient safety or quality that may emerge.

Comment: Two medical specialty societies recommended that cardiothoracic procedures and spine-related procedures be the last procedures removed from the IPO list due to clinical and resource intensity these procedures require.

Response: We appreciate the commenter's feedback. We will consider these comments for future rulemaking.

Comment: A few commenters suggested that procedures removed from the IPO list receive an interim assignment to a new technology APC to help collect claims data and subsequently assign the procedures to clinical APCs. These commenters suggested that we assign a default 31 percent device offset for procedures removed from the IPO list that are low-volume and are assigned to a device-intensive APC. They felt that current APCs may need to be restructured due to the lack of appropriate comparison procedures to those procedures being removed from the IPO list. In addition, the commenter argued that we did not provide an analysis to support our proposal to assign a given HCPCS/CPT code to a proposed APC or C–APC from the perspective of clinical or resource use similarity. They stated that in Table 31 of the proposed rule, we referenced related services for the musculoskeletal services proposed for removal from the IPO list for 2021; however, we proposed to assign these codes to different APCs than the APCs to which the comparator services are assigned. The commenter also stated that we did not provide information on proposed device offset amounts or how complexity adjustments were considered for procedures proposed for IPO List removal.

Response: As specified in our regulation at 42 CFR 419.31(a)(1), CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. As we stated in the CY 2012 OPPS/ASC final rule (76 FR 74224), the OPPS is a prospective payment system that provides payment for groups of services that share clinical and resource use characteristics. It should be noted that for all codes newly paid under the OPPS, including codes removed from the IPO list, our policy has been to assign the service or procedure to an APC based on feedback from a variety of sources, including but not limited to, review of the clinical similarity of the service to existing procedures; advice from CMS medical advisors; information from interested specialty societies; and review of all other information available to us, including information provided to us by the public, whether through meetings with stakeholders or additional information that is mailed or otherwise communicated to us (84 FR 61229). Therefore, we believe assigning procedures removed from the IPO list to existing clinical APCs that are similar in clinical characteristics and resource costs is appropriate. We note that procedures assigned to new technology APCs do not fit into existing APC groups, unlike the procedures transitioning from the IPO list. For further information on new technology APCs, we refer readers to Section III.C. We note that we will reevaluate the APC assignments for procedures removed from the IPO list once we have hospital outpatient claims data and, if appropriate, reassign and/or restructure APC assignments. For procedures that we are removing from the IPO list in CY 2021, we will apply offset calculations and assessment in determining device intensive status at the HCPCS/CPT code level (81 FR 79657). We refer readers to Section IV.B for more information on device-intensive assignments for procedures.

In summary, after consideration of the public comments, we are finalizing our proposal with modification to eliminate the IPO list over the course of the next 3 years, starting with the proposed removal of 266 musculoskeletal-related services and 16 HOP Panel recommended services and related anesthesia codes, for a total of 298 services, as provided in Table 48 in CY 2021. We plan to provide considerations for physicians and other health care providers when determining whether a service may be more appropriately performed in the inpatient or outpatient setting for a beneficiary, but again we emphasize that decisions regarding appropriate care setting are complex medical judgments. We are also finalizing our proposal, without modification, to amend 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024. We believe that the developments in surgical technique and technological advances in the practice of medicine, as well as the various safeguards discussed above, including, but not limited to, physician clinical judgment, state and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, and other CMS initiatives will ensure that procedures removed from the IPO list and provided in the outpatient setting will be done so safely.

Table 48 lists the final procedures, including long descriptors and CPT/HCPCS codes and status indicators (if applicable) that are removed from the IPO list for CY 2021. These services are included in Addendum B to the CY 2021 OPPS/ASC final rule as well.

BILLING CODE 4120–01–P

TABLE 48: SERVICES REMOVED FROM THE INPATIENT ONLY (IPO) LIST FOR CY 2021 (N=298)

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
00192	Anesthesia for procedures on facial bones or skull; radical surgery (including prognathism)	N	N/A
00474	Anesthesia for partial rib resection; radical procedures (eg, pectus excavatum)	N	N/A
00604	Anesthesia for procedures on cervical spine and cord; procedures with patient in the sitting position	N	N/A
00904	Anesthesia for; radical perineal procedure	N	N/A
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	N	N/A
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	N	N/A
01140	Anesthesia for interpelviabdominal (hindquarter) amputation	N	N/A
01150	Anesthesia for radical procedures for tumor of pelvis, except hindquarter amputation	N	N/A
01212	Anesthesia for open procedures involving hip joint; hip disarticulation	N	N/A
01232	Anesthesia for open procedures involving upper two-thirds of femur; amputation	N	N/A
01234	Anesthesia for open procedures involving upper two-thirds of femur; radical resection	N	N/A
01274	Anesthesia for procedures involving arteries of upper leg, including bypass graft; femoral artery embolectomy	N	N/A
01404	Anesthesia for open or surgical arthroscopic procedures on knee joint; disarticulation at knee	N	N/A
01486	Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement	N	N/A
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	N/A
01634	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; shoulder disarticulation	N	N/A

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
01636	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; interthoracoscapular (forequarter) amputation	N	N/A
01638	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement	N	N/A
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	N	N/A
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	N	N/A
01756	Anesthesia for open or surgical arthroscopic procedures of the elbow; radical procedures	N	N/A
0202T	Posterior vertebral joint(s) arthroplasty (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	J1	5115
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical	J1	5115
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic	J1	5115
20661	Application of halo, including removal; cranial	Q1	5113
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (eg, pediatric patients, hydrocephalus, osteogenesis imperfecta)	Q1	5113
20802	Replantation, arm (includes surgical neck of humerus through elbow joint), complete amputation	J1	5116
20805	Replantation, forearm (includes radius and ulna to radial carpal joint), complete amputation	J1	5116
20808	Replantation, hand (includes hand through metacarpophalangeal joints), complete amputation	J1	5116
20816	Replantation, digit, excluding thumb (includes metacarpophalangeal joint to insertion of flexor sublimis tendon), complete amputation	J1	5114
20824	Replantation, thumb (includes carpometacarpal joint to MP joint), complete amputation	J1	5114
20827	Replantation, thumb (includes distal tip to MP joint), complete amputation	J1	5114

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
20838	Replantation, foot, complete amputation	J1	5116
20955	Bone graft with microvascular anastomosis; fibula	J1	5114
20956	Bone graft with microvascular anastomosis; iliac crest	J1	5114
20957	Bone graft with microvascular anastomosis; metatarsal	J1	5114
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	J1	5114
20969	Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, metatarsal, or great toe	J1	5114
20970	Free osteocutaneous flap with microvascular anastomosis; iliac crest	J1	5114
21045	Excision of malignant tumor of mandible; radical resection	J1	5165
21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (for example, for long face syndrome), without bone graft	J1	5165
21142	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	J1	5165
21143	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	J1	5165
21145	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	J1	5165
21146	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	J1	5165
21147	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	J1	5165
21151	Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining autografts)	J1	5165
21154	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); without LeFort I	J1	5165
21155	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I	J1	5165
21159	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I	J1	5165
21160	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I	J1	5165

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)	J1	5165
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)	J1	5165
21182	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting less than 40 sq cm	J1	5165
21183	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 40 sq cm but less than 80 sq cm	J1	5165
21184	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm	J1	5165
21188	Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)	J1	5165
21194	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)	J1	5165
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	J1	5165
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (for example, for hemifacial microsomia)	J1	5165
21255	Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)	J1	5165
21268	Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; combined intra- and extracranial approach	J1	5165
21343	Open treatment of depressed frontal sinus fracture	J1	5165
21344	Open treatment of complicated (for example, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches	J1	5165
21347	Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches	J1	5165

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
21348	Open treatment of nasomaxillary complex fracture (lefort ii type); with bone grafting (includes obtaining graft)	J1	5165
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)	J1	5165
21422	Open treatment of palatal or maxillary fracture (lefort i type);	J1	5165
21423	Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches	J1	5165
21431	Closed treatment of craniofacial separation (lefort iii type) using interdental wire fixation of denture or splint	J1	5165
21432	Open treatment of craniofacial separation (lefort iii type); with wiring and/or internal fixation	J1	5165
21433	Open treatment of craniofacial separation (lefort iii type); complicated (for example, comminuted or involving cranial nerve foramina), multiple surgical approaches	J1	5165
21435	Open treatment of craniofacial separation (lefort iii type); complicated, utilizing internal and/or external fixation techniques (for example, head cap, halo device, and/or intermaxillary fixation)	J1	5165
21436	Open treatment of craniofacial separation (lefort iii type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)	J1	5165
21510	Incision, deep, with opening of bone cortex (for example, for osteomyelitis or bone abscess), thorax	J1	5114
21602	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	J1	5114
21603	Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	J1	5114
21615	Excision first and/or cervical rib;	J1	5114
21616	Excision first and/or cervical rib; with sympathectomy	J1	5114
21620	Ostectomy of sternum, partial	J1	5114
21627	Sternal debridement	J1	5114
21630	Radical resection of sternum;	J1	5114
21632	Radical resection of sternum; with mediastinal lymphadenectomy	J1	5114
21705	Division of scalenus anticus; with resection of cervical rib	J1	5114

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
21740	Reconstructive repair of pectus excavatum or carinatum; open	J1	5114
21750	Closure of median sternotomy separation with or without debridement (separate procedure)	J1	5114
21825	Open treatment of sternum fracture with or without skeletal fixation	J1	5114
22010	Incision and drainage, open, of deep abscess (subfascial), posterior spine; cervical, thoracic, or cervicothoracic	J1	5114
22015	Incision and drainage, open, of deep abscess (subfascial), posterior spine; lumbar, sacral, or lumbosacral	J1	5114
22110	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical	J1	5114
22112	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic	J1	5114
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar	J1	5114
22116	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	N	N/A
22206	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); thoracic	J1	5114
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); lumbar	J1	5114
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	N/A
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical	J1	5114
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic	J1	5114
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar	J1	5114
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (list separately in addition to primary procedure)	N	N/A

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
22220	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical	J1	5114
22222	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic	J1	5114
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	J1	5114
22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	N	N/A
22318	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; without grafting	J1	5115
22319	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; with grafting	J1	5115
22325	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; lumbar	J1	5115
22326	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; cervical	J1	5115
22327	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; thoracic	J1	5115
22328	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; each additional fractured vertebra or dislocated segment (list separately in addition to code for primary procedure)	N	N/A
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	J1	5116
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	J1	5116
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (list separately in addition to code for primary procedure)	N	N/A
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-c1-c2 (atlas-axis), with or without excision of odontoid process	J1	5116

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	J1	5116
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	J1	5116
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace	J1	5116
22590	Arthrodesis, posterior technique, craniocervical (occiput-c2)	J1	5116
22595	Arthrodesis, posterior technique, atlas-axis (c1-c2)	J1	5116
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below c2 segment	J1	5116
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)	J1	5116
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	J1	5116
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	N/A
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments	J1	5116
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments	J1	5116
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments	J1	5116
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments	J1	5116
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments	J1	5116
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments	J1	5116
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments	J1	5116
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments	J1	5116

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
22830	Exploration of spinal fusion	J1	5115
22841	Internal spinal fixation by wiring of spinous processes (list separately in addition to code for primary procedure)	N	N/A
22843	Posterior segmental instrumentation (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	N/A
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	N/A
22846	Anterior instrumentation; 4 to 7 vertebral segments (list separately in addition to code for primary procedure)	N	N/A
22847	Anterior instrumentation; 8 or more vertebral segments (list separately in addition to code for primary procedure)	N	N/A
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	N/A
22849	Reinsertion of spinal fixation device	J1	5116
22850	Removal of posterior nonsegmental instrumentation (for example, harrington rod)	J1	5115
22852	Removal of posterior segmental instrumentation	J1	5115
22855	Removal of anterior instrumentation	J1	5115
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar	J1	5116
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	J1	5116
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	J1	5116
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	J1	5115
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	J1	5115
23200	Radical resection of tumor; clavicle	J1	5114
23210	Radical resection of tumor; scapula	J1	5114
23220	Radical resection of tumor, proximal humerus	J1	5114

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (for example, total shoulder)	J1	5073
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (for example, total shoulder))	J1	5115
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	J1	5115
23900	Interthoracoscapular amputation (forequarter)	J1	5115
23920	Disarticulation of shoulder;	J1	5115
24900	Amputation, arm through humerus; with primary closure	J1	5115
24920	Amputation, arm through humerus; open, circular (guillotine)	J1	5115
24930	Amputation, arm through humerus; re-amputation	J1	5114
24931	Amputation, arm through humerus; with implant	J1	5115
24940	Cineplasty, upper extremity, complete procedure	J1	5115
25900	Amputation, forearm, through radius and ulna;	J1	5115
25905	Amputation, forearm, through radius and ulna; open, circular (guillotine)	J1	5115
25915	Krukenberg procedure	J1	5114
25920	Disarticulation through wrist;	J1	5114
25924	Disarticulation through wrist; re-amputation	J1	5114
25927	Transmetacarpal amputation;	J1	5113
26551	Transfer, toe-to-hand with microvascular anastomosis; great toe wrap-around with bone graft	J1	5114
26553	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, single	J1	5114
26554	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, double	J1	5114
26556	Transfer, free toe joint, with microvascular anastomosis	J1	5114
26992	Incision, bone cortex, pelvis and/or hip joint (for example, osteomyelitis or bone abscess)	J1	5114
27005	Tenotomy, hip flexor(s), open (separate procedure)	J1	5114
27025	Fasciotomy, hip or thigh, any type	J1	5114
27030	Arthrotomy, hip, with drainage (for example, infection)	J1	5114
27036	Capsulectomy or capsulotomy, hip, with or without excision of heterotopic bone, with release of hip flexor muscles (ie, gluteus medius, gluteus minimus, tensor fascia latae, rectus femoris, sartorius, iliopsoas)	J1	5114
27054	Arthrotomy with synovectomy, hip joint	J1	5113
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); superficial	J1	5114

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
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)	J1	5114
27075	Radical resection of tumor; wing of ilium, 1 pubic or ischial ramus or symphysis pubis	J1	5114
27076	Radical resection of tumor; ilium, including acetabulum, both pubic rami, or ischium and acetabulum	J1	5114
27077	Radical resection of tumor; innominate bone, total	J1	5115
27078	Radical resection of tumor; ischial tuberosity and greater trochanter of femur	J1	5115
27090	Removal of hip prosthesis; (separate procedure)	J1	5073
27091	Removal of hip prosthesis; complicated, including total hip prosthesis, methylmethacrylate with or without insertion of spacer	J1	5073
27120	Acetabuloplasty; (for example, whitman, colonna, haygroves, or cup type)	J1	5115
27122	Acetabuloplasty; resection, femoral head (for example, girdlestone procedure)	J1	5115
27125	Hemiarthroplasty, hip, partial (for example, femoral stem prosthesis, bipolar arthroplasty)	J1	5115
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	J1	5115
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	J1	5115
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	J1	5115
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	J1	5115
27140	Osteotomy and transfer of greater trochanter of femur (separate procedure)	J1	5115
27146	Osteotomy, iliac, acetabular or innominate bone;	J1	5114
27147	Osteotomy, iliac, acetabular or innominate bone; with open reduction of hip	J1	5114
27151	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy	J1	5114
27156	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy and with open reduction of hip	J1	5114
27158	Osteotomy, pelvis, bilateral (for example, congenital malformation)	J1	5114
27161	Osteotomy, femoral neck (separate procedure)	J1	5114
27165	Osteotomy, intertrochanteric or subtrochanteric including internal or external fixation and/or cast	J1	5114
27170	Bone graft, femoral head, neck, intertrochanteric or subtrochanteric area (includes obtaining bone graft)	J1	5114

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
27175	Treatment of slipped femoral epiphysis; by traction, without reduction	J1	5114
27176	Treatment of slipped femoral epiphysis; by single or multiple pinning, in situ	J1	5115
27177	Open treatment of slipped femoral epiphysis; single or multiple pinning or bone graft (includes obtaining graft)	J1	5114
27178	Open treatment of slipped femoral epiphysis; closed manipulation with single or multiple pinning	J1	5114
27181	Open treatment of slipped femoral epiphysis; osteotomy and internal fixation	J1	5114
27185	Epiphyseal arrest by epiphysiodesis or stapling, greater trochanter of femur	J1	5114
27187	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate, femoral neck and proximal femur	J1	5114
27222	Closed treatment of acetabulum (hip socket) fracture(s); with manipulation, with or without skeletal traction	J1	5111
27226	Open treatment of posterior or anterior acetabular wall fracture, with internal fixation	J1	5114
27227	Open treatment of acetabular fracture(s) involving anterior or posterior (one) column, or a fracture running transversely across the acetabulum, with internal fixation	J1	5114
27228	Open treatment of acetabular fracture(s) involving anterior and posterior (two) columns, includes t-fracture and both column fracture with complete articular detachment, or single column or transverse fracture with associated acetabular wall fracture, with internal fixation	J1	5114
27232	Closed treatment of femoral fracture, proximal end, neck; with manipulation, with or without skeletal traction	J1	5112
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	J1	5114
27240	Closed treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with manipulation, with or without skin or skeletal traction	J1	5112
27244	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with plate/screw type implant, with or without cerclage	J1	5114
27245	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with intramedullary implant, with or without interlocking screws and/or cerclage	J1	5114
27248	Open treatment of greater trochanteric fracture, includes internal fixation, when performed	J1	5114

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
27253	Open treatment of hip dislocation, traumatic, without internal fixation	J1	5113
27254	Open treatment of hip dislocation, traumatic, with acetabular wall and femoral head fracture, with or without internal or external fixation	J1	5113
27258	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc);	J1	5113
27259	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc); with femoral shaft shortening	J1	5113
27268	Closed treatment of femoral fracture, proximal end, head; with manipulation	J1	5113
27269	Open treatment of femoral fracture, proximal end, head, includes internal fixation, when performed	J1	5112
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed	J1	5116
27282	Arthrodesis, symphysis pubis (including obtaining graft)	J1	5115
27284	Arthrodesis, hip joint (including obtaining graft);	J1	5116
27286	Arthrodesis, hip joint (including obtaining graft); with subtrochanteric osteotomy	J1	5116
27290	Interpelviabdominal amputation (hindquarter amputation)	J1	5116
27295	Detachment of hip joint	J1	5116
27303	Incision, deep, with opening of bone cortex, femur or knee (for example, osteomyelitis or bone abscess)	J1	5114
27365	Radical resection of tumor, femur or knee	J1	5114
27445	Arthroplasty, knee, hinge prosthesis (for example, walldius type)	J1	5115
27448	Osteotomy, femur, shaft or supracondylar; without fixation	J1	5114
27450	Osteotomy, femur, shaft or supracondylar; with fixation	J1	5114
27454	Osteotomy, multiple, with realignment on intramedullary rod, femoral shaft (for example, sofield type procedure)	J1	5114
27455	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); before epiphyseal closure	J1	5114
27457	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); after epiphyseal closure	J1	5114
27465	Osteoplasty, femur; shortening (excluding 64876)	J1	5114
27466	Osteoplasty, femur; lengthening	J1	5114

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
27468	Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer	J1	5114
27470	Repair, nonunion or malunion, femur, distal to head and neck; without graft (for example, compression technique)	J1	5114
27472	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	J1	5114
27486	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	J1	5115
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component	J1	5115
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee	J1	5114
27495	Prophylactic treatment (nailing, pinning, plating, or wiring) with or without methylmethacrylate, femur	J1	5114
27506	Open treatment of femoral shaft fracture, with or without external fixation, with insertion of intramedullary implant, with or without cerclage and/or locking screws	J1	5114
27507	Open treatment of femoral shaft fracture with plate/screws, with or without cerclage	J1	5114
27511	Open treatment of femoral supracondylar or transcondylar fracture without intercondylar extension, includes internal fixation, when performed	J1	5114
27513	Open treatment of femoral supracondylar or transcondylar fracture with intercondylar extension, includes internal fixation, when performed	J1	5114
27514	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	J1	5114
27519	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	J1	5114
27535	Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	J1	5114
27536	Open treatment of tibial fracture, proximal (plateau); bicondylar, with or without internal fixation	J1	5114
27540	Open treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, includes internal fixation, when performed	J1	5114
27556	Open treatment of knee dislocation, includes internal fixation, when performed; without primary ligamentous repair or augmentation/reconstruction	J1	5114

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
27557	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	J1	5114
27558	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	J1	5114
27580	Arthrodesis, knee, any technique	J1	5115
27590	Amputation, thigh, through femur, any level;	J1	5116
27591	Amputation, thigh, through femur, any level; immediate fitting technique including first cast	J1	5116
27592	Amputation, thigh, through femur, any level; open, circular (guillotine)	J1	5116
27596	Amputation, thigh, through femur, any level; re-amputation	J1	5114
27598	Disarticulation at knee	J1	5115
27645	Radical resection of tumor; tibia	J1	5114
27646	Radical resection of tumor; fibula	J1	5114
27702	Arthroplasty, ankle; with implant (total ankle)	J1	5115
27703	Arthroplasty, ankle; revision, total ankle	J1	5115
27712	Osteotomy; multiple, with realignment on intramedullary rod (for example, sofield type procedure)	J1	5115
27715	Osteoplasty, tibia and fibula, lengthening or shortening	J1	5115
27724	Repair of nonunion or malunion, tibia; with iliac or other autograft (includes obtaining graft)	J1	5114
27725	Repair of nonunion or malunion, tibia; by synostosis, with fibula, any method	J1	5114
27727	Repair of congenital pseudarthrosis, tibia	J1	5114
27880	Amputation, leg, through tibia and fibula;	J1	5116
27881	Amputation, leg, through tibia and fibula; with immediate fitting technique including application of first cast	J1	5114
27882	Amputation, leg, through tibia and fibula; open, circular (guillotine)	J1	5114
27886	Amputation, leg, through tibia and fibula; re-amputation	J1	5114
27888	Amputation, ankle, through malleoli of tibia and fibula (for example, syme, pirogoff type procedures), with plastic closure and resection of nerves	J1	5115
28800	Amputation, foot; midtarsal (for example, chopart type procedure)	J1	5113
G0412	Open treatment of iliac spine(s), tuberosity avulsion, or iliac wing fracture(s), unilateral or bilateral for pelvic bone fracture patterns which do not disrupt the pelvic ring includes internal fixation, when performed	J1	5114

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
G0414	Open treatment of anterior pelvic bone fracture and/or dislocation for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation when performed (includes pubic symphysis and/or superior/inferior rami)	J1	5115
G0415	Open treatment of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation, when performed (includes ilium, sacroiliac joint and/or sacrum)	J1	5115
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral	J1	5184
35800	Exploration for postoperative hemorrhage, thrombosis or infection; neck	J1	5184
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation)	J1	5193
37617	Ligation, major artery (eg, post-traumatic, rupture); abdomen	J1	5183
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	J1	5362
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	J1	5331
44300	Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression) (separate procedure)	J1	5302
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)	T	5055
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)	J1	5341
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	J1	5341
44602	Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation	J1	5303
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	J1	5341
49255	Omentectomy, epiploectomy, resection of omentum (separate procedure)	J1	5341
51840	Anterior vesicourethropexy, or urethropexy (eg, marshall-marchetti-krantz, burch); simple	J1	5415
56630	Vulvectomy, radical, partial;	J1	5415

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	J1	5194

BILLING CODE 4120–01–C

X. Nonrecurring Policy Changes

A. Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61359 through 61363), we implemented a policy for CY 2020 and subsequent years to change the generally applicable minimum required level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and CAHs. However, some groups of services were not subject to the change in the required supervision level and those services continue to have a minimum default level of supervision that is higher than general supervision.

On January 31, 2020, Health and Human Services Secretary Alex M. Azar II determined that a PHE exists retroactive to January 27, 2020 [98] 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.[99] On March 13, 2020, the President of the U.S. declared the COVID–19 outbreak in the U.S. constitutes a national emergency,[100] beginning March 1, 2020. On March 31, 2020, we issued an interim final rule with comment period (IFC) to give individuals and entities that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of COVID–19. The goal of the IFC issued on March 31, 2020, was to provide the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health (85 FR 19232).

In the IFC issued March 31, 2020, we adopted a policy to reduce, on an interim basis for the duration of the PHE, the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service, including the initiation portion of the service, for which we had previously required direct supervision. We also specified in the IFC issued March 31, 2020, that, for the duration of the PHE for the COVID–19 pandemic, the requirement for direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence of the physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

These policies were adopted on an interim final basis for the duration of the PHE. However, in the CY 2021 OPPS/ASC proposed rule, we stated that we believed these policies are appropriate outside of the PHE and should apply permanently. Therefore, we proposed to adopt these policies for CY 2021 and beyond as described in more detail below.

1. General Supervision of Outpatient Hospital Therapeutic Services Currently Assigned to the Non-Surgical Extended Duration Therapeutic Services (NSEDTS) Level of Supervision

NSEDTS describe services that have a significant monitoring component that can extend for a lengthy period of time, that are not surgical, and that typically have a low risk of complications after the assessment at the beginning of the service. The minimum default supervision level of NSEDTS was established in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72003 through 72013) as being direct supervision during the initiation of the service, which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner (§ 410.27(a)(1)(iv)(E)). In this case, initiation means the beginning portion of the NSEDTS, which ends when the patient is stable and the supervising physician or the appropriate nonphysician practitioner determines that the remainder of the service can be delivered safely under general supervision. We originally established general supervision as the appropriate level of supervision after the initiation of the service because it is challenging for hospitals to ensure direct supervision for services with an extended duration and a significant monitoring component, particularly for CAHs and small rural hospitals.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61359 through 61363), we changed the generally applicable minimum required level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision for hospitals and CAHs. We made this change because we believe it is critical that hospitals have the flexibility to provide the services Medicare beneficiaries need while minimizing provider burden. In the IFC issued March 31, 2020 (85 FR 19266), we assigned, on an interim basis, a minimum required supervision level of general supervision for NSEDTS services, including during the initiation portion of the service, during the PHE. Changing the minimum level of supervision to general supervision during the PHE gives providers additional flexibility to handle the burdens created by the COVID–19 PHE.

We believe changing the level of supervision for NSEDTS permanently for the duration of the service would be beneficial to patients and outpatient hospital providers as it would allow greater flexibility in providing these services and reduce provider burden, and thus, improve access to these

[98] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[99] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx.*

[100] *https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.*

services in cases where the direct supervision requirement may have otherwise prevented some services from being furnished due to lack of availability of the supervising physician or nonphysician practitioner. In addition, as we explained in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61360), our experience indicates that Medicare providers will provide a similar quality of hospital outpatient therapeutic services, including NSEDTS, regardless of whether the minimum level of supervision required under the Medicare program is direct or general. We note that the requirement for general supervision for an entire NSEDTS does not preclude these hospitals from providing direct supervision for any part of a NSEDTS when the practitioners administering the medical procedures decide that it is appropriate to do so. Many outpatient therapeutic services, including NSEDTS, may involve a level of complexity and risk such that direct supervision would be warranted even though only general supervision is required.

In addition, CAHs and hospitals in general continue to be subject to conditions of participation (CoPs) that complement the general supervision requirements for hospital outpatient therapeutic services, including NSEDTS, to ensure that the medical services Medicare patients receive are properly supervised. CoPs for hospitals require Medicare patients to be under the care of a physician (42 CFR 482.12(c)(4)), and for the hospital to ''have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital'' (42 CFR 482.22). The CoPs for CAHs (42 CFR 485.631(b)(1)(i)) require physicians to provide medical direction for the CAHs' health care activities, consultation for, and medical supervision of the health care staff. The physicians' responsibilities in hospitals and CAHs include supervision of all services performed at those facilities. In addition, physicians must also follow state laws regarding scope of practice.

Therefore, we proposed to establish general supervision as the minimum required supervision level for all NSEDTS that are furnished on or after January 1, 2021. This would be consistent with the minimum required level of general supervision that currently applies for most outpatient hospital therapeutic services. General supervision, as defined in our regulation at § 410.32(b)(3)(i), means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure; and as provided under § 410.27(a)(1)(iv)(C), certain non-physician practitioners can provide the required supervision of services that they can personally furnish in accordance with state law and all other applicable requirements. Because we proposed a minimum required level of general supervision for NSEDTS, including during the initiation of the service, we proposed to delete paragraph (a)(1)(iv)(E) from the regulations at § 410.27. We sought public comment on this proposal.

Comment: All commenters supported our proposal to change the minimum required level of supervision to general supervision for all NSEDTS that are furnished on or after January 1, 2021. Several commenters appreciated the additional flexibility to deliver care while acknowledging that practitioners administering individual medical procedures continue to have the discretion to increase the level of supervision when necessary. Commenters similarly acknowledged that CoPs for hospitals and CAHs and state scope of practice requirements also might lead to higher level of supervision for a part or all of an NSEDTS. One commenter, MedPAC, supported our proposal, but encouraged CMS to be diligent in monitoring NSEDTS performed under general supervision, especially services that involve risk of serious complications.

Response: We appreciate the support for our proposal from the commenters. We will monitor NSEDTS for safety or service quality issues that may arise from the change to general supervision as the minimum default level of supervision for the initiation period of these services.

After reviewing the public comments we received, we are finalizing our proposal without modification to establish general supervision as the minimum required supervision level for all NSEDTS that are furnished on or after January 1, 2021. In addition, we are finalizing our proposal to delete paragraph (a)(1)(iv)(E) from the regulations at § 410.27, which will reflect that, starting in CY 2021, the entirety of NSEDTS has a minimum required supervision level of general supervision.

2. Direct Supervision of Pulmonary Rehabilitation Services, Cardiac Rehabilitation Services, and Intensive Cardiac Rehabilitation Services Using Interactive Telecommunications Technology

Direct physician supervision was the standard set forth in the April 7, 2000 OPPS final rule with comment period (68 FR 18524 through 18526) for supervision of hospital outpatient therapeutic services covered and paid by Medicare in hospitals and provider-based departments of hospitals, including for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services provided to hospital outpatients. As we explained in the CY 2011 OPPS/ASC final rule with comment period, the statutory language of sections 1861(eee)(2)(B) and (eee)(4)(A) and section 1861(fff)(1) of the Act (as added by section 144(a)(1) of Pub. L. 110–275) defines cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation programs as ''physician supervised.'' More specifically, section 1861(eee)(2)(B) of the Act establishes that, for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation programs, ''a physician is immediately available and accessible for consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed.'' As we explained in the CY 2009 OPPS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, referencing the April 7, 2000 OPPS final rule (65 FR 18525)), the ''presumption'' or ''assumption'' of direct supervision means that direct physician supervision is the standard for all hospital outpatient therapeutic services. We have assumed this requirement is met on hospital premises because staff physicians would always be nearby in the hospital. In other words, the requirement is not negated by a presumption that the requirement is being met. Recently, some stakeholders suggested we have the authority to change the default minimum level of supervision for pulmonary rehabilitation services, cardiac rehabilitation services, and intensive cardiac rehabilitation services to general supervision because of the policy we adopted in CY 2020 to change the generally applicable minimum required level of supervision for most other hospital outpatient therapeutic services from direct supervision to

general supervision (84 FR 61359 through 61363). For the reasons explained above, we disagree that we can change the default level of supervision for these services to general supervision under current law.

In the IFC issued March 31, 2020 (85 FR 19246), we implemented a policy for the duration of the PHE that allows the direct supervision requirement for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services to be met by the virtual presence of the supervising physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks to COVID–19 for the beneficiary or health care provider. While we adopted this policy to help improve the availability of rehabilitation services during the PHE and reduce the burden for providers, we also believed the policy to allow direct supervision provided by the virtual presence of the physician could continue to improve access for patients and reduce burden for providers after the end of the PHE. In some cases, depending upon the circumstances of individual patients and supervising physicians, we believed that telecommunications technology could be used in a manner that would facilitate the physician's immediate availability to furnish assistance and direction without necessarily requiring the physician's physical presence in the location where the service is being furnished. For example, use of real-time audio and video telecommunications technology could allow a supervising physician to observe the patient during treatment as they interact with or respond to the in-person clinical staff. Thus, the supervising physician's immediate availability to furnish assistance and direction during the service could be met virtually without requiring the physician's physical presence in that location.

Therefore for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, we proposed to change our regulation at § 410.27(a)(1)(iv)(D) to specify that, beginning on or after January 1, 2021, direct supervision for these services includes virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician. We clarify that the virtual presence required for direct supervision using audio/video real-time communications technology would not be limited to mere availability of the physician, but rather real-time presence via interactive audio and video technology throughout the performance of the procedure. We sought public comment on this proposal.

Comment: Many commenters wanted more clarity on our proposal to meet the direct supervision requirement for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services through virtual presence. Commenters were unsure what the phrase ''real-time presence via interactive audio and video technology throughout the performance of the procedure'' meant. Some commenters were concerned that our proposal would require the supervising practitioner to observe a rehabilitation service during the entire time the service is being administered, which would be comparable to personal supervision. That type of standard, according to the commenters, would actually be more burdensome than the current direct supervision requirement through physical presence.

Other commenters stated that, while they were generally in favor of permitting direct physician supervision through virtual presence for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, they would prefer that we require the supervising practitioner simply be ''immediately available'' through audio/visual real-time communications technology, and not be required to provide real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure. A few commenters also encouraged us to align our proposal on direct supervision through virtual presence with what had been proposed in the CY 2021 PFS proposed rule (85 FR 50115 through 50116), which discussed requiring only immediate availability to engage using audio/visual technology to provide direct supervision.

Response: We believe the commenters have made some important points about our proposal. CMS continues to work to reduce burden on providers under the Medicare program, and we want to ensure that while expanding access to medical care and promoting patient safety, we do not implement policies that increase provider burden. In this case, our proposal appears to have required a higher level of participation by the physician providing direct supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services through virtual presence than would be required if they were providing direct supervision of the services in person. In addition, our proposal was not aligned with the proposal in the CY 2021 PFS proposed rule to permit direct supervision requirements to be met through virtual presence through the later of the end of the year in which the PHE ends or December 31, 2021; and to specify that the direct supervision requirement could be met by the supervising practitioner being immediately available to engage via interactive real-time audio/video communications technology, without requiring real-time presence or observation of the service via interactive audio/video technology throughout the performance of the procedure. This lack of alignment could lead to additional burden for providers having to accommodate different levels of virtual engagement depending on whether a rehabilitation service is furnished as an outpatient hospital service or a physicians' service.

Comment: A few commenters either opposed the proposal or wanted to place substantial limits on when direct supervision through virtual presence could be used to furnish pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. One commenter, MedPAC, opposed the proposal because they believe it is unclear whether telehealth is beneficial or harmful to the quality of care received for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. MedPAC encouraged us to study the policy further before implementing our proposal. Another commenter expressed support for permitting the direct supervision of rehabilitation services through virtual presence, but only if the supervising practitioner has first seen both the patient and the site of service in person, initiated the treatment, and provides subsequent services that show active participation in, and management of, the course of treatment. A third commenter did not explicitly state that they were against allowing direct supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services through virtual presence, and the commenter expressed support for permitting direct supervision through virtual presence during the current PHE to avoid the risks associated with COVID–19. However, the commenter believes that the policy to allow direct supervision through virtual presence should end for all medical services including pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services at the end of the PHE. The commenter felt that practitioners cannot adequately

supervise procedures, especially complex and high-risk procedures, and meet all of a patient's clinical needs, unless they are physically available to participate in the administration of the medical service. Furthermore, the commenter suggested that we adopt limits on the number of clinical staff members a supervising practitioner may engage with simultaneously through audio and visual technology, and limits on a supervising practitioner's incident to relationships with outpatient hospital providers that are fulfilled primarily through the use of audio and visual technology before allowing direct supervision through virtual presence after the end of the PHE. This request was for all outpatient hospital services, and not just for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services.

Response: We appreciate the concerns expressed by some commenters about the potential risks of allowing direct supervision using virtual presence. We note that, during the PHE, virtual presence of the supervising physician using interactive audio/video real-time communications technology is an available option for direct supervision, but it is not a requirement. Providers and physicians are free to use their own judgment to determine whether direct supervision through virtual presence is appropriate for the rehabilitation services being administered, or if the supervising physician should provide direct supervision in person. Also, providers will need to meet conditions of participation and state scope of work requirements in the location where the service is administered. Finally, we will monitor the use of interactive audio/video real-time communications technology to meet the direct supervision requirement to determine whether there is a negative impact on the quality of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services.

Comment: Several commenters supported our proposal to allow the use of virtual presence to meet the direct physician supervision requirements for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services as proposed and they did not request modifications to our proposal.

Response: We thank the commenters for their support of our proposal.

After consideration of the public comments received for our proposal, we have decided to modify the proposal in the CY 2021 OPPS/ASC proposed rule. We believe we need to continue to explore the appropriateness of permitting direct supervision through virtual presence before extending this policy permanently beyond the end of the PHE. The public comments we received, along with feedback we have received since the implementation of the policy in IFC–1 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. Therefore, we are finalizing our proposed policy to permit direct supervision of these services using virtual presence only until the later of the end of the calendar year in which the PHE ends or December 31, 2021. 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 judgement of the supervising practitioner, as discussed in IFC–1 (85 FR 19246).

When the policy to permit direct supervision through virtual presence ends, we will resume our current policy to require direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, and that the supervising practitioner must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. This does not mean that the supervising practitioner must be present in the room when the procedure is performed.

In response to questions received since we issued our interim policy for the PHE, we are clarifying that, to the extent our policy allows direct supervision through virtual presence using audio/video real-time communications technology during the PHE, the requirement could be met by the supervising practitioner being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure. We intend our policy to permit direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services to be consistent with the policy to permit direct supervision through virtual presence in section II.D.9. of the CY 2021 PFS final rule, which we cross reference here. We also are revising the regulatory text in 42 CFR 410.27(a)(1)(iv)(D) to reflect our revised policy, and to align the regulation with similar language describing direct supervision through virtual presence in the physician office setting in 42 CFR 410.32(b)(3)(ii).

B. Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2021 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 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. Thus, for purposes of the 2-Midnight *presumption,* the ''clock'' starts at the point of admission as an inpatient.

With respect to the 2-Midnight *benchmark,* however, the starting point is when the beneficiary begins receiving hospital care either as a registered outpatient or after inpatient admission. That is, for purposes of determining whether the 2-Midnight benchmark is met and, therefore, whether an inpatient admission is appropriate for Medicare Part A payment, we consider the physician's expectation including the total time spent receiving hospital care—not only the expected duration of care after inpatient admission, but also any time the beneficiary has spent (before inpatient admission) receiving outpatient services, such as observation services, treatments in the emergency department, and procedures provided in the operating room or other treatment area. From the medical review perspective, while the time the beneficiary spent as an outpatient before the admission order is written is not considered inpatient time, it is considered during the medical review process for purposes of determining whether the 2-Midnight benchmark was met and, therefore, whether payment is appropriate under Medicare Part A. For beneficiaries who do not arrive through the emergency department or are directly receiving inpatient services (for example, inpatient admission order written prior to admission for an elective admission), the starting point for medical review purposes is when the beneficiary starts receiving medically responsive services following arrival at the hospital. For Medicare payment purposes, both the decision to keep the patient at the hospital and the expectation of needed duration of the stay must be supported by documentation in the medical record based on factors such as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event during hospitalization.

With respect to inpatient stays spanning less than 2 midnights after admission, we instructed contractors that, although such claims would not be subject to the presumption, the admission may still be appropriate for Medicare Part A payment because time spent as an outpatient should be considered in determining whether there was a reasonable expectation that the hospital care would span 2 or more midnights. In other words, even if an inpatient admission was for only 1 Medicare utilization day, medical reviewers are instructed to consider the total duration of hospital care, both pre- and post-inpatient admission, as well as the reasonable expectations of the admitting physician regarding duration of hospital care, when making the determination of whether the inpatient stay was reasonable and necessary for purposes of Medicare Part A payment.

We continue to believe that use of the 2-Midnight benchmark gives appropriate consideration to the medical judgment of physicians and furthers the goal of clearly identifying when an inpatient admission is appropriate for payment under Medicare Part A. More specifically, as we described in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), factors such as the procedures being performed and the beneficiary's condition and comorbidities apply when the physician formulates his or her expectation regarding the need for hospital care, while the determination of whether an admission is appropriately billed and paid under Medicare Part A or Part B is generally based upon the physician's medical judgment regarding the beneficiary's expected length of stay. We have not identified any circumstances where the 2-Midnight benchmark restricts the physician to a specific pattern of care, because the 2-Midnight benchmark does not prevent the physician from ordering or providing any service at any hospital, regardless of the expected duration of the service. Rather, this policy provides guidance on when the hospitalized beneficiary's care is appropriate for coverage and payment under Medicare Part A as an inpatient, and when the beneficiary's care is reasonable and necessary for payment under Medicare Part B as an outpatient.

2. Current Policy for Medical Review of Inpatient Hospital Admissions Under Medicare Part A

As mentioned previously, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), we provided guidance for payment purposes that specified that, generally, a hospital inpatient admission is considered reasonable and necessary if a physician or other qualified practitioner (collectively, ''physician'') orders such admission based on the expectation that the beneficiary's length of stay will exceed 2 midnights or if the beneficiary requires a procedure specified as inpatient-only under § 419.22 of the regulations. We finalized at § 412.3 of the regulations that services designated under the OPPS as inpatient only procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A. In addition, we finalized 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.

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.

We note that, 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.

In other words, for purposes of Medicare payment, an inpatient admission is payable under Part A if the documentation in the medical record supports either the admitting physician's reasonable expectation that the patient will require hospital care spanning at least 2 midnights, or the physician's determination based on factors such as those identified previously that the patient nonetheless

requires care on an inpatient basis. The exceptions for procedures on the IPO list and for ''rare and unusual'' circumstances designated by CMS as national exceptions were unchanged by the CY 2016 OPPS/ASC final rule with comment period.

As we stated in the CY 2016 OPPS/ASC final rule with comment period, the decision to formally admit a patient to the hospital is subject to medical review. 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 was 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.

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.

3. Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2021 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 period 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 2020 OPPS/ASC final rule with comment period, procedures that have been removed from the IPO list are exempt from claim denial by the BFCC–QIOs based on site-of-service and from eligibility for referral to RACs for noncompliance with the 2-Midnight rule within the 2-calendar years following their removal from the IPO list.

As stated in section IX. of this final rule with comment period, we are finalizing our policy to eliminate the IPO list in CY 2021 with a transitional period of 3 years. For CY 2021, we are finalizing our proposal to remove all musculoskeletal procedures from the IPO list. The elimination of the IPO list will mean that procedures currently on the IPO list will be subject to the 2-Midnight rule (both the 2-Midnight benchmark and 2-Midnight presumption).

We believe that with the elimination of the IPO list, the 2-Midnight benchmark will remain an important metric to help guide when Part A payment for inpatient hospital admissions is appropriate. With more services available to be paid in the hospital outpatient setting, it will be 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. With the elimination of the IPO list, this policy will no longer be applicable. Instead, just as for services removed from the IPO list, the elimination of the IPO list will mean that any service that was once on the IPO list 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 2020 OPPS/ASC final rule with comment period, procedures that have been removed from the IPO list are exempt from certain medical review activities to assess compliance with the 2-Midnight rule within the first 2 calendar years of their removal from the IPO list. 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 2-year 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 2-year exemption period.

We explained in the CY 2021 OPPS/ASC proposed rule that, based on the information available to us as the time, we continued to believe that in order to facilitate compliance with our payment policy for inpatient admissions, the 2-year exemption from certain medical review activities by the BFCC–QIOs for services removed from the IPO list under the OPPS in CY 2021 and subsequent years was appropriate. Accordingly, we proposed to retain the existing 2-year exemption even in the event that we finalized the proposal to eliminate the IPO list. However, given that a large number of services would be removed from the IPO list at once during the proposed transition to eliminate the list, we sought comment on whether this 2-year period was appropriate or whether a longer or shorter period would be more appropriate in order for providers to gain experience with applying the 2-Midnight rule to these services.

We also explained that we continued 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 was 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. Nonetheless, we solicited public comments regarding the appropriate period of time for this exemption. Commenters could indicate whether and why they believed the 2-year period was appropriate, or whether they believed a longer or shorter exemption period would be more appropriate.

In summary, for CY 2021 and subsequent years, 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. We encouraged 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 noted that we would monitor changes in site-of-service to determine whether changes may be necessary to certain CMS Innovation Center models. Finally, while we proposed to retain the current 2-year exemption period, given that a large number of services would be removed from the IPO as part of the transition towards the elimination of the list, we sought comment on whether that time period remained appropriate, or if a longer or shorter period may be more warranted.

Many commenters offered suggestions on the appropriate length of time for exemptions 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. These comments are summarized below.

Comment: Numerous stakeholders including medical professional societies, health systems, and hospital associations supported the proposal to continue the 2-year exemption 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) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. While these commenters expressed their support for continuing the 2-year exemption, they further stated that a longer exemption period would be more appropriate. Some commenters suggested that anywhere between 3 to 6 years or indefinitely would be appropriate. Commenters felt 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. One commenter noted that because providers have no experience assessing procedures on the IPO list against the 2-Midnight benchmark, they will require time to update their processes to make appropriate decisions about whether to admit patients for the large numbers of procedures being removed from the IPO list. Commenters stressed that providers need time without the fear of audits to update their procedures so they can make appropriate decisions about admitting patients based on their specific conditions and recovery needs. They further noted that having an extension of the exemption period would provide stability to the healthcare systems and ensure that clinician judgment, shared decision-making with the patient, and a focus on high quality outcomes drive the selection of the appropriate site-of-service for care.

Response: We thank these commenters for their support of our proposal to continue the 2-year exemption 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) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. We understand that the 2-year exemption might not be sufficient given the magnitude of the change for providers. We agree that additional time would be more appropriate for hospitals and practitioners to adjust their billing and clinical systems, as well as develop their own internal processes to determine the appropriate setting of care for their patients. We recognize that providers may not be experienced with assessing procedures on the IPO list against the 2-Midnight benchmark and that a longer exemption would allow them ample time to update their processes to make appropriate decisions about whether to admit patients for the large numbers of procedures being removed from the IPO list. We are mindful of the important role medical review plays in maintaining the integrity of the Medicare program but understand why providers might be anxious about balancing a new landscape for services with their concerns about claim denials or RAC referrals. Accordingly, as discussed more fully below, we are finalizing an indefinite exemption period rather than the 2-year period proposed.

Comment: We heard from many commenters that the two-year

exemption was appropriate when CMS was removing a smaller volume of procedures from the IPO list. However, commenters felt that the unprecedented volume of procedures becoming subject to the 2-Midnight rule would necessitate a longer exemption period. Many commenters believe that the extra time would allow for the education of hospital staff and physician/non-physician practitioners and operational processes to be established and refined.

Response: We agree that the two-year exemption was appropriate when CMS was removing a smaller, more targeted population of procedures from the IPO. We also agree that since the agency is changing the landscape in where procedures can be performed that a longer exemption would be more appropriate. Accordingly, as discussed more fully below, we are finalizing an indefinite exemption period for procedures removed from the IPO list due to the elimination of that list.

Comment: A large contingent of commenters felt that CMS should extend the exemption indefinitely. Some expressed that 2 years is not enough time for adequate evidence and research to be conducted to demonstrate that procedures removed from the IPO list can be performed safely for Medicare beneficiaries in hospital outpatient settings. As such, they commented that CMS should extend the medical review exemption period until such evidence is widely available and there is data indicating that the procedure removed from the IPO list is more commonly performed on an outpatient basis. One commenter specified that procedures that have an average length of stay of 2 days or more or are performed on an inpatient basis more than a threshold percentage of the time (for example, 70 or more percent) should be exempted from the medical review activities outlined earlier in this section. Another commenter noted that procedures should be removed from exemption from medical review under the 2-Midnight rule as medical technology practice changes, inpatient length of stay declines, and procedures become more commonly performed on an outpatient basis. Another commenter suggested that CMS should use claims data from several payers (that is, Medicare, commercial payers, Veterans Affairs hospitals, etc.) in order to determine when procedures removed from the IPO list are routinely and safely performed in the outpatient setting and no longer require an indefinite exemption.

Most commenters that suggested the indefinite exemption stressed it was appropriate because even with the elimination of the IPO list it will still be medically necessary for a large number of these procedures to be performed in the inpatient setting. A commenter stated that applying the 2-Midnight rule to some of these procedures was not practical, as they are either exclusively performed on an inpatient basis or have an average length of stay of two days or longer. Another commenter noted that complex medical decisions are not always straightforward, and while CMS claims its intent is to defer to physician judgement on the appropriate site-of-service, this deference is not always incentivized during medical reviews and thus reflected in the RAC's review practices. Many commenters were concerned about the compliance burden on hospitals and health care providers as they seek to navigate providing care in the appropriate setting while balancing 2-Midnight enforcement.

Response: We agree with the commenters' suggestions that an indefinite exemption period is appropriate. Further, we are convinced that the medical review exemption should apply until evidence is widely available and there is data indicating that the procedure removed from the IPO list is more commonly performed on an outpatient basis. Accordingly, we are finalizing an indefinite exemption from the specified medical review activities for procedures removed from the IPO list as a result of the elimination of that list. This exemption will apply to each procedure until such time as the procedure is more commonly performed on an outpatient basis. We will use Medicare claims data to determine when a procedure is more commonly performed on an outpatient basis. We will compare on a yearly basis the number of times a given procedure is performed inpatient versus outpatient. We will define ''more commonly performed'' as being done more than fifty percent of the time in the outpatient setting. As with the 2-Midnight presumption, we will still maintain the ability to conduct medical reviews where there is evidence of systemic fraud or abuse.

We would like to emphasize 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 bill in compliance with the 2-Midnight rule. The exemption is not from the 2-Midnight rule but from certain medical review procedures and certain site-of-service claim denials. We do not believe that there will be any significant additional burden in complying with the 2-Midnight rule. It is standard practice for providers to sufficiently document medically necessity in medical records. Providers are expected to do this whether the 2-Midnight rule or any associated exemption applies or not.

Comment: Commenters suggested that CMS could reevaluate the exemption once there is sufficient data indicating that the procedure is being more commonly performed in the outpatient setting. One commenter recommended that CMS only remove the exemption once sufficient evidence exists that the procedure is being performed routinely and safely in the outpatient setting, which they believed is unlikely to develop within two years. They added that without an extension of the exemption period providers might not receive payment for care for inpatient settings even when it is the appropriate site of care. Many commenters stated that ending the exemption too early could create pressure on providers to perform a medical service in the outpatient setting despite medical judgement suggesting otherwise.

Response: We agree with commenters and will be finalizing a policy that indefinitely extends the exemption for all procedures removed from the IPO list after January 1, 2021. We will consider removing the exemption for a procedure once we have claims data that indicates it is being performed more in the outpatient setting than the inpatient setting. We do not agree with commenters that the exemption, whether it be indefinite, shorter or longer would create any hindrance to providers receiving the appropriate payment for care in the inpatient setting when the documentation in the medical record supports the inpatient setting as the appropriate site of care. In such a scenario, the claim would generally be payable under Part A pursuant to either the 2-Midnight rule at 42 CFR. 412.3(d)(1) or the case-by-case exception at § 412.3(d)(3). We also believe it is important for CMS to be able to continue to conduct medical reviews in situations in which there is evidence of systemic fraud or abuse.

Comment: We received comments suggesting that CMS establish a list of procedures that would be exempt from medical review under the 2-Midnight rule permanently. One commenter suggested that CMS provide an explicit exception to the 2-Midnight rule for procedures that are removed from the IPO list where the beneficiary is at higher risk as identified by factors such as age, dual-eligible status, presence of certain comorbidities, social factors,

environmental factors, and patient body mass index. Another commenter stated that certain procedures with high average length of stay, such as organ transplants, are likely to never be performed outpatient absent significant improvements in technology. They added that, based on criteria similar to that of the current IPO list, CMS could use average length of stay information and site-of-service patterns to determine whether the exemption would continue for a given procedure and deference provided to the physician.

Response: We thank the commenters for their suggestions and will consider additional metrics for determining whether a procedure requires a 2-Midnight medical review exemption in the future.

Comment: We received many comments suggesting that if the elimination of the IPO list is being driven by the belief that the physician should determine the correct level of care based upon individual patient needs and comorbidities and the physician certifies this need, these level of care audits should be discontinued. Many commenters felt that physicians should be able to select the appropriate site-of-service without having that decision questioned by subjecting the procedure to medical review for site-of-service under the 2-Midnight rule. Some commenters expressed that site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) constituted a barrier to payment for procedures performed in the inpatient setting. Moreover, if site-of-service determinations are based on a physician's clinical judgment regarding the care setting that is best suited to meet a given patient's medical needs that decision should not be subject to any review.

Response: As stated earlier in this section, we continue to believe that use of the 2-Midnight benchmark gives appropriate consideration to the medical judgment of physicians and furthers the goal of clearly identifying when an inpatient admission is appropriate for payment under Medicare Part A. More specifically, as we described in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), factors such as the procedures being performed and the beneficiary's condition and comorbidities apply when the physician formulates his or her expectation regarding the need for hospital care, while the determination of whether an admission is appropriately billed and paid under Medicare Part A or Part B is generally based upon the physician's medical judgment regarding the beneficiary's expected length of stay. We have not identified any circumstances where the 2-Midnight benchmark restricts the physician to a specific pattern of care, because the 2-Midnight benchmark does not prevent the physician from ordering or providing any service at any hospital, regardless of the expected duration of the service. Rather, this policy provides guidance on when the hospitalized beneficiary's care is appropriate for coverage and payment under Medicare Part A as an inpatient, and when the beneficiary's care is reasonable and necessary for payment under Medicare Part B as an outpatient. Further, as we stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70545), section 1154(a)(1) of the Act authorizes BFCC–QIOs to review whether services and items billed under Medicare are reasonable and medically necessary and whether services that are provided on an inpatient basis could be appropriately and effectively provided on an outpatient basis.

BFCC–QIOs will continue to conduct initial medical reviews for both the medical necessity of the services, and the medical necessity of the site-of-service. BFCC–QIOs will continue to be permitted and expected to deny claims if the service itself is determined not to be reasonable and medically necessary. For procedures removed from the IPO list on or after January 1, 2021, BFCC–QIOs will not make referrals to RACs for noncompliance with the 2-Midnight rule for such procedures until the procedure is no longer subject to the medical review exemption because it is more commonly performed in the outpatient setting then the inpatient setting. RACs will not conduct reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list until they are no longer subject to the medical review exemption, and claims for procedures that are removed from the IPO list that are identified as noncompliant with the 2-Midnight rule will not be denied with respect to the site-of-service under Medicare Part A until they are no longer subject to the medical review exemption. Providers are still expected to bill in compliance with the 2-Midnight rule even if the procedure is exempt from medical review activities. The BFCC–QIOs will continue to review claims and provide education when providers submit noncompliant claims, despite the fact that they will not be denying such claims during the exemption period. CMS may also still conduct medical review where there is evidence of systemic fraud or abuse.

We continue to believe that the 2-Midnight rule plays a useful role in providing clarity to hospitals and physicians while addressing the program integrity concerns surrounding appropriate inpatient admissions. We believe that extending the exemption while providing education to providers when they submit noncompliant claims will alleviate providers' concerns about adjusting to new procedures being subject to the 2-Midnight rule.

Comment: Some commenters approached the policy concerns more broadly and implored CMS to reevaluate the meaningfulness of the 2-Midnight rule considering the agency's shift toward site-neutrality. A few commenters went as far to suggest that CMS rescind the 2-Midnight rule in its entirety.

Response: We thank the commenters for their suggestions, but note that they are outside the scope of the proposed rule. Moreover, we believe that with more choices in site-of-service the 2-Midnight rule continues to be meaningful and necessary. It continues to be important to determine whether an inpatient admission is appropriate for Medicare Part A payment. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), in which we clarified our policy regarding when an inpatient admission is considered reasonable and necessary for purposes of Medicare Part A payment. Eliminating the IPO list does not change the agency's stance on the 2-Midnight rule.

Comment: Some commenters expressed concern that the elimination of the IPO list along with the continued application of the 2-Midnight rule would increase paperwork and administrative burden. Commenters were particularly concerned about the documentation required when a patient is admitted for a short stay to undergo a procedure that should only be performed on an inpatient basis. Many commenters were concerned that the burden will fall on physicians to provide appropriate documentation for Part A payment when the physician determines that it is medically reasonable and necessary to conduct these procedures on an inpatient basis. Commenters stressed that subjecting these procedures to the 2-Midnight rule would significantly increase provider documentation burden, which is counter to CMS' recent stated efforts to reduce physicians' administrative burden. Many commenters felt that subjecting additional procedures to the 2-Midnight rule would result in increased documentation and audit

burden, both of which would increase the administrative cost of procedures.

Response: The decision to eliminate the IPO list is based upon CMS's determination that it is no longer appropriate to categorically specify that Medicare only pays for certain procedures when they are performed in an inpatient hospital setting. Instead, as with other procedures, the determination of the appropriate site-of-service is a complex medical decision to be made on a case-by-case basis. We continue to expect providers and physicians to document the medical necessity of any inpatient admission.

We believe that exempting procedures that are removed from the IPO list 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) until the procedure is more commonly performed in the outpatient setting then the inpatient setting will give providers the requisite time to adjust to any additional changes associated with the elimination of the IPO list. As we indicated in the CY 2016 OPPS/ASC Final Rule (80 FR 70543), we believe that the documentation requirements for admitting physicians are not overly burdensome because they are consistent with Medicare's longstanding documentation requirements, which predate the adoption of the 2-Midnight rule.

Comment: We heard from many commenters that CMS has an essential role to play in the education of stakeholders on the 2-Midnight rule, its exceptions, and outpatient selection criteria. Some commenters felt that not enough providers are aware that CMS policy allows for case-by-case exceptions to the 2-Midnight rule based on patient history, co-morbidities and risk of adverse events. Many commenters requested that CMS provide additional education on the case-by-case exceptions to the 2-Midnight rule. One commenter felt that such education would help ensure that concerns about audits are not unduly influencing the selection of an outpatient setting unless it is medically appropriate. One commenter specifically requested that CMS issue educational guidance to providers and Medicare contractors, similar to MLN Matters articles, reinforcing that surgeons determine whether a particular procedure should be performed on an inpatient or outpatient basis, and there is no presumption that procedures should be performed on an outpatient basis. Other commenters felt that providing hospitals and clinicians with clear and consistent standards against which they can perform will alleviate some of the administrative and financial burden otherwise associated with this kind of substantial policy overhaul.

Response: We understand the importance of education and guidance when implementing policy changes. Therefore, in the future, we plan to provide considerations for the selection of site-of-service for a procedure to support physicians' decision-making. We note that these guidelines will be for informational or educational purposes only and will not be intended to prohibit payment of procedures that were previously included on the IPO list in the outpatient setting.

CMS is finalizing a policy to exempt procedures removed from the IPO list as part of its elimination from certain medical review activities associated with the 2-Midnight rule. As noted previously, however, these procedures are not an exception to the 2-Midnight rule. Providers are still expected to comply with the 2-Midnight rule even if the procedure is exempt from medical review activities. The BFCC–QIOs will continue to review claims and provide education when providers submit noncompliant claims, despite the fact that they will not be denying such claims during the exemption period. This is different from the 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.

Comment: Numerous commenters were concerned about how the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) and Recovery Audit Contractors (RACs) would handle the rapid influx of procedures now subject to review. Many commenters felt that it was essential for CMS to begin outreach to the BFCC–QIOs to ensure that best practices for audits and education to providers regarding compliance with short-stay admission policies are universally adopted and communicated prior to the start of CY 2021. Commenters further asserted that this will help mitigate some of the administrative burden for outpatient hospitals and surgeons performing services previously flagged as inpatient-only procedures. One commenter noted that BFCC–QIOs contract awards are being delayed by vendor protests. They were concerned that few hospitals have actually had the opportunity to engage with the BFCC–QIOs to review cases recently removed from the IPO list, such as TKAs and THAs. They felt it will be important to ensure that these discussion sessions can occur so that the exemption can serve its intended purpose.

Response: We understand commenters' concerns and will work with the BFCC–QIOs as appropriate to address any issues as they arise. The BFCC–QIOs will continue to review claims even while procedures are exempt from denial based on site-of-service in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule.

We appreciate the stakeholders' feedback regarding the appropriate period of time for this exemption. After considering the concerns, suggestions, and recommendations from commenters, we have decided to finalize our proposal with modifications. Instead of the 2-year exemption, procedures removed from the IPO list on or after January 1, 2021 will be 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) indefinitely, until the procedure is more commonly performed in the outpatient setting then the inpatient setting. As a result, in order for the exemption to end for a specific procedure, we will require claims data for the service indicating that the procedure is performed more commonly on an outpatient rather than inpatient basis in a given year. 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 procedure was performed more than 50 percent of the time in the outpatient setting. We will revisit in rulemaking whether and when an exemption for a procedure should be ended. Thus, for each procedure removed from the IPO list on or after January 1, 2021, the exemption will continue until terminated in future rulemaking. We may consider additional metrics in the future that could assist us in determining when the exemption period should end for a procedure. This will only apply to procedures removed from the IPO list beginning in CY 2021. We may revisit procedures that were removed from the IPO list prior to January 1, 2021 and extend their exemption if we deem it necessary. Conversely, we may shorten

the exemption period for a procedure if necessary. In the future, we may examine the exemption status of any procedure that was formerly on the IPO list and lengthen, shorten or end their exemption.

As we stated earlier, procedures removed from the IPO list in prior years were targeted and selected in small numbers. In those cases, 2-years was an appropriate time frame to allow providers to become more comfortable with how to comply with the 2-Midnight rule. Eliminating the IPO list is a larger scale change that creates brand new considerations in determining site-of-service for providers and beneficiaries. This is a significant change, and based upon feedback from commenters, we have reevaluated our stance on the exemption period for procedures removed from the IPO list. We now feel that the magnitude of this change calls for an indefinite exemption, with CMS reevaluating that exemption once procedures are more commonly performed in the outpatient setting.

We agree with the commenters who suggested that an indefinite exemption period from certain medical review activities for procedures removed from the IPO list would be necessary to allow providers to become more familiar with how to comply with the 2-Midnight rule. The indefinite exemption will help hospitals and clinicians become used to the availability of payment under both the hospital inpatient and outpatient setting for procedures removed from the IPO list. Further, we are persuaded by the comments asserting that an indefinite exemption period will 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 also believe that an extended exemption period will further facilitate compliance with our payment policy for inpatient admissions.

We believe that extending the exemption period until procedures are more commonly performed in the outpatient setting than the inpatient setting will let providers comfortably gain experience with the application of the 2-Midnight rule to these procedures. While these procedures will be exempt from certain medical review activities related to the 2-Midnight rule, providers are not excepted from compliance with the 2-Midnight rule. That is an important distinction. As we stated earlier, providers are still expected to bill in compliance with the 2-Midnight rule. It is standard practice that the factors supporting the determination that inpatient care is required will be documented in the medical records. The BFCC–QIOs will still have the opportunity to review claims for exempt procedures 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 until the procedure is no longer subject to the exemption. We believe that the longer exemption from the medical review for procedures removed from the IPO list will give providers and BFCC–QIOs time to understand the documentation necessary to support Part A payment for those patients for which the admitting physician determines that the procedures should be furnished in an inpatient setting.

Additionally, CMS may still conduct medical review in cases in which there is evidence of systemic fraud or abuse occurring. Finally, we are amending 42 CFR 412.3 to clarify when a procedure removed from the IPO is exempt from certain medical review activities. 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.

XI. CY 2021 OPPS Payment Status and Comment Indicators

A. CY 2021 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 2021, we did not propose to make any changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2020 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 did not receive any public comments on the proposed definitions of the OPPS status indicators for CY 2021. We believe that the existing definitions of the OPPS status indicators will continue to be appropriate for CY 2021. Therefore, we are finalizing our proposed policy without modifications.

The complete list of the payment status indicators and their definitions that would apply for CY 2021 is displayed in Addendum D1 to the CY 2021 OPPS/ASC final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

CY 2021 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to the CY 2021 OPPS/ASC final rule with comment period, which are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

B. CY 2021 OPPS Comment Indicator Definitions

In the CY 2021 OPPS/ASC proposed rule, we proposed to use four comment indicators for the CY 2021 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2020 and we proposed to continue their use in CY 2021. The CY 2021 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 OPPS comment indicators for CY 2021 are listed in Addendum D2 to the CY 2021 OPPS/ASC final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

We did not receive any public comments on the proposed definitions of the OPPS comment indicators for CY 2021.

We believe that the existing CY 2020 definitions of the OPPS comment indicators continue to be appropriate for CY 2021. Therefore, we are using those definitions without modification for CY 2021.

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 2020 report.

A. OPPS Payment Rates Update

The March 2020 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 2020 report for a complete discussion of these recommendations.[101] We appreciate MedPAC's recommendations, but as MedPAC acknowledged in its March 2020 report, the Congress would need to change current law to enable us to implement its recommendations. Comments received from MedPAC for other OPPS policies are discussed in the applicable sections of this rule.

B. ASC Conversion Factor Update

In the March 2020 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.[102] As a result, for CY 2021, 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 2021 (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 MFP-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 MFP-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 the CY 2021 OPPS/ASC proposed rule, we proposed to apply the MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2021 ASC payment amounts.

C. ASC Cost Data

In the March 2020 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.[103]

We recognize that the submission of cost data could place additional administrative burden on most ASCs. We are interested in 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. We did not propose any cost reporting requirements for ASCs in the CY 2021 OPPS/ASC proposed rule.

Comments received from MedPAC for other ASC payment system policies are discussed in the applicable sections of this rule. The full March 2020 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 and 2020 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080, and 84 FR 61370 through 61410, respectively).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under 42 CFR 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, that would not be expected to pose a significant risk to beneficiary safety 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

[101] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, pp.94–95. Available at: *http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0.*

[102] 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.*

[103] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services. Available at: *http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0.*

procedure (''overnight stay''). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate to be furnished to Medicare beneficiaries in ASCs. As discussed in detail in Section XIII.C.1.d of this final rule with comment period, we are finalizing changes to the way procedures are added to the CPL.

Historically, we have defined 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).

In the August 2, 2007 final rule (72 FR 42495), we also established our policy to 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; and (5) certain radiology services for which separate payment is allowed under the OPPS. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66932 through 66934), we expanded the scope of ASC covered ancillary services to include certain diagnostic tests within the medicine range of Current Procedural Terminology (CPT) codes for which separate payment is allowed under the OPPS when they are provided integral to an ASC covered surgical procedure. Covered ancillary services are specified in 42 CFR 416.164(b) and, as stated previously, are eligible for separate ASC payment. 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 (42 CFR 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 covered 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 that we have determined do not pose a significant safety risk, would not expect to require an overnight stay when performed in an ASC, and that are separately paid under the OPPS (72 FR 42478).

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. We now define 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 have determined are not expected to pose a significant risk to beneficiary safety when performed in an ASC, for which

standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and are separately paid under the OPPS.

B. 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. 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 includes Category I, II, and III CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

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

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2021 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we proposed to solicit public comments in the CY 2021 OPPS/ASC proposed rule (and respond to those comments in this final rule with comment period) or whether we are soliciting public comments in this final rule with comment period (and responding to those comments in the CY 2022 OPPS/ASC final rule with comment period).

We note that we sought public comments in the CY 2020 OPPS/ASC final rule with comment period (84 FR 62375) on the new and revised Level II HCPCS codes effective October 1, 2019 or January 1, 2020. These new and revised codes were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2020 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2020 OPPS/ASC final rule with comment period. In the CY 2021 OPPS/ASC proposed rule, we stated that we will finalize the treatment of these codes under the ASC payment system in this CY 2021 OPPS/ASC final rule with comment period.

2. April 2020 HCPCS Codes for Which We Solicited Public Comments in the Proposed Rule

For the April 2020 update, there were no new CPT codes, however, there were several new Level II HCPCS codes. In the April 2020 ASC quarterly update (Transmittal 10046, CR 11694, dated April 13, 2020), we added four new Level II HCPCS codes to the list of covered ancillary services. Table 32 of the CY 2021 OPPS/ASC proposed rule displayed the new Level II HCPCS codes that were implemented on April 1, 2020, along with their proposed payment indicators for CY 2021.

We invited public comments on the proposed payment indicators and payment rates for the new HCPCS codes that were recognized as ASC ancillary services in April 2020 through the quarterly update CRs, as listed in Table 32 of the CY 2021 OPPS/ASC proposed rule. We proposed to finalize their payment indicators in this CY 2021 OPPS/ASC final rule with comment period.

We did not receive any public comments on the proposed ASC payment indicator assignments for the new Level II HCPCS codes implemented in April 2020. Therefore, we are finalizing the proposed ASC payment indicator assignments for these codes, as indicated in Table 49 below. We note that several of the temporary drug HCPCS C-codes have been replaced with permanent drug HCPCS J-codes, effective January 1, 2021. Their replacement codes are also listed in Table 49. The final payment rates for these codes can be found in Addendum BB to this final rule with comment period (which is available via the internet on the CMS website). In addition, the status indicator meanings can be found in Addendum DD1 to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 49.—NEW LEVEL II HCPCS CODES FOR ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2020

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 PI
C9053*	J0791	Injection, crizanlizumab-tmca, 5 mg	K2
C9056**	J0223	Injection, givosiran, 0.5 mg	K2
C9057#	J1201	Injection, cetirizine hydrochloride, 0.5 mg	K2
C9058##	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg	K2

*HCPCS code C9053, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0791 (Injection, crizanlizumab-tmca, 5 mg) effective July 1, 2020.

**HCPCS code C9056, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0223 (Injection, givosiran, 0.5 mg) effective July 1, 2020.

#HCPCS code C9057, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J1201 (Injection, cetirizine hydrochloride, 0.5 mg) effective July 1, 2020.

##HCPCS code C9058, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code Q5120 (Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg) effective July 1, 2020.

3. July 2020 HCPCS Codes for Which We Solicited Public Comments in the Proposed Rule

In the July 2020 ASC quarterly update (Transmittal 10188, Change Request 11842, dated June 19, 2020), we added several separately payable Category III CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 33 of the CY 2020 OPPS/ASC proposed rule displayed the new HCPCS codes that were effective July 1, 2020.

In addition, through the July 2020 quarterly update CR, we also implemented ASC payments for two new Category III CPT codes as ASC covered ancillary services, effective July 1, 2020. These codes were listed in Table 34 of the CY 2020 OPPS/ASC proposed rule, along with the proposed comment indicator and payment indicator.

We invited public comments on these proposed payment indicators for the new Category III CPT code and Level II HCPCS codes newly recognized as ASC covered surgical procedures or covered ancillary services in July 2020 through the quarterly update CRs, as listed in Tables 32, 33, and 34 of the proposed rule.

We did not receive any public comments on the proposed ASC payment indicator assignments for the new Category III CPT codes or Level II HCPCS codes implemented in July 2020. Therefore, we are finalizing the proposed ASC payment indicator assignments for these codes, as indicated in Table 50 and 51 below. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2021. Their replacement codes are listed in Table 50. The final payment rates for these codes can be found in Addendum AA and BB to this final rule with comment period (which is available via the internet on the CMS website). In addition, the status indicator meanings can be found in Addendum DD1 to this final rule with comment period (which is available via the internet on the CMS website).

BILLING CODE 4120–01–P

TABLE 50.—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2020

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 PI
C1748	C1748	Endoscope, single-use (that is, disposable), upper GI, imaging/illumination device (insertable)	J7
C1849	C1849	Skin substitute, synthetic, resorbable, per square centimeter	N1
C9059	J1738	Injection, meloxicam, 1 mg	K2
C9061	J3241	Injection, teprotumumab-trbw, 10 mg	K2
C9063	J3032	Injection, eptinezumab-jjmr, 1 mg	K2
C9122	C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	K2
C9759	C9759	Transcatheter intraoperative blood vessel microinfusion(s) (for example, intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed	N1
C9762	C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging	Z2
C9763	C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging	Z2

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 PI
C9764	C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	G2
C9765	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	J8
C9766	C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	G2
C9767	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	J8
G2170*	G2170*	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (for example, transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed	G2
G2171**	G2171**	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (for example, vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	J8
J0223	J0223	Injection, givosiran, 0.5 mg	K2
J0691	J0691	Injection, lefamulin, 1 mg	K2
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	K2
J0791	J0791	Injection, crizanlizumab-tmca, 5 mg	K2
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	K2
J1201	J1201	Injection, cetirizine hydrochloride, 0.5 mg	K2
J1429	J1429	Injection, golodirsen, 10 mg	K2
J1558	J1558	Injection, immune globulin (Xembify), 100 mg	K2

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 PI
J7169	J7169	Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 10 mg	K2
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	K2
J7333	J7333	Hyaluronan or derivative, visco-3, for intraarticular injection, per dose	N1
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	K2
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	K2
J9246	J9246	Injection, melphalan (evomela), 1 mg	K2
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	K2
Q4227#	Q4227#	Amniocore, per square centimeter	N1
Q4228#	Q4228#	BioNextPATCH, per square centimeter	N1
Q4229#	Q4229#	Cogenex amniotic membrane, per square centimeter	N1
Q4230#	Q4230#	Cogenex flowable amnion, per 0.5 cc	N1
Q4231#	Q4231#	Corplex P, per cc.	N1
Q4232#	Q4232#	Corplex, per square centimeter	N1
Q4233#	Q4233#	Surfactor or Nudyn, per 0.5 cc	N1
Q4234#	Q4234#	Xcellerate, per square centimeter	N1
Q4235#	Q4235#	Amniorepair or altiply, per square centimeter	N1
Q4236#	Q4236#	CarePATCH, per square centimeter	N1
Q4237#	Q4237#	Cryo-cord, per square centimeter	N1
Q4238#	Q4238#	Derm-maxx, per square centimeter	N1
Q4239#	Q4239#	Amnio-maxx or Amnio-maxx lite, per square centimeter	N1
Q4240#	Q4240#	Corecyte, for topical use only, per 0.5 cc	N1
Q4241#	Q4241#	Polycyte, for topical use only, per 0.5 cc	N1
Q4242#	Q4242#	Amniocyte plus, per 0.5 cc	N1
Q4244#	Q4244#	Procenta, per 200 mg	N1
Q4245#	Q4245#	Amniotext, per cc	N1
Q4246#	Q4246#	Coretext or Protext, per cc	N1
Q4247#	Q4247#	Amniotext patch, per square centimeter	N1
Q4248#	Q4248#	Dermacyte Amniotic Membrane Allograft, per square centimeter	N1
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	K2
Q5120	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg	K2
0594T	0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	J8

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 PI
0596T	0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	R2
0597T	0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	R2
0600T	0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	J8
0601T	0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	J8
0614T	0614T	Removal and replacement of substernal implantable defibrillator pulse generator	J8
0616T	0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens	J8
0617T	0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens	J8
0618T	0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange	J8
0619T	0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	J8

*HCPCS code C9754, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2170 effective July 1, 2020.

**HCPCS code C9755, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2171 effective July 1, 2020.

#HCPCS codes Q4227 through Q4248: 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.

TABLE 51.—NEW CATEGORY III CPT CODE FOR COVERED ANCILLARY SERVICE EFFECTIVE ON JULY 1, 2020

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	CY 2021 PI
0598T	0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (for example, lower extremity)	Z2
0599T	0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (for example, upper extremity) (List separately in addition to code for primary procedure)	N1

BILLING CODE 4120–01–C

4. October 2020 HCPCS Codes for Which We Are Soliciting Public Comments in This Final Rule With Comment Period

In the past, we released new and revised HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48947), for CY 2021, consistent with our established policy, we proposed that the Level II HCPCS codes that will be effective October 1, 2020 would be flagged with comment indicator ''NI'' in Addendum BB to the CY 2021 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment indicator for CY 2021. We did not receive any public comments on our proposal. As we stated in the CY 2021 OPPS/ASC proposed rule, we are inviting public comments in this CY 2021 OPPS/ASC final rule with comment period on the interim ASC payment indicator for these codes that we intend to finalize in the CY 2022 OPPS/ASC final rule with comment period.

5. January 2021 HCPCS Codes

a. Level II HCPCS Codes for Which We Are Soliciting Public Comments in This Final Rule With Comment Period

Consistent with past practice, we are soliciting comments on the new Level II HCPCS codes that are effective January 1, 2021 in the CY 2021 OPPS/ASC final rule with comment period, thereby updating the ASC payment system for the calendar year. These codes are released to the public via the CMS HCPCS website, and also through the January OPPS quarterly update CRs. 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 the CY 2021 OPPS/ASC proposed rule, most Level II HCPCS codes are not released until 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, we stated in the CY 2021 OPPS/ASC proposed rule with comment period that the Level II HCPCS codes that will be effective January 1, 2021 would be released to the public through this CY 2021 OPPS/ASC final rule with comment period, January 2021 ASC Update CR, and the CMS HCPCS website (85 FR 48948).

In addition, for CY 2021, we proposed to continue our established policy of assigning comment indicator ''NI'' in Addendum AA and Addendum BB to the CY 2021 OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2021 to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We are inviting public comments in this CY 2021 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2022 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Solicited Public Comments in the 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/ASC final rule. 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 the resort to 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), solicit public comments, and finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2021 OPPS update, we received the CPT codes that will be effective January 1, 2021 from AMA in time to be included in the proposed rule. The new, revised, and deleted CPT codes were listed in Addendum AA and Addendum BB to the CY 2021 OPPS/ASC proposed rule. The new and revised CPT codes were assigned to comment indicator ''NP'' in Addendum AA and Addendum BB of the CY 2021 OPPS/ASC 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, along with a proposed ASC payment indicator assignment, and that comments would be accepted on the proposed ASC payment indicator.

Further, we note that the CPT code descriptors that appeared in Addendum AA and BB to the CY 2021 OPPS/ASC proposed rule were short descriptors and did not fully describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and the long descriptors for the new and revised CY 2021 CPT codes in Addendum O to the proposed rule so that the public could adequately comment on the proposed ASC payment indicator assignments. The 5-digit placeholder codes were listed in Addendum O, specifically under the column labeled ''CY 2021 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code''. The final CPT code numbers are included in this CY 2021 OPPS/ASC final rule with comment period, and can be found in Addendum AA, Addendum BB, and Addendum O.

For new and revised CPT codes effective January 1, 2021 that were received in time to be included in the CY 2021 OPPS/ASC proposed rule, we proposed the appropriate payment indicator assignments, and solicited public comments on the payment assignments. We stated we would accept comments and finalize the payment indicators in this CY 2021 OPPS/ASC final rule with comment period. We received comments on the ASC payment indicators for certain new CPT codes that will be effective January 1, 2021. These comments, and our responses, can be found in section XIII.C. (Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services) of this final rule with comment period.

Also, we note that we inadvertently omitted four new HCPCS codes, specifically, CPT codes 0627T, 0628T, 0629T, and 0630T, effective January 1, 2021 from Addendum AA of the CY 2021 OPPS/ASC proposed rule. The procedures described by the four new HCPCS codes are displayed in Addendum AA of this CY 2021 OPPS/ASC final rule with comment period with comment indicator ''NI'' to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We are inviting public comments on the ASC payment indicators for CPT codes 0627T, 0628T, 0629T, and 0630T, which will be finalized in the CY 2022 OPPS/ASC final rule with comment period.

Finally, shown in Table 35 of the CY 2021 OPPS/ASC proposed rule (85 FR 48949) and reprinted in Table 52 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 52.—COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2020	HCPCS (CPT and Level II codes)	April 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
July 2020	HCPCS (CPT and Level II codes)	July 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
October 2020	HCPCS (CPT and Level II codes)	October 1, 2020	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period
January 2021	CPT Codes	January 1, 2021	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2021	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period

C. 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 by 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) Changes for CY 2021 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2021 OPPS/ASC proposed rule (85 FR 48949 through 48953), 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. We reviewed the most recent claims volume and utilization data (CY 2019 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 2020 OPPS/ASC final rule with comment period (84 FR 61376 through 61380).

Our review of the CY 2019 volume and utilization data of covered surgical procedures currently assigned a payment indicator of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) resulted in our identification of six covered surgical procedures that we believe met the criteria for designation as permanently office-based. The data indicated that these procedures are performed more than 50 percent of the time in physicians' offices, and we believe that the services were of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT codes that we proposed to permanently designate as office-based for CY 2021 are listed as Table 53.

BILLING CODE 4120–01–P

TABLE 53: PROPOSED ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2021

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
11760	Repair of nail bed	G2	P3*
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)	J8	P3*
23077	Radical resection of tumor (eg, sarcoma), soft tissue of shoulder area; less than 5 cm	G2	P2*
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	G2	P2*
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	G2	P2*
67500	Retrobulbar injection; medication (separate procedure, does not include supply of medication)	G2	P3*

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the PFS proposed rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS proposed rule.

We also reviewed CY 2019 volume and utilization data and other information for 18 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 2020 OPPS/ASC final rule with comment period (84 FR 61380 through 61383). These procedures were surgical procedures that were designated as temporarily office-based in the CY 2019 OPPS/ASC final rule with comment period or were new CPT codes for CY 2020 that were designated as temporarily office-based. Of these 18 procedures, for each procedure, there were fewer than 50 claims in our data and no claims data for 11 of the 18 procedures described by CPT codes 64454, 64624, 65785, 67229, 0402T, 0512T, 0551T, 0566T, 0588T, 93985 and 93986. Therefore, we proposed to continue to designate these procedures, shown in Table 54, as temporarily office-based for CY 2021. The procedures for which the proposed office-based designation for CY 2021 is temporary are indicated by an asterisk in Addendum AA to the CY 2021 OPPS/ASC proposed rule with comment period (which is available via the internet on the CMS website).

TABLE 54: PROPOSED CY 2021 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2020 OPPS/ASC PROPOSED RULE

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	P3*
64624	Destruction by neurolytic agent, 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*

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
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*
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	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 final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

For the remaining seven procedures of the 18 procedures designated as temporarily office-based as shown in Table 56 and Table 57 in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61380 through 61383), we proposed to permanently assign an office-based designation for five of the procedures, represented by CPT codes 10007, 10011, 11102, 11104, and 11106. After reviewing CY 2019 volume and utilization data for these five procedures, the claims data were sufficient to indicate that these covered surgical procedures are performed predominantly in physicians' offices (greater than 50 percent of the time) and, therefore, we proposed to permanently assign one of the office-based payment indicators, specifically ''P2,'' ''P3'' or ''R2,''—to these codes for CY 2021 as shown in Table 55. For the two remaining procedures that had temporary office-based designations for CY 2020, described by CPT codes 10005 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion) and 10009 (Fine needle aspiration biopsy, including ct guidance; first lesion), utilization data are sufficient to indicate that these covered surgical procedures are not performed predominantly in physician's offices (performed in physician's offices less than 50 percent of the time) and, therefore, we proposed to assign a non office-based payment indicator—''G2''—to these codes for CY 2021 as shown in Table 55.

TABLE 55: PROPOSED CY 2021 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	P3	G2
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3	P3*
10009	Fine needle aspiration biopsy, including ct guidance; first lesion	P2	G2
10011	Fine needle aspiration biopsy, including mr guidance; first lesion	R2	R2*
11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	P3	P3*
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	P2	P3*
11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	P3	P3*

* Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

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 temporarily as 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 2021 we proposed to designate two new CY 2021 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 in Table 56 would be predominantly performed in physicians' offices. We believe the procedures described by CPT codes 0596T (Temporary female intraurethral valve-pump (that is, voiding prosthesis); initial insertion, including urethral measurement) and 0597T (Temporary female intraurethral valve-pump (that is, voiding prosthesis); replacement) are similar to CPT code 55285 (Cystourethroscopy for treatment of the female urethral syndrome with any or all of the following: urethral meatotomy, urethral dilation, internal urethrotomy, lysis of urethrovaginal septal fibrosis, lateral incisions of the bladder neck, and fulguration of polyp(s) of urethra, bladder neck, and/or trigone) which is currently on the list of covered surgical procedures and assigned a proposed payment indicator ''A2''—Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight.—for CY 2021. While CPT code 52285 is not subject to office-based determinations as it is assigned an ''A2'' payment indicator, we note that this procedure is predominantly performed in a physician office setting (52 percent based on CY 2019 claims). As such, we proposed to add CPT codes 0596T and 0597T in Table 56 to the list of temporarily office-based covered surgical procedures.

TABLE 56: PROPOSED CY 2021 PAYMENT INDICATORS FOR NEW CY 2021 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2021 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator**
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	R2**
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	R2**

** Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

Comment: Some commenters supported our proposed temporary office-based designations as well as the removal of temporary office-based designations for CPT codes 10005 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion) and 10009 (Fine needle aspiration biopsy, including ct guidance; first lesion). Many commenters did not support our proposed temporary office-based designation for CPT code 64624 (Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed). Commenters argued that the office setting does not represent the predominant site of care where this procedure is furnished, noting that this procedure is more likely to be performed in a hospital outpatient department or ASC setting. Commenters note that CY 2020 claims and utilization data support this position.

Response: We thank commenters for the support of our proposed temporary office-based designations. For the first two quarters of CY 2020, we reviewed over 5,000 claims submitted for CPT code 64624. We observed that this procedure was performed 23.9 percent of the time in an office setting for the first two quarters of CY 2020, significantly less than the 50 percent threshold for a permanent office-based designation. Therefore, we agree with commenters that removing the temporary office-based designation for CPT code 64624 is appropriate. For CY 2021, we are finalizing a payment indicator of ''G2''—(Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight)—for CPT code 64624.

After consideration of the public comments we received, we are finalizing our proposal, without modifications, to remove the temporary office-based designation for CPT codes 10005 and 10009. Additionally, we are finalizing our proposal, with modifications, to designate the procedures shown in Table 57 as temporarily office-based for CY 2021. Further, after consideration of the public comments we received, we are finalizing our proposal, without modifications, to designate the procedures shown in Table 58 as permanently office-based beginning CY 2021.

TABLE 57: ASC COVERED SURGICAL PROCEDURES TO BE DESIGNATED AS TEMPORARILY OFFICE-BASED FOR CY 2021

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2021 ASC Payment Indicator**
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (report medication separately)	R2**
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2**
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	R2**
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	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**
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	R2**
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	R2**

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2021 ASC Payment Indicator**
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3**
65785	Implantation of intrastromal corneal ring segments	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**
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2**
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2**

** Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

TABLE 58: ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2021

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2021 ASC Payment Indicator**
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3**
10011	Fine needle aspiration biopsy, including mr guidance; first lesion	R2**
11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	P3**
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	P3**
11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	P3**
11760	Repair of nail bed	P3**
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)	P3**
23077	Radical resection of tumor (eg, sarcoma), soft tissue of shoulder area; less than 5 cm	R2**
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	R2**
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	P2**
67500	Retrobulbar injection; medication (separate procedure, does not include supply of medication)	P3**

** Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

BILLING CODE 4120–01–C

(3) Comment Solicitation on Office-Based Exemption for Dialysis Vascular Access Procedures

As we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59036), the office-based utilization for CPT codes 36902 and 36905 (dialysis vascular access procedures) was greater than 50 percent. However, we did not designate CPT codes 36902 and 36905 as office-based procedures for CY 2019. These codes became effective January 1, 2017 and CY 2017 was the first year we had claims volume and utilization data for CPT codes 36902 and 36905. We shared commenters' concerns that the available data were not adequate to make a determination that these procedures should be office-based, and believed it was premature to assign office-based payment status to those procedures for CY 2019. For CY 2019, CPT codes 36902 and 36905 were assigned payment indicators of ''G2''—Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative weight.

As we stated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61378), volume and utilization data for CPT code 36902 for CY 2018 showed the procedure was performed more than 50 percent of the time in physicians' offices. However, the office-based utilization for CPT code 36902 had fallen from 62 percent based on 2017 data to 52 percent based on 2018 data. In addition, there was a sizeable increase in claims for this service in ASCs—from approximately 14,000 in 2017 to 38,000 in 2018. In light of these changes in utilization and due to the high utilization of this procedure in all settings (over 125,000 claims in 2018), we believed it may have been premature to assign office-based payment status to CPT code 36902 for CY 2020. Therefore, for CY 2020, we finalized our proposal to not designate CPT code 36902 as an office-based procedure, but to continue to assign CPT code 36902 a payment indicator of ''G2''—non office-based surgical procedure paid based on OPPS relative weights. Additionally, CY 2018 volume and utilization data for CPT code 36905 showed the procedure was not performed more than 50 percent of the time in physicians' offices and we finalized our proposal to retain its payment indicator of ''G2''—non office-based surgical procedure based on OPPS relative weights for CY 2020.

For the CY 2021 OPPS/ASC proposed rule, we reviewed CY 2019 volume and utilization data for CPT code 36902 and determined that this procedure was performed less than 50 percent of the time in physicians' offices. We note that the office-based utilization for CPT code 36902 has fallen from 52 percent in 2018 to 41 percent in 2019. Similarly,

CY 2019 volume and utilization data for CPT code 36905 continues to show that this procedure was performed less than 50 percent of the time in physician's offices. Therefore, we did not propose to designate CPT codes 36902 and 36905 as office-based procedures for CY 2021.

In past rulemaking, commenters have requested we permanently exempt dialysis vascular access procedures from office-based designations similar to our exemption for radiology services that involve certain nuclear medicine procedures and radiology services that involve contrast agents (42 CFR 416.171(d)(1) and (2)) (83 FR 59036). Commenters contended that an office-based designation for dialysis vascular access procedures (in particular CPT codes 36902 and 36905) would result in a lower ASC payment rate if frequently used additional services, which are often packaged under the ASC payment system but separately payable under the Physician Fee Schedule, are factored into the analysis. Therefore, an office-based designation and payment at Physician Fee Schedule amounts under the ASC payment system may provide an inappropriate and lower global payment, after factoring in additional surgical procedures and/or ancillary items and services, when compared to the Physician Fee Schedule. Further, commenters have noted that ASCs are generally able to provide a wider array of dialysis vascular access procedures than are typically available in the physician office setting and at a lower Medicare payment rate than the hospital outpatient department setting. Providing an office-based ASC payment rate using PFS non facility PE RVUs for dialysis vascular access procedures may reduce the number of ASCs willing to perform such services and, subsequently, reduce beneficiary access for dialysis vascular access procedures in an ASC setting. Such an outcome may inadvertently encourage migration of dialysis vascular access procedures-related services to the more expensive hospital outpatient department setting.

While current volume and utilization data shows that dialysis vascular access procedures are not predominantly performed in a physician's office setting, future data for office-based designations may illustrate a different result. ASC rates established at PFS non facility PE RVU values may reduce the number of ASCs performing these procedures and inadvertently encourage greater utilization in the hospital outpatient department setting. While we did not propose an exemption from payment at physician fee schedule non-facility PE RVU amounts as characterized by payment indicator ''P3'' for CY 2021, we contemplated implementing such an exemption in the future if necessary and sought comment on whether we might be justified in establishing a permanent exemption from Physician Fee Schedule non facility PE RVU amounts for dialysis vascular access procedures under § 416.171(d) in future rulemaking.

Comment: Some commenters supported a permanent exemption from Physician Fee Schedule non facility PE RVU amounts for dialysis vascular access procedures under § 416.171(d) in future rulemaking. However, other commenters, while supportive, did not believe an exemption was necessary as office utilization for such procedures was unlikely to rise above the 50 percent threshold.

Response: We appreciate the commenters' feedback regarding a potential exemption from Physician Fee Schedule non facility PE RVU amounts for dialysis vascular access procedures under § 416.171(d). We agree with commenters that such an exemption is not necessary at this time; however, we may consider such a proposal for future rulemaking.

b. ASC Covered Surgical Procedures To Be Designated as Device-Intensive

(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 2021

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. Corresponding to this change in the cost criterion we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC and involve the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2. of 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 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

Based on our modified device-intensive criteria, for CY 2021, we proposed 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 2018 OPPS claims and cost report data available for the CY 2020 OPP/ASC proposed rule.

The ASC covered surgical procedures that we proposed to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2021, are assigned payment indicator ''J8'' and are included in ASC Addendum AA to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website). The CPT code, the CPT code short descriptor, and the proposed CY 2021 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).

As discussed in section IV.A. of this final rule with comment period, we are approving the BAROSTIM NEO™ system for transitional pass-through device payment status. The applicant has stated that the BAROSTIM NEO™ would be reported with CPT code 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)). There have been no device costs reported for CPT code 0266T in CY 2019 claims or in previous calendar years. Therefore, we are assigning a device offset percentage to 0266T in CY 2021 based on the clinically-similar procedure 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)). Based on our review of CY 2019 claims data, CPT code 0268T has a device offset percentage of 96.04 percent. Therefore, for CY 2021, we are assigning device-intensive status to CPT code 0266T with a device offset percentage of 96.04 percent.

Comment: Some commenters requested that device-intensive designations for procedures under the ASC payment system be based solely on device-intensive designations under the OPPS.

Response: We are not accepting the commenters' recommendation. As we have stated in past rulemaking (79 FR 66924), under 42 CFR 416.167 and 416.171, most ASC payment rates are based on the OPPS relative payment weights, and our ASC policy with respect to device-intensive procedures is designed to be consistent with the OPPS. As such, a ''device-intensive'' designation identifies those procedures with significant device costs and applies to services that are performed both in the hospital outpatient department and the ASC setting. We believe that the device-intensive methodology for ASCs should align with the device-intensive policies for OPPS, and, therefore, procedures should not be device intensive in the ASC setting if they are not device intensive in the hospital outpatient setting. Accordingly, to be assigned device-intensive status in the ASC setting, the procedure must be identified as device-intensive in the hospital outpatient setting and have a device offset percentage that exceeds the 30 percent threshold as calculated using our standard ratesetting methodology as stated in 42 CFR 416.171(b)(2).

Comment: Several commenters requested that we restore the device-intensive status for CPT code 0200T (Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed), noting that we proposed device-intensive status for this procedure under the OPPS.

Response: Based on updated claims data for this final rule with comment period, CPT code 0200T has a device offset percentage of 20.39 percent based on the standard ratesetting methodology. Therefore, CPT code 0200T is ineligible for device-intensive status under the ASC payment system and we are finalizing a payment indicator of ''G2'' CPT code 0200T for CY 2021.

Comment: One commenter recommended that we assign device-intensive status to CPT code 66174 (Transluminal dilation of aqueous outflow canal; without retention of device or stent).

Response: Based on updated claims data for this final rule with comment period, CPT code 66174 has a device offset percentage of 24.70 percent. Therefore, CPT code 66174 is ineligible for device-intensive status under the ASC payment system. We are finalizing a payment indicator of ''A2''—Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight—for CPT code 66174 for CY 2021.

Comment: Some commenters supported the Advisory Panel on Hospital Outpatient Payment (HOP Panel) recommendation that CMS consider lowering the ASC device-intensive threshold from 30 percent to 25 percent to better capture device costs in the ASC setting.

Response: Our established policy under the ASC payment system, as discussed at greater length in section XIII.G. of this final rule, is to scale prospective ASC relative payment weights by comparing total payment using current year ASC scaled relative payment weights with the total payment using the prospective ASC relative payment weights, holding ASC utilization, the ASC conversion factor, and the mix of services constant from the claims year. Lowering the device-intensive threshold would have the effect of assigning a greater amount of device costs, and increasing estimated ASC expenditures for the prospective year. The increase in prospective year expenditures can be attributable to portions of ASC non-device costs, which are otherwise calculated using an ASC conversion factor that is lower than the OPPS conversion factor, being replaced with device costs which are calculated using the higher OPPS conversion factor so that device costs are held constant between the OPPS and ASC payment system. The increase in estimated prospective year expenditures would put additional downward pressure on the ASC weight scalar and otherwise reduce ASC payment rates for most surgical procedures. Accordingly, we do not believe it would be appropriate to lower the ASC device-intensive threshold at this time.

Comment: One commenter requested that we reevaluate our device cost calculations with respect to the device

offset percentage difference between CPT codes 64910 (Nerve repair; with synthetic conduit or vein allograft (*e.g.,* nerve tube), each nerve) and 64912 (Nerve repair; with nerve allograft, each nerve, first strand (cable)). The commenter noted that the device offset percentage for CPT code 64912 has historically been greater than the device offset percentage for CPT code 64910.

Response: We appreciate the commenters' recommendation. We note that CPT codes 64910 and 64912 each had less than 50 claims for this CY 2021 OPPS/ASC final rule with comment period. For relatively lower volume procedures such as these, the limited sample sizes may cause greater fluctuation in device cost statistics for these procedures on a year-to-year basis. The amount of packaged costs submitted on a claim, the hospital charges reported on the claim, as well as the cost-to-charge ratios for the hospitals that submitted these claims, can have a substantial impact on our device cost calculations for relatively lower volume procedures. However, we believe continuing to use our device-intensive methodology results in the most accurate and reliable device cost statistics for capturing changes in device costs over time and for purposes of determining device-intensive status and device offset percentages.

After consideration of the public comments we received, we are designating the ASC covered surgical procedures displayed in Addendum AA with payment indicator ''J8'' as device-intensive and subject to the device-intensive procedure payment methodology for CY 2021.

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 proposed 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 2021 and subsequent calendar years. Specifically, for CY 2021 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 did not propose any other changes to our policies related to no/cost full credit or partial credit devices.

In the CY 2021 OPPS/ASC proposed rule, we did not propose any changes to these policies and we did not receive any comments on our policies related to no/cost full credit or partial credit devices. Therefore, we are finalizing continuing our existing policies for CY 2021 and subsequent years.

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 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.

Under our current regulations at 42 CFR 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2008 are surgical procedures that meet the general standards specified in 42 CFR 416.166(b) and are not excluded under the general exclusion criteria specified in 42 CFR 416.166(c). Specifically, under 42 CFR 416.166(b), the general standards provide that covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. Section 42 CFR 416.166(c) sets out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) Generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under 42 CFR 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under 42 CFR 411.15.

For purposes of identifying procedures eligible to be added to the covered surgical procedure list, we define surgical procedures as those procedures described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category I and III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range (83 FR 59044 through 59045), that we have determined do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS. We proposed to continue to apply the revised definition of ''surgery'' we adopted in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), which includes certain ''surgery-like'' procedures that are assigned codes outside the CPT surgical range, for CY 2021 and subsequent years.

As discussed above, section 1833(i)(1) of the Act requires the Secretary to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can be safely performed on an ambulatory basis in an ASC, a CAH, or an HOPD and to review and update the list of ASC procedures at least every 2 years. The report accompanying the legislation establishing section 1833(i)(1) of the Act explained that Congress intended procedures routinely performed on an ambulatory basis in a physician's office that do not generally require the more elaborate facilities of an ASC not to be included in the list of ASC covered procedures (H.R. Rep. No. 96–1167, at 390–91, reprinted in 1980 U.S.C.C.A.N. 5526, 5753–54).

In consideration of the statutory requirements and legislative history, in the implementing regulations of the current ASC system (effective in 2008), which we adopted in the August 2, 2007 final ASC rule (72 FR 42487), we excluded procedures that would otherwise pose a significant safety risk to the typical Medicare beneficiary if performed in the ASC setting. However, we agreed with stakeholders who have noted that ASCs are increasingly able to safely provide a greater range of services as medical practice continues to evolve and advance. We also believe that physicians play an important role and should be able to exercise their clinical judgment in making site-of-service determinations. Accordingly, CMS has continued to reexamine the process of how we determine which procedures are payable under Medicare when furnished in the ASC setting, keeping in mind the statutory requirement in section 1833(i)(1)(A) of the Act that the Secretary must specify those surgical procedures that are appropriately performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ASC, CAH or HOPD as part of reviewing and updating the list of procedures.

In the CY 2020 OPPS/ASC final rule with comment period, we added total knee arthroplasty and several coronary intervention procedures to the ASC CPL (84 FR 61386 through 61397). Although the coronary intervention procedures involved blood vessels that could be considered major, based on our policy to consider the involvement of major blood vessels in the context of the clinical characteristics of the individual procedures and to maintain logical and clinical consistency in excluding procedures from the ASC CPL (72 FR 42481), as well as our review of the clinical characteristics of the procedures and their similarity to other procedures that were included on the ASC CPL, we believed these procedures could be safely performed in the ASC setting for appropriate beneficiaries. In the CY 2019 OPPS/ASC final rule with comment period, we also noted that in light of our conditions of coverage for ASCs, including 42 CFR 416.42, which require surgical procedures to be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the

ASC, we believe that the CfCs provide further assurance that services furnished in the ASC setting are held to a high standard of safety. While we acknowledged in the CY 2019 OPPS/ASC final rule with comment period that it could be more appropriate for certain beneficiaries to receive the coronary intervention procedures we were adding to the ASC CPL in a hospital-level setting, which typically has a higher level of emergency staff and equipment available, including onsite cardiac surgery backup, when compared to an ASC setting, we also noted that many beneficiaries could be ideal candidates to receive these services in an ASC setting and that beneficiaries and their physicians should be able to choose an appropriate site of service for surgeries based on the clinical characteristics of the patient and other factors (83 FR 59046). We continue to believe that relatively healthy and less complex patients would benefit from the shorter length of stay and reduced cost-sharing that would be expected in an ASC setting.

In the August 2, 2007 final rule with comment period establishing the revised ASC payment system, we discussed criteria for excluding procedures from the ASC CPL (72 FR 42478 through 42484). In that same final rule, we adopted the current general standards and general exclusion criteria described above. One of the general exclusion criteria we established for the revised ASC payment system, at § 416.166(c)(6), excludes any procedure on the OPPS Inpatient Only (IPO) list, which is a list of procedures for which we do not make payment under the OPPS and that are typically performed in the hospital inpatient setting because of the nature of the procedure, the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, and the underlying physical condition of the patient (65 FR 18456). We also stated that we believed that any procedures for which we did not allow payment in the hospital outpatient setting due to safety concerns would not be safe to perform in an ASC (72 FR 42478). We stated that we were committed to revising the ASC CPL so that it excludes only those surgical procedures that pose significant safety risks to beneficiaries or that are expected to require an overnight stay (72 FR 42479).

Also in the August 2, 2007 final rule with comment period, we discussed the exclusion of procedures involving major blood vessels, but we noted that it was important to maintain flexibility in our review of procedures for safe performance in the ASC setting, consistent with our past practice regarding this criterion (72 FR 42481). We discussed that there were some procedures already on the ASC list being safely performed in ASCs that involve blood vessels that would generally be defined as major. We did not agree with commenters that it would be logical or clinically consistent for us to adopt a specific definition of major blood vessels to evaluate procedures for exclusion from ASC payment (72 FR 42481). We noted the involvement of major blood vessels is best considered in the context of the clinical characteristics of individual procedures.

We noted that we proposed to exclude surgical procedures that were expected to involve major blood vessels, major or prolonged invasion of body cavities, extensive blood loss, or that are emergent or life-threatening in nature from ASC payment, based on evaluation by our medical advisors (72 FR 42478 through 42479). We also noted that most of the procedures that our medical advisors identified as involving any of the characteristics listed in 42 CFR 416.65(b)(3) also require overnight or inpatient stays, reinforcing our belief that they should be excluded from ASC payment (72 FR 42478 through 42479). We also disagreed, at that time, that all procedures performed in HOPDs were appropriate for performance in ASCs. This was due in part to the fact that we believed that HOPDs were able to provide much higher acuity care, and because hospitals were subject to more stringent infection prevention, documentation, and patient assessment requirements than ASCs. As discussed in the August 2, 2007 final rule with comment period, ASCs were not required to meet patient safety standards consistent with those in place for hospitals (that is, hospital conditions of participation), and ASCs were not required, and are not currently required, to have the trained staff and equipment needed to provide the breadth and intensity of care that hospitals are required to maintain (72 FR 42479).

Many of these concerns have been addressed with the passage of time. We believe that our approach needs to evolve away from the criteria we established in 2008, in order to reflect the significant advances in medical practice and ASC capabilities over the last 12 years. In particular, we believe that significant advancements in medical practice, surgical techniques, medical technology, and other factors have allowed certain ASCs to safely perform procedures that were once too complex, including those involving major blood vessels and other general exclusion criteria. We acknowledge that ASCs and hospitals have different health and safety requirements. Despite this fact, ASCs often undergo accreditation as a condition of state licensure and share some similar licensure and compliance requirements with hospitals as well as meet Medicare conditions for coverage (see 42 CFR 416.40 through 416.54).

As mentioned above, in recent years, we have added procedures to the ASC CPL that were largely considered hospital inpatient procedures in the past, such as total knee arthroplasty (TKA) and certain coronary intervention procedures. As the practice of medicine has evolved, hospital lengths of stay have become shorter for many surgical procedures. Many services that used to be predominantly performed in the hospital inpatient setting are now routinely performed in the hospital outpatient setting on an ambulatory basis. Further, many procedures that are currently only payable as hospital outpatient services under Medicare fee-for-service are safely performed in the ASC setting for other payors. While we recognize that non-Medicare patients tend to be younger and have fewer comorbidities than the Medicare population, we note that careful patient selection can identify Medicare beneficiaries who are suitable candidates for these services in the ASC setting. Further, Medicare Advantage plans are not obligated to adopt the ASC CPL as it exists in Medicare fee-for-service and, based on Medicare Advantage encounter data, many MA enrollees have had services performed in the ASC setting that are not currently payable under Medicare fee-for-service.

In addition, the COVID–19 pandemic has highlighted the need for more healthcare access points throughout the country. Many ASCs temporarily closed or significantly scaled back their operations based on state and federal recommendations to delay elective procedures during the public health emergency associated with COVID–19 while some ASCs opted to temporarily enroll as hospitals. Looking ahead to after the pandemic, it will be more important than ever to ensure that the health care system has as many access points and patient choices for all Medicare beneficiaries as possible. Because the pandemic has forced many ASCs to close, thereby decreasing Medicare beneficiary access to care in that setting, we believe allowing greater flexibility for physicians and patients to choose ASCs as the site of care, particularly during the pandemic, would help to alleviate both access to care concerns for elective procedures as well as access to emergency care

concerns for hospital outpatient departments.

(1) Changes to the List of ASC Covered Surgical Procedures for CY 2021

Historically, we have reviewed the clinical characteristics of procedures and consulted with stakeholders and our clinical advisors to determine if those procedures would meet our existing regulatory criteria under 42 CFR 416.2 and 416.166. Our regulation at 416.166(b) specifies the general standard criteria for covered surgical procedures, and requires that covered surgical procedures be surgical procedures: (1) That are separately paid under OPPS, (2) that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and (3) 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. Additionally, 42 CFR 416.166(b) requires that a procedure not meet our exclusion criteria set forth in 42 CFR 416.166(c).

For CY 2021, we proposed to continue to apply our current policies and criteria set forth in 42 CFR 416.2 and 416.166 for updating the ASC CPL. In addition, we proposed two alternative options for modifying our approach to adding surgical procedures to the ASC CPL—(1) a nomination process for adding new procedures to the ASC CPL, and (2) a broader approach under which we would revise our regulatory criteria at 42 CFR 416.166 to evaluate potential additions to the ASC CPL. Under our first alternative proposal, a proposed nomination process along with modifications to certain regulatory criteria, we would accept and consider nominations submitted by March 1st, 2021 in our rulemaking for CY 2022. Under our second alternative proposal, we proposed to revise our regulatory criteria by removing certain general exclusions at 42 CFR 416.166(c) and under the revised criteria, we proposed to add certain surgical procedures to the ASC CPL beginning in CY 2021. We expected either of these options would have the effect of expanding the ASC CPL, while maintaining the balance between safety and access for Medicare beneficiaries.

A. Standard ASC CPL Review Process for CY 2021

For CY 2021, consistent with our current policy for reviewing the ASC CPL, we conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC CPL, and that meet the definition of surgery to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, and as explained in more detail below, we proposed to update the list of ASC covered surgical procedures by adding eleven procedures to the list for CY 2021 as shown in Table 40 of the CY 2021 OPPS/ASC proposed rule. Procedures that we proposed to add to the ASC CPL for CY 2021 include total hip arthroplasty (THA), vaginal colpopexy, transcervical uterine fibroid ablation, and intravascular lithotripsy procedures, among others. After reviewing the clinical characteristics of these eleven procedures and consulting with our clinical advisors, we determined that these procedures are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. We have assessed each of the proposed procedures against the regulatory safety criteria in the regulation at 42 CFR 416.166(c) and believe that none of the procedures meet the general exclusion criteria.

Of the eleven procedures we proposed to add, we believed that the THA procedure merited additional discussion in the CY 2021 OPPS/ASC proposed rule, given prior discussion of the procedure in past rulemaking, to explain our belief that the procedure meets existing safety criteria for purposes of adding this procedure to the ASC CPL. In the CY 2018 OPPS/ASC proposed rule, we solicited public comments on whether the THA procedure, CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft), met the criteria to be added to the ASC CPL. In the CY 2018 OPPS/ASC final rule with comment period, we noted that some commenters argued many ASCs are equipped to perform this procedure and orthopedic surgeons in ASCs are increasingly performing this procedure safely and effectively on non-Medicare patients and appropriate Medicare patients (82 FR 59412). Commenters also stated that adding THA to the ASC CPL would allow for greater choices in care settings for Medicare patients, would provide a more patient-centered approach to joint arthroplasty procedures, and would potentially be safer in some cases when performed in an outpatient setting to prevent certain hospital-acquired infections (82 FR 59412).

However, other commenters recommended that ASCs obtain enhanced certification from a national accrediting organization that certifies an ASC meets higher quality standards and can safely perform joint arthroplasty procedures (82 FR 59412). Some commenters opposed adding THA to the ASC CPL, as they believed the vast majority of ASCs are not equipped to safely perform these procedures on patients and the vast majority of Medicare patients are not suitable candidates to receive ''overnight'' joint arthroplasty procedures in an ASC setting (82 FR 59412). For CY 2018, we did not finalize adding THA to the ASC CPL, but noted that we would take commenters' suggestions and recommendations into consideration for future rulemaking.

In the CY 2021 OPPS/ASC proposed rule, we sought to continue to promote site neutrality, where possible, between the hospital outpatient department and ASC settings, and expand the ASC CPL to include as many procedures that can be performed in the HOPD as reasonably possible to advance that goal. Further, we believed that there are at least a subset of Medicare beneficiaries who may be suitable candidates to receive THA procedures in an ASC setting based on the beneficiaries' clinical characteristics. We believe physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations, including for THA. We believe THA would meet our existing regulatory requirements established under 42 CFR 416.2 and 416.166(b) and (c) for covered surgical procedures in the ASC setting. In light of this information and the public comments submitted in support of adding THA to the ASC CPL in response to our CY 2018 public comment solicitation, we proposed to add THA to the ASC CPL in CY 2021, as shown in Table 40 of the CY 2021 OPPS/ASC proposed rule.

We proposed to add a total of eleven procedures, displayed in Table 40 of the CY 2021 OPPS/ASC proposed rule, with their HCPCS code long descriptors, to the list of ASC covered surgical procedures for CY 2021. We sought public comment on our proposal, including any medical evidence or literature to support the commenters' views on whether or not we should add any of these procedures to the ASC CPL for CY 2021. In addition, we also sought comment on the two alternative proposals described below. Note that under both alternative proposals, we still proposed to add the eleven

procedures proposed under this section for CY 2021.

Comment: Multiple commenters supported adding the eleven procedures we proposed to add to the ASC CPL under the established process for assessing procedures for inclusion on the ASC CPL. They noted that orthopedic surgeons in ASCs are increasingly performing these eleven procedures safely and effectively on non-Medicare-fee-for-service patients and appropriate Medicare patients. Two of these procedures, total hip arthroplasty (THA) and autologous chondrocyte knee implantation, received significant support from commenters. Commenters noted that due to advancements in clinical practice, less invasive techniques, patient selection, improved perioperative anesthesia, alternative postoperative pain management and expedited rehabilitation protocols, these procedures can be safely and effectively performed for Medicare beneficiaries in the ASC setting. These commenters observed that patients are typically not expected to require active medical monitoring and care at midnight following these procedures.

Several commenters opposed the addition of THA to the CPL due to the risk of jeopardizing patient safety as well as expanded beneficiary coinsurance obligations. These commenters also recommended CMS ensure beneficiaries are informed in advance that, unlike under the OPPS, ASC cost-sharing is not capped at the inpatient deductible and could exceed cost sharing in the hospital outpatient setting for the same procedure. One commenter stated that CMS should delay adding THA to the ASC CPL until there is more robust outcomes data available.

Response: We thank commenters for providing public comments on the appropriateness of adding THA and other procedures to the ASC CPL and recognize their concerns for ensuring patient health and quality care. As we have noted in the CY 2019 OPPS/ASC final rule (83 FR 59046) and the CY 2020 OPPS/ASC final rule (84 FR 61354), we continue to believe that the appropriate site of service for any surgical procedure, including THA, should be based on the physician's assessment of the patient and tailored to the individual patient's needs. We believe there are a number of less medically complex Medicare beneficiaries that could appropriately receive THA in an ASC setting. For these beneficiaries, physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations.

We are aware that beneficiaries may incur greater cost-sharing for THA procedures in an ASC setting under our proposal, but note that this is not an occurrence that is unique to THA. As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59389), section 4011 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1834 of the Act by adding a new subsection (t), which requires the Secretary to make available to the public via a searchable website, with respect to an appropriate number of items and services, the estimated payment amount for the item or service under the OPPS and ASC payment system and the estimated beneficiary liability applicable to the item or service. We implemented this provision by providing our Outpatient Procedure Price Lookup tool available via the internet at *https://www.medicare.gov/procedure-price-lookup*. This web page allows beneficiaries to compare their potential cost-sharing liability for procedures performed in the hospital outpatient setting versus the ASC setting. We believe this tool helps inform beneficiaries of potential cost-sharing amounts for receiving a service in the ASC setting compared to the outpatient setting, and note that this tool would include a comparison of cost-sharing liability for THA in the outpatient hospital and ASC settings in the future. Given these reasons, we do not believe a delay in the implementation of our proposed additions to the ASC CPL is warranted based on concerns relating to beneficiary safety or the potential for greater cost sharing expenses for beneficiaries.

We assessed each of the eleven procedures we proposed to add to the ASC CPL using the existing regulatory safety criteria and determined that these procedures meet each of the criteria. Based on our review of the clinical characteristics of the procedures and their similarity to other procedures that are currently included on the ASC CPL, we believe the eleven procedures (CPT codes 0266T, 0268T, 0404T, 21365, 27130, 27412, 57282, 57283, 57425, C9764, and C9766) can be safely performed in the ASC setting and note that the physician should determine whether a particular beneficiary would be a good candidate to undergo a procedure in the ASC setting rather than the hospital setting based on the clinical assessment of the patient. We agree with commenters who stated that advancements in clinical practice, less invasive techniques, patient selection, improved perioperative anesthesia, alternative postoperative pain management and expedited rehabilitation protocols have allowed these procedures to safely be performed in an ASC setting.

Therefore, in this final rule with comment period, we are finalizing our proposal without modification to add these eleven procedures to the ASC CPL. These procedures, listed in Table 59 of this CY 2021 OPPS/ASC final rule, are:

- CPT code 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)),
- CPT code 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed),
- CPT code 0404T (Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency),
- CPT code 21365 (Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches,
- CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
- CPT code 27412 (Autologous chondrocyte implantation, knee)
- CPT code 57282 (Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus))
- CPT code 57283 (Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)
- CPT code 57425 (Laparoscopy, surgical, colpopexy (suspension of vaginal apex))
- CPT code C9764 (Revascularization, endovascular, open or percutaneous, lower extremity artery (ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed
- CPT code C9766 (Revascularization, endovascular, open or percutaneous, lower extremity artery (ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed.

(1) Proposed Changes to General Exclusion Criterion for Procedures Requiring Inpatient Care To Conform to Proposed Changes to the Underlying Requirements Under the OPPS

As described in section IX.B. of the CY 2021 OPPS/ASC proposed rule, CMS proposed to eliminate the OPPS IPO list and amend 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024. We believed that retaining § 416.166(c)(6) would ensure that procedures that are largely performed on an inpatient basis and cannot be safely performed on an ambulatory basis will not be added to the CPL prematurely. As a result, we proposed to revise the regulatory language and modify this standard to exclude procedures designated as requiring inpatient care under § 419.22(n) as of December 31, 2020.

Comment: Commenters had concerns about modifying the general exclusion criteria at § 416.166(c)(6) to exclude procedures designated as requiring inpatient care.

Several commenters supported retaining the exclusion of procedures designated as requiring inpatient care, due to patient safety and quality of care concerns. These commenters urged caution in how CMS modifies criteria and adds procedures to the CPL, with one noting that they do not believe there is currently enough information to determine if these procedures would be clinically appropriate to perform in an outpatient or ASC setting.

Other commenters opposed this modification and believed this exclusionary criterion should be removed. These commenters urged CMS not to finalize this proposal, as they believe it is counter to CMS' intention to expand physician and patient choice.

Response: We thank commenters for their suggestions. As we discuss in more detail later in this section, we believe that retaining regulatory text similar to § 416.166(c)(6) in CY 2021 will ensure that procedures that cannot be safely performed on an ambulatory basis will not be added to the CPL. As a result, we are modifying this standard for CY 2021 and future years to exclude procedures designated as requiring inpatient care under § 419.22(n) as of December 31, 2020. We are revising the regulatory language at § 416.166(c)(6) to reflect this change at § 416.166(b)(2)(i)(A).

(2) Alternative Proposals Under Consideration for CY 2021

In the CY 2021 OPPS/ASC proposed rule (85 FR 48958), we stated that, for CY 2021, we are continuing to build on our efforts to maximize patient and physician choice and access to care by exploring broader approaches to adding procedures to the ASC CPL in order to further increase the availability of ASCs as an alternative site of care for Medicare beneficiaries, often at a lower cost than other options. In light of the current national Public Health Emergency related to COVID–19 and its anticipated lasting effects on the health care system, we noted that we also believe a broader approach for adding procedures to the ASC CPL would allow for a more efficient use of healthcare resources and infrastructure. An expansion of the ASC CPL would maximize the ability of ASCs to divert patients that can be safely treated in an ASC setting away from the hospital setting, which would preserve the capacity of hospitals to treat more acute patients. We explained that expanding the procedures placed on the ASC CPL would also build on the policy changes we have made in recent years to further site neutrality between the HOPD and ASC settings. In light of these objectives, we proposed two alternatives to our existing policy of adding procedures to the ASC CPL, each of which we believed would further support these goals.

a. Alternative Proposal To Create a Nomination Process

Under the first approach, we proposed a nomination process for adding new procedures to the ASC CPL. We explained that this process would involve soliciting recommendations from external stakeholders, like medical specialty societies and other members of the public, for procedures that may be suitable candidates to add to the ASC CPL. As discussed in greater detail below, under this approach, we proposed to provide parameters as guidelines that we would strongly encourage stakeholders to consider in nominating procedures for the ASC CPL. We noted that we anticipated 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 provided in an ASC.

While members of the public may already suggest procedures to be added to the CPL through meetings with CMS or through public comments to the proposed rule, we stated in the proposed rule that we believe it may be beneficial to adopt a streamlined process under which the public, particularly specialty societies that are very familiar with procedures in their specialty, can nominate procedures based on the latest evidence available as well as input from their memberships. We noted that we believe this revised process could increase transparency in how we are assessing procedures to add to the ASC list and also help ensure that we are assessing the list in a more streamlined fashion.

We proposed that the nomination process would be conducted through annual notice and comment rulemaking and the final determinations regarding nominated procedures would be decided in the final rule. Specifically, for the OPPS/ASC rulemaking for a calendar year, we would request stakeholder nominations by March 1 of the previous calendar year, with all nominations received by that date considered in the next applicable rulemaking cycle, likely the rulemaking for the following calendar year. Any nominations received after that date, including those received through comments as part of the rulemaking cycle, would generally be addressed in rulemaking the following year. CMS would evaluate procedures nominated by stakeholders based on the applicable statutory and regulatory requirements for ASC covered surgical procedures and the additional parameters specified in detail below. We proposed to establish the nomination process in the CY 2021 final rule to begin in CY 2021, for surgical procedures that could be added to the ASC CPL beginning in CY 2022. We proposed a process under which nominated procedures would be included in the proposed rule for that calendar year, along with a summary of the policy and factual justification for adding or not adding each procedure, which would allow members of the public to assess and provide comment on nominated procedures during the public comment period. We indicated that, after reviewing comments provided during the public comment period, CMS would finalize adding the procedures that meet the requisite criteria to the ASC CPL in the final rule. In the event that CMS disagreed with any procedures nominated, we would provide a specific rationale in the final rule. We stated that, in certain cases, CMS may need to defer a final determination regarding a nominated procedure to future rulemaking in order to provide sufficient time to evaluate and make the

most appropriate decision about the nominated procedure.

Under this alternative proposal, we proposed to update the ASC CPL by considering whether nominated procedures meet the requirements for covered surgical procedures under 42 CFR 416.166(b), which sets out the general standards for covered surgical procedures, requiring that surgical procedures be separately paid under the OPPS, 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 also proposed to eliminate the general exclusion criteria in 42 CFR 416.166(c)(1) through (5) such that nominated procedures would not have to meet those criteria. Further, we proposed to modify § 416.166(c)(6) to align the regulatory text with the proposed elimination of the IPO list. Finally, we proposed that nominated procedures would need to meet the general exclusions at 42 CFR 416.166(c)(7) and (8).

With respect to the existing general exclusion at 42 CFR 416.166(c)(6), which excludes procedures designated as requiring inpatient care under 42 CFR 419.22(n) from classification as covered surgical procedures, we noted that this alternative proposal would modify this standard since the IPO list is being proposed to be eliminated beginning in CY 2021, as described in section IX.B of the CY 2021 OPPS/ASC proposed rule. Therefore, we proposed to modify this criterion to exclude procedures designated as requiring inpatient care under § 419.22(n) as of December 31, 2020. In other words, we would not accept any nominations for procedures to add to the ASC CPL if the procedure is on the CY 2020 IPO list. We proposed to retain the criteria at § 416.166(c)(6) through (8) and eliminate the five exclusions currently at § 416.166(c)(1) through (5) because we believed that the general standards at § 416.166(b) provide sufficient guardrails to ensure, along with appropriate patient selection and the complex medical judgment of the physician, that procedures can be performed safely on an ambulatory basis, including certain procedures that may involve these five exclusions. We explained that we believed this alternative proposal could balance the goals of increasing physician and patient choice and expanding site neutral options with patient safety considerations.

Additionally, we also proposed parameters for stakeholders to consider and specifically address in nominating procedures to add to the ASC CPL. These parameters would be general guidelines, not requirements, and we sought public comment on these suggested parameters including language changes, recommendations for additional parameters, potential unintended implications of the parameters we proposed, and whether we should finalize these parameters if this alternative proposal is finalized in the CY 2021 final rule.

We stated that we believe a nomination process will take time to develop and stakeholders will need time to consider and evaluate potential nominations. We proposed to implement this process for CY 2021 in order to accept nominations for procedures to be added to the ASC CPL beginning in CY 2022.

b. Alternative Proposal To Revise Criteria and Add Codes to the ASC–CPL

In the CY 2021 OPPS/ASC proposed rule (85 FR 4896), we also considered another alternative approach that would allow for more immediate changes to the ASC CPL for CY 2021 and beyond. Specifically, under this alternative proposal, we proposed to keep the existing general standards under 42 CFR 416.166(b) that currently require covered surgical procedures to be surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website, separately paid under the OPPS, not 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. However, under this alternative proposal, we proposed to eliminate five of the current general exclusion criteria at 42 CFR 416.166(c)(1) through (5). We considered whether these five exclusionary criteria may no longer be necessary to determine what procedures can be safely added to the ASC CPL because many ASCs are currently able to safely provide services with these characteristics based on prior stakeholder feedback and public comments we have received.

We explored whether it is appropriate to remove the general exclusion criteria, which we explained would allow physicians practicing in the ASC setting, who have the greatest familiarity and insight into the needs of individual beneficiaries, to use their complex medical judgment to determine whether they can safely perform a procedure in the ASC, given the entirety of the circumstances, including the clinical profile of the patient, the surgical back-up available at the ASC, and the ability to safely and timely respond to unexpected complications. Under this alternative proposal, we stated that we would keep the remaining three general exclusion criteria at 42 CFR 416.166(c)(6) through (8), as the original reasons we adopted them in CY 2008 continue to exist, subject to the proposed modifications to § 416.166(c)(6). These criteria would continue to prohibit the addition of certain procedures to the ASC CPL, namely those that are: designated as requiring inpatient care under 42 CFR 419.22(n) as of December 31, 2020; can only be reported using a CPT unlisted surgical procedure code; or otherwise excluded under 42 CFR 411.15. We proposed to retain these criteria and eliminate the previous five criteria because we believe that the general standards alone are sufficient guardrails to ensure, along with appropriate patient selection and complex medical judgment of the physician, that the procedure can be performed safely on an ambulatory basis, including procedures that involve these five characteristics.

We noted that, with respect to the existing general exclusion at 42 CFR 416.166(c)(6), which excludes procedures designated as requiring inpatient care under 42 CFR 419.22(n) from classification as covered surgical procedures, the alternative proposal would modify this standard since the IPO list was proposed to be eliminated beginning in CY 2021, as described in section IX.B of the CY 2021 OPPS/ASC proposed rule. Therefore, we proposed to modify this criterion to exclude procedures designated as requiring inpatient care under 419.22(n) as of December 31, 2020. In other words, not all procedures on the current (that is, CY 2020) IPO list would necessarily meet the remaining revised criteria to be added to the ASC CPL. However, because any procedure not on the IPO can be performed safely on an ambulatory basis in the hospital outpatient setting, we believe that the remaining criteria in 42 CFR 416.166, most notably the exclusion of services that are on the current IPO list, could sufficiently limit the expansion of the ASC CPL to those services that can be safely performed on an ambulatory basis. As previously mentioned, we proposed to retain the criteria in § 416.166(c)(6) through (8) and

eliminate the five criteria currently at § 416.166(c)(1) through (5) because we believe that the general standards at § 416.166(b) provide sufficient guardrails to ensure, along with appropriate patient selection and the complex medical judgment of the physician, that procedures can be performed safely on an ambulatory basis, including certain procedures that may involve these five characteristics. We explained that we believed this alternative proposal could balance the goals of increasing physician and patient choice and expanding site neutral options with patient safety considerations.

We identified approximately 270 potential surgery or surgery-like codes that we believed would meet the proposed revised criteria for being added to the ASC CPL under 42 CFR 416.166. That is, we reviewed these procedures and found that they would meet the proposed revised regulatory requirements that would be in effect if we were to adopt this alternative proposal. Specifically, the identified procedures under this alternative proposal were surgical procedures 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 of the beneficiary at midnight following the procedure, that have not been designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, that can be reported without using a CPT unlisted surgical procedure code, and are not otherwise excluded under 42 CFR 411.15.

Additionally, we noted that, while several of the identified procedures may typically require active medical monitoring and care at midnight following the procedure, we expect that an appropriately selected patient population in the ASC setting would be healthier and less complex and would likely not require active monitoring or medical care at midnight following the procedure. We believed that these procedures are safe to perform in an ASC setting because all procedures identified are already payable in the HOPD setting and, therefore, are already safely performed on an ambulatory basis, consistent with the statutory requirement under section 1833(i)(1) of the Act. We proposed to retain the general standard criteria, as we believe these criteria are sufficient to ensure that procedures meet the statutory requirements and can be safely performed in ASCs. We sought public comment on whether any of these procedures would typically require care after midnight, and, therefore, should not be added to the ASC CPL.

We stated that we believed this alternative proposal could have beneficial effects for Medicare beneficiaries and healthcare professionals. For beneficiaries, expansion of the ASC CPL would increase access to procedures in ambulatory surgery settings, often at a lower cost. ASCs and healthcare professionals would also benefit from this proposal as this expansion would better utilize the potential of existing healthcare resources and expand the capacity of the healthcare system. Further, under this alternative, physicians would have greater flexibility to divert patients who can be safely treated in the ASC setting away from hospitals and preserve hospital capacity for more acute patients.

We acknowledged that this approach was a departure from the existing criteria that we established effective beginning in 2008. However, we believed that this approach would expand and build upon our 2008 policy intent. In the August 2, 2007 final rule with comment period, we discussed criteria for procedures excluded from the ASC CPL under the revised ASC payment system (72 FR 42478 through 42484). However, although there are differences, much of the underlying rationale we used to develop the August 2, 2007 final rule revised criteria remains true under the broader CY 2021 proposal. For example, in the August 2, 2007 final rule with comment period, we indicated that we believed that any procedure for which we did not allow payment in the hospital outpatient setting due to safety concerns would not be safe to perform in an ASC (72 FR 42478). Much like we are considering now, we excluded from the ASC list any procedure on the IPO list, and committed to excluding surgical procedures that pose significant safety risks to beneficiaries or that are expected to require an overnight stay (72 FR 42478 through 42479). Although there are some differences when comparing our CY 2008 criteria and the proposed CY 2021 criteria, such as removing several of the original general exclusion criteria, permitting the addition of procedures to the ASC CPL that would have been prohibited by those criteria, and the different accreditation requirements and conditions of participation requirements between HOPDS and ASCs, these concerns have largely been addressed by the progress in medical practice and ASC capabilities in the twelve years since the criteria were developed as previously noted. We noted that, in particular, given advances in the practice of medicine and the evolving nature of ASCs, we believe ASCs are now better equipped to safely perform procedures that were once too complex or risky to be performed safely on Medicare beneficiaries in the ASC setting. As previously mentioned, although ASCs and hospitals have different health and safety requirements, many ASCs often undergo accreditation as a condition of state licensure and share some similar licensure and compliance requirements with hospitals. We recognized that each of these requirements provides additional safeguards for the health and safety of Medicare beneficiaries receiving surgical procedures in an ASC.

(3) Comment Solicitation on Potential Revisions to the ASC Conditions for Coverage if Alternative 2 Is Adopted

In the proposed rule (85 FR 48962), we stated that we were considering allowing more invasive and lengthy surgical procedures to be performed in ASCs. We were seeking public input regarding what revisions to the ASC CfCs would be needed, if any, to ensure patient safety in response to the additional range of complex services that would be added to the ASC–CPL and noted that we might adopt such revisions as final in the CY 2021 final rule.

We also solicited comments on specific examples contained within the current ASC CfCs. We noted that we were especially interested in public comments about some specific CfCs and whether they should be more prescriptive and require additional elements. Those items included expanded risk evaluations, additional nursing personnel, requiring staff be trained in Advanced Cardiac Life Support, and the requirement that ASCs identify certain patient conditions or more complex procedures that require a medical history and physical examination prior to surgery.

(3) Summary of Proposals

For CY 2021, we proposed to add eleven procedures using the standard ASC CPL review process under our current regulations. In addition, we included two alternative proposals that we noted that we might finalize for CY 2021. One alternative was to establish a nomination process for CY 2021, which would allow us to propose to add nominated procedures beginning in CY 2022. Under this proposal, external stakeholders, such as professional

specialty societies, would nominate procedures that can be safely performed in the ASC setting based on the requirements in the ASC regulations, revised as described in the CY 2021 OPPS/ASC proposed rule (that is, retaining the general standard criteria and eliminating five of the general exclusion criteria), along with suggested parameters and all other regulatory standards. CMS would review and finalize procedures through annual rulemaking.

Alternatively, we proposed to revise the ASC CPL criteria under 42 CFR 416.166, retaining the general standard criteria and eliminating five of the general exclusion criteria. Using these revised criteria, we proposed to add approximately 270 potential surgery or surgery-like codes to the CPL that are not on the CY 2020 IPO list. We proposed to finalize only one of these alternative proposals, and we welcomed public comment as to which policy should be adopted in the final rule.

After consideration of the issues discussed earlier in this section, we noted that we believed that these proposed policies struck an appropriate balance between flexibility for physicians to exercise their complex medical judgment in factoring in patient safety considerations and flexibility for patients to choose from more settings of care in which to receive surgical procedures.

Comment: Many commenters were concerned that the alternative proposal to revise the general exclusion criteria at 42 CFR 416.166(c) and add 267 potential surgery or surgery-like procedures that are not on the current IPO list to the ASC–CPL list would not give adequate consideration to patient safety or stakeholder input. One commenter urged CMS not to finalize this alternative proposal, which the commenter believed would eliminate several safety ''guardrails.'' Another commenter stated that CMS should not remove the proposed exclusion criteria for the ASC CPL at 42 CFR 416.166(c) in light of what the commenter believed were oversight, quality, and safety concerns. Specifically, the commenter felt that procedures excluded by these safeguards were major and potentially life-threatening procedures that were appropriately excluded from ASCs, ASCs are not generally equipped to handle extensive blood loss or emergent and life-threatening procedures, the time waiting for emergency transport to a hospital would potentially place beneficiary life in jeopardy, and that these risks may occur even if a physician believes that the individual beneficiary's clinical condition would allow these procedures to be performed in an ASC.

Several commenters supported the alternative proposal to revise the general exclusion criteria at 42 CFR 416.166(c) and add 267 potential surgery or surgery-like procedures not on the current IPO list to the ASC CPL. They believed that medical research and technological advances have allowed for similar outcomes and a comparable quality of care for patients in both the outpatient hospital and ASC settings. One commenter supported this alternative proposal because they believed expanding the ASC CPL would increase the availability of ASCs as alternative care sites and preserve inpatient hospital capacity for higher acuity patients. The commenter agreed with CMS that significant advancements in medical practice, surgical techniques, and technology have allowed certain ASCs to perform procedures that were once too complex to be safely performed in an ASC.

Some commenters urged CMS not to treat ASCs as the equivalent of hospital outpatient departments because, as the commenter explained, they are not regulated as hospitals and do not have the necessary resources on site to provide the higher level of care necessary to perform many of the surgical procedures we would add to the ASC CPL if our proposal is finalized.

One commenter supported removing the five exclusionary criteria at 42 CFR 416.166(c)(1) through (5), stating that physicians are best equipped to make decisions about site of service for their patients.

Response: Under § 416.166, covered surgical procedures are those surgical procedures that meet the general standards specified in § 416.166(b) and are not excluded under the general exclusion criteria specified in § 416.166(c). Both of our alternatives included a proposal to eliminate the exclusion criteria at § 416.166(c)(1) through (5), which currently require that covered surgical procedures do not include 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; or (5) commonly require systemic thrombolytic therapy. While these are important considerations in determining whether a surgical procedure may be safely performed in an ASC, we considered that it may no longer be necessary for CMS to apply these five exclusionary criteria because, as we have heard from many stakeholders, ASCs are currently and increasingly able to safely provide services with these characteristics.

We have previously recognized the importance of increasing flexibility in our review of procedures for safe performance in the ASC setting, and we have been able to add surgical procedures to the ASC CPL that were once considered hospital inpatient procedures, including, for example, total knee arthroplasty and certain coronary intervention procedures involving major blood vessels. We believe it important that we adapt the ASC CPL in light of the significant advances in medical practice, surgical techniques, and ASC capabilities that have enabled some ASCs to safely perform procedures that were once too complex for the ASC setting, including those involving major blood vessels and other general exclusion criteria. Indeed, as we noted earlier, many procedures that are currently only payable as hospital outpatient services under Medicare are safely performed in the ASC setting for other payors. We acknowledge that non-Medicare patients tend to be younger and have fewer comorbidities than the Medicare population, but careful patient selection can identify Medicare beneficiaries who are suitable candidates to receive these services in the ASC setting. We have long recognized the importance of ensuring that the health care system has as many access points and patient choices for all Medicare beneficiaries as possible, and we believe it is important that we continue to support greater flexibility for physicians and patients to choose ASCs as the site of care in supporting those important goals.

We agree with commenters who support our proposal to revise the general exclusion criteria at § 416.166(c), to eliminate § 416.166(c)(1) through (5), because medical advances and careful patient selection have allowed procedures that were once too complex for the ASC setting to now be safely performed in ASCs. Importantly, physicians have always played a critically significant role in determining the appropriate site of care for their patients, and we believe it is appropriate that patient choice and physician judgement determine whether a surgical procedure may be safely performed in the ASC setting for each individual patient. Therefore, we are finalizing our proposal for CMS to no longer apply the exclusion criteria at § 416.166(c)(1) through (5) beginning on January 1, 2021. However, while CMS will no longer apply those five criteria in determining whether a procedure is a covered surgical procedure, we believe they are important safety factors that

physicians consider in making site-of-service determinations for their specific beneficiaries. Accordingly, general exclusions one through five will continue to be displayed under a new paragraph (d) titled ''Physician considerations beginning January 1, 2021,'' at § 416.166(d) for physicians to consider in selecting the most appropriate site of service for their patients.

Consistent with our recognition of the primary importance of the role physicians play in exercising their clinical judgment for each specific patient to assess whether a covered surgical procedure can be safely performed in the ASC setting, for all the same reasons we identify above, we are also recognizing that physicians are better-positioned than CMS to determine that a surgical procedure is not expected to pose a significant safety risk for a specific beneficiary and is one for which standard medical practice for the specific beneficiary dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. While these two considerations, currently reflected in § 416.166(b), are ones that CMS has made to date in determining whether a surgical procedure is a covered surgical procedure, we are also shifting the responsibility for these two considerations from CMS to physicians, as now reflected in § 416.166(d)(1) and (2).

CMS will continue to designate procedures as covered surgical procedures. That is, we will continue to determine that surgical procedures can be covered surgical procedures if, under current § 416.166(b), they are separately paid under the OPPS, and, under current § 416.166(c)(6) through (8), are not designated as requiring inpatient care under 42 CFR 419.22(n), are not only able to be reported using a CPT unlisted surgical procedure code, or are not otherwise excluded under 42 CFR 411.15. We are revising § 416.166(b) to reflect these requirements for procedures to be designated by CMS as covered surgical procedures. With regard to the criterion at current § 416.166(c)(6), that is, covered surgical procedures are those not designated as requiring inpatient care under 42 CFR 419.22(n), as described in section IX.B. of the CY 2021 OPPS/ASC proposed rule, CMS is eliminating the OPPS IPO list and amending 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a three-year transition, with the IPO list eliminated in its entirety by January 1, 2024. Therefore, we are specifying in revised § 416.166(b) that covered surgical procedures may not include those surgical procedures that are designated as requiring inpatient care under 42 CFR 419.22(n) as of December 31, 2020. If CMS determines that a surgical procedure meets the four requirements at revised § 416.166(b), CMS will designate the procedure a covered surgical procedure and place it on the ASC CPL. Physicians then have the opportunity to assess whether their specific patients can or cannot safely receive such covered surgical procedure in the ASC setting based on the considerations now reflected in § 416.166(d).

We disagree with the commenters who believe that expansion of the ASC CPL would negatively affect beneficiary safety or quality of care. We believe the policy we are finalizing to allow patients and physicians to determine the most appropriate site of care for an individual patient will continue to ensure patient safety. As we discuss above, physicians and patients are best-positioned to make patient-specific site-of-service determinations for their individual patients. Physicians have the greatest familiarity with and understanding of the needs of their individual patients and will use their complex medical judgment to determine whether a procedure can be safely performed in the ASC, given their patients' clinical profiles, available surgical back-up at the ASC, and the ability to safely and timely respond to unexpected complications, among other important considerations.

We believe there are numerous other safety considerations that will affect a physician's decision to perform a particular service in the ASC setting, separate from the inclusion of the procedure on the ASC CPL and the physician's medical judgment. These include the Medicare Conditions for Coverage (CfCs), Medicare's ASC quality rating program (ASCQR), public and private accreditations and certifications, malpractice insurance premiums, and the pressures of market competition, all of which could be negatively impacted if an ASC does not appropriately take patient safety concerns into account when deciding to perform a particular procedure in the ASC setting. We are confident that all of these factors will help to ensure facilities and providers carefully assess each patient and determine the most appropriate site of service for procedures on the ASC CPL.

In accordance with our final policy that CMS will apply the four criteria at new § 416.166(b)(2), we are adding the 267 surgery and surgery-like codes to the ASC CPL we proposed to add under the second alternative because they meet the requirements at new § 416.166(b)(2). This policy is in keeping with our policy changes made in recent years to further site neutrality between the HOPD and ASC settings. With this addition of procedures to the ASC CPL, CMS is making available a broader range of surgical procedures that Medicare will pay for when performed in the ASC setting, which will further increase the availability of ASCs as an alternative site of care for Medicare beneficiaries, while also ensuring patient safety through CMS's and physicians' respective roles in determining that procedures can be safely performed in an ASC.

Physicians are not required to maintain new documentation of their determination that procedures meet the revised CPL regulatory criteria, beyond what they are already required by Medicare. At this time, we believe that additional documentation and compliance activities associated with the revision of the CPL criteria are not necessary, as we noted earlier there remain many factors that encourage ASCs and physicians to appropriately consider patient safety in making site-of-service determinations for individual beneficiaries.

Comment: The majority of commenters supported the alternative proposal to establish a process for the public to nominate procedures for addition to the ASC CPL. These commenters generally supported this proposal because they believed it would better address beneficiary safety concerns than the alternative proposal to remove the general exclusion criteria at § 416.166(c)(1) through (5). Several commenters noted that this alternative proposal would formalize the review process that occurs currently, provide transparency, and increase opportunity for engagement with providers and external stakeholders. One commenter believed that establishing a formal nomination process would streamline the process for specialty societies to suggest procedures that can be safely performed in ASCs. Several commenters believed a nomination process would avoid the potential patient safety risks associated with adding 267 procedures to the ASC CPL before stakeholders are able to review the procedures and analyze whether they are appropriate to furnish in an ASC. One commenter believed that CMS should formalize a stakeholder nomination process for future years with greater transparency and standardization. Another commenter recommended that CMS

give greater consideration to nominations from professional specialty societies, which include physicians who have clinical expertise regarding procedures that can be performed in an ASC.

A number of commenters, largely hospitals and hospital associations, opposed both alternatives and raised safety concerns about expanding the ASC CPL. These commenters stated that both proposals would ''substantially weaken the agency's process'' and explained that Medicare beneficiary safety and quality of care could be negatively affected if Medicare pays for these higher risk surgical procedures when performed in an ASC. A few commenters believed we should finalize both alternative proposals, which they viewed as complementary and not mutually exclusive. Another commenter felt that finalizing both proposals would remove a barrier to physicians exercising their clinical judgment as to the appropriate setting of care for a particular patient.

Response: In the CY 2021 OPPS/ASC proposed rule (85 FR 48959), we proposed a nomination process that would involve CMS updating the ASC CPL if we determined that a nominated procedure met the requirements for covered surgical procedures under the regulations at 42 CFR 416.166, as we proposed to amend them. We proposed that the nomination process would be conducted through annual notice and comment rulemaking such that stakeholders would nominate surgical procedures they believed should be added to the ASC CPL by March 1, and CMS would propose and potentially finalize those nominated procedures for addition to the ASC CPL in the next applicable rulemaking cycle. We explained in the proposed rule that we believed a nomination process would provide external stakeholders, including specialty societies and physicians, a formalized process for notifying CMS of procedures that should be added to the ASC CPL. As with our other alternative proposal, we also proposed that we would revise the general exclusion criteria at § 416.166(c) by eliminating § 416.166(c)(1) through (5).

With regard to the proposal to eliminate the general exclusions at § 416.166(c), which as we noted was a common feature of both alternative proposals, we discussed previously in this section that we are finalizing this proposal beginning January 1, 2021. We believe physicians may consider each of those five safety factors at current § 416.166(c)(1) through (5) in making site-of-service determinations for their specific beneficiaries. In addition, we explained that physicians will now consider whether a surgical procedure is not expected to pose a significant safety risk for specific beneficiaries and is one for which standard medical practice dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure—criteria at § 416.166(b) that have until now been part of CMS's process for adding procedures to the ASC CPL. While CMS will still designate surgical procedures as covered surgical procedures and add them to the ASC CPL, we will apply only the following four criteria. The procedure is: (1) Separately paid under the OPPS; (2) not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020; (3) not only able to be reported using a CPT unlisted surgical procedure code; or (4) not otherwise excluded under § 411.15.

In light of the policies we are finalizing, we believe it is still appropriate for us to adopt a process whereby stakeholders notify CMS of procedures to be added to the ASC CPL, but a slightly different and simpler process than the nomination process alternative we proposed. We agree with commenters that a formalized process whereby the public notifies CMS of procedures to be added to the ASC CPL would provide more transparency and increase opportunities for CMS to engage with providers and external stakeholders in adding procedures to the ASC CPL. However, because CMS will now be applying only the four criteria listed in new § 416.166(b)(2) to determine whether a surgical procedure is a covered surgical procedure, and given that CMS's role will be more limited than it was when it applied the more subjective safety criteria, CMS will be able to more expeditiously determine whether a surgical procedure meets the regulatory requirements for inclusion on the ASC CPL, and therefore, we do not believe a full nomination process is necessary.

CMS will add surgical procedures to the ASC CPL as we become aware of new surgical procedures that meet the four requirements at new § 416.166(b)(2), but we expect the industry may become aware of other procedures that CMS may not know about, and has therefore not considered for inclusion on the ASC CPL. In that case, a member of the public may notify CMS of a surgical procedure any time they believe a surgical procedure meets the requirements at new § 416.166(b)(2). CMS will confirm whether the procedure does in fact meet those requirements and will add it to the ASC CPL if it does. In accordance with the new regulations we are finalizing at new § 416.166(d), physicians will then assess whether their specific patients can or cannot safely receive such covered surgical procedure in the ASC setting based on the patient-specific considerations reflected in new § 416.166(d). The process we are finalizing is not a nominations process so much as a notification process, which we are adding at new § 416.166(e), titled ''Additions to the list of ASC covered surgical procedures beginning January 1, 2021,'' to provide that we will add surgical procedures to the ASC CPL as follows: (1) CMS identifies a surgical procedure that meets the requirements at paragraph (b)(2) of this section. (2) CMS is notified of a surgical procedure that could meet the requirements at paragraph (b)(2) of this section and CMS confirms that such surgical procedure meets those requirements.

Comment: In the CY 2021 OPPS/ASC proposed rule (85 FR 48959 through 48960), we suggested parameters for stakeholders to use when evaluating procedures for nomination. Two commenters agreed that the parameters were appropriate and would be essential considerations during the proposed nomination process but recommended modifications, such as removing the fourth parameter on nearby facilities or adding an additional parameter evaluating whether data are available to inform the appropriate clinical support and monitoring for patients in an ASC setting. Another commenter noted that the parameters were a useful baseline for adding procedures and could be refined with exceptions or counterexamples in future years.

Response: We thank the commenters for their feedback. We proposed that stakeholders would consider the parameters we described in the proposed rule and address them in a nomination process. As we have indicated, we are not adopting the nomination process described in the proposed rule. Rather, we are adopting a simpler approach whereby entities may notify CMS of procedures they believe meet the four requirements at new § 416.166(b)(2). If CMS confirms a procedure does meet those four requirements, CMS will add it to the ASC CPL. At that point, it will be up to physicians to determine whether a procedure on the ASC CPL is safe for their specific patients to receive in an ASC. We are not adopting the parameters we discussed in the proposed rule because we are not adopting the more formal nomination process we described in that rule. However, in keeping with our final

policies, which emphasize the importance of physicians' safety determinations for their specific patients in deciding whether to perform a covered surgical procedure in an ASC, physicians should find the parameters useful in deciding whether to perform a covered surgical procedure on a particular ASC patient.

Comment: We received a few comments that specifically addressed the requested information regarding the expansion of the existing ASC CfCs. Commenters that supported adopting the alternative proposal to revise the criteria and add additional procedures to the ASC CPL did not believe it would be necessary to change the ASC CfCs if the alternative proposal is finalized. Commenters that did not support the proposed changes to the ASC CPL process and criteria suggested that CMS expand the ASC CfCs if either of the alternative proposals is finalized. One commenter also suggested that CMS reinstate the CFCs that were removed in the 2019 Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction final rule (84 FR 51732, 51737 through 52739). Other commenters recommended we work with clinical experts and other stakeholders to make appropriate changes to the CfCs.

Response: We thank the commenters for their helpful responses to the RFI. In keeping with our efforts to reduce provider burden and our stated objectives of prioritizing patient choice and physician judgement in determining the most appropriate site of service for a beneficiary, we are declining to modify the ASC CfCs at this time. We believe there are numerous considerations which effectively incentivize careful patient selection in ASCs, including accreditation requirements, insurer and provider privileges, state licensure requirements, and competitive market forces, to name only a few. Additionally, we will continue all measures described in our current CfCs and in Appendix L of the State Operations Manual. We may revisit modifying the ASC CfCs in the future should the need arise.

After consideration of the public comments we received, we are finalizing our proposal to add eleven procedures using the standard ASC CPL review process under our current regulations. In addition, we are revising the definition of covered surgical procedures at § 416.166(a) to conform to the changes we are making to the requirements for covered surgical procedures at § 416.166(b)(1) and (2) and (c), whereby CMS will determine whether the four specified criteria are met as the basis for adding surgical procedures to the ASC CPL. CMS will add 267 procedures to the ASC CPL, based upon these changes to the regulatory criteria. We also recognize that physicians may consider certain safety factors when determining the most appropriate site of care for a specific patient. We are adding a new § 416.166(d) to reflect these considerations. Finally, we are adding new § 416.166(e), which describes how CMS will add a surgical procedure to the ASC CPL, either on its own initiative or based on a notification from the public that a procedure not currently on the ASC CPL meets the criteria for addition to the ASC CPL.

New CPT and HCPCS codes for covered procedures and their final payment indicators for CY 2021 can be found in section XIII.B of this CY 2021 OPPS/ASC Final Rule. All ASC covered procedures and their final payment indicators for CY 2021 are also included in Addendum BB to this CY 2021 OPPS/ASC final rule (which is available via the internet on the CMS website).

BILLING CODE 4120–01–P

TABLE 59: FINAL ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2021 UNDER STANDARD REVIEW PROCESS

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
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)	J8
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J8
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency	G2
21365	Open treatment of complicated (e.g., comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches	G2
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	J8
27412	Autologous chondrocyte implantation, knee	G2
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)	G2
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)	G2
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)	G2
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	G2
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	G2

TABLE 60: FINAL ADDITIONS TO THE ASC CPL UNDER SECOND ALTERNATIVE PROPOSAL CONSIDERED FOR CY 2021

CY 2021 CPT/ HCPCS Code	CY 2021 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

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
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
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
21365	Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches	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

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
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
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
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	J8
27179	Open treatment of slipped femoral epiphysis; osteoplasty of femoral neck (heyman type procedure)	G2
27235	Percutaneous skeletal fixation of femoral fracture, proximal end, neck	G2
27412	Autologous chondrocyte implantation, knee	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

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	G2
32560	Instillation, via chest tube/catheter, agent for pleurodesis (eg, talc for recurrent or persistent pneumothorax)	G2
32561	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); initial day	G2
32562	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); subsequent day	G2
32601	Thoracoscopy, diagnostic (separate procedure); lungs, pericardial sac, mediastinal or pleural space, without biopsy	G2
32604	Thoracoscopy, diagnostic (separate procedure); pericardial sac, with biopsy	G2
32606	Thoracoscopy, diagnostic (separate procedure); mediastinal space, with biopsy	G2
32607	Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral	G2
32608	Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral	G2
32609	Thoracoscopy; with biopsy(ies) of pleura	G2
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction	G2
33272	Removal of subcutaneous implantable defibrillator electrode	G2
34101	Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision	G2
34111	Embolectomy or thrombectomy, with or without catheter; radial or ulnar artery, by arm incision	G2
34201	Embolectomy or thrombectomy, with or without catheter; femoropopliteal, aortoiliac artery, by leg incision	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
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

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
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
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	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
	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	
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
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

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
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
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 2021 CPT/ HCPCS Code	CY 2021 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
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
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)	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
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)	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
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),	J8

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
	percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)	
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
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

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
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
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,	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
	aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)	
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
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)	J8
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	G2
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J8
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
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency	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	J8

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
	intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	
0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])	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

This section was inadvertently omitted from the CY 2021 OPPS/ASC Proposed Rule. We are finalizing the continuation of our existing policies relating to covered ancillary services without change. 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 2021. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2020, but will be packaged under the CY 2021 OPPS, to maintain consistency with the OPPS, we would also package the ancillary service under the ASC payment system for CY 2021. 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 2021 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.

Comment: One commenter requested that we add CPT code 91040 (Esophageal balloon distension study, diagnostic, with provocation when performed) to our list of covered ancillary services. Commenter stated that esophageal balloon distension studies are often performed in conjunction with esophagogastroduodenoscopy procedures. The commenter noted that not adding this procedure sets a standard that an ancillary service must be performed 100 percent of the time with the surgical procedure in order for it to be considered integral, which results in a smaller subset of ancillary procedures being eligible for payment in the ASC setting.

Response: Services included in our list of covered ancillary services must be integral to the performance of a covered surgical procedure. However, based on the description of the procedure, we do not believe this service is integral to the performance of the surgical procedures identified by the commenter, specifically CPT codes 43235 (Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)), 43236 (Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance), or 43239 (Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple), or other surgical procedures. Therefore, we are not adding CPT code 91040 to the list of ASC covered ancillary services for CY 2021.

New CPT and HCPCS codes for covered ancillary services and their final payment indicators for CY 2021 can be found in section XIII.B of this CY 2021 OPPS/ASC Final Rule. All ASC covered ancillary services and their

final payment indicators for CY 2021 are also included in Addendum BB to this CY 2021 OPPS/ASC final rule (which is available via the internet on the CMS website).

D. Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services

1. 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 2020 OPPS/ASC final rule with comment period (84 FR 61397 through 61400), we updated the CY 2019 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2'', ''G2'', and ''J8'' using CY 2018 data, consistent with the CY 2020 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2020 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 2020 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 2020 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 2020 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. Update to ASC Covered Surgical Procedure Payment Rates for CY 2021

We proposed to update ASC payment rates for CY 2021 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 2021 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 to determine proposed relative payment weights under the ASC standard methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''.

We proposed 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 the CY 2021 OPPS/ASC proposed rule. Therefore, we proposed to update the payment amount for the service portion of the device-intensive procedures using the standard ASC rate setting methodology and the payment amount for the device portion based on the proposed CY 2021 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 2021 MPFS nonfacility PE RVU-based amount or the proposed CY 2021 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2020, for CY 2021 we proposed 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. A summary of the comments received and our responses to those comments are set forth below.

Comment: One commenter disagreed with the proposed CY 2021 ASC payment rates for the surgical procedures described by the following CPT/HCPCS codes, requesting that CMS increase payment in the ASC setting for the following codes:

- CPT 22869 (Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level)
- CPT 62287 (Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography

and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar)

- CPT 64575 (Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve))
- CPT 64454 (Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed)
- CPT 64624 (Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed)

Response: We update the data on which we establish payment rates each year through rulemaking and note that ASC rates are derived from OPPS payment rates, which are required to be reviewed and updated at least annually under section 1833(t)(9) of the Act. Based on our analysis of the latest hospital OPPS and ASC claims data used for this final rule with comment period, we are updating ASC payment rates for CY 2021 using the established rate calculation methodologies under § 416.171 of the regulations and our definition of device-intensive procedures, as discussed in section XII.C.1.b. of this CY 2021 OPPS/ASC final rule with comment period. We do not generally make additional payment adjustments to specific procedures. Therefore, we are finalizing the payment indicators for the HCPCS codes 22869, 62287, 64575, 64454, and 64624 as proposed.

Comment: Two commenters recommended that CMS eliminate the prohibition against ASC billing for services using an unlisted CPT surgical procedure code.

Response: Under § 416.166(c)(7), covered surgical procedures do not include procedures that can only be reported using a CPT unlisted surgical procedure code. As discussed in the August 2, 2007 final rule (72 FR 42485), it is not possible to know what specific procedure would be represented by an unlisted code, and therefore, it is not possible to evaluate procedures reported by unlisted CPT codes according to applicable regulatory criteria at § 416.166. Therefore, we are not accepting this recommendation.

After consideration of the public comments we received, we are finalizing our proposed policies without modification to calculate the CY 2021 payment rates for ASC covered surgical procedures according to our established rate calculation methodologies under § 416.171 and using the modified definition of device-intensive procedures as discussed in section XIII.C.1.b. of this CY 2021 OPPS/ASC final rule. For covered office-based surgical procedures, the payment rate is the lower of the final CY 2021 MPFS nonfacility PE RVU-based amount or the final CY 2021 ASC payment amount calculated according to the ASC standard ratesetting methodology. The final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the PFS PE RVUs and the conversion factor effective January 1, 2021. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

c. Limit on ASC Payment Rates for Low-Volume Device-Intensive Procedures

As stated in section XIII.D.1.b. of this CY 2021 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 2021 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 our new 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. For CY 2020, this policy only affected HCPCS code 0308T, which had very low claims volume (7 claims from CY 2018 used for CY 2020 ratesetting in the OPPS). Additionally, we amended § 416.171(b) of the regulations to reflect the new limit on ASC payment rates for low-volume device-intensive procedures. CMS' existing regulation at § 416.171(b)(2) requires the payment for the device portion of a device-intensive procedure to be set at an amount derived from the payment rate for the equivalent item under the OPPS using our standard ratesetting methodology. We added paragraph (b)(4) to § 416.171 to require that, notwithstanding paragraph (b)(2), low volume device-intensive procedures where the otherwise applicable payment rate calculated based on the standard methodology for device-intensive procedures would exceed the payment rate for the equivalent procedure set under the OPPS, the payment rate for the procedure under the ASC payment system would be equal to the payment rate for the same procedure under the OPPS.

Based on our review of CY 2019 claims using our standard ratesetting methodology, there are no low volume device-intensive procedures that would exceed the rate paid under the OPPS for the same procedure. However, there was a single claim containing CPT code 0308T that was unable to be used for the CY 2021 OPPS/ASC proposed rule ratesetting process as it was packaged into a comprehensive APC. As a result, there was no available cost data from CY 2019 claims data to construct relative payment weights for CPT code 0308T. As discussed in section III.D.2., under the OPPS, we proposed to establish the payment weight for the CY 2021 OPPS for CPT code 0308T using the CY 2020 OPPS final rule median cost of $20,229.78 and relative payment weight as reflecting the most recent claims and cost data. Similarly, as there were no usable claims with CPT code 0308T from CY 2019, which we would normally use for the CY 2021 OPPS/ASC proposed rule under our standard ratesetting methodology to establish an appropriate payment rate in CY 2021 for CPT code 0308T using the most recent claims and cost data, we proposed to establish the payment rate under the ASC payment system for CY 2021 using the CY 2020 final rule OPPS median cost and relative payment weight as reflecting the most recent available claims and cost data.

However, CPT code 0308T was designated as a low volume device-intensive procedure in CY 2020. For CY 2020, under the low-volume procedure payment policies in effect through CY 2019, the available claims data would have resulted in a payment rate of approximately $111,019.30 for CPT code 0308T when performed in the ASC setting, which would have been several times greater than the OPPS payment rate. Therefore, for CY 2020 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 the procedures. This policy had the effect of limiting the ASC payment rate for CPT code 0308T to the applicable payment rate under the OPPS (which was

$20,675.62 in CY 2020). Therefore, for the CY 2021 OPPS/ASC proposed rule, we proposed to apply a payment rate under the ASC payment system equal to the OPPS payment rate for CPT code 0308T, which is $20,994.57 in the CY 2021 OPPS/ASC proposed rule. Further, in the absence of claims data for the CY 2021 OPPS/ASC proposed rule, we also proposed in this CY 2021 OPPS/ASC proposed rule to continue the CY 2020 final rule device offset percentage of 90.18 percent for CPT code 0308T.

Comment: Commenters supported our proposal to apply a payment rate under the ASC payment system equal to the OPPS payment rate for CPT code 0308T and to continue the CY 2020 final rule device offset percentage of 90.18 percent for CPT code 0308T.

Response: We thank the commenters for their support. After consideration of the public comments we received, for CY 2021, we are finalizing 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 the procedures. Based on our review of CY 2019 claims using our standard ratesetting methodology for this final rule with comment period, there are no low volume device-intensive procedures that would exceed the rate paid under the OPPS for the same procedure. However, claims data show two claims containing CPT code 0308T that are unable to be used for this CY 2021 OPPS/ASC final rule with comment period ratesetting process. Under the low-volume device intensive procedure policy that we are adopting in this final rule with comment period, the ASC payment rate for CPT code 0308T is limited to the applicable payment rate under the OPPS (which is $20,766.56 in CY 2021). Further, in the absence of claims data for this final rule with comment period, we are finalizing our proposal to continue to use the CY 2020 final rule device offset percentage of 90.18 percent for CPT code 0308T in CY 2021.

2. Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the 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 of 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 2021 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 the CY 2021 OPPS/ASC proposed rule, for CY 2019, we finalized a policy to unpackage and pay separately at ASP + 6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting, even though payment for these drugs continues to be packaged under the OPPS. 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.

Comment: One commenter recommended that CMS solicit comments from stakeholders regarding development of a more transparent and consistent policy regarding valuation of pass-through devices implanted in the ASC setting. The commenter further notes that CMS has published its method for valuing pass-through devices implanted in the hospital outpatient setting clearly in the **Federal Register**, and that, in the ASC setting, payment for a qualifying procedure and the associated pass-through device should be separate. However, the commenter disagreed with CMS's approach to valuation of pass-through devices implanted in the ASC setting as contractor-priced.

Response: We thank the commenter for their recommendation. We will take the commenters' concerns into consideration in determining if additional instructions or future guidance for the MACs are warranted.

b. Payment for Covered Ancillary Services for CY 2021

We proposed 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 2021 OPPS and ASC payment rates and subsequent year payment rates. We also proposed to continue to set the CY 2021 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 2021 and subsequent year payment rates.

Covered ancillary services and their final payment indicators for CY 2021 are listed in Addendum BB of this CY 2021 OPPS/ASC final rule with comment period (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 final payment indicators and rates set forth in the proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2021. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final 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 2021 ASC Packaging Policy for Non-Opioid Pain Management Treatments

Section 6082 of the ''Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act,'' also referred to as the ''SUPPORT for Patients and Communities Act'' (SUPPORT Act) (Pub. L. 115–271) was enacted on October 24, 2018. Section 6082(a) of the SUPPORT Act requires in part that the Secretary: ''(i) shall, as soon as practicable, 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; (ii) may, as the Secretary determines appropriate, conduct subsequent reviews of such payments; and (iii) shall consider the extent to which revisions under this subsection to such 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.'' Section 6082(b) of the SUPPORT Act requires that the Secretary conduct a similar type of review in ambulatory surgical centers.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59066 through 59072), we finalized the policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019. We also finalized conforming changes to § 416.164(a)(4) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to package payment for drugs and biologicals for which separate payment is not allowed under the OPPS into the ASC payment for the covered surgical procedure. We added a new § 416.164(b)(6) to include non-opioid pain management drugs that function as a supply when used in a surgical procedure as covered ancillary services that are integral to a covered surgical procedure. Finally, we finalized a change to § 416.171(b)(1) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to pay for ASC covered ancillary services an amount derived from the payment rate for the equivalent item or service set under the OPPS.

For the CY 2020 OPPS/ASC proposed rule (84 FR 39424 through 39427), we reviewed payments under the ASC 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 available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives to determine whether our packaging policies reduced the use of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39426), we proposed to continue our policy to pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC

setting for CY 2020. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61177), 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+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, the only FDA-approved drug that met these criteria was Exparel.

We conducted an evaluation to determine whether there are payment incentives for using opioids instead of non-opioid alternatives in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61176 to 61180). The results of our review and evaluation of our claims data did not provide evidence to indicate that the OPPS packaging policy had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. Our updated review of claims data for the CY 2020 proposed rule showed a continued decline in the utilization of Exparel® in the ASC setting, which supported our proposal to continue paying separately for Exparel® in the ASC setting.

4. Evaluation and CY 2021 Payment for Non-Opioid Alternatives

Over the last 2 years, we have conducted detailed evaluations of our payment policies regarding the use of opioids and non-opioid alternatives. We have reviewed multiple years of Medicare claims data, all public comments received on this topic, and studies and data from external stakeholders. Each of these reviews have led to the consistent conclusion that CMS's packaging policies are not discouraging the use of non-opioid alternatives or impeding access to these products, with the exception of Exparel, which was the only non-opioid pain management drug that functions as a surgical supply when furnished in the ASC setting.

Section 6082(a) of the SUPPORT Act also provides that after an initial review, the Secretary can conduct subsequent reviews of covered payments as the Secretary deems appropriate. In light of the fact that CMS has conducted a thorough review of payments for opioids and evidence-based non-opioid alternatives for pain management to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives, we did not believe that conducting a similar review for CY2021 would be a fruitful effort. After careful consideration, we concluded we had fulfilled the statutory requirement to review payments for opioids and evidence-based non-opioid alternatives for pain management to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives, as described in the CY 2020 OPPS/ASC rulemaking. We are committed to evaluating our current policies to adjust payment methodologies, if necessary, in order to ensure appropriate access for beneficiaries amid the current opioid epidemic. However, we did not believe conducting a similar CY 2021 review would yield significantly different outcomes or new evidence that would prompt us to change our payment policies under the OPPS or ASC payment system.

Current claims data suggest that CMS' current policies are not providing a disincentive for the utilization of non-opioid alternatives, including Exparel, in the hospital outpatient department or ASC. A preliminary claims analysis showed that the total units of Exparel employed in the ASC setting has increased over the last year. From CY 2015 to CY 2018, we saw an annual decline in the total units of Exparel furnished in the ASC setting, with 244,756 total units provided in CY 2015 dropping to 60,125 total units provided in CY 2018. In CY 2019, ASCs furnished a total of 1,379,286 units of Exparel. Due to this positive trend that reflects the increased use of non-opioid treatment for pain, we did not believe that further changes are necessary under the ASC payment system for non-opioid pain management drugs that function as a surgical supply in the ASC setting. Therefore, for CY 2021, we proposed to continue our policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures 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.

The comments we received and our responses to those comments are set forth below.

Comment: Multiple commenters, including individual stakeholders, hospital and physician groups, national medical associations, device manufacturers, and groups representing the pharmaceutical industry, supported the proposal to continue to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting, such as Exparel, for CY 2021. These commenters believed that packaged payment for non-opioid alternatives presents a barrier to access to non-opioid pain management drugs and that separate payment for non-opioid pain management drugs would be an appropriate response to the opioid drug abuse epidemic. Several commenters suggested that CMS expand this policy, including commenters who asked that CMS develop a policy that pays separately for drugs that are administered at the time of ophthalmic surgery and have an FDA-approved indication to treat or prevent postoperative pain.

Response: We appreciate these comments. After reviewing the information provided by the commenters, we continue to believe that separate payment is appropriate for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2021. Therefore, as discussed in greater detail below, we are finalizing our proposal to continue to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting without modification.

Comment: Several commenters requested that the drug Omidria, CPT J1097, (*phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), be excluded from the ASC payment system packaging policy once its pass-through status expires on September 30, 2020, because they believe it is a non-opioid pain management drug that functions as a surgical supply when furnished in the ASC setting. Omidria is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain in cataract or intraocular surgeries. The commenters stated that extensive clinical evidence has been published in medical literature demonstrating that Omidria reduces dependence on opioids for patients undergoing cataract surgery and postoperative prescription opioids. The commenters noted that OMIDRIA is FDA-approved for intraocular use in cataract procedures, a pain management drug, a non-opioid, and functions, and was previously packaged, as a surgical supply during cataract surgery according to CMS' definition of a surgical supply. Commenters asserted that the use of Omidria decreases

patients' need for fentanyl during surgeries and provided an unpublished manuscript that has been submitted, but not approved, for publication in a peer-reviewed journal, which suggested that Omidria reduces opioid use after surgery based on pill counts.

Response: We thank commenters for their feedback on Omidria. Omidria received pass-through status for a 3-year period from 2015 to 2017. After expiration of its pass-through status, it was packaged under both the OPPS and the ASC payment system. Subsequently, Omidria's pass-through status under the OPPS was reinstated in October 1, 2018 through September 30, 2020 as required by section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141), which means that Omidria continued to be paid separately under the ASC payment system through September 30, 2020. We note that our previous review of the clinical evidence submitted by commenters during CY 2020 rulemaking concluded that the studies the commenter submitted were not sufficiently compelling to revise our payment policy for Omidria. Moreover, the results of a CMS analysis of cataract procedures performed on Medicare beneficiaries in the OPPS between January 2015 and July 2019 comparing procedures performed with Omidria to procedures performed without Omidria did not demonstrate a significant decrease in fentanyl utilization during the cataract surgeries in the OPPS when Omidria was used. Our findings also did not suggest any decrease in opioid utilization post-surgery for procedures involving Omidria.

However, we continue to believe the separate payment is appropriate for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2021. After careful consideration of the commenters' assertion that Omidria meets this definition, we believe that Omidria qualifies as a non-opioid pain management drug that functions as a surgical supply when furnished in the ASC setting and will therefore exclude Omidria from packaging under the ASC payment system beginning October 1, 2020, and in CY 2021, in accordance with this policy.

Comment: Two commenters briefly mentioned the drug IV acetaminophen, CPT code J0131, which they believe may reduce opioid usage if CMS paid separately for the drug. These commenters believed CPT code J0131 is a highly effective medication that also decreases use of post-operative opioids.

Response: We thank commenters for their comments. We do not find it appropriate to pay separately for IV acetaminophen as suggested by these commenters due to our drug packaging threshold policies, which are discussed in section V.B.1.a to this final rule with comment period. In accordance with section 1833(t)(16)(B) of the Act, we finalized our proposal to set the drug packaging threshold for CY 2021 to $130. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid prescriptions, we encourage providers to use them when medically necessary.

Comment: Commenters suggested modified payment for ''pain block'' CPT codes 64415, 64416, 64417, 64445, 64446, 64447, 64448, and 64450. Two commenters stated that providers use these pain blocks to mitigate the post-operative pain that is otherwise typically addressed with short-term opioid use. Additionally, a few commenters noted that CPT code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*) used for treatment of ocular inflammation and pain following ophthalmic surgery is administered through CPT code 0356T (*Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each*). These commenters felt CPT code 0356T, which commenters state describes the administration of CPT code J1096, should also receive separate or additional payment due to the alleged clinical benefits of the drug, including treatment of pain.

Response: We thank the commenters for their suggestions. The ''pain block'' procedure codes and drug administration code discussed above do not qualify as non-opioid pain management drugs that function as surgical supplies, and therefore, do not qualify for separate payment when furnished in the ASC setting. At this time, we have not found compelling evidence to revise our policies to provide separate payment for the non-opioid pain management alternatives described above under the OPPS or ASC payment systems for CY 2021. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid prescriptions, we encourage providers to use them when medically appropriate. For a greater discussion on CPT code 0356T, please see section III. D. (Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus (APC 5692)) of this final rule with comment period.

Comment: Some commenters encouraged CMS to establish permanent separate payment for drugs that are currently on drug pass-through status in the OPPS and ASC settings, such as Dexycu (HCPCS code J1095). Regarding Dexycu specifically, one commenter stated that permanent separate payment for ophthalmic drugs is appropriate due to growing evidence that these drugs reduce reliance on opioids used in association with cataract surgeries. They noted that they were conducting a new, comprehensive study of a longitudinal claim dataset that will provide deeper insights into the association between cataract surgery and opioid utilization, as well as the role of Dexycu in reducing the prescribing of opioids.

Response: We refer readers to section V.A., ''OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals'' of this final rule with comment period regarding pass-through payments under the OPPS. Once a drug's pass-through status expires, we determine whether that drug is eligible for separate payment under our policy for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting. We thank commenters for conducting studies regarding their specific products and look forward to reviewing the results.

Comment: Commenters requested separate payment for various non-drug pain management treatments that they believe are viable alternatives to opioids, such as ERAS® protocols or spinal cord stimulators (SCS), that they believe decrease the number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure. For SCS, several commenters noted that this therapy may lead to a reduction in the use of opioids for chronic pain patients. They noted that neurostimulation is a key alternative to opioid prescription for the management and recommended that CMS increase access to SCS.

Response: We appreciate the responses from commenters on this topic. At this time, we have not found compelling evidence that our current payment policies discourage use of the various non-drug alternatives for non-opioid pain management commenters described, such that separate payment would be warranted under the OPPS or ASC payment systems for CY 2021. We do not find it appropriate to revise our policies at this time based on these comments; however, we plan to take these comments and suggestions into consideration for future rulemaking. We agree that providing incentives to avoid or reduce opioid prescriptions may be one of several strategies for addressing the opioid epidemic. To the extent that

the items and services mentioned by the commenters are effective alternatives to opioid drugs, we encourage providers to use them when medically appropriate. We look forward to working with stakeholders as we further consider suggested refinements to the OPPS and the ASC payment system to encourage use of non-opioid pain management treatments.

After consideration of the public comments that we received, we are finalizing the policy to continue to unpackage and pay separately at ASP + 6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2021 as proposed. We will continue to analyze the issue of access to other non-opioid alternatives for pain management in the OPPS and ASC settings. This policy is also discussed in section II.A.3.b. of this final rule with comment period.

E. 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 that is found 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 2021

We did not receive any requests for review to establish a new NTIOL class for CY 2021.

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 did not propose to revise the payment adjustment amount for CY 2021.

The comments and our responses to the comments are set forth below.

Comment: One commenter requested that we re-evaluate our payment adjustment for new NTIOL class. Commenters noted that our $50 payment adjustment has not been adjusted since CY 1999 and that the stagnant payment adjustment has been a barrier to intraocular lens innovation. The commenter requested that the $50 be inflated to 2021 dollars and updated by inflation in subsequent years.

Response: We thank the commenter for their recommendation. We did not propose revising the payment adjustment amount for CY 2021. However, we will take the commenter's recommendations into consideration in future rulemaking.

4. Announcement of CY 2022 Deadline for Submitting Requests for CMS Review of Applications for a New Class of NTIOLS

In accordance with § 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective beginning in CY 2022, requests for review of applications for a new class of new technology IOLs must be received by 5:00 p.m. EST, on March 1, 2021. Send requests via email to *outpatientpps@cms.hhs.gov* or by mail to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include the information requested on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs*.

F. 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.

2. ASC Payment and Comment Indicators for CY 2021

For CY 2021, we proposed 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 2021 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2021 compared to the CY 2020 descriptors are included in ASC Addenda AA and BB to the CY 2021 OPPS/ASC proposed rule were labeled with proposed comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes were open for comment as part of the 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 current calendar year; and denoted that comments would be accepted on the proposed ASC payment indicator for the new code.

For the CY 2021 update, we proposed to add 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 to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website). New drug HCPCS codes that do not have claims data or payment rate information are currently assigned to OPPS status indicator ''E2''—Not paid by Medicare when submitted on outpatient claims (any outpatient bill type). These codes are categorized and included in the ASC payment system as nonpayable codes and are currently assigned an ASC payment indicator ''Y5''—Non-surgical procedure/item not valid for Medicare purposes because of coverage, regulation and/or statute; no payment made—because that is the ASC payment indicator that currently best describes the status of these HCPCS codes. However, ''Y5'' assignments include both drug codes that would not be integral to the performance of a surgical procedure and are therefore not payable in the ASC payment system and codes that may become separately payable in the ASC payment system. Since there is not a separate payment indicator that describes the subset of drug codes that will become payable when claims data or payment information is available, the existing ASC payment indicators cannot currently communicate the distinction between these two classes of drugs. Therefore, for CY 2021 and subsequent calendar years, we proposed to add 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 to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

In the CY 2021 OPPS/ASC proposed rule, we stated we would respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2021 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 of the CY 2021 OPPS/ASC 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 2021 update.

We did not receive any public comments on the proposed ASC payment and comment indicators. Therefore, we are finalizing their use as proposed without modification. Addenda DD1 and DD2 to this CY 2021 OPPS/ASC final rule (which are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for CY 2021.

G. 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 2021 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*).

For CY 2021, the proposed CY 2021 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 15–01 and 17–01).

We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). For example, for CY 2014, we applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA) and CBSA 08 (Rural Delaware).

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 continue 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 2021 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.

Consistent with our established policy, we proposed to scale the CY 2021 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 proposed to compare the total payment using the CY 2020 ASC relative payment weights with the total payment using the CY 2021 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2020 and CY 2021. We proposed to use the ratio of CY 2020 to CY 2021 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2021. The proposed CY 2021 ASC weight scalar was 0.8494. 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 the CY 2021 OPPS/ASC proposed rule, we had 90 percent of CY 2019 ASC claims data available.

A summary of the comments we received and our responses to those comments are set forth below.

Comment: Many commenters believe that CMS needs to reduce the disparity in payments between ASCs and HOPDs. Commenters stated that ASC payment rates are less than 50 percent of the HOPD payment rates for some high volume procedures. Many of these same commenters support the discontinuation of the ASC weight scalar, which they believe is the cause of the payment gap between ASCs and HOPDs. Commenters suggested that the ASC weight scalar as currently applied may make it economically infeasible for ASC facilities to continue to perform Medicare cases, hurting beneficiaries by limiting their access to high-quality outpatient surgical care. One commenter highlighted this concern and suggested that while expansion of the ASC Covered Procedures List would allow more procedures to be performed in the ASC, these additional procedures will not be performed in the ASC if ASC payment rates are lowered to unsustainable levels over time. Multiple commenters suggested that eliminating the secondary rescaling of the ASC relative payment weights, and instead applying the OPPS relative payment weights to ASC services, would allow ASCs to continue to provide quality surgical care for Medicare patients. They provided that, while they understand the additional scaling factor that CMS applies to the ASC relative payment weights maintains budget neutrality within the ASC payment system, this scaling contributes to the large payment differentials for similar services between the ASC and HOPD systems.

Response: We thank commenters for flagging this important issue. As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59421) we share commenters' concerns about the effects of payment disparities between the OPPS and ASC payment systems. We note that applying the weight scalar in calculation of ASC payment rates, which is 0.8591 for this final rule with comment period, ensures that the ASC payment system remains budget neutral. We understand the commenters do not believe it is necessary to calculate a weight scalar under the ASC payment system. The commenters contend that application of the weight scalar to ASC payment rates has led to increasingly large differences in the amount of payment for similar services between the OPPS and the ASC payment system. We understand commenters' concerns, however, we are unable to calculate a single weight scalar for both the OPPS and the ASC payment system without rescaling OPPS payment weights in a non-budget neutral manner. We will take the points that the commenters raised into consideration as part of our efforts to improve choice and competition in the Medicare program. However, as noted in previous rulemaking (83 FR 59076), we do not believe that the ASC cost structure is identical to the hospital cost structure. Further, we do not collect cost data from ASCs, and therefore we lack the necessary data to assess the actual differences in costs between the hospital outpatient department and ASC settings.

To create an analytic file to support calculation of the weight scalar and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2019 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2019 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file is available to the public as a supporting data file for the CY 2021 OPPS/ASC proposed rule and is posted on the CMS website at: *http://http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html.*

Comment: One commenter noted that our CY 2021 NPRM ASC Supplier Specific file incorrectly assigned certain ASCs in the previous CBSA of 16974 (Chicago-Naperville-Arlington Heights, IL) to the default CBSA 14 (Illinois)

rather than the new CBSA of 16984 (Chicago-Naperville-Evanston, IL) applicable to their location.

Response: We appreciate the commenter's observation and agree that ASCs in the previous CBSA of 16974 were erroneously assigned to default CBSA 14 rather than the new CBSA of 16984. We have corrected the CBSA assignment for these ASCs for this final rule with comment period.

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 2021, 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 2021 ASC wage indexes. Specifically, holding CY 2019 ASC utilization, service-mix, and the proposed CY 2021 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2020 ASC wage indexes and the total adjusted payment using the proposed CY 2021 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 2020 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2021 ASC wage indexes and applied the resulting ratio of 0.9999 (the proposed CY 2021 ASC wage index budget neutrality adjustment) to the CY 2020 ASC conversion factor to calculate the proposed CY 2021 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 MFP-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 MFP-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.

As stated in the CY 2021 OPPS/ASC proposed rule, the hospital market basket update for CY 2021 was projected to be 3.0 percent, as published in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32738), based on IHS Global Inc.'s (IGI's) 2019 fourth quarter forecast with historical data through the third quarter of 2019.

We finalized the methodology for calculating the MFP 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). As stated in the CY 2021 OPPS/ASC proposed rule (85 FR 32739), the proposed MFP adjustment for CY 2021 was projected to be 0.4 percentage point, as published in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32739) based on IGI's 2019 fourth quarter forecast.

For CY 2021, we proposed to utilize the hospital market basket update of 3.0 percent minus the MFP adjustment of 0.4 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.6 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a 2.6 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2021 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 2021 OPPS/ASC proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We proposed to utilize the hospital market basket update of 3.0 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.4 percentage point MFP adjustment. Therefore, we proposed to apply a 0.6 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also proposed that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update or MFP adjustment), we would use such data, if appropriate, to determine the CY 2021 ASC update for the CY 2021 OPPS/ASC final rule with comment period.

For CY 2021, we proposed to adjust the CY 2020 ASC conversion factor ($47.747) by the proposed wage index budget neutrality factor of 0.9999 in addition to the MFP-adjusted hospital market basket update of 2.6 percent discussed above, which resulted in a proposed CY 2021 ASC conversion factor of $48.984 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2020 ASC conversion factor ($47.747) by the proposed wage index budget neutrality factor of 0.9999 in addition to the quality reporting/MFP-adjusted hospital market basket update of 0.6 percent discussed above, which resulted in a proposed CY 2021 ASC conversion factor of $48.029.

The comments we received on our proposals for updating the CY 2021 ASC

conversion factor and our responses are set forth below.

Comment: The majority of commenters supported continued use of the hospital market basket for updating ASC payments on an annual basis. Some commenters suggested that maintaining alignment in the update factor used in the OPPS and ASC payment system will encourage the migration of care to the lower cost ASC setting and ensure that ASCs remain a viable high quality and lower cost option for patients. Other commenters supported this approach as it would promote site-neutrality between the two settings of care through more comparable payment. Other commenters supported the continued use of the hospital market basket to update ASC payment rates, but believed that the migration of services to ASCs would be limited due to the ASC budget neutrality adjustments. Specifically, commenters stated that CMS' current approach to maintaining budget neutrality in the ASC payment system caused increasingly large differences in the amount of payment for similar services provided in the ASC and HOPD settings, and there was no evidence of corresponding changes in capital and operating costs between the ASC and HOPD settings to support this growing payment differential. Commenters suggested that widening the gap in payment amounts for similar services provided in the ASC and hospital outpatient department settings could make it economically infeasible for ASCs to perform certain procedures for Medicare beneficiaries, causing financial hardships for ASCs, discouraging them from furnishing those procedures, and thereby discouraging the migration of services from the HOPD to the ASC setting.

Response: We appreciate the commenters' support. We believe using the same update factor to calculate payments to ASC and hospital outpatient departments encourages the migration of services from the hospital setting to the ASC setting, and could potentially increase the presence of ASCs in health care markets or geographic areas where previously there were none or few. The migration of services from the higher cost hospital outpatient setting to the ASC setting is likely to result in savings to beneficiaries and the Medicare program. This policy will also further our goal of giving both physicians and beneficiaries a greater choice in selecting the care setting that best suits their needs.

Comment: Several commenters provided input on collecting cost data from ASCs. They suggested that if CMS chooses to collect cost data from ASCs, for instance to develop a market basket, the agency should consider establishing a market basket that can be applied to both the ASC and hospital outpatient setting. They believed this would ensure that payments using the same relative weights and update factor would remain aligned over time, noting that HOPDs and ASCs incur similar types of costs.

These commenters offered to work with CMS in developing a survey or other low burden data collection activity. They suggested an initial effort to identify and calculate expense categories as a percentage of total expenses to help determine the appropriate weights and price proxies for the ASC setting. These commenters also urged CMS to recognize the variability among ASCs and recognize that cost experience can differ depending on factors such as specialties served, facility size, and geographic location. Commenters also requested that CMS keep in mind the administrative burdens placed on ASC staff in meeting current regulatory requirements and that requiring any formal cost reports from ASCs may run counter to the agency's desire to establish policies that allow ASCs to deliver services to Medicare beneficiaries efficiently.

Response: We thank the commenters for their input and we will take these suggestions into consideration in future policy development. As discussed in the CY 2019 OPPS/ASC final rule with comment period, we will continue to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and potentially propose a plan to collect such information during the 5-year period in which CMS has updated the ASC payment methodology to rely upon the hospital market basket as the update factor (83 FR 59077). We will continue to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner for future policy development.

After consideration of the public comments we received, consistent with our proposal that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update and MFP), we would use such data, if appropriate, to determine the CY 2021 ASC update for the CY 2021 OPPS/ASC final rule with comment period, we are incorporating more recent data to determine the final CY 2021 ASC update.

For this CY 2021 OPPS/ASC final rule with comment period, the 10-year moving average growth of the MFP for FY 2021 is projected to be –0.1 percentage point, based on IGI's June 2020 macroeconomic forecast, as published in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58797). However, under section 1833(i)(2)(D)(v) of the Act, the Secretary is required to reduce (not increase) the annual update factor by changes in economy-wide productivity. Accordingly, we are applying a final MFP adjustment of 0.0 percentage point for CY 2021.

Therefore, for this CY 2021 OPPS/ASC final rule with comment period, the hospital market basket update for CY 2021 is 2.4 percent, as published in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58796–7), based on IGI's 2020 second quarter forecast with historical data through the first quarter of 2020. The MFP adjustment for this CY 2020 OPPS/ASC final rule with comment period is 0.0 percentage point, as published in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58797).

For CY 2021, we are finalizing the hospital market basket update of 2.4 percent minus the MFP adjustment of 0.0 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.4 percent for ASCs meeting the quality reporting requirements. Therefore, we apply a 2.4 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2021 ASC payment rates. We are finalizing the hospital market basket update of 2.4 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.0 percentage point MFP adjustment. Therefore, we apply a 0.4 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs not meeting the quality reporting requirements.

For CY 2021, we are adjusting the CY 2020 ASC conversion factor ($47.747) by a wage index budget neutrality factor of 1.0012 in addition to the MFP-adjusted hospital market basket update of 2.4 percent, discussed above, which results in a final CY 2021 ASC conversion factor of $48.952 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are adjusting the CY 2020 ASC conversion factor ($47.747) by the wage index budget neutrality factor of 1.0012 in addition to the quality reporting/MFP-adjusted hospital market basket update of 0.4 percent discussed above, which results in a final CY 2021 ASC conversion factor of $47.996.

3. Display of Final CY 2021 ASC Payment Rates

Addenda AA and BB to this CY 2021 OPPS/ASC final rule (which are available on the CMS website) display the final ASC payment rates for CY 2021 for covered surgical procedures and covered ancillary services, respectively. 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 final rates, the final payment indicators and rates set forth in this CY 2021 OPPS/ASC final rule are based on a comparison using the PFS rates that would be effective January 1, 2021. For a discussion of the PFS rates, we refer readers to the CY 2021 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 final payment rates included in addenda AA and BB to this CY 2021 OPPS/ASC final 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 final CY 2021 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 CY 2021, we proposed to add a new column to ASC Addendum BB titled ''Drug Pass-Through Expiration during Calendar Year'' where we would 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 ''Final CY 2021 Payment Weight'' are the final relative payment weights for each of the listed services for CY 2021. The final 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 final CY 2021 payment rate displayed in the ''Final CY 2021 Payment Rate'' column, each ASC payment weight in the ''Final CY 2021 Payment Weight'' column was multiplied by final CY 2021 conversion factor of $48.952. 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 final CY 2021 ASC conversion factor uses the CY 2021 MFP-adjusted hospital market basket update factor of 2.4 percent (which is equal to the projected hospital market basket update of 2.4 percent minus a projected MFP adjustment of 0.0 percentage point).

In Addendum BB, there are no relative payment weights displayed in the ''Final CY 2021 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Final CY 2021 Payment'' column displays the final CY 2021 national unadjusted ASC payment rates for all items and services. The final CY 2021 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 2021.

XIV. 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, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The Hospital OQR Program is generally aligned with the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) 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.

3. Regulatory History of the Hospital OQR Program

We refer readers to the CY 2008 through 2019 OPPS/ASC final rules with comment period (72 FR 66860 through 66875; 73 FR 68758 through 68779; 74 FR 60629 through 60656; 75 FR 72064 through 72110; 76 FR 74451 through 74492; 77 FR 68467 through 68492; 78 FR 75090 through 75120; 79 FR 66940 through 66966; 80 FR 70502 through 70526; 81 FR 79753 through 79797; 82 FR 59424 through 59445; 83 FR 59080 through 59110; and 84 FR 61410 through 61420) for the regulatory history of the Hospital OQR Program. We have codified certain requirements under the Hospital OQR Program at § 419.46.

4. Codify Statutory Authority for Hospital OQR Program

The Hospital OQR Program regulations are codified at § 419.46. In the CY 2021 OPPS/ASC proposed rule (85 FR 48984), we proposed 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. We proposed to redesignate the existing paragraphs (a) through (h) as paragraphs (b) through (i) and codify the Hospital OQR Program's statutory authority at new § 419.46(a). Because of the proposed redesignations, the cross-references throughout § 419.46 were also proposed to be updated. Table 61 shows the correlation between the proposed cross-references.

TABLE 61: Correlation Between the Cross-References Proposed to be Removed and Added Throughout § 419.46

Proposed Newly Redesignated Paragraphs	Proposed Cross-references to be Removed	Proposed Cross-references to be Added
(d)(3)(ii) and (iii)	(c)(2)	(d)(2)
(g)(2)(viii)	(e)(1)	(f)(1)
(i)(1)	(h)(2) and (3)	(i)(2) and (3)
(i)(3)	(h)(2)	(i)(2)
(i)(3)(ii)	(h)(3)(i)(A)	(i)(3)(i)(A)

We requested public comment on this proposal.

We refer readers to section XIV.E. of the CY 2021 OPPS/ASC proposed rule for a detailed discussion of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements for the CY 2023 payment determination (85 FR 48772).

The following is a summary of the comment we received and our response that comment.

Comment: A commenter supported our proposal to codify the statutory authority for the Hospital OQR Program.

Response: We thank the commenter for their support.

After consideration of the public comments received, we are finalizing our proposals as proposed.

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 did not propose any changes to these policies.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously adopted a policy to retain measures from a previous year's Hospital OQR Program measure set for subsequent years' measure sets in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471). For more information regarding this policy, we refer readers to that final rule with comment period. We codified this policy at § 419.46(h)(1) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). We did not propose any changes to these policies.

3. Removal of Quality Measures From the Hospital OQR Program Measure Set

a. Immediate Removal

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635), we finalized a process for removal of Hospital OQR Program measures, based on evidence that the continued use of the measure as specified raises patient safety concerns.[104] We codified this policy at § 419.46(h)(2) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). In the case of suspension or removal due to patient safety concerns, action would need to be taken quickly and may not coincide with rulemaking cycles (77 FR 68472). In this case, we would promptly remove the measure and notify hospitals of its removal, and confirm the removal of the measure in the next rulemaking cycle. We did not propose any changes to these policies.

b. Consideration Factors for Removing Measures

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60635), we finalized 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.[105] We codified this policy at § 419.46(h)(3) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59083 through 59085), we clarified, finalized, and codified at § 419.46(h)(3) an updated set of factors[106] and policies for determining whether to remove measures from the Hospital OQR Program. We refer readers to that final rule with comment period for a detailed discussion of our policies regarding measure removal factors. We did not propose any changes to these policies.

4. Summary of Hospital OQR Program Measure Set for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61410 through 61420) for a summary of the previously adopted Hospital OQR Program measure set for the CY 2022 payment determination and subsequent years.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48985), we did not propose any changes to the previously adopted measure set. Table 62 summarizes the previously finalized Hospital OQR Program measure set for the CY 2023

[104] 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.

[105] 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.

[106] We note that we previously referred to these factors as ''criteria'' (for example, 77 FR 68472 through 68473); we now use the term ''factors'' in order to align the Hospital OQR Program terminology with the terminology we use in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

payment determination and subsequent years.

TABLE 62: Hospital OQR Program Measure Set for the CY 2023 Payment Determination and Subsequent Years

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	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**

† We note that NQF endorsement for this measure was removed.
* Measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).
** Measure 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).

The following is a summary of the comments we received and our response those comments.

Comment: A few commenters supported retaining the current Hospital OQR Program measure set.

Response: We thank commenters for their support.

5. 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://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244*. 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 did not propose any changes to these policies.

6. Public Display of Quality Measures

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.

a. Codification

In the 2009 OPPS/ASC final rule with comment period (73 FR 68778), we finalized that hospitals sharing the same CMS Certification Number (CCN) must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes. While we previously finalized this policy, it was not codified. In the CY 2021 OPPS/ASC proposed rule (85 FR 48987, we proposed to codify this policy by adding language at the

redesignated paragraph (d)(1). The newly redesignated paragraph (d)(1) would specify that ''Hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.'' We solicited public comment on our proposal. The following is a summary of the comment we received and our response that comment.

Comment: One commenter expressed concern with the proposal to codify this previously finalized policy to combine Hospital OQR Program data for multiple hospitals under the same CCN. The commenter believes that CMS should publicly report data for individual facilities (that is, campuses and locations), not by CCN.

Response: We disagree with the commenter; we believe data should be reported by CCN, because it is difficult to identify cases by facilities since billing is done under CCNs. Under our current policy, we publish quality data by the corresponding hospital CCN and indicate instances where data from two or more hospitals are combined to form the publicly reported measures on the Hospital Compare website and the successor Care Compare website. In the CY 2014 OPPS/ASC proposed rule (78 FR 43645), we noted that in a situation in which a larger hospital has taken over ownership of a smaller hospital, the smaller hospital's CCN is replaced by the larger hospital's CCN (the principal CCN). For data display purposes, we only display data received under the principal CCN. If both hospitals submit data, those data are not distinguishable in the warehouse [107] and are calculated together as one hospital.

After consideration of the public comments received, we are finalizing our proposal as proposed.

b. Overall Hospital Quality Star Rating

In the CY 2021 OPPS/ASC proposed rule (85 FR 48987), we proposed a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Rating). The Overall Star Rating would utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital OQR Program. 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.

C. Administrative Requirements

1. QualityNet Account and Security Administrator/Security Official

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(a) in that final rule with comment period.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed 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. To be clear, this proposed update in terminology would not change the individual's responsibilities or add burden. We proposed to revise existing § 419.46(a)(2) and redesignate § 419.46(b)(2), by replacing the term ''security administrator'' with the term ''security official.'' The redesignated paragraph (b)(2) would read: ''Identify and register a QualityNet security official as part of the registration process under paragraph (b)(1) of this section.''

We invited public comment on our proposal. However, we did not receive any comments on this proposal. We are finalizing our proposal as proposed.

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 procedural requirements regarding participation status at § 419.46(a) and (b).

In the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed to revise existing § 419.46(b), redesignated § 419.46(c), by removing the phrase ''submit a new participation form'' to align with previously finalized policy. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59103through 83 FR 59104), we removed submission of Notice of Participation (NoP) form as a program requirement. We also proposed to update internal cross-references as a result of the redesignations discussed under section XIV.A.4. of the CY 2021 OPPS/ASC proposed rule. The proposed redesignated § 419.46(c) would specify that a withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.46(i), and is required to renew participation as specified in § 419.46(b) in order to participate in any future year of the Hospital OQR Program. Our proposal also included updated cross-referenced provisions in the redesignated § 419.46(c).

We solicited public comment on our proposal. However, we did not receive any comments on this proposal. We are finalizing our proposal as proposed.

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) where we finalized our policies for data submission deadlines. We codified these submission requirements at § 419.46(c). The submission deadlines for the CY 2023 payment determination and subsequent years are illustrated in Table 63.

[107] The data reviewed are maintained in the CMS Integrated Data Repository (IDR). The IDR is a high volume data warehouse integrating Medicare Parts A, B, C, and D, and DME claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at *https://www.cms.gov/Research-Statistics-Data-andSystems/Computer-Data-and-Systems/IDR/index.html.*

TABLE 63: CY 2023 Payment Determination and Subsequent Years

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2021 (April 1 - June 30)	11/1/2021
Q3 2021(July 1 – September 30)	2/1/2022
Q4 2021 (October 1 - December 31)	5/1/2022
Q1 2022 (January 1 - March 31)	8/1/2022

In the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed a change to our submission deadlines to align with statute. We proposed that all 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,'' beginning with the effective date of this rule. Section 1872 of the Act, incorporates section 216(j) of the Act, to apply to Title XVIII, the Medicare program to which the Hospital OQR Program is administered. We proposed that all deadlines occurring on a Saturday, Sunday, 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 which is not a Saturday, Sunday, legal holiday, or any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order.

We proposed to revise our policy regarding submission deadlines at existing § 419.46(c)(2), redesignated § 419.46(d)(2). The newly redesignated paragraph (d)(2) would specify 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 are extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order. We invited public comment on our proposal. The following is a summary of the comments we received and our responses to those comments.

Comment: A few commenters supported our proposal to codify in order to make it consistent with section 216(j) of the Act. One commenter also stated that it would reduce the need for employees to work on holidays or weekends in order to submit Hospital OQR Program measures.

Response: We thank the commenters for their support. We agree with commenters that this policy change would lessen the need for employees to work on holidays or weekends.

After consideration of public comments, we are finalizing our proposal as proposed.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2023 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 did not propose any changes to these policies.

The following previously finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2022 payment determination and subsequent years:

- *OP–2:* Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (NQF #0288);
- *OP–3:* Median Time to Transfer to Another Facility for Acute Coronary Intervention (NQF #0290);
- *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 2023 Payment Determination and Subsequent Years

Currently, the following previously finalized Hospital OQR Program claims-based measures are required for the CY 2022 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; and
- *OP–36:* Hospital Visits after Hospital Outpatient Surgery (NQF #2687).

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 did not propose any changes to these policies.

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 2023 Payment Determination and Subsequent Years

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. We did not propose any changes to the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures.

5. Data Submission Requirements for Measures for Data Submitted via a Web-based Tool for the CY 2022 Payment Determination and Subsequent Years

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 CMS QualityNet website (*www.qualitynet.org* for a discussion of the requirements for measure data submitted via the CMS QualityNet Secure Portal (also referred to as the HQR system secure portal) for the CY 2017 payment determination and subsequent years. In addition, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the requirements for measure data submitted via the CDC NHSN website. We did not propose any changes to these policies.

The following previously adopted quality measures will require data to be submitted via a CMS web-based tool for the CY 2023 payment determination and subsequent years with the exception of OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) for which data submission remains voluntary:

- *OP–22:* Left Without Being Seen (NQF #0499);
- *OP–29:* Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); and
- *OP–31:* Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

6. Population and Sampling Data Requirements for the CY 2021 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 did not propose any changes to these policies.

7. 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 we formalized a review and corrections period for chart-abstracted measures in the Hospital OQR Program. Per the previously finalized policy, the Hospital OQR Program implemented a 4-month review and corrections period for chart-abstracted measure data, which runs concurrently with the data submission period. During the review and corrections period for chart-abstracted data, hospitals can enter, review, and correct data submitted directly to CMS for the chart-abstracted measures.

b. Web-Based Measures

In the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed 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. Hospitals would have a review and corrections period for web-based measures, which would run concurrently with the data submission period. The review and corrections period for web-based measures is from the time the submission period opens to the submission deadline. During this review and corrections period, hospitals can enter, review, and correct data submitted directly to CMS. However, after the submission deadline, hospitals would not be allowed to change these data. The expansion of the existing policy for chart-abstracted measures to data submitted via the CMS web-based tool would accommodate a growing diversity of measure types in the Hospital OQR Program. We solicited public comment on our proposal. The following is a summary of the comments we received and our responses to those comments.

Comment: A few commenters supported our proposal to expand the review and corrections policy for chart-abstracted measures to apply to measure data submitted via the CMS web-based tool. The commenters stated that it is appropriate for hospitals to have an opportunity to review and correct data submitted on any existing and future measures using a web-based tool.

Response: We thank the commenters for their support. As the diversity of measure types continues to increase, we agree that hospitals should have an opportunity to enter, review and correct data submitted to our web-based tool. This begins with data submitted during CY 2022 for the CY 2023 payment determination.

After consideration of public comments, we are finalizing our proposal as proposed.

c. Codification of the Review and Corrections Periods for Measure Data Submitted to the Hospital OQR Program

We note that the previously finalized policy relating to the review and corrections period for chart-abstracted measures has not yet been codified. Therefore, in the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed to codify the review and corrections period policy for measure data submitted to the Hospital OQR Program for chart-abstracted measure data, as well as for the proposed policy for measure data submitted directly to CMS via the CMS web-based tool. Specifically, we proposed to add a new paragraph (c)(4) to § 419.46, redesignated § 419.46(d). The new paragraph (d)(4) would provide that for both chart-abstracted and web-based measures, hospitals have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, hospitals can enter, review, and correct data submitted. However, after the submission deadline, this data cannot be changed. We solicited public comment on our proposal. The following is a summary of the comment we received and our response to that comment.

Comment: One commenter supported our proposed updates to codify the review and corrections period policy for chart-abstracted measure data submitted to the Hospital OQR Program, as well as the proposed policy for measure data submitted directly to CMS via the CMS web-based tool.

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing our proposal as proposed.

7. Hospital OQR Program Validation Requirements

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), and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), and § 419.46(e) for our policies regarding validation. In the CY 2021 OPPS/ASC proposed rule (85 FR 48772), while we did not propose changes to our validation policies, we proposed to codify certain previously finalized policies. These policies are discussed in detail in section XIV.D.8.b of the proposed rule.

a. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

(1) Background

In the CY 2018 final rule (82 FR 59441 through 59443), we finalized a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction. Under the informal process, hospitals that were selected and received a score for validation may request an educational review to better understand the results. A hospital has 30 calendar days from the date the validation results are made available via the QualityNet Secure Portal (also referred to as the HQR System) to contact the CMS designated contractor, currently known as the Validation Support Contractor (VSC), to request an educational review (82 FR 59442). In response to a request, the VSC obtains and reviews medical records directly from the Clinical Data Abstraction Center (CDAC) and provides feedback (82 FR 59442). CMS, or its contractor, generally provides educational review results and responses via a secure file transfer to the hospital (82 FR 59442). In the CY 2018 final rule (82 FR 59441 through 59443), we (1) formalized this process; and (2) specified that if the results of an educational review indicate that we incorrectly scored a hospital's medical records selected for validation, the corrected quarterly validation score would be used to compute the hospital's final validation score at the end of the calendar year. We did not propose any changes to this finalized policy.

(2) Codification of Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

The previously finalized policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction finalized in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59442), has not yet been codified at § 419.46. In the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed to codify those policies by adding a new paragraph (e)(4) to § 419.46, redesignated § 419.46(f). The new paragraph (f)(4) would specify that hospitals that are selected and receive a score for validation of chart-abstracted measures may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation for chart-abstracted measures was incorrectly scored, the corrected quarterly validation score will be used to compute the hospital's final validation score at the end of the calendar year.

We invited public comment on this proposal. We did not receive any comments on this proposal. We are finalizing our proposal as proposed.

8. Extraordinary Circumstances Exception (ECE) Process for the CY 2021 Payment Determination and Subsequent Years

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(d) for a complete discussion of our extraordinary circumstances exception (ECE) process under the Hospital OQR Program. We did not propose any changes to these policies.

9. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2021 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), and § 419.46(f) for our reconsideration and appeals procedures.

In alignment with our proposal to change submission deadlines, in section XIV.D.1. of the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed a change to our reconsideration deadlines. We proposed that all 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,'' beginning with the effective date of this rule. Section 1872 of the Act, incorporates section 216(j) of the Act, to apply to Title XVIII, the Medicare program to which the Hospital OQR Program is administered. Under this proposal, all deadlines occurring on a Saturday, Sunday, 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 which is not a Saturday, Sunday, 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. Specifically, we proposed to remove ''the first business day on or after'' from existing § 419.46(f)(1), redesignated § 419.46(g)(1), to ensure consistency with section 216(j) of the Act. The redesignated paragraph (g)(1) would provide that a hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program for a particular calendar year. Except as provided in paragraph (e), a hospital must submit a reconsideration request to CMS via the QualityNet website, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day as defined in § 419.46(d)(2), of the affected payment year as determined using the date the request was mailed or submitted to CMS.

We invited public comment on our proposal. However, we did not receive any comments on this proposal. We are finalizing our proposal as proposed.

E. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2021 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 the CY 2021 OPPS/ASC proposed rule.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2021

We proposed to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2021 annual payment update factor. For the CY 2021 OPPS/ASC proposed rule, the proposed reporting ratio was 0.9805, which when multiplied by the proposed full conversion factor of $83.697 equaled a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $82.016. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2021 OPPS/ASC proposed rule, we proposed 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 proposed to continue to exclude services paid under New Technology APCs. We proposed 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 proposed 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 proposed 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 proposed 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 the CY 2021 OPPS/ASC final rule with comment period, the final reporting ratio is 0.9805, which when multiplied by the final full conversion factor of 82.797 equals a final conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of 81.183. We are finalizing our proposal 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. We are also finalizing our proposals to implement the policy through the use of a reporting ratio, and 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 hospitals that fail to meet the Hospital OQR Program requirements for CY 2021 payment.

XV. 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 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 Initiative and our approach for evaluating quality program measures.

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 CYs 2014 through 2020 OPPS/ASC final rules with comment period (78 FR 75122; 79 FR 66966 through 66987; 80 FR 70526 through 70538; 81 FR 79797 through 79826; 82 FR 59445 through 59476; 83 FR 59110 through 59139; and 84 FR 61420 through 61434, respectively) for an overview of the regulatory history of the ASCQR Program. We have codified certain requirements under the ASCQR Program at 42 CFR, part 16, subpart H (42 CFR 416.300 through 416.330). In the CY 2021 OPPS/ASC proposed rule (85 FR 48993), we proposed to update certain currently codified program policies and propose a review and corrections period as well as other administrative changes. We discuss these proposals and applicable public comments in more detail below in sections XV.C. and XV.D.

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 did not propose any changes to these policies.

2. Policies for 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 did not propose any changes to this policy.

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 42 CFR 416.320 an updated set of factors [108] and the process for removing measures from the ASCQR Program. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59111 through 59115) for a detailed discussion of our process regarding measure removal. We did not propose any changes to this policy.

3. Summary of ASCQR Program Quality Measure Set Previously Finalized for the CY 2024 Payment Determination and for Subsequent Years

In the CY 2021 OPPS/ASC proposed rule (85 FR 48992), we did not propose to remove any existing measures or to adopt any new measures for the CY 2023 payment determination. Table 64 summarizes the previously finalized ASCQR Program measure set for the CY 2024 payment determination and subsequent years.

[108] 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 used in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

TABLE 64: Finalized ASCQR Program Measure Set for the CY 2024 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****

† NQF endorsement was removed.
* Measure finalized for suspension in reporting beginning with the CY 2021 payment determination (CY 2019 data collection) until further action in future rulemaking as discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123).
** 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).
*** Measure finalized for delay in reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).
**** Measure will be added beginning with the CY 2024 payment determination as set forth in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61421 through 61428).

The following is a summary of the comment we received and our response that comment.

Comment: A few commenters supported retaining the current measure set.

Response: We thank commenters for their support; we agree that at this time no changes to the ASCQR Program measure set are necessary.

4. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CYs 2012 through 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 did not propose any changes to these policies.

5. 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 did not propose any changes to these policies.

6. ASCQR Program Measures and Topics for Future Considerations

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making regarding care and quality improvement in the ASC setting. We also seek measures that would facilitate meaningful comparisons between ASCs and hospitals providing comparable services. Therefore, we invited public comment on new measures for our consideration that address care quality in the ASC settings as well as on additional measures that could facilitate comparison of care provided in ASCs and hospitals.

The following is a summary of the comments we received and our responses to those comments.

Comment: Several commenters provided recommendations regarding both new quality measures for CMS to consider as well as measures to facilitate the comparison of care provided in ASCs and hospitals. One commenter requested that we require measures for surgical procedures that occur in both the ASC and outpatient hospital settings be reflected in the measure sets of both programs. For example, currently the Hospital OQR Program contains measures of surgical procedures that

also occur in ASCs, but there is no comparable measure in the ASCQR Program. The commenter recommended that such measures be specified so that for in common surgical procedures analysis for both settings was possible.

Response: We thank the commenters for their recommendations regarding measures to facilitate the comparison of care provided in ASCs and hospitals and the request for measures of surgical procedures that occur in both settings to be reflected in the measure sets of both programs. We understand the commenters concern that such measures be specified to allow for an analysis of both settings for common surgical procedures. We agree that there are surgical procedures that occur in both ASC and outpatient hospital settings that may not be currently reflected in both programs' measure sets. We will evaluate the feasibility of the commenters' recommendations and take them into consideration as we determine future updates to the ASCQR Program measure set.

Comment: A few commenters recommended we adopt measures related to patient and caregiver engagement, experience, and safety. Commenters suggested these measures to ensure providers deliver equitable, patient-centered care and provide patients and their caregivers a standardized way to compare providers and organizations. A few commenters also suggested CMS broaden the focus on safety to include workforce safety measures as a way to examine workforce burnout and turnover. One of these commenters requested that CMS employ an annual web-based workforce engagement survey to allow quality performance to be factored into payment and performance-based incentives.

Response: We thank the commenters for their recommendations regarding the adoption of measures related to patient and caregiver engagement, experience, and workforce safety. We refer readers to the CY 2017 OPPS/ASC final rule with comment period where we adopted ASC–15a–e (81 FR 79803 through 79817), and finalized data collection and data submission timelines (81 FR 79822 through 79824). These measures assess patients' experience with care following a procedure or surgery in an ASC by rating patient experience as a means for empowering patients and improving the quality of their care. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451), we finalized a delay in the implementation of the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based Measures (ASC–15a–e) beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking. We will investigate the feasibility of the commenters' recommendation to focus on workforce safety measures for consideration toward future updates to the ASCQR Program measure set.

Comment: Several commenters had specific suggestions of measures for future consideration. These measures include: Normothermia (ASC–13), Unplanned Anterior Vitrectomy (ASC–14), Toxic Anterior Segment Syndrome (TASS) (ASC–16), Hospital-level Risk-standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550), and Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome (NQF #3025).

Response: We note that in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79801 through 79803), the Normothermia (ASC–13) and Unplanned Anterior Vitrectomy (ASC–14) were adopted into the ASCQR Program for the CY 2020 payment determination and subsequent years; we thank the commenter for their support of these measures. While we proposed the adoption of Toxic Anterior Segment Syndrome (TASS) (ASC–16) for the ASCQR Program (82 FR 52594), we did not finalize the adoption of this measure due to concerns that the burden of the measure would outweigh the benefits. We will consider the suggested measures not currently included in the ASCQR Program as well as reconsider the Toxic Anterior Segment Syndrome (TASS) (ASC–16) measure as we develop and refine the ASCQR Program measure set.

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 proposed rule with comment period (85 FR 48993), we proposed to use the term ''security official'' instead of ''security administrator'' to denote the 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. To be clear, this proposed update in terminology would not change the individual's responsibilities or add burden. We also proposed to revise § 416.310(c)(1)(i) by replacing the term ''security administrator'' with the term ''security official''. The new sentence would read ''A QualityNet security official is necessary to set up such an account for the purpose of submitting this information.'' We invited public comment on our proposals.

The following is a summary of the comment we received and our response that comment.

Comment: One commenter expressed concern with the terminology change of ''security administrator'' to ''security official,'' despite no changes in responsibility of the individual(s). The commenter suggested that the current term is sufficient and any changes to the title may cause undue confusion.

Response: We thank the commenter for their input and acknowledge the commenter's concern about potential confusion. However, we believe the term ''security official'' more clearly conveys the exercise of authority invested in the role and want to ensure adequate recognition. While an administrator is a person who performs official duties in a sphere, an official is a person having official duties, specifically as a representative of an organization. Thus, the term ''security official'' more aptly describes this role as a representative one.

After consideration of the comment received, we are finalizing our proposal as proposed.

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 42 CFR 416.305. We did not propose any changes to these policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Data Collection and Submission

a. Update of Language Generally

We previously codified our existing policies regarding data collection and submission under the ASCQR Program at 42 CFR 416.310. We currently use the phrases ''data collection period'' and ''data collection time period'' interchangeably in § 416.310(a) through (c). We believe that using one, consistent phrase will streamline and simplify the section and our policies to help avoid potential confusion. As such, we proposed to remove the phrase ''data collection time period'' in all instances where it appears in § 416.310, and replace it with the phrase ''data collection period''—specifically at § 416.310(a)(2), (b), (c)(1)(ii), and (c)(2), as well as replacing the phrase ''time period'' with ''period'' in § 416.310(c)(1)(ii) for language consistency. We invited comment on our proposal.

The following is a summary of the comment we received and our response that comment.

Comment: One commenter supported the proposal to remove the phrase ''data collection time period'' in all instances where it appears in § 416.310 and replace it with the phrase ''data collection period''. The commenter agreed that using one consistent phrase will help avoid potential confusion.

Response: We thank the commenter for their support. We agree that the change will reduce confusion and believe that using one consistent phrase will streamline the language across policies.

After consideration of the public comment received, we are finalizing our proposals as proposed.

b. 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 42 CFR 416.310(a)(1) and (2).

We did not propose any changes to these requirements. We note that data submission for the following claims-based measures using QDCs was suspended as finalized in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123 and 83 FR 59134 through 59135) until further action in rulemaking:

- *ASC–1:* Patient Burn;
- *ASC–2:* Patient Fall;
- *ASC–3:* Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- *ASC–4:* Hospital Transfer/Admission.

Furthermore, we noted 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.

c. 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. We did not propose any changes to these policies.

As noted above, while data submission for certain claims-based measures using QDCs was suspended, 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.

d. 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 42 CFR 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.
- *ASC–19:* Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357)

We did not propose any changes to the requirements for non-QDC based, claims-based measures.

e. 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 CMS QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) secure portal) to host our CMS online data submission tool: *https://www.qualitynet.org.* 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 42 CFR 416.310(c)(1)(i).

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
- *ASC–14:* Unplanned Anterior Vitrectomy

We did not propose any changes to these policies for data submitted via a CMS online data submission tool.

(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 42 CFR 416.310(c)(2).

As we noted in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59135), no measures submitted via a non-CMS online data submission tool remain in the ASCQR Program beginning with the CY 2020 payment determination. We did not propose any changes to our non-CMS online data submission tool reporting requirements; these requirements would apply to any future non-CMS online data submission tool measures adopted in the ASCQR Program.

f. Requirements for Data Submission for ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79822 through 79824) for our previously finalized policies regarding survey administration and vendor requirements for the CY 2020 payment determination and subsequent years. In addition, we codified these policies at 42 CFR 416.310(e). However, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451) we delayed implementation of the ASC15a–e: OAS CAHPS—Survey-based-measures beginning with the CY 2020 payment determination (CY 2018 data submission) until further action in future rulemaking, and we refer readers to that discussion for more details. We did not propose any changes to this policy.

g. ASCQR Program Data Submission Deadlines

While the ASCQR Program has established submission deadlines (42 CFR 416.310), there is no specified policy for deadlines falling on nonwork days. Therefore, we proposed that all program deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Social Security Act (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)). Section 1872 of the Act, incorporates section 216(j) of the Act, to apply to Title XVIII, the Medicare program under which the ASCQR Program is administered. As such, in the CY 2021 OPPS/ASC proposed rule (85 FR 48994), we proposed to add this policy for the submission deadlines associated with the ASCQR Program beginning with the effective date of this rule. We also proposed to codify this policy by adding a new paragraph (f) at § 416.310, which would provide 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 are extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order. We invited public comment on our proposals.

The following is a summary of the comments we received and our responses to those comments.

Comment: A few commenters supported the proposal to move forward all program deadlines falling on a nonwork day consistent with section 216(j) of the Act, 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days.'' The commenters also supported the proposal to codify this policy by adding a new paragraph (f) at § 416.310.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS continue to publish the revised deadline when the routinely established deadline falls on a nonwork day.

Response: We thank the commenter for this input. We will continue to publish revised reporting deadlines, which can be monitored and verified via the QualityNet website (*https://www.qualitynet.org*).

After consideration of the public comments received, we are finalizing our proposal as proposed.

2. Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool in the ASCQR Program

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).[109] For example, ASCs collect measure data from January 1, 2019 through December 31, 2019 and submit these data to CMS from January 1, 2020 through May 15, 2020. 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 proposed rule with comment period (85 FR 48994), we proposed to formalize that process and establish a review and corrections period similar to that being proposed for the Hospital OQR Program in section XIV.D.7 of the CY 2021 OPPS/ASC proposed rule. For the ASCQR Program, we proposed to implement a review and corrections period which would run concurrently with the data submission period beginning with the effective date of this rule. During this review and corrections period, ASCs could enter, review, and correct data submitted directly to CMS. However, after the submission deadline, ASCs would not be allowed to change these data. We also proposed to codify this review and corrections period at new paragraph (c)(1)(iii) in § 416.310, which would provide that for measures submitted to CMS via a CMS online tool, ASCs have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, ASCs can enter, review, and correct data submitted. After the submission deadline, this data cannot be changed. We invited public comment on our proposals, including on the burden and benefits of such a review and corrections period. The following is a summary of the comments we received and our responses to those comments.

Comment: A few commenters supported our proposal to create and codify a review and corrections period for data submitted through a CMS online data submission tool. One commenter stated that this policy would give ASCs an opportunity to review their data and correct errors prior to a submission deadline.

Response: We thank the commenters for their support of this proposed policy change. We agree that it will provide ASCs time to review their data and identify errors prior to submission deadlines. We continue to encourage providers to submit data as early as possible, leaving adequate time to make any necessary corrections.

Comment: One commenter suggested that we extend the timeline for the review period. Specifically, the commenter recommended that we give ASCs one additional month following the data submission deadline to review and correct their data. The commenter

[109] ASCQR Program Data Submission Deadlines. Available at: *https://www.qualitynet.org/asc/data-submission#tab2*.

emphasized that recent natural disasters have caused practices to prioritize patient care and facility operations over data submission, such that data may not be submitted until late in the submission period. The commenter further explained that allowing a one-month review period after the submission deadline would help to mitigate the impact of natural disasters and facilitate the improved integrity of ASCQR Program data.

Response: We thank the commenter for this policy recommendation and the insights about the impact of natural disasters on ASCs. As noted previously, the current data submission period for measures submitted via a CMS online data submission tool is from January 1 through May 15 during the calendar year subsequent to the current data collection period (84 FR 61432). We believe that four and a half months should provide ample time to review, correct, and submit data from the prior year. However, we note that if an ASC is not able to submit data because it has experienced an extraordinary circumstance, such as a natural disaster, the ASC may request an exception under the ASCQR Program Extraordinary Circumstance Exceptions (ECE) policy. As described in section XV.D.4 of this final rule with comment period, ASCs must complete and submit the ECE form, along with any required information and supporting documentation, within 90 calendar days of the date of the extraordinary circumstance.[110]

After consideration of the comments received, we are finalizing our proposal as proposed.

3. 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 did not propose any changes to this policy.

4. Extraordinary Circumstances Exception (ECE) Process for the CY 2020 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 42 CFR 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 did not propose any changes to these policies.

E. 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 2021, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the multifactor productivity (MFP)-adjusted hospital market basket update factor. The MFP adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-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 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 MFP 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).

[110] For more information on the ECE policy, we refer stakeholders to the QualityNet website at *https://www.qualitynet.org/asc/data-submission#tab2.*

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 2020 OPPS/ASC final rules with comment period we did not make any other changes to these policies. We proposed the continuation of these policies for CY 2021 in the CY 2021 OPPS/ASC proposed rule (85 FR 48995 through 48996), did not receive any public comments on these policies, and are finalizing the continuation of these policies for CY 2021.

XVI. Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years

A. Background

The Overall Star Rating provides a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS programs, in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars. The Overall Star Rating was first introduced and reported on *Hospital Compare* in July 2016 [111] and has been refreshed six times,[112] [113] [114] [115] two of which included minor methodology updates,[116] [117] over the past 3 years. *Hospital Compare,* and any successor site, is a public website hosted by CMS with transparent information and data on over 100 quality measures for over 5,300 hospitals, nationwide in the United States (U.S.), for consumers and researchers. In this rule, for the Overall Star Rating, the term ''publish'' refers to the public posting of the Overall Star Rating and ''refresh'' refers to the public posting quality measure and program data on *Hospital Compare* or its successor website.

During development of the Overall Star Rating, we established guiding principles to use methods that were scientifically valid, inclusive of hospitals and measure information, accounted for the heterogeneity of available measures and hospital reporting, and accommodated changes in the underlying measures.[118] In addition, we aimed to provide alignment with the information displayed on *Hospital Compare* and the measures and methods used within CMS programs, transparency of Overall Star Rating methods, and responsiveness to stakeholder input. After the launch of the Overall Star Rating in July 2016 and as the Overall Star Rating gained broader use by multiple stakeholders, we added new guiding principles to guide reevaluation of the methodology.[119]

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed a methodology which includes elements of the current methodology as well as updates (we refer readers to section E. Current and Proposed Overall Star Rating Methodology of the proposed rule) that aim to increase simplicity of the methodology, predictability of measure emphasis within the methodology over time, and comparability of ratings among hospitals. We also proposed to include Veterans Health Administration (VHA) hospitals (we refer readers to section C. Veterans Health Administration Hospitals in Overall Star Rating) and proposed to include Critical Access Hospitals (CAHs) (we refer readers to section B. Critical Access Hospitals in the Overall Star Rating) in

[111] Centers for Medicare & Medicaid Services. (2016, July 27). *First Release of the Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from *www.cms.gov/newsroom*: *https://www.cms.gov/newsroom/fact-sheets/first-release-overall-hospital-quality-star-rating-hospital-compare.*

[112] Centers for Medicare & Medicaid Services. (2016, May). *Overall Hospital Quality Star Rating on Hospital Compare: July 2016 Updates and Specifications Report.*

[113] Centers for Medicare & Medicaid Services. (2016, October). *Overall Hospital Quality Star Rating on Hospital Compare: December 2016 Updates and Specifications Report.*

[114] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare: July 2017 Updates and Specifications Report.*

[115] Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from *qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[116] Centers for Medicare & Medicaid Services. (2018, November 30). Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report. Retrieved from *qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[117] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[118] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[119] Ibid.

the Overall Star Rating. In addition, we proposed to establish the Overall Hospital Quality Star Rating and methodology at subpart J of part 412 (proposed § 412.190).

Because of our production timeline to calculate and distribute Overall Star Rating results in time for hospitals to preview the ratings in advance of publication, we used the CY 2021 OPPS/ASC proposed rule to propose the methodology for the Overall Star Rating even though it includes not only hospital outpatient measures, but also hospital inpatient measures, which are generally discussed in the Inpatient Prospective Payment System (IPPS) rule. We plan to reference the finalized policies for the Overall Star Rating from this CY 2021 OPPS/ASC final rule in the coming FY 2022 IPPS/LTCH rule.

1. Purpose, Authority, and Applicable Hospital Quality Data

a. Purpose

In 2014, to inform the initial methodology for the Overall Star Rating, we conducted a review of the literature as well as a review of prior and current star rating efforts. This review supported the notion that patients care about information on hospital quality, but that patient use of this information is limited by low understanding of quality information. Additionally, we heard feedback that hospital quality information is often intimidating as displayed and is not user-friendly in comparison to other consumer ratings. The key findings of the review were consistent with consumer priorities to bring a wide variety of measures together into a single overall star rating. Therefore, we sought to help consumers understand hospital quality information through development of a summary measure, which combines publicly reported quality information in an easy-to-understand rating that is familiar to consumers.

The primary objective of the Overall Star Rating was to use an established, evidence-based statistical approach to summarize hospital quality measure results reported on *Hospital Compare* with the goal of assigning acute care hospitals and facilities that provide acute inpatient and outpatient care in the U.S. to an overall rating between one and five whole stars.[120] The Overall Star Rating is meant to complement other hospital quality information publicly posted on *Hospital Compare* or its successor website, including the individual measure scores and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Star Rating.[121] The original guiding principles of the Overall Star Rating was to use scientifically valid methods that are inclusive of hospitals and measure information, able to account for different hospitals reporting on different measures, and able to accommodate changes in the underlying measures over time.[122] We also aimed to create alignment with *Hospital Compare* and CMS programs, transparency of the methods for calculating the Overall Star Rating, and responsiveness to stakeholder input through various and ongoing engagement activities.

The goal of the Overall Star Rating is to summarize hospital quality information in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars, to increase transparency and empower stakeholders to make more informed decisions about their healthcare. To this end, we proposed that (1) the Overall Star Rating is a summary of certain publicly reported hospital measure data for the benefit of stakeholders, such as patients, consumers, and hospitals, (2) the guiding principles of the Overall Star Rating are to use scientifically valid methods, inclusive of hospitals and measure information and able to accommodate measure changes; alignment with *Hospital Compare* or its successor websites and CMS programs; provide transparency of the methods for calculating the Overall Star Rating; be responsive to stakeholder input; and (3) to codify this at § 412.190(a).

We invited public comment on our proposals as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: One commenter supported the purpose of the Overall Star Rating and appreciated that the tool consolidates and streamlines the various hospital quality measures into a single metric.

Response: We thank the commenter for their support and agree that the Overall Star Rating effectively combines multiple dimensions of hospital quality into an overall rating. Review of the literature and engagement with patients and patient advocates confirmed that patients care about hospital quality information but find it difficult to understand. Therefore, the Overall Star Rating is meant to provide a summary of hospital quality information based on publicly available quality measure results in a way that is simple and easy for patients to understand.

Comment: Many commenters opposed the purpose of the Overall Star Rating, noting that a single composite rating oversimplifies the various complex factors that must be considered when assessing hospital quality of care. Commenters further stated that an overall composite rating obscures details about care and does not allow for an accurate comparison of hospitals.

Several commenters questioned the usefulness of the Overall Star Rating for patients as a tool to make informed decisions about where to seek care. Specifically, some commenters noted the Overall Star Rating cannot be used by patients to compare hospitals based on their specific condition or treatment needs and alternatively suggested reported star ratings or information based on service lines. One commenter recommended that CMS focus on measures specific to clinical conditions or treatments and patient clinical or demographic characteristics, which may be more helpful to patients than an overall rating.

Response: As stated in section A.1.a. Purpose of this final rule, review of the literature and consumer engagement supported the notion that patients care about information on hospital quality, but that quality measurement, often in the form of multiple measure scores as rates and ratios, is intimidating and difficult to understand. The primary purpose of the Overall Star Rating is to provide a summary of certain existing hospital quality information in a way that is easy for patients to understand, by assigning hospitals between one and five stars, to increase transparency and empower stakeholders to make more informed decisions about their healthcare. The Overall Star Ratings methodology is designed to summarize the underlying measures in a manner that maintains the validity of the underlying measures that have undergone rigorous development and reevaluation processes, including testing, stakeholder vetting, National Quality Forum (NQF) evaluation, and rulemaking. Furthermore, the Overall Star Rating is meant to complement, not replace, the existing individual

[120] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[121] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[122] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

measures reported on *Hospital Compare* or its successor website and accommodate stakeholder needs to either or concurrently view an overall rating and individual measures, which may be more pertinent to a specific condition or hospital service of interest. We also provide performance summaries for the Overall Star Rating measure groups for patients and stakeholders wishing more granular information on hospital Overall Star Rating performance.

We appreciate commenter suggestions for the development of star ratings by service lines, rather than overall. CMS and its development contractor had previously investigated the feasibility of star ratings for different measure groupings including by condition, procedure, or service line. CMS' development contractor brought the concept, options, and findings to the Technical Expert Panel (TEP), Patient & Patient Advocate Work Group, and a public comment period.[123] While stakeholders, including providers and patients, were interested in the concept of creating star ratings for individual clinical domains, we ultimately found insufficient existing measures to group measures or calculate star ratings by conditions, procedures, or service lines. However, we will continue to explore the possibility of calculating star ratings based on clinical domains as the available measures within CMS hospital quality programs evolve.

Comment: Commenters also suggested continued stakeholder engagement to gain a better understanding of how to make the Overall Star Rating useful to patients, with some commenters recommending user-customized star ratings for which patients can set measure or measure group weights based on their own values and needs.

Response: We appreciate commenter suggestions for user-customized star ratings, which we also evaluated and brought in front of stakeholders during work group meetings, as well as a public comment period.[124] Ultimately, a majority of stakeholders did not support the concept of user-customized star ratings. Prior comments suggested that user-customized star ratings would be too confusing for patients, difficult for hospitals to explain, require elaborate testing, and not allow hospitals to use the Overall Star Rating for quality improvement.

After consideration of the public comments received, we are finalizing our proposals as proposed.

b. Subsection (d) Hospitals

The Overall Star Rating includes measures that (1) capture quality of care at hospitals and facilities providing acute inpatient and outpatient care and (2) are publicly reported on *Hospital Compare* or its successor websites. CMS currently publicly reports information regarding the performance of individual hospitals in the following CMS quality programs: Hospital Inpatient Quality Reporting (IQR) Program, Hospital Readmission Reduction Program (HRRP), Hospital-Acquired Condition (HAC) Reduction Program, Hospital Value-Based Purchasing (VBP) Program, and Hospital Outpatient Quality Reporting (OQR) Program. Such authority is granted under applicable sections 1833 and 1886 of the Act.[125]

Specifically, under sections 1886(b)(3)(B)(viii)(VII) and 1833(t)(17)(E) of the Act for the Hospital IQR and OQR Programs respectively, the Secretary of the Department of Health and Human Services (Secretary) is required to make quality information available to the public. Section 1886(b)(3)(B)(viii)(VII) of the Act states that ''The Secretary shall establish procedures for making information regarding measures submitted under this clause available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to furnished in inpatient settings in on the internet website of the Centers for Medicare & Medicaid Services.'' Section 1833(t)(17)(E) of the Act states that ''The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the internet website of the Centers for Medicare and Medicaid Services.'' We believe that these requirements allow the agency to create the Overall Star Rating as a means to summarize existing publicly reported quality measure data from the Hospital IQR and OQR Programs, along with quality measure data from other hospitals, in a form and manner that improves accessibility of hospital quality information for the benefit of patients and consumers.

In addition, the HRRP (under section 1886(q)(6)(A) of the Act) and the HAC Reduction Program (under section 1886(p)(6)(A) of the Act) require that the Secretary must make information regarding readmission and hospital acquired condition rates for hospitals available to the public. Specifically, section 1886(q)(6)(A) of the Act states that ''The Secretary shall make information available to the public regarding readmission rates of each subsection (d) hospital under the program'' and section 1886(p)(6)(A) of the Act states that ''The Secretary shall make information available to the public regarding hospital acquired conditions of each applicable hospital.'' Similar to Hospital IQR and OQR Programs, we believe that these requirements allow the agency to create and publicly release the Overall Star Rating as a means to summarize existing publicly reported quality measure data from the HRRP and HAC Reduction Program, along with quality measure data from other hospitals, in a form and manner that improves accessibility of hospital quality information for the benefit of patients and consumers.

Our use of data reported by hospitals under the Hospital VBP Program in the Overall Star Ratings is supported by section 1886(o)(10)(A)(i) of the Act. Specifically, section 1886(o)(10)(A) of the Act states that the Secretary shall make information available to the public regarding the performance of individual hospitals under the Program, including (i) the performance of the hospital with respect to each measure that applies to the hospital; (ii) the performance of the hospital with respect to each condition or procedure; and (iii) the hospital performance score assessing the total performance of the hospital. Hospitals that participate in the Hospital VBP Program report data on each Hospital VBP Program measure for a specified performance period that applies to the program year. Under our proposed Overall Star Rating methodology, which we describe in detail below, we would use these Hospital VBP Program measure rates, in combination with measure rates reported by various hospitals under the Hospital IQR

[123] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[124] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[125] U.S. Congress. (1934) *United States Code: Social Security Act, 18 U.S.C. 1833 and 1886.*

Program, Hospital OQR Program, HRRP, and HAC Reduction Program to calculate and make public a star rating that applies to the hospital for a corresponding star rating period, making that star reflective of the hospital's measured level of quality in all of these programs.

The Overall Star Rating does not use data reported by hospitals under the Prospective Payment System-Exempt Cancer Hospitals Quality Reporting (PCHQR) Program, the Inpatient Psychiatric Facilities (IPF) Quality Reporting Program, or the Ambulatory Surgical Centers Quality Reporting (ASCQR) Program.

Beginning with publication of Overall Star Rating in CY 2021 and subsequent years, we proposed to: (1) Continue to use data publicly reported on a CMS website from the programs described above as a basis to calculate the Overall Star Rating, and (2) codify this at § 412.190(b)(2).

We invited public comment on our proposals. However, we did not receive any comment. We are finalizing our proposals as proposed.

B. Critical Access Hospitals in the Overall Star Rating

1. Current Critical Access Hospitals in the Overall Star Rating

The current Overall Star Rating is calculated based on certain data that is publicly reported on a CMS website and includes data from hospitals and facilitates that provide acute inpatient and outpatient care, including CAHs. Many CAHs currently voluntarily submit measure data consistent with certain CMS quality programs and elect to have their quality measure data publicly reported through their QualityNet account by selecting Optional Public Reporting Notice of Participation. We note, however, that the Hospital OQR Program no longer uses a Notice of Participation form (83 FR 59103 through 59104). Submission of data through the Hospital OQR Program is considered participation specifically in that program. If a CAH elects to voluntarily submit data and have their quality measure data publicly reported, they are subsequently eligible to receive a star rating so long as they meet the specified reporting thresholds, discussed in detail in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating of this final rule.

We note that many CAHs do not meet the minimum threshold to receive a star rating due to serving too few patients to report some of the underlying measures. To date, typically anywhere from 48 to 55 percent of CAHs report enough measures to receive a star rating.

2. Inclusion of Critical Access Hospitals in the Overall Star Rating

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to continue to include voluntary measure data from CAHs for the purpose of calculating Overall Star Rating through authority in section 1704 of the Public Health Service Act (PHSA).[126] Section 1704 of the PHSA states that the Secretary is authorized to conduct and support by grant or contract (and encourage others to support) such activities as may be required to make information respecting health information and health promotion, preventive health services, and education in the appropriate use of health care available to the consumers of medical care, providers of such care, schools, and others who are or should be informed respecting such matters. We believe that this authority allows the agency to include CAHs in Overall Star Rating because the purpose of the Overall Star Rating is to summarize hospital quality information in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars, to increase transparency and empower stakeholders to make informed decisions about their healthcare. We have an existing contract mechanism through our current Healthcare Quality Analytics and Reports (HCQAR) contract, which would continue under a future similar contract vehicle as appropriate, for the calculation of the Overall Star Rating for all hospitals that provide acute inpatient and outpatient care, including CAHs, and for the dissemination of reports to these hospitals prior to publication. Any hospital or facility providing acute inpatient and outpatient care, including CAHs, with measure or measure group scores reported on *Hospital Compare* or its successor websites are given a confidential hospital-specific report (HSR) during the Overall Star Rating preview where they may review their measure, measure group, and star rating results prior to public release. The Overall Star Rating preview period and confidential hospital-specific reports are discussed in more detail in section F. Preview Period of this final rule.

In addition, section 1851(d) of the Act allows the Secretary to disseminate information to Medicare beneficiaries to promote informed choice among coverage options.[127] Many CAHs are located in remote areas that face unique challenges in resources and are often one of the only options for patients to seek care.[128] We believe it is important to include CAH data when available because it aligns with CMS goals of healthcare transparency, consumer choice, and the guiding principle of the Overall Star Rating, which is to include as much information as possible about hospital quality. The inclusion of CAHs in the Overall Star Rating has been supported by the Health Resources and Services Administration (HRSA) through their ongoing work with rural hospitals and facilities that provide acute inpatient and outpatient care, including CAHs. HRSA encourages CAHs to report quality measure data as part of quality improvement and public reporting and supports the inclusion of publicly reported measure scores for CAHs within the Overall Star Rating. Additionally, as part of ongoing stakeholder engagement activities, we have heard from some CAHs that they are interested in receiving a star rating and that voluntary measure reporting places no additional burden on CAHs.

Therefore, we proposed that CAHs that wish to be voluntarily included in the Overall Star Rating must have elected to both (a) voluntarily submit quality measures included in and as specified by CMS hospital programs and (b) publicly report their quality measure data on one of CMS' public websites. We proposed to codify this at § 412.190(b)(3). CAHs that do not elect to participate or that elect to withhold their data from public reporting will not be included in the Overall Star Rating calculation. Since CAHs voluntarily report measures, CAHs may have their Overall Star Rating withheld from public release provided they submit a timely request, as described in more detail under section G. Overall Star Rating Suppressions of this final rule.

Of note, the proposal to peer group hospitals by the number of measure groups, as outlined in section E.7. Approach to Peer Grouping Hospitals of this final rule, was dependent on CAH participation in the Overall Star Rating since CAHs make up approximately half of the hospitals within the three measure peer group and excluding CAHs from the Overall Star Rating would not provide a sufficient amount

[126] Public Health Service Act of 2019, Public Law 116–69, Page 133 Stat. 1134, codified as amended at 42 U.S.C. 201.

[127] U.S. Congress. (1934) United States Code: Social Security Act, 42 U.S.C. 1851.

[128] Centers for Medicare & Medicaid Services. (2013, April 9). *Critical Access Hospitals.* Retrieved from *www.cms.gov*: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CAHs.*

of hospitals to make peer group comparisons.

We invited public comment on our proposals to: (1) Include CAHs in the Overall Star Rating that wish to be voluntarily included in the Overall Star Rating and have elected to both (a) voluntarily submit quality measures included in and specified under CMS hospital programs and (b) publicly report their quality measure data on Hospital Compare or its successor site; and (2) to codify these at § 412.190(b)(3). We note that for the purposes of the rest of this discussion, we will refer to both subsection (d) hospitals and CAHs as ''hospitals.'' The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters expressed general support for the inclusion of CAHs in the Overall Star Rating. Commenters noted that inclusion of CAHs will improve transparency and increase usability for consumers while also incentivizing CAHs to participate in measure reporting.

Response: We thank commenters for their support and agree that continuing to include CAHs within the Overall Star Rating improves the transparency and usability of the Overall Star Rating for patients. Most CAHs do participate in measure reporting but have too few cases to meet the minimum case counts to receive publicly reported scores for some narrowly focused quality measures, such as condition- and procedure-specific measures, and therefore do not meet the reporting thresholds to receive a star rating (section E.6.b. Minimum Reporting Thresholds for Receiving a Star Rating of this final rule).

Comment: Some commenters particularly supported the inclusion of CAHs if it resulted in peer grouping and comparison of CAHs separately from other hospitals. However, several commenters expressed concerns about the inclusion of the CAHs in the Overall Star Rating, recommending that CMS refrain from comparing CAHs to other acute care hospitals. Some commenters requested separate measurement or ratings for CAHs, noting that any other risk adjustment would not appropriately capture differences in demographics and healthcare resources for CAHs and other acute care hospitals. Some commenters recommended improved consumer interpretability of the Overall Star Rating for CAHs versus other types of hospitals. Specifically, commenters suggested that CMS provide clear details on the services available for each hospital and the number of hospitals assigned to each star rating based on these services.

Response: Feedback from stakeholders, including the Patient & Patient Advocate Work Group, stated that critical access status is not a meaningful approach to grouping hospitals to patients and it is important to be able to compare star ratings across hospital types. As discussed under section E.7.b. Peer Grouping of this final rule, we are finalizing our proposal to peer group hospitals by the number of measure groups in which at least 3 measures are reported. We had considered CAH status as a peer grouping variable, but found appreciable differences in summary score cutoffs for each star rating category between CAHs and non-CAHs, which would make differences in star rating assignments difficult for stakeholders, including providers, to understand and explain. Furthermore, feedback from the Patient & Patient Advocate Work Group consistently indicated that peer grouping by CAH status would be misleading and unhelpful to patients, particularly for patients with limited hospital options in their community. We also heard from stakeholders that it is important for patients to be able to compare star ratings across hospital types. We note that *Hospital Compare* or its successor websites does provide general information on the hospital type and services provided at each hospital alongside the Overall Star Rating, including for example, emergency care services. Historically, we have publicly posted the Overall Star Rating input file and SAS pack at the time of the Overall Star Rating publication so that stakeholders may review and replicate the methodology and thus, coupled with hospital characteristic data, have the ability to review the types of hospitals assigned to each star rating.

After consideration of the public comments received, we are finalizing our proposals as proposed.

C. Veterans Health Administration Hospitals in the Overall Star Rating

In the CY 2021 OPPS/ASC proposed rule, we proposed to include quality measure data from Veterans Health Administration hospitals (VHA hospitals) for the purpose of calculating Overall Star Rating beginning with the CY 2023. CMS has an existing contract mechanism with the Veterans Health Administration (VHA) through an Interagency Agreement to publish their hospitals' quality measure data on *Hospital Compare* [129] in accordance with section 206(c) of the Veterans Access, Choice, and Accountability Act (Choice Act) of 2014 (Pub. L. 113–146).[130]

Furthermore, section 1704 of the PHSA [131] allows the Secretary to make health information available to consumers of medical care through grant or contract mechanism including, but not limited to, the publication of health information. In addition, section 1851(d) of the Act allows the Secretary to disseminate information to Medicare beneficiaries to promote informed choice among coverage options.[132] We believe this includes the publication of quality measure data and Overall Star Rating for VHA hospitals.

Therefore, in the CY 2021 OPPS/ASC proposed rule, we proposed to include VHA hospitals in the Overall Star Rating beginning in CY 2023. Including VHA hospitals in the Overall Star Rating beginning in CY 2023 allows CMS to establish the methodology through the CY 2021 OPPS/ASC proposed rule and host confidential reporting of the Overall Star Rating for VHA hospitals prior to public release of VHA star ratings. In order to be eligible to receive a star rating, VHA data would be subject to the same reporting threshold as subsection (d) hospitals and CAHs included in the Overall Star Rating (finalized as three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each measure group, as discussed in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating of this final rule).

We anticipate that adding VHA hospital data to the Overall Star Rating calculation would influence national results due to several steps in the Overall Star Rating methodology that inherently assess quality measure performance in a relative manner, or by comparing hospitals to other hospitals. This influence is present in three places of the Overall Star Rating methodology: in the standardization of individual measure scores, in the standardization of measure group scores, and in the calculation of star ratings using k-means

[129] Centers for Medicare & Medicaid Services. (2016, October 19). *Veterans Health Administration Hospital Performance Data.* Retrieved July 6, 2020, from *www.cms.gov*; *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/VA-Data.*

[130] Veterans Access, Choice, and Accountability Act of 2014, Public Law 113–146, Page 128 Stat. 1754, codified as amended at 38 U.S.C. 1703C(b)(1).

[131] Public Health Service Act of 2019, Public Law 116–69, Page 133 Stat. 1134, codified as amended at 42 U.S.C. 201.

[132] U.S Congress. (1934) United States Code: Social Security Act, 42 U.S.C. 1851.

clustering. The addition of VHA hospitals has no direct influence on CMS-administered programs, however. CMS program impacts, including payment and burden, are assessed based on hospitals participating in CMS' programs and do not include VHA hospitals in those determinations. CMS intends to provide more information about the statistical impact of adding VHA hospitals to the Overall Star Rating and discuss procedural aspects in a future rule.

We invited public comment on our proposal to include VHA hospitals in the Overall Star Rating beginning with CY 2023. The following is a summary of the comments we received and our responses to those comments.

Comment: One commenter supported the inclusion of VHA hospitals within the Overall Star Rating since it will allow veterans to compare non-VHA and VHA hospitals when making healthcare decisions. Regardless of support, commenters requested impact analyses of the inclusion of VHA hospitals on the Overall Star Rating results.

Response: We thank commenters for their feedback. We agree that including VHA hospitals within the Overall Star Rating promotes transparency and provides veterans with the ability to compare hospitals and make empowered decisions about their healthcare. Details of the inclusion of VHA hospitals within the Overall Star Rating as well as impact analyses will be addressed through future rulemaking.

Comment: Most commenters opposed the inclusion of VHA hospitals within the Overall Star Rating because they treat patients with an inherently different case mix, demographics, and often for select clinical conditions.

Response: We acknowledge that VHA hospitals treat a unique patient population. However, the Veterans' Access to care through Choice, Accountability, and Transparency Act (Choice Act) of 2014 (Pub. L. 113–146) allows veterans to seek healthcare at non-VHA hospitals under certain circumstances,[133] section 1704 of the PHSA allows the Secretary to make health information available to consumers of medical care,[134] and section 1815 (d) of the Act allows the Secretary to disseminate information to Medicare beneficiaries to promote informed choice among coverage options.[135] Including VHA hospitals within the Overall Star Rating executes these provisions by providing veterans and Medicare beneficiaries with star ratings for VHA hospitals, effectively allowing them to compare VHA and non-VHA hospitals when making decisions about where to seek care.

After consideration of the public comments received, we are finalizing our proposal as proposed. As stated above, details of the inclusion of VHA hospitals within the Overall Star Rating, including impact analyses, will be addressed through future rulemaking.

D. History of the Overall Hospital Quality Star Rating

Prior to introduction of the Overall Star Rating on the *Hospital Compare* website in July 2016, we engaged stakeholders throughout development of the methodology. CMS' Overall Star Rating development contractor convened both a TEP, consisting of national statistical experts, providers, purchasers, and patient advocates, and a Patient & Advocate Work Group, as well as hosted two public input periods[136] [137] to gain stakeholder feedback on aspects of the methodology. Specifically, feedback was solicited on topics such as measure inclusion and groupings, statistical and non-statistical approaches to summarizing measures, weightings for individual measures and measure groups, and approaches to classifying hospitals to star ratings. In 2015, we hosted a confidential hospital dry run to provide all hospitals and facilities that provide acute inpatient and outpatient care with a private report on their measure performance, measure group scores, and star ratings results, which allowed hospitals to preview their preliminary results without public posting and to familiarize themselves with the methodology.[138] Concurrent with the July 2016 preview period, we also hosted a National Provider Call to present the final methodology and answer stakeholder questions.[139]

For the initial July 2016 and each subsequent release of the Overall Star Rating, including October 2016, December 2016, December 2017, February 2019, and January 2020, we have continuously provided resources to maintain transparency and facilitate understanding of the methods, including three National Provider Calls[140] [141] [142] as well as methodology reports,[143] hospital-specific reports,[144] and open access datasets with quality measure data used to calculate the Overall Star Rating (referred to as the public input file), and SAS programing code used to calculate the Overall Star Rating, along with supporting documents to allow stakeholders to understand and replicate the Overall Star Rating results.

Since the introduction of the Overall Star Rating on the *Hospital Compare* website in July 2016, the Overall Star Rating development contractor has continued to engage stakeholders by convening two additional TEPs, maintaining the Patient & Advocate Work Group, convening a new Provider Leadership Work Group, consisting of hospital quality and medical staff, and hosting two additional public input periods.[145] [146] As a result of ongoing

[133] Veterans Access, Choice, and Accountability Act of 2014, Public Law 113–146, Page 128 Stat. 1754, codified as amended at 38 U.S.C. 1703C(b)(1).

[134] Public Health Service Act of 2019, Public Law 116–69, Page 133 Stat. 1134, codified as amended at 42 U.S.C. 201.

[135] U.S Congress. (1934) United States Code: Social Security Act, 42 U.S.C. 1851.

[136] Centers for Medicare & Medicaid Services. (2015, January). *Hospital Compare Star Ratings Public Comment Report 1: Measure Selection for Hospital Star Ratings.*

[137] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[138] Centers for Medicare & Medicaid Services. (2018, September 18). *Hospital Compare Overall Star Ratings Dry Run Q&A.* Retrieved from *www.qualitynet.org: https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab4.*

[139] Centers for Medicare & Medicaid Services. (2015, August 13). *Centers for Medicare & Medicaid Services Hospital Compare Overall Star Ratings Methodology MLN Connects National Provider Call.* Retrieved from *www.cms.gov: https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2015-08-13-Star-Ratings.*

[140] Ibid.

[141] Centers for Medicare & Medicaid Services. (2016, May 12). *Centers for Medicare & Medicaid Services Overall Hospital Quality Star Ratings on Hospital Compare National Provider Call.* Retrieved from: *https://www.qualityreportingcenter.com/en/inpatient-quality-reporting-programs/hospital-inpatient-quality-reporting-iqr-program/archived-events/hiqr-event134/.*

[142] Centers for Medicare & Medicaid Services. (2017, November 30). *Centers for Medicare & Medicaid Services Hospital Quality Star Ratings on Hospital Compare December 2017 Methodology Enhancements National Provider Call.* Retrieved from: *https://www.qualityreportingcenter.com/en/inpatient-quality-reporting-programs/hospital-inpatient-quality-reporting-iqr-program/archived-events/hiqr-event107/.*

[143] Centers for Medicare & Medicaid Services. (2018, January). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from: *https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf.*

[144] Centers for Medicare & Medicaid Services. *Hospital-Specific Reports.* Retrieved from: *https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/reports.*

[145] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[146] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

reevaluation and stakeholder engagement, we updated the methodology in December 2017 and February 2019. CMS also hosted a National Provider Call [147] to facilitate the December 2017 methodology enhancements and nine listening sessions to facilitate the February 2019 methodology enhancements. The current methodology includes enhancements made in December 2017 [148] and February 2019.[149]

1. Reevaluation of the Overall Hospital Quality Star Rating Methodology

The Overall Star Rating is a summary of certain existing hospital quality information, which is collected and reported as part of several CMS programs to improve and make transparent the quality of care provided at hospitals that provide acute inpatient and outpatient care. As the underlying measures reported on *Hospital Compare* have been added, updated, and removed, and as stakeholders have begun using the methodology for purposes beyond consumer transparency, including provider quality improvement efforts, we have refined the methodology of the Overall Star Rating. Since the first reporting of the Overall Star Rating in July 2016, we have maintained an active monitoring and re-evaluation process for the methodology, as well as engaged stakeholders for continuous feedback. Based on this ongoing reevaluation work, we have released multiple, iterative updates to the methodology in December 2017 [150] and February 2019 [151] that addressed stakeholder concerns revealed through previous stakeholder engagement by the TEP [152] [153] and during public input. We refer readers to section E.4.a.(2) Latent Variable Modeling Measure Loadings of this final rule for an overview of the February 2019 methodology updates.

Between 2018 and 2019, CMS' Overall Star Rating development contractor received input on several potential methodology updates through two TEP meetings,[154] three Patient & Advocate Work Group meetings, two Provider Leadership Work Group meetings, nine public listening sessions,[155] and one public input period.[156] Through these reevaluation analyses and stakeholder engagement, we identified three aforementioned overarching areas of improvement for the Overall Star Rating methodology—simplicity of the methodology, predictability of measure emphasis within the methodology over time, and comparability of ratings among hospitals that provide acute inpatient and outpatient care.[157] [158] Simplicity of the methodology means we aim to reduce the statistical complexity of the methodology, while maintaining a representative summary of hospital quality data, so that stakeholders can better understand how the Overall Star Rating is calculated. Predictability of measure emphasis within the methodology over time means we aim to create a methodology that assigns similar measure weight, or emphasis, to each measure to calculate measure group scores and Overall Star Rating over time (each Overall Star Rating publication). Comparability of ratings among hospitals means we aim to create a methodology that compares hospitals that are more similar to each other, such as the measures they report or services they provide, when calculating the Overall Star Rating.

[147] Centers for Medicare & Medicaid Services. (2016, 12 May). *Overall Hosptial Quality Star Ratings on Hospital Compare.* Retrieved from *www.qualityreportingcenter.com*: *https://www.qualityreportingcenter.com/globalassets/migrated-pdf/iqr_20160512_npc-overall-star-rating_vfinal5.9.16.508.pdf.*

[148] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[149] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019).* Retrieved from *www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2.*

[150] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[151] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019).* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2.*

[152] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[153] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[154] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[155] Centers for Medicare & Medicaid Services. (2019, November). *Overall Hospital Quality Star Rating Listening Session Meeting Summary Report.* Retrieved from *https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report.*

[156] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[157] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[158] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

Since the original introduction of the Overall Star Rating, stakeholders have requested a less complex, or simplified, methodology so that providers can better understand the methodology, interpret their star rating, and use the Overall Star Rating to identify areas for quality improvement.[159] We developed the current methodology under the original principles of the Overall Star Rating, which was to use a statistical approach to summarize quality measures for patients.[160]The current methodology aims to prioritize patient usability and employs data-driven statistical modeling approaches, including latent variable modeling [161] and k-means clustering,[162] to calculate measure group scores and to assign hospital summary scores to star ratings. In summary, the current methodology is designed to rely on data for several critical steps in the star ratings calculation. A couple of the proposed methodology updates aim to increase the simplicity of the methodology for health care providers seeking to replicate, better understand, or communicate an interpretation of the Overall Star Rating, including (1) regrouping measures into five measure groups, rather than seven, due to measure removals as a result of the Meaningful Measure Initiative discussed below in section E.3.b.(2) New Measure Group: Timely and Effective Care of this final rule and (2) using a simple average of measure scores to calculate measure group scores discussed below in section E.4. Step 3: Calculation of Measure Group Scores of this final rule.

Several proposed refinements aim to address the predictability of measure emphasis within the methodology over time. Between the December 2017 and the intended July 2018 publication of the Overall Star Rating, there were no Overall Star Rating methodology updates; however, there were several measure-level updates, including the introduction of two new measures (Severe Sepsis and Septic Shock: Early Management Bundle and Pneumonia Excess Days in Acute Care), the removal of one measure (Pneumonia 30-day Readmission), and updated specifications for the CMS Patient Safety Indicator Composite (CMS PSI–90) measure.[163] The updates to the underlying measures for the July 2018 confidential preview period resulted in differences in the emphasis of measure contributions to the star rating calculation from previous releases.[164] These observed changes in star ratings were similar to star rating increases and decreases observed between reporting periods for other CMS star rating programs, however greater than the increases and decreases observed in prior Overall Star Rating publications. While some increases and decreases in star ratings are expected as hospital performance worsens or improves relative to other hospitals in the nation and as measures are added, updated, and removed from the Overall Star Rating calculation, results from the July 2018 confidential preview period illuminated the extent of the sensitivity of a data-driven statistical model to underlying measure updates. As a result of this unexpected change in measure emphasis, we did not move forward with public release of the July 2018 Overall Star Rating and instead focused on potential improvements to the methodology and stakeholder engagement. Several of the proposed methodology updates, including (1) regrouping measures into five measure groups, rather than seven, due to measure removals as a result of the Meaningful Measure Initiative, discussed below in section E.3.b.(2) New Measure Group: Timely and Effective Care of this final rule; (2) use of a simple average of measure scores to calculate measure group scores, discussed below in section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule; and (3) requiring at least three measures in three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating discussed below in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating of this final rule, aim to address concerns around the predictability of measure emphasis, and in turn star ratings, over time.

Comparability of the Overall Star Rating is a commonly expressed priority by stakeholders.[165] [166] Hospitals that provide acute inpatient and outpatient care differ in size or patient volume, geographical location, urban or rural location, patient populations treated, and services offered. In turn, hospitals differ in the number and type of quality measures reported. All hospitals providing acute inpatient and outpatient care, regardless of differences in any of these characteristics, are included within the Overall Star Rating calculation and are eligible to receive a star rating. Stakeholders, primarily providers on the TEP, Provider Leadership Work Group, and during a public input period, have highly recommended that the Overall Star Rating account for differences in hospital case-mix or type to increase comparability of hospital star ratings.[167] [168] Several of the proposed methodology updates, including (1) stratifying the Readmission measure group according to proportion of dual-eligible patients at each hospital discussed below in section E.4.d.(2) Proposal to Stratify Only the Readmission Measure Group Scores of this final rule; (2) requiring at least three measures in three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating discussed below in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating of this final rule; and (3) peer grouping hospitals by number of measure groups, discussed below in section E.7. Approach to Peer Grouping Hospitals of this final rule, aim to increase the comparability of hospitals for patients and providers.

[159] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[160] Centers for Medicare & Medicaid Services. (2018, January). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from: *https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf.*

[161] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[162] Illowsky, B., & Dean, S. (2013). *Introductory Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[163] Centers for Medicare & Medicaid Services. *Hospital-Specific Reports.* Retrieved from: *https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/reports.*

[164] Centers for Medicare & Medicaid Services. (2018, May). Quarterly Updates and Specifications Report: July 2018. Retrieved from: *https://www.qualitynet.org/files/5d0d3abf764be766b0104a21?filename=StarRatingsJul18_UpdtSpecsRpt.pdf.*

[165] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[166] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[167] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[168] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

In 2019, we conducted extensive analyses and engaged multiple stakeholder groups to evaluate each of the proposed methodology updates outlined below. Most notably, CMS' Overall Star Rating development contractor recruited and convened a third TEP to provide technical input,[169] a second Provider Leadership Work Group to provide policy input, and a second Patient & Advocate Work Group to provide input on usability, and we hosted a public listening session,[170] all to gain a range of new perspectives on the current methodology and potential methodology updates.

E. Current and Proposed Overall Star Rating Methodology

1. Overview

The current Overall Star Rating methodology can be outlined within six steps briefly described here and, in more detail, further below. In the first step, the measures are selected from among those reported on *Hospital Compare* to include as much information as possible while considering whether the measures are suitable for combination within the Overall Star Rating. In the first step, the measure scores are also standardized to be consistent in terms of direction (that is, higher scores are better) and numerical magnitude. In the second step, the measures are grouped into one of seven measure groups. Third, for each group, a statistical model, called a latent variable model (LVM), is used to determine a group score for each hospital reporting on measures in that group. In the fourth step, a weight is applied to each measure group score and all available measure groups are averaged to calculate the hospital summary score. In the fifth step, hospitals that provide acute inpatient and outpatient care reporting too few measures and measure groups are excluded. Finally, hospital summary scores are organized into five categories, representing the five star ratings, using an algorithm process called k-means clustering. K-means clustering is a method to cluster data so that observations within one cluster are more similar to each other than observations in another cluster.[171]

In the CY 2021 OPPS/ASC proposed rule, for public release of the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to both retain and update certain aspects of the current Overall Star Rating methodology, as outlined below within each of the six steps of the current methodology. Generally, we proposed to retain the following aspects of the current Overall Star Rating methodology:

- An annual publication cycle using data posted on *Hospital Compare* or its successor site from data publicly reported within the prior year; for example, the Overall Star Rating published in January 2020 used data publicly reported from the October 2019 refresh;
- Suppression policy for subsection (d) hospitals;
- Inclusion of measures publicly reported on *Hospital Compare* or its successor sites that meet specific inclusion and exclusion criteria and standardization of measure score within Step 1: Selection and Standardization of Measures for Inclusion in the Overall Star Rating;
- Publicly displaying measure group level information for measure groups for which a hospital has at least three measures, use of weighted average of measure group scores to calculate summary scores and measure group reweighting to account for measure group scores which are not reported within Step 4: Calculation of Hospital Summary Scores as a Weighted Average of Group Scores; and
- Use of k-means clustering to assign hospitals that provide acute inpatient and outpatient care to one of five star ratings within Step 6: Application of Clustering Algorithm to Obtain a Star Rating.

We proposed to make the following methodology updates:

- Regroup measures as a result of the Meaningful Measure Initiative (83 FR 41147 through 41148) by combining the three process measure groups into one group, Timely and Effective Care, within Step 2: Assignment of Measures to Groups;
- Update the calculation of measure group scores to include standardization of measure group scores and to use a simple average of measure scores, rather than latent variable modeling;
- Stratify the Readmission measure group scores using the proportion of dual-eligible patients at each hospital within Step 3: Calculation of Measure Group Scores;
- Change the reporting thresholds to receive a star rating to three measures within three measure groups, one of which must be Mortality or Safety of Care, within Step 5: Application of Minimum Thresholds for Receiving a Star Rating; and
- Apply peer grouping of hospitals that provide acute inpatient and outpatient care based on number of measure groups between Step 5: Application of Minimum Thresholds for Receiving a Star Rating and Step 6: Application of Clustering Algorithm to Obtain a Star Rating. These are discussed in more detail in section E.7. Approach to Peer Grouping Hospitals of this final rule.

We received numerous comments on the overall concept of methodology updates. The comments were not specific to any individual update. The following is a summary of the comments we received and our responses to those comments.

Comment: Some stakeholders provided broad comments on CMS' proposals in entirety. Most of those commenters supported CMS' proposals and the efforts to increase simplicity, predictability, and comparability of the Overall Star Rating methodology as a result of previous stakeholder input. Commenters stated that they believe a more simple and predictable methodology would result in more transparency, the ability for stakeholders to understand, predict, and replicate results, and reduced administrative burden for providers while increasing the accuracy and usability of the Overall Star Rating for patients. Commenters stated that the methodology proposals result in comparisons of more similar providers, such as large vs small hospitals.

Response: We thank the commenters for their support. We agree that the proposals will increase simplicity and predictability of the Overall Star Rating methodology. We also agree that the proposals provide more transparency and understanding of the methodology for stakeholders, including both providers and patients, and will increase the comparability of hospital star ratings.

Comment: One commenter requested that CMS conduct further reliability and validity testing before finalizing the proposed methodology.

Response: We analyzed each methodology proposal both independently, as well as collectively. We presented findings within each section of the Overall Star Rating proposals, as well as overall impact analyses to facilitate public understanding and comments. Most

[169] Ibid.

[170] Centers for Medicare & Medicaid Services. (2019, November). *Overall Hospital Quality Star Rating Listening Session Meeting Summary Report.* Retrieved from *https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report.*

[171] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

sections of the Overall Star Ratings proposals contained reliability and validity considerations, for example consistency of hospital assignments to peer groups over time (see section E.7. Approach to Peer Grouping Hospitals of this final rule). While there is currently no consensus standard for measuring reliability and validity for summary measures, such as the Overall Star Rating, we have historically conducted reliability and validity testing that has been shared in detail with TEPs and work groups as well as in public documentation.[172] [173] We will continue to provide updated reliability and validity testing within the methodology report, which will be posted for the preview period (see section F. Preview Period of this final rule). In addition, through ongoing reevaluation, we will continue to monitor the reliability and validity of the Overall Star Rating methodology.

2. Step 1: Selection and Standardization of Measures for Inclusion in the Overall Star Rating

a. Timeframe

(1) Current Timeframe

Generally, for CMS quality programs, we update measure data results on the *Hospital Compare* or its successor websites quarterly in January, April, July, and October of each year. In the past, the Overall Star Rating was published on *Hospital Compare* both quarterly and biannually. Beginning in February 2019, the Overall Star Rating was published annually. In January 2020, the Overall Star Rating continued the annual publication cycle with the additional approach of using data publicly posted on *Hospital Compare* in a quarter prior to the update to calculate star ratings. For example, we used October 2019 publicly reported measure data on *Hospital Compare* to calculate Overall Star Rating results for the January 2020 publication.[174] Note that the data collection period for each measure varies depending on measure specifications that set minimum case requirements to ensure individual measure reliability and meet the requirements of CMS quality programs, as detailed in each program's respective rules as well as on *Hospital Compare* or its successor website.

(2) Retain Current Timeframe With Modification

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027) for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to retain the current timeframe with modification, such that the Overall Star Rating would continue to be published once annually; however, instead of using data from the same quarter as or the quarter prior to the publication of the Overall Star Rating, we would use publicly available measure results on *Hospital Compare* or its successor websites from a quarter within the prior year. As mentioned above, for CMS quality programs, we generally update measure data results on the *Hospital Compare* or its successor websites quarterly in January, April, July, and October of each year. Therefore, we would use publicly reported data from one of those four *Hospital Compare* refreshes to calculate the Overall Star Rating. For example, for a January 2021 Overall Star Rating release, we could use data refreshed on *Hospital Compare* in April, July or October of 2020. We proposed to codify this timeframe at § 412.190(c).

We believe publishing the Overall Star Rating once a year is appropriate because it may minimize period to period changes in hospital star ratings that may result from small changes in individual hospital and national performance for the underlying measures. Furthermore, publishing the Overall Star Rating once a year would allow time for the star ratings to reflect improvements or updates in hospital performance on the underlying measures. It also is aligned with the current cycle of many underlying measures, particularly highly weighted outcome measures that are also refreshed annually.[175] Also, using data publicly reported on *Hospital Compare* or its successor websites within the prior year, rather than data publicly reported concurrent with the Overall Star Rating, would allow providers more time, beyond the standard 30 days, to review their star rating as well as the measure and measure group results that contribute to their star rating during the confidential preview period (we refer readers to section F. Preview Period of this final rule). Hospitals that provide acute inpatient and outpatient care may use this additional time to more thoroughly anticipate and understand their results, as well as generate communication or improvement strategies.

We invited public comment on our proposals to: (1) Publish the Overall Star Rating once annually using data publicly reported on *Hospital Compare* or its successor websites from a quarter within the prior year, and (2) codify this at § 412.190(c). The following is a summary of the comments we received and our responses to those comments.

Comment: Several commenters supported CMS' proposal to continue an annual publication of the Overall Star Rating, with some commenters expressing appreciation for the codification of the annual publication within a rule to increase predictability of Overall Star Rating publications.

Response: We appreciate commenters support for our proposal to continue an annual publication of the Overall Star Rating. Publishing the Overall Star Rating once a year allows for sufficient time between ratings to reflect improvements or updates in hospital performance on the underlying measures. Updating the Star Ratings annually also aligns with the current cycle of many underlying measures, particularly highly weighted outcomes measures, that are also refreshed annually, for example in July of each year.

Comment: Some commenters recommended that CMS prioritize using the most recent available data over providing hospitals extra time to review their underlying measure performance and expressed concern that the data used to determine the Overall Star Rating does not reflect current quality of care. One commenter recommended CMS designate a specific prior quarter's data rather than ''any prior quarter'', unless there are extreme circumstances.

Response: As requested by providers,[176] publishing the Overall Star

[172] Centers for Medicare & Medicaid Services. (2018, January). Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0). Retrieved from: *https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf.*

[173] Centers for Medicare & Medicaid Services. (2017, December). Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0). Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[174] Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from qualitynet.org: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[175] For the Hospital VBP Program, this includes: MORT30–AMI, MORT30–CABG, MORT30–COPD, MORT30–HF, MORT30–HF, MORT30–PN; HAI1 through HAI6, and COMP–HIP–KNEE; For the Hospital IQR Program, this includes: MORT30–STK, PSI–4, READM30–HOSPWIDE, EDAC–AMI, EDAC–HF, EDAC–PN, and COMP–HIP–KNEE; For the Hospital OQR Program, this includes: OP–32, OP–35, OP–36; For the HRRP, this includes: READM30–CABG, READM30–COPD, and READM30-Hip/Knee; and for the HAC Reduction Program, this includes: PSI–90 and HAI–1 through HAI–6.

[176] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

Rating using data publicly reported on *Hospital Compare* or its successor websites within the prior year will allow providers more time to review their measure scores, measure group scores, and star rating results during the confidential preview period. We acknowledge that the measures included in CMS payment programs and the Overall Star Rating use a range of data measurement periods with data reflecting outcomes from up to three years ago in order to collect enough data to calculate reliable hospital scores, however each measure is updated as often as quarterly and as seldom as annually to incorporate more recent data. Furthermore, using data from any quarter within the prior year provides CMS with flexibility to calculate the Overall Star Rating and maintain transparency for patient healthcare decisions in the event of potentially compromised measure score calculation or CMS program-level data disruption due to a public health emergency, for example.

Comment: Several commenters requested CMS update the Overall Star Rating more frequently, either quarterly or biannually, to provide consumers with more recent and meaningful data. Another commenter recommended that the annual Overall Star Rating publication align with the July *Hospital Compare* data refresh.

Response: We appreciate commenter requests for more frequency of the Overall Star Rating publications and acknowledge commenters' request to use more current data to calculate the Overall Star Ratings. We acknowledge that the measures included in CMS payment programs and the Overall Star Rating use a range of data measurement periods with data reflecting outcomes from up to three years ago. However, publishing the Overall Star Rating annually may minimize period to period shifts in hospital star ratings that may result in small changes in individual hospital and national performance on the underlying measures. We have received feedback from stakeholders [177] that hospitals increasing or decreasing star rating categories on a quarterly or bi-annual basis may encounter difficulties explaining the increase or decrease in star rating to hospital leadership and patients. An annual refresh will allow adequate time to reflect improvements or updates in hospital performance on the underlying measures. While a publication of the Overall Star Ratings in July of every year would align in timing with the scheduled refresh of many highly weighted outcome measures, such as readmission and mortality measures, the underlying data used to calculate the Overall Star Rating would not align since we will use data from a quarter within the prior year (see section E.2.a.(2) Retain Current Timeframe With Modification of this final rule). A publication of the Overall Star Rating in October or January could reflect July *Hospital Compare* data refreshes.

Comment: One commenter requested CMS suspend the proposed 2021 publication of the Overall Star Rating to finalize the methodology changes and include an independent audit of the methodology prior to publication in 2022.

Response: The Overall Star Rating proposals were vetted through extensive reevaluation activities and stakeholder engagement, including TEP,[178] [179] Provider Leadership Work Group, and Patient & Patient Advocate Work Group meetings, a public input period,[180] and CMS listening sessions.[181] In addition, the NQF convened a separate, independent TEP [182] that also reviewed and provided broad support for these proposals.

After consideration of the public comments received, we are finalizing our proposals as proposed.

b. Measure Inclusion

(1) Current Measure Inclusion

Generally, measures publicly reported on *Hospital Compare* or its successor site through CMS quality programs, specifically the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, were used to calculate Overall Star Rating. We did not include publicly reported measures from any CMS programs not measuring acute inpatient or outpatient care or pertaining to specialty hospitals, such as cancer hospitals, and ambulatory surgical centers, such as the PCHQR Program, IPFQR Program, or Ambulatory ASCQR Program. The goal of Overall Star Rating is to summarize quality of care at hospitals providing acute inpatient and outpatient care and thus, only include measure scores representing quality of acute inpatient and outpatient care.

Any measures that were removed or suspended from one of the listed quality programs and not displayed on *Hospital Compare* or successor websites were not included.

(2) Retain Current Measure Inclusion

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), we proposed to continue the same practice by incorporating measures summarizing quality of care at inpatient and outpatient care hospitals in the Overall Star Rating. Specifically, for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to use certain measures publicly reported on the *Hospital Compare* or successor websites through certain CMS quality programs, specifically the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, to calculate the Overall Star Rating. We also proposed to codify this policy at § 412.190(b)(1).

We believe hospital inpatient and outpatient measures publicly reported on *Hospital Compare* or its successor websites are appropriate for the Overall Star Rating because they capture the quality of care at hospitals providing acute inpatient and outpatient care and provide a snapshot of quality when combined together. We recognize that measures reported on *Hospital Compare* or its successor websites undergo a rigorous development process which includes extensive measure testing, vetting by stakeholders, evaluation by the NQF, and undergo rulemaking for inclusion in CMS programs and public reporting. As such, the Overall Star Rating methodology uses the measures as specified under the CMS programs, and measure scores as reported on *Hospital Compare* or its successor websites at the time of the Overall Star Rating calculation. As noted above, any measures that are removed or suspended from one of the listed quality programs and not displayed on *Hospital Compare* or successor websites are not

[177] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[178] Centers for Medicare & Medicaid Services. (2018, June). Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.

[179] Centers for Medicare & Medicaid Services. (2019, November). Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[180] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[181] Centers for Medicare & Medicaid Services. (2019, November). Overall Hospital Quality Star Rating Listening Session Meeting Summary Report. Retrieved from *https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report.*

[182] National Quality Forum. (2019, November 6). National Quality Forum Hosptial Quality Star Ratings Summit. Retrieved from *www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

included. Additional measure exclusions are discussed in the next section. Also, we refer readers to sections B. Critical Access Hospitals in the Overall Star Rating and C. Veterans Health Administration Hospitals in Overall Star Rating of this final rule for our discussions about CAHs and VHA hospitals.

We invited public comment on our proposals: (1) Use measures publicly reported on *Hospital Compare* or its successor websites through certain CMS quality programs, specifically the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Programs, for the Overall Star Rating in CY 2021 and subsequent years, and (2) codify this policy at § 412.190(b)(1). The following is a summary of the comments we received and our responses to those comments.

Comment: Several commenters expressed general support for the continued Overall Star Rating measure selection criteria, as proposed.

Response: We thank commenters for their support and agree that the measure selection criteria ensures the inclusion of existing measures reported within CMS quality programs and on *Hospital Compare* or its successor website for hospitals that provide acute inpatient and outpatient care.

Comment: Some commenters recommended changes to the measure selection criteria, specifically recommending removing measures with annual volatility and only including NQF-endorsed measures that are valid, reliable, and aligned with other existing measures. Several commenters provided further feedback on specific measures included within the Overall Star Rating with some commenters expressing concern with healthcare-associated infection (HAI) measure risk adjustment, recommending the removal of the PSI–90 measure, and one commenter supporting the inclusion of electronic clinical quality measures. Those that commented specifically on the PSI–90 measure expressed concern that the measure was developed as a tool for hospitals to identify potential safety events, rather than quality measurement within CMS programs, utilizes administrative claims, rather than chart-abstracted data, disadvantages hospitals that have high volume of surgeries, results in surveillance bias, and has inadequate risk adjustment and poor reliability. They requested that CMS implement better alternative safety quality measures or update, benchmark, and audit the PSI–90 measure.

Response: One of the guiding principles of the Overall Star Rating is to use methods that are inclusive of measure information publicly available on *Hospital Compare* or its successor websites through CMS quality programs. As measures are updated within, removed from, or added to CMS quality programs and *Hospital Compare* or its successor website, the measures are subsequently updated within, removed from, or added to the Overall Star Rating, unless the measures meet one of the specified measure exclusion criteria.

While changes in results that reflect updates in individual and national hospital performance are expected, we agree that extreme volatility on the individual measures and Overall Star Rating poses challenges for hospitals and consumers interpreting results. To increase the predictability and reduce extreme volatility of the Overall Star Rating, in the CY 2021 OPPS/ASC proposed rule, we proposed to establish an annual publication of the Overall Star Rating, preventing shifts in star ratings within a given year, and to use a simple average of measure scores to calculate measure group scores, for more balanced and consistent measure emphasis within groups.

Measures that are included within CMS quality programs and reported on *Hospital Compare* or its successor websites undergo a rigorous development process which include extensive measure testing, stakeholder vetting, evaluation by the NQF, and rulemaking. While most measures included within the Overall Star Rating are NQF-endorsed, NQF endorsement is not required.

Existing measures within CMS quality programs were developed and implemented to fulfill important gaps in measurement and areas for quality improvement. We continuously monitor and reevaluate measures for evidence, opportunities for performance improvement, and potential methodology updates. For example, under the Hospital IQR Program, we adopted updates to the PSI–90 measure for the FY 2018 payment determination and subsequent years, which addressed stakeholder feedback on the component weighting within the composite measure (81 FR 57128– 57133). We appreciate support for the inclusion of electronic measures within CMS quality programs and the Overall Star Rating. Although electronic measures are not currently required for public reporting and therefore are not included in the Overall Star Rating at this time, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58437), CMS finalized proposal policy to begin public display of electronic quality measure data starting with data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years. As electronic measures become required within CMS quality programs, electronic measures will be subsequently included within the Overall Star Rating.

Comment: One commenter recommended that CMS evaluate measures for validity and reliability if data from CY 2020 are excluded and the measurement periods are extended to enhance sample size as a result of COVID–19.

Response: On March 27, 2020, we granted exceptions under certain Medicare quality reporting and value-based purchasing programs.[183] [184] In addition, the Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency Interim Final Rule (IFC) (85 FR 54820) updated the extraordinary circumstances exceptions granted for the Hospital Acquired Condition (HAC) Reduction Program, Hospital Readmissions Reduction Program (HRRP), and Hospital VBP Program for the PHE for COVID–19 as a result of the PHE for COVID–19. This IFC also announced that with respect to the Hospital VBP Program, HRRP, HAC Reduction Program, if, as a result of a decision to grant a new nationwide ECE without request or a decision to grant a substantial number of individual ECE requests, we do not have enough data to reliably compare national performance on measures, we may propose to not score facilities, hospitals based on such limited data or make the associated payment adjustments for the affected program year.

We are currently analyzing how our exemptions granted and the COVID–19 pandemic impact the measures within

[183] CMS Press Release, dated March 22, 2020, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19. Located at *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[184] CMS Guidance Memo, dated March 27, 2020, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19. Located at *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

various CMS quality programs. We note that the Overall Star Rating is calculated using individual measures publicly reported through CMS quality programs and on *Hospital Compare* or its successor website. The Overall Star Rating uses data publicly reported through CMS quality programs and thus, data excluded from those CMS quality programs, will be subsequently excluded from the Overall Star Rating. Hospitals can also utilize established processes under each program in order to review and correct individual measure scores. We refer readers to the QualityNet website: *https://qualitynet.org/* for additional program-related information. We also refer readers to section G. of this final rule; we may also consider suppression of the Overall Star Rating if we determine that due to a public health emergency underlying measure data were substantially affected.

After consideration of the public comments received, we are finalizing our proposals as proposed.

c. Measure Exclusions

(1) Current Measure Exclusions

Of the measures publicly reported on the *Hospital Compare* website through the CMS quality programs listed in a previous section, in the past, we have excluded some measures from the Overall Star Rating methodology for various reasons. The measures excluded fall into the following categories:

- Measures with no more than 100 hospitals reporting performance publicly, as these measures would not produce reliable measure group scores based on so few hospitals;
- Structural measures not amenable to inclusion in a summary scoring calculation alongside process and outcome measures, as these measures cannot be as easily combined with other measures captured on a continuous scale with more granular data;
- Non-directional measures (for which it is unclear whether a higher or lower score is better, such as payment measures), as these measures cannot be standardized to form an aggregate measure group score;
- Measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs, that is the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program and Hospital VBP Program, due to the purpose of Overall Star Rating being a summary of measure information as displayed on *Hospital Compare* or its successor websites;
- Overlapping measures (for example, measures that are identical to another measure, measures with substantial overlap in cohort and/or outcome, and measures that are part of an already-included composite measure), in order to avoid duplicative measure results within the methodology; and
- Measures with statistically significant negative loadings estimated by the LVM as described further in section E.4.a.(2) Latent Variable Model Measure Loadings of this final rule.

In February 2019, we excluded measures for which the LVM estimates a statistically significant negative loading, which indicated the measure had an inverse relationship with other measures in the group.[185] LVM is the a statistical method for combining information that represents a latent trait, in this case measures within a measure group that represent an aspect of hospital quality, to estimate a numerical score, in this case measure group scores.[186] Measure loadings are the contribution, or emphasis, of each measure as assigned by the LVM.[187] Latent variable modeling and measure loadings are described in more detail under section E.4. Step 3: Calculation of Measure Group Scores of this final rule.

(2) Retention and Update of Select Measure Exclusions

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we intended to continue to exclude certain measures used to calculate the Overall Star Rating. We believe these measure exclusions remain appropriate moving forward because the Overall Star Rating is a summary of the existing publicly reported measures of hospital quality of care but not all measure scores can be reliably or appropriately combined with other measure scores. These are discussed in more detail below.

1. We proposed to continue to exclude measures that only 100 hospitals or less publicly report. These measures would not produce reliable measure group scores based on too few hospitals.

2. We proposed to continue to exclude measures that are not able to be standardized and otherwise not amenable to inclusion in a summary score calculation alongside process and outcome measures or measures that cannot be combined in a meaningful way. This includes measures that cannot be as easily combined with other measures captured on a continuous scale with more granular data.

3. We proposed to continue to exclude non-directional measures for which it is unclear whether a high or lower score is better. Without directional scores these measures cannot be standardized to be combined with other measures and form an aggregate measure group score as detailed in section E.2.d Measure Score Standardization of this final rule.

4. We proposed to continue to exclude measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs.

5. We proposed to continue to exclude measures that overlap with another measure in terms of cohort or outcome; this includes component measures that are part of an already-included composite measure. This exclusion criterion avoids duplicative measure results within the Overall Star Rating methodology. In general, we would determine which measures to include or exclude based on the level of information provided by the measure. For example, we would include a composite measure, such as PSI–90, over the component measures, such as PSI–03. As another example, we would include the excess days in acute care (EDAC) measures over the readmission measures, because while both measure sets have the same cohort, the EDAC measures capture a broader outcome inclusive of emergency department visits and observation stays in addition to the unplanned readmissions captured by both measures.

We also proposed to codify these exclusions at § 412.190(d)(1)(i). We noted that we did not propose to continue to exclude measures with statistically significant negative loadings estimated by the LVM. (Measure loadings are the contribution, or emphasis, of each measure as assigned by the LVM.[188] and are further discussed in section E.4.a.(2) Latent Variable Model Measure Loadings of this final rule). This is because, in section E.4.b. of the CY 2021 OPPS/ASC proposed rule, we proposed to calculate measure group scores using a simple average of measure scores, instead of latent variable modeling. Should that proposal be finalized, measure loadings would no longer be produced as a product of latent variable modeling and, therefore, the exclusion criteria of

[185] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019).* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2.*

[186] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[187] Ibid.

[188] Ibid.

measures with statistically significant negative loadings would no longer be necessary. However, should that proposal not be finalized, we would continue using LVM to calculate measure group scores and exclude measures with statistically significant negative loadings as discussed in section E.4.a.(2) Latent Variable Modeling Measure Loadings of this final rule.

We invited public comment on our proposal as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: Several commenters expressed general support for the continued Overall Star Rating measure exclusion criteria, as proposed.

Response: We thank commenters for their support and agree that the measure exclusion criteria ensures the measures included within the Overall Star Rating can be easily standardized and combined in a meaningful way with other measures to form aggregate measure group scores.

We are finalizing our proposals as proposed.

d. Measure Score Standardization

(1) Current Measure Score Standardization

In the past, once the relevant measures were excluded, the remaining measures are standardized to a single, common scale to account for differences in measure score units, such as ratios or rates, and direction, specifically whether a higher or lower score indicates better quality.[189] It is necessary to standardize all measure scores to the same scale (that is, units and direction) for combination into and calculation of measure group scores. To standardize, we used a statistical technique to calculate Z-scores for each measure.[190] A Z-score is a standard deviation score, which relays the amount of variation in a dataset, or in this case, the variation in hospital measure scores. In the Overall Star Rating, Z-scores were produced by subtracting the national mean measure score from each hospital's measure score and dividing by the standard deviation [191] across hospitals. Standard deviation is a number that measures how far data values are from their average.[192] See the measure score standardization example and Table 65. In addition, we changed the direction of all measures that indicate better performance with a lower score so that they were reversed to uniformly indicate that a higher score indicates better performance for all the measures prior to combination with other measures to calculate measure group scores.

(2) Retention of Current Measure Score Standardization

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to continue to standardize measure scores as it allows for measures, which are different in units and direction, to be combined into aggregate measure group scores. Specifically, we proposed that once applicable measures are excluded, we would standardize the remaining measures by calculating Z-scores for each measure prior to being combined in an aggregate measure group score so that all measures are on a single, common scale. That is, we would subtract the national mean measure score from each hospital's measure score and divide the difference by the measure standard deviation in order to standardize measures. We also proposed to codify this at § 412.190(d)(2).

Example of Standardization of Measure Score

Standardized measures score (HAI–6) = − (0.470 − 0.694)/0.49 = 0.46

[189] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[190] DeVore, G.R. (2017, January 17). ''Computing the Z score and centiles for cross-sectional analysis: a practical approach.'' Journal of Ultrasound in Medicine 36.3: 459–473.

[191] Illowsky, B., & Dean, S. (2013). *Introductary Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[192] Ibid.

TABLE 65: Example of Standardization of Measure Scores Within Safety of Care Measure Group

Measure Name	Measure Score	Measure National Mean Score	Measure Standard Deviation	Standardized Measure Score
COMP-HIP-KNEE Hospital-Level Risk Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)	3.22%	2.66%	0.005	-1.13
HAI-1 Central-Line Associated Bloodstream Infection (CLABSI)	1.233	0.736	0.66	-0.75
HAI-2 Catheter-Associated Urinary Tract Infection (CAUTI)	0.747	0.806	0.64	0.09
HAI-3 Surgical Site Infection (SSI) from Colon Surgery	0.000	0.826	0.68	1.21
HAI-4 Surgical Site Infection (SSI) Abdominal Hysterectomy	0.000	0.867	0.89	0.97
HAI-5 Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	0.166	0.843	0.69	0.98
HAI-6 Clostridium Difficile (C. difficile)	0.470	0.694	0.49	0.46
PSI-90 Complication/Patient Safety for Selected Indicators	0.999	0.996	0.18	0.02

We invited public comment on our proposals to standardize measure scores and codify this policy at § 412.190(d)(2). However, we received no comments on these proposals.

We are finalizing our proposals as proposed.

e. Measure Score Winsorization

(1) Current Measure Score Winsorization

In the past, to avoid extreme outlier performance that may be potentially inaccurate or pose technical challenges to statistical estimates, the standardized measure scores were Winsorized [193] at the 0.125th and 99.875th percentiles of a standard normal distribution so that all measure scores range from negative 3 to positive 3 (−3 to 3). Winsorization [194] is a common strategy used to set extreme outliers to a specified percentile of the data. This step was necessary in order to minimize the impact of extreme measure score outliers on the performance of the latent variable modeling (LVM) (we refer readers to section E.4.a.(1) Latent Variable Modeling Overview of this final rule for details). We chose to Winsorize the 0.125th and 99.875th percentiles to minimize the number of scores requiring Winsorization, while also allowing the models to perform properly and produce results. This approach to measure inclusion and standardization within the Overall Star Rating has been vetted previously through the TEP,[195] [196] Patient & Advocate Work Group, and a public input period.[197]

(2) Elimination of Measure Score Winsorization Moving Forward

We refer readers to section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule, where we finalized to calculate measure group scores using a simple average of measure scores for the Overall Star Rating beginning in CY 2021 and subsequent years, instead of latent variable modeling, as was used in the past. Because Winsorization was only necessary to minimize the impact of extreme outliers prior to statistical modeling to ensure model stability, the absence of LVM would eliminate the need for Winsorization. Eliminating Winsorization would be consistent with the proposal to replace the LVM with a

[193] Kwak, S.K., & Kim, J.H. (2017, July 27). ''Statistical data preparation: Management of missing values and outliers.'' Korean journal of anesthesiology 70.4: 407.

[194] Ibid.

[195] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[196] Centers for Medicare & Medicaid Services. (2014, December). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[197] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

simple average of measure scores, would support the goal of refinements to simplify the methodology, and would retain the original, observed performance of outlier hospitals within the calculations. However, in the proposed rule, we stated that should we not finalize our proposal to adopt the simple average of measure scores and retain LVM to calculate measure group scores, as discussed in section E.4.a. Current Approach to Calculating Measure Group Scores Using Latent Variable Modeling of this final rule, we would continue to Winsorize measure scores to minimize the impact of extreme outliers. We refer readers to section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule where we are finalizing the policy to use a simple average of measure scores.

We invited public comment on our proposals as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: Several commenters supported the removal of measure score Winsorization with the use of simple average of measure scores.

Response: We thank commenters for their support and agree that measure score Winsorization is no longer necessary with a simple average of measure scores to calculate measure group scores.

Comment: A few commenters suggested that CMS retain measure score Winsorization with the simple average of measure scores approach to reduce potential measurement error or effect of a single measure within the Overall Star Rating calculation.

Response: We refer readers to section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule where we are adopting use of a simple average of measure scores to calculate measure group scores and disagree with commenters that measure score Winsorization should be retained with the use of a simple average of measure scores. Winsorization of measure scores was previously necessary with LVM in order to minimize the impact of extreme measure score outliers prior to statistical modeling to ensure model stability but it is no longer necessary with a simple average of measure scores. Removing Winsorization is consistent with our intent to simplify the Overall Star Rating methodology and use a simple average of measure scores to calculate measure group scores. In addition, removing measure score Winsorization allows CMS to retain the underlying measure scores, as calculated, to be used within the Overall Star Rating, better reflecting measure performance for outlier hospitals. The Overall Star Rating includes measure scores reported within CMS quality programs and reported on *Hospital Compare* or its successor websites, which underwent and continue to undergo rigorous development and reevaluation processes that include substantial validation testing to minimize measurement error. Furthermore, use of a simple average of measure scores to calculate measure group scores will create equal weighting within measure groups, therefore, diminishing the possibility of one or a few measures from having more effect on a hospital's star rating.

3. Step 2: Assignment of Measures to Groups

a. Past Assignment of Measures to Groups

In the past, we have grouped measures into one of seven measure groups: Mortality, Safety of Care, Readmission, Patient Experience, Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging. Measures were grouped this way to align with the Hospital VBP Program [198] and the previous display of *Hospital Compare,*[199] to clinically reflect shared components of hospital quality, allow for measures to be added or removed as they are added or removed from public reporting, and to be useful to patients in making healthcare decisions as communicated by the Patient & Advocate Work Group. Grouping measures is also consistent with other CMS star rating initiatives, including Nursing Home Compare Star Ratings,[200] Medicare Plan Finder Star Ratings,[201] and Dialysis Facility Compare.[202]

b. New Measure Group and Continuation of Certain Groups

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to consolidate the three process measure groups—Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging—into one process measure group: Timely and Effective Care. We also proposed to retain the current structure of the Mortality, Safety of Care, and Readmission, and the Patient Experience measure groups. These are discussed in more detail below.

(1) Continuation of the Mortality, Safety of Care, Readmission, and Patient Experience Measure Groups

The Mortality, Safety of Care, Readmission, and Patient Experience measure groups were used in the past as noted above. The Mortality, Safety of Care, Readmission, and Patient Experience measure groups contain an adequate number of publicly reported measures to produce robust measure group scores, reflective of differences in hospital quality. These measure groups were not as affected as the process of care measure groups, discussed in the next section, by the Meaningful Measure Initiative (83 FR 41147 through 41148).[203] In the CY 2021 OPPS/ASC proposed rule, for the Overall Star Rating beginning CY 2021 and subsequent years, we proposed to continue to use these measure groups. We also proposed to codify these measure groups at § 412.190(d)(3).

We invited public comment on our proposals as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: Several commenters recommended that CMS continue to assess the various measure groups and group weights, now and in the future, to ensure measure groups and weights are balanced and reflect areas of importance to patients. One commenter noted that the composition of measures available on *Hospital Compare* or its successor websites will continue to evolve, and that CMS should consider longer-term solutions for measure groupings to prevent frequent regroupings and subsequent instability in scores. One commenter supported CMS' measure groups but also recommended that CMS review other existing metrics as an

[198] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[199] Centers for Medicare & Medicaid Services. (2019) *Hospital Compare.* Retrieved from: *www.medicare.gov/hospitalcompare*: *https://www.medicare.gov/hospitalcompare/search.html*?.

[200] Centers for Medicare and Medicaid Services (2019, October). Design for Nursing Home Compare. Retrieved from *www.cms.gov*: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/usersguide.pdf.*

[201] Centers for Medicare and Medicaid Services (2019, October 1). Medicare 2020 Part C & D Star Ratings Technical Notes. Retrieved from *www.cms.gov*: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/Prescription DrugCovGenIn/Downloads/Star-Ratings-Technical-Notes-Oct-10–2019.pdf.*

[202] Centers for Medicare and Medicaid Services (2016, June). Technical Notes on the Updated Dialysis Facility. Retrieved from dialysisdata.org: *https://dialysisdata.org/sites/default/files/content/Methodology/UpdatedDFCStarRating Methodology.pdf.*

[203] Ibid.

example of aggregating quality, safety, and patient experience and engaging hospitals on improvement efforts on specific target areas and service lines. Another commenter specifically expressed concern with the Safety of Care measure group being comprised of HAI measures, the PSI–90 measure, and the Total Knee Arthroplasty/Total Hip Arthroplasty complication measure, which all have dissimilar risk adjustment approaches, making it difficult for consumers to understand and hospitals to target improvement within the Safety of Care measure group.

Response: We appreciate the commenters' suggestions for ongoing reevaluation of measure groupings over time and as *Hospital Compare* or its successor websites evolve. We will continue to monitor the number and groupings of the underlying measures that comprise the Overall Star Rating. While measures within a group may differ in specifications, including risk adjustment, the measure regroupings were identified and implemented based on alignment with clinical components of hospital quality, the Hospital VBP Program, the previous display of *Hospital Compare,* and input received from stakeholders during TEP and Patient & Patient Advocate Work Group meetings and public input periods. The Overall Star Rating is meant to summarize and reflect the existing measures on *Hospital Compare* or its successor website. As part of ongoing reevaluation, we will continue to monitor the available measures reported within CMS quality programs for inclusion and grouping within the Overall Star Rating. The best way for hospitals to improve on the Overall Star Rating is to improve performance on the underlying measures. The adoption of a simple average of measure scores to calculate measure group scores would assign equal weights within measure groups, allow hospitals to better predict measure contributions, and target quality improvement efforts for improved measure group scores and star ratings (see section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule).

After consideration of the public comments we received, we are finalizing our proposals as proposed.

(2) New Measure Group: Timely and Effective Care

Since the first release of the Overall Star Rating, measures have been: (1) Developed and adopted in CMS programs to address measurement gaps, and also (2) removed as a result of the Meaningful Measures Initiative (83 FR 41147 through 41148).[204] However, there has been a steady overall reduction in both the number of measures in CMS quality programs, as well as the number of measures publicly reported and available for inclusion in the Overall Star Rating—from 64 measures in the first publication of Overall Star Rating in 2016, to 51 measures for the most recent January 2020 publication.

More specifically, as finalized in the CY 2018 [205] and CY 2019 OPPS/ASC [206] final rules, and the FY 2019 IPPS/LTCH PPS final rule,[207] resulting from the Meaningful Measure Initiative (83 FR 41147 through 41148),[208] the following 12 process measures have been removed from the Hospital IQR and Hospital OQR Programs, and therefore, also from public reporting and the Overall Star Rating process measure groups between CY 2019 and CY 2021.

From the Effectiveness of Care measure group:

- Influenza Immunization (IMM–2) (83 FR 41151),
- Influenza Vaccination Coverage Among Healthcare Personnel (OP–27) (83 FR 37179 through 37186),
- Aspirin at Arrival (OP–4) (82 FR 59430),
- Colonoscopy Interval for Patients with a History of Adenomatous Polyps (OP–30) (83 FR 37179 through 37186), and
- Incidence of potentially preventable VTE (VTE–6) (83 FR 41151).

From the Timeliness of Care measure group:

- Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED–1b) (83 FR 41151),
- Median Time to ECG (OP–5) (83 FR 37179 through 37186),
- Door to Diagnosis Evaluation by a Qualified Medical Professional (OP–20) (82 FR 59430),
- Median Time to Pain Management for Long Bone Fracture (OP–21) (82 FR 59428), and
- Median Time to Fibrinolysis (OP–1) (83 FR 37179 through 37186).

From the Efficient Use of Medical Imaging group:

- Thorax CT—Use of Contrast Material (OP–11) (83 FR 37179 through 37186), and
- Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT) (OP–14) (83 FR 37179 through 37186).

The aforementioned measure removals from CMS quality programs and public reporting ultimately result in two of the previously used measure groups, Timeliness of Care and Efficient Use of Medical Imaging, being comprised each of only three measures, which would not produce robust or predictable measure group scores.

Therefore, in the CY 2021 OPPS/ASC proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed combining three previously used measure groups—Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging—into one group entitled Timely and Effective Care. We also proposed to codify this new group at § 412.190(d)(3). This new consolidated group would reflect the principles of measure reduction under the Meaningful Measures Initiative and align with the current display of measures on *Hospital Compare.*[209] This consolidation would be necessary to ensure that a sufficient number of measures exist in this group.[210] [211] [212] In general, the TEP supported regrouping of measures into five measure groups with one process measure group (Timely and Effective Care) given the available measures and scheduled removal of measures in the upcoming years.[213]

[204] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 41147 (Aug 17, 2018) (to be codified at 42 CFR parts 412, 413, 424 and 495).

[205] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 59216 (Dec 14, 2017) (to be codified at 42 CFR parts 414, 416, and 419).

[206] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 58818 (Nov 21, 2018) (to be codified at 42 CFR parts 416 and 419).

[207] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 41151 (Aug 17, 2018) (to be codified at 42 CFR parts 412, 413, 424 and 495).

[208] Ibid.

[209] Centers for Medicare & Medicaid Services. *Hospital Compare.* (2019). Retrieved from *www.medicare.gov/hospitalcompare*: *https://www.medicare.gov/hospitalcompare/search.html?*.

[210] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 41151 (Aug 17, 2018) (to be codified at 42 CFR parts 412, 413, 424 and 495).

[211] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 59216 (Dec 14, 2017) (to be codified at 42 CFR parts 414, 416, and 419).

[212] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 58818 (Nov 21, 2018) (to be codified at 42 CFR parts 416 and 419).

[213] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

In order to simulate the potential effects of these proposals, we used October 2019 publicly reported measure data on *Hospital Compare* to test the January 2020 Overall Star Rating to determine how many hospitals would be eligible to receive a star under the proposed measure grouping. Of the 4,576 hospitals that provide acute inpatient care, including CAHs, and reported measures on *Hospital Compare* in October 2019, 180 more hospitals (3,780 hospitals total) would have met the current reporting thresholds (that is, at least three measures in at least three measure groups, one of which must be an outcome group) to receive a star rating with the proposed five measure groups as compared to the original seven measure groups (3,600 hospitals). Additionally, the proposed new grouping would allow approximately 157 additional CAHs, of the 1,306 CAHs with measure scores included within the Overall Star Rating, to receive a star rating. To note, with the current methodology of seven measure groups, these 157 CAHs usually do not meet the minimum threshold to receive a star rating due to serving too few patients to report the underlying measures in each of the individual process groups. The minimum reporting threshold requirements are discussed in section E.6.b. Minimum Reporting Thresholds for Receiving a Star Rating of this final rule.

The above estimations of how many hospitals would receive a star rating are based on the measure regrouping methodology proposed in this rule; we note that other proposals may also influence hospitals meeting or not meeting reporting thresholds for star ratings. This measure regrouping proposal aligns with the guiding principles of the Overall Star Rating,[214] which include being inclusive of hospitals and measure information, accommodating changes in the underlying measures, and accounting for the heterogeneity of available measures. We invited public comment on our proposed measure groupings and codification of those groupings. The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters expressed support for grouping the Effectiveness of Care, Timelines of Care, and Efficient Use of Medical Imaging into one Timely and Effective Care measure group, especially considering the recent and future measure removals from public reporting as a result of the Meaningful Measures Initiative. Several commenters noted that combining these measure groups would allow more hospitals to qualify for scoring, particularly small hospitals and CAHs, and would align with CMS' goal of being inclusive of hospitals and measure information.

Response: We appreciate the support for our proposal and agree that combining the Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging measure groups into one measure group, Timely and Effective Care, aligns with the guiding principle for inclusivity of measure and hospital information within the Overall Star Rating (see section A.1.a. Purpose of this final rule) by allowing more hospitals to meet the reporting thresholds to receive a star rating (see section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating of this final rule). Using January 2020 Overall Star Rating data (October 2019 public reporting data), when isolated, regrouping process measures into one measure group, Timely and Effective Care, results in 180 more hospitals meeting the reporting threshold to receive a star rating.

After consideration of the public comments we received, we are finalizing our proposals as proposed.

4. Step 3: Calculation of Measure Group Scores

In the past, we have used latent variable modeling (LVM) to calculate measure group scores. In the CY 2021 OPPS/ASC proposed rule, we proposed to replace LVM with a simple average of measure group scores to increase the simplicity of the methodology and predictability of measure weights within the methodology. LVM and the proposal to utilize a simple average of measure group scores is discussed in detail below.

a. Current Approach to Calculating Measure Group Scores Using Latent Variable Modeling

Latent Variable Modeling[215] (LVM) is a statistical approach used to combine or summarize multiple pieces of information, such as hospital quality measures, into a single number, such as measure group scores. LVM is described further within section E.4.a.(1) Latent Variable Modeling Overview of this final rule. Notably, LVM estimates loadings, or the contribution of each measure within each of the measure groups, using the data from hospitals that provide acute inpatient and outpatient care, as described in section E.4.a.(2) Latent Variable Modeling Measure Loadings of this final rule. LVM also produces point estimates and standard errors for each hospitals' measure group score, allowing for the calculation of confidence intervals to assign hospitals with at least three measures in a measure group to ''above,'' ''same as,'' or ''below the national average,'' as described in section E.4.a.(3) Measure Group Performance Categories.

(1) Latent Variable Modeling Overview

Latent Variable Modeling[216] (LVM) is a statistical approach used to combine or summarize multiple pieces of information and has been used to summarize information in a variety of settings ranging from education to healthcare.[217] [218] [219] The purpose for using LVM is to quantify the underlying quality trait, or an aspect of quality, as a number which best explains the correlation and variation of measures in a given group.

In the past, we have employed LVM to estimate measure group scores for each of the seven measure groups. In this context, LVM accounted for the relationship, or correlation, between measures for a given hospital so that measures that are more consistent with each other have a greater influence on the underlying aspect of quality calculated as a measure group score.[220] In addition, the LVM also accounted for differences in the size of each hospital's measure denominator so that measures with larger denominators also have more influence on the measure group score.[221]

When we developed the initial methodology for Overall Star Rating, we investigated multiple approaches to calculating measure group scores,

[214] Centers for Medicare & Medicaid Services. (2018, January). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from: *https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf.*

[215] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[216] Ibid.

[217] Henderson CR. Best Linear Unbiased Estimation and Prediction under a Selection Model. Biometrics 1975;31:423–47.

[218] Shwartz M, Ren J, Pekoz EA, Wang X, Cohen AB, Restuccia JD. Estimating a composite measure of hospital quality from the Hospital Compare database: differences when using a Bayesian hierarchical latent variable model versus denominator-based weights. Med Care 2008;46:778–85.

[219] Landrum M, Bronskill S, Normand S–L. Analytic Methods for Constructing Cross-Sectional Profiles of Health Care Providers. Health Services and Outcomes Research Methodology 2000;1:23–47.

[220] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[221] Ibid.

including simple or weighted averages of measures, as well as more complex approaches such as LVM and factor analyses.[222] Both the simple and weighted average approaches take the sum of measures, either with equal (that is, simple) or varying weights (that is, weighted), and divide by the number of measures a hospital reports in the measure group. Both LVM[223] and factor analysis[224] attempt to identify underlying traits, in this case quality of acute inpatient and outpatient care, within large datasets, such as hospital measure scores. Each approach was reviewed by the TEP and presented for public input prior to the launch of Overall Star Rating in 2016. We ultimately chose LVM to calculate measure group scores based on support from the TEP,[225] which favored the ability of LVM to utilize data to account for the relationship between measures, measures which are not reported, and sampling variation.[226]

Each LVM assumes that each measure in a measure group reflects information about an underlying aspect or domain of hospital quality as represented by each of the measure groups. For example, safety, mortality, or readmission are each aspects of quality represented by a distinct set of individual measures. Previously, we constructed a separate LVM for each of the seven measure groups. Each LVM estimated a quantitative value, or measure group score, for the group's underlying aspect of quality for each hospital that reports enough measures in each group.

LVM accounts for the correlation between measures by allowing measures that are more consistent with each other to have a greater influence on the measure group scores.[227] The LVM also accounts for differences in the size of each hospital's measure denominator so that measures with larger denominators have more influence on the measure group score, since their measure scores are considered more precise.[228] A measure's influence on the measure group score, or loading, is derived by the LVM, ultimately by using the national performance of each measure, as well as the correlation between measures to find the best combination of measure emphasis for each measure group.[229] Measure loadings are further discussed below in section E.4.a.(2) Latent Variable Model Measure Loadings of this final rule. The loading represents the measure's relationship to the underlying aspect of quality and therefore, the measure's contribution to the measure group score.[230] Measure loadings were re-estimated for each publication of the Overall Star Rating and were the same value for all hospitals that provide acute inpatient and outpatient care. In other words, LVM accounts for measures which are not reported by estimating and assigning the same measure loading values to all hospitals, regardless of differences in the number of measures hospitals report.

The LVM for each measure group can be explained using the below path diagram presented in Figure 1. In the sample path diagram, the ovals represent the measure group scores, calculated using LVM, and hospital summary scores, calculated by a weighted average of measure group scores. The measure group score is not directly observed but estimated from the LVM using the individual measures. The arrows between the measure group scores and each individual measure represent the relationship of that measure to the aspect of quality reflected by each measure with respect to the other measures in that group; each arrow has a different degree of association, also known as a ''loading'' or coefficient, which is explained in detail within section E.4.a.(2) Latent Variable Modeling Measure Loadings of this final rule. The small circles on the left represent the residual error within each hospital for each of the measures included in the Overall Star Rating. The residual error (ε) is the variation which could not be explained by the measure group score (random effect).

Figure 1. Sample Path Diagram of Group Specific LVM

The LVM equation used to derive a hospital's measure group score is as follows:

$$Y_{khd} = \mu_{kd} + \gamma_{kd}\alpha_{hd} + \varepsilon_{khd},\ k=1,\ldots,N_d$$

$$\alpha_{hd} \sim N(0,1) \text{ and } \varepsilon_{khd} \sim N(0, \sigma_{kd}^2)$$

Let Y_{khd} denote the standardized score for hospital h and measure k in measure group d. α_{hd} is the hospital-specific group-level latent trait (random effect) for hospital h and measure group d and follows a normal distribution[231] with mean 0 and variance 1. The estimated value of α_{hd} will be used as a measure group score. γ_{kd} is the loading (regression coefficient of the latent variable) for measure k, which shows the relationship with the measure group score of measure group d. N_d is the total number of measures in measure group d. The assumption of unit variance here is an innocuous choice of units required to identify the parameter μ_{kd} and γ_{kd}. For detailed descriptions of the LVM model parameters and equation, please see the Overall Hospital Quality Star Rating on *Hospital Compare* Methodology Report (v3.0).[232]

(2) Latent Variable Modeling Measure Loadings

In the past, the LVMs within the Overall Star Rating methodology estimate loadings for each measure within each of the measure groups. A measure's loading indicates its relative contribution to a hospital's measure group score, with higher loadings indicating measures with more influence.[233] A measure's loading is

[222] Oh, J.H., et al. (2016, October 17). ''A factor analysis approach for clustering patient reported outcomes.'' Methods of information in medicine 55.05: 431–439.

[223] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[224] Oh, J.H., et al. (2016, October 17). ''A factor analysis approach for clustering patient reported outcomes.'' Methods of information in medicine 55.05: 431–439.

[225] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[226] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[227] Ibid.

[228] Ibid.

[229] Ibid.

[230] Ibid.

[231] Illowsky, B., & Dean, S. (2013). *Introductary Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[232] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[233] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

specific to the measure and the same for all hospitals reporting that measure.

A measure loading is a regression coefficient,[234] which is estimated through the LVM by using a statistical approach called maximum likelihood. Maximum likelihood[235] uses the observed data for each measure in a group, including the national performance on the measure and the measure's relationship to other measures in the group, to find the best combination of measure emphasis for the aspect of quality represented by the measure group. In other words, measure score variation nationally and the correlation between measures in a measure group influence measure loadings. Measures with more variation nationally and higher correlations with other measures in a measure group have higher measure loadings because such measures are assumed to convey more information about a given aspect of acute inpatient and outpatient quality of care than measures with limited variation or less correlation with other measures in the same group.

The LVM also accounts for sampling variation, or differences in the amount of information available for different hospitals to estimate loadings. For example, for each measure, some hospitals may report a score based on data from fewer cases while other hospitals report scores based on more cases, resulting in differing precision for each hospital's individual measure score. We accounted for these differences in case size by giving more weight to measures with larger denominators. Measure scores based on larger denominators are assumed to have more precise measure scores and therefore contribute more when estimating measure loadings. The weighted likelihood equation for accounting for sampling variation within each measure group is as follows:

$$L = \prod_{k=1}^{K} \prod_{h=1}^{H} (L(Y_{khd}))^{w_{khd}} \quad w_{khd} = \frac{n_{khd}}{\sum_{h=1}^{N_{kd}} n_{khd}} \times N_{kd}$$

L is the likelihood function. N_{kd} is the total number of hospitals for measure k in measure group d and N_{kd} is the denominator for hospital h and measure k in measure group d. A hospital with a larger denominator will be weighted more in the LVM. The specified weighted likelihood is maximized with respect to all the parameters in the first LVM equation.

Measures with higher loadings have a greater association and impact on the measure group score than measures with lower loadings. Measures highly correlated with other measures in the measure group and the measure group score, measures with large denominators, and measures more commonly reported are likely to have higher loadings because they are generally expected to provide more information about a hospital's quality profile than other measures.

In February 2019, we made an update to remove measures with statistically significant negative loadings from the LVM calculations.[236] Measure loadings can be positive or negative. Measures with statistically significant negative loadings have an inverse relationship with other measures in the group. Although negative loadings rarely occur and are almost always statistically insignificant, some stakeholders, including those on the TEP, and during a public input period, expressed concern that measures with negative loadings could be perceived to promote lower quality with respect to measure group scores.[237] [238] [239] [240] [241] While internal analyses have not identified any substantial effect of measures with negative loadings on hospital star ratings, CMS understood the theoretical concern and decided to remove measures with statistically significant negative loadings, beginning in February 2019.[242]

Measure loadings were re-estimated for each publication of the Overall Star Rating and could change dynamically as the measure methodologies, hospitals' performance, and the relationship between measures evolved.

(3) Measure Group Performance Categories

We reported Overall Star Rating measure group performance categories to individual hospitals that provide acute inpatient and outpatient care and on *Hospital Compare* in order to provide context for measure group scores in comparison to all other hospitals in the nation. Performance categories were not calculated by the LVM, nor did they have influence on star ratings. Rather, they were assigned categories of ''above'', ''same as'', or ''below the national average'' as additional public information on each of the measure groups a hospital reports by comparing a hospital's measure group score to the national average measure group score.

These measure group performance categories were assigned using information from the LVM, separate from measure loadings. For each measure group, LVM produced a point estimate[243] and standard error[244] for each hospital's measure group score that we used to construct a 95 percent confidence interval.[245] A point estimate is a statistic close to the exact value in a dataset, whereas the standard error is a measure of the variability, or how spread out individual points are around the average in the dataset, and both are used to construct a confidence interval, or a range of reasonable values in which we expect a value to fall.[246] We compared this 95 percent confidence interval to the national mean measure group score. Measure group scores with confidence intervals that fall entirely

[234] Ibid.

[235] Cole, S.R., Chu, H., & Greenland, S. (2014, January 15) ''Maximum likelihood, profile likelihood, and penalized likelihood: a primer.'' American journal of epidemiology 179.2: 252–260.

[236] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019)*. Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2*.

[237] Centers for Medicare & Medicaid Services. (2015, June 8). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare*.

[238] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report*.

[239] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report*. Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815*.

[240] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel*.

[241] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare*.

[242] Centers for Medicare & Medicaid Services. (2018, November 30). *Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report*. Retrieved from *qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2*.

[243] Illowsky, B., & Dean, S. (2013). Introductary Statistics. Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics*.

[244] Ibid.

[245] Ibid.

[246] Ibid.

above the national average were considered ''above the national average'', confidence intervals that include the national average were considered ''same as the national average'', and confidence intervals that fall entirely below the national average were considered ''below the national average''.

b. Use of a Simple Average of Measure Scores To Calculate Measure Group Scores

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to eliminate use of the LVM and instead use a simple average of measure scores to calculate measure group scores.

We recognize that LVM may be challenging for stakeholders to understand and explain to others. Stakeholders, specifically providers, serving on the Provider Leadership Work Group and during a public input period,[247] have requested a less complex methodology that can be easily understood by their organization, explained to their patients, and used to identify areas for quality improvement. In addition, LVM is a data-driven statistical approach that relies on underlying measure data to re-estimate measure loadings[248] for each release of the Overall Star Rating. Since the underlying measure data is refreshed variably based on the measure and CMS quality program requirements—either quarterly, biannually, or annually—the estimated measure loadings based on the underlying data for each annual publication of the Overall Star Rating were unpredictable, further complicating understanding of the methodology and efforts to allocate resources for quality improvement.

Therefore, in the CY 2021 OPPS/ASC proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to discontinue the use of the LVM, and instead, propose to adopt a simple average of measure scores to calculate measure group scores. This method would average the measure scores a hospital reports within a given measure group, which have been standardized, to calculate the measure group scores. In other words, we would take 100 percent divided by the number of measures reported to give us the percentage each measure would weigh; this measure weight would then be multiplied by the standardized measure score to calculate the measure's weighted score. Then, all of the individual measure weighted scores within a group would be added together to calculate the measure group score. We also proposed to codify this policy at § 412.190(d)(4).

For example, if a hospital reports all eight measures in the Safety of Care measure group, the measure weights would be determined by calculating 100 percent divided by eight measures reported (100 percent / 8 reported measures = 12.5 percent) and each measure would be weighted 12.5 percent within the group. The standardized measure scores for each of the eight measures would then be multiplied by the weight of 12.5 percent and summed to determine the Safety of Care measure group score. See Table 66 for an example of measure weights in which a hospital reports all eight measures within Safety of Care. For the Readmission measure group for example, a hospital's score on the Hospital-Wide, All-Cause Unplanned Readmission measure, which includes most patient admissions at a hospital, would have the same influence as their score on the condition specific Chronic Obstructive Pulmonary Disease (COPD) Readmission measures, which includes significantly fewer patients.

Example of Simple Average of Measure Scores To Calculate Measure Group Scores

$$\text{Measure group score} = [(-1.13 * 0.125) + (-0.75 * 0.125) + (0.09 * 0.125) + (1.21 * 0.125) + (0.97 * 0.125) + (0.98 * 0.125) + (0.46 * 0.125) + (0.02 * 0.125)] = 0.23$$

BILLING CODE 4120–01–P

[247] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report*. Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815*.

[248] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

TABLE 66: Example of Simple Average of Measure Scores to Calculate of Safety of Care Measure Group Score

Measure Name	Example Measure Score	Standardized Measure Score	Measure Weights	Weighted Standardized Measure Scores*	Safety of Care Measure Group Score
COMP-HIP-KNEE Hospital-Level Risk Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)	3.22%	-1.13	12.5%	-0.14	0.23
HAI-1 Central-Line Associated Bloodstream Infection (CLABSI)	1.233	-0.75	12.5%	-0.09	
HAI-2 Catheter-Associated Urinary Tract Infection (CAUTI)	0.747	0.09	12.5%	0.01	
HAI-3 Surgical Site Infection (SSI) from Colon Surgery	0.000	1.21	12.5%	0.15	
HAI-4 Surgical Site Infection (SSI) Abdominal Hysterectomy	0.000	0.97	12.5%	0.12	
HAI-5 Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	0.166	0.98	12.5%	0.12	
HAI-6 Clostridium Difficile (C. difficile)	0.470	0.46	12.5%	0.06	
CMS PSI-90 Patient Safety and Adverse Events Composite	0.999	0.02	12.5%	0.003	

*Please note that measure group scores are continuous and rescaled. Negative and positive scores do not denote good or bad performance.

Under certain circumstances, hospitals may not report all measures within a measure group. However, we note that the proposed minimum threshold is three measures within three measure groups, one of which must be Mortality or Safety of Care. Once this threshold is met, any additional measures or groups may contribute to a hospital's star rating. We refer readers to section E.6. Step 5 Application of Minimum Thresholds for Receiving a Star Rating of this final rule. As an example, if a hospital reports three measures in the Safety of Care measure group, the measure weights would be determined by calculating 100 percent divided by three measures reported (100 percent / 3 reported measures = 33.3 percent) and each measure would be weighted 33.3 percent within the group. The standardized measure scores for each of the three measures would then be multiplied by the weight of 33.3 percent and summed to determine the Safety of Care measure group score. See Table 67 for an example of measure weights in which a hospital reports three measures within Safety of Care.

Example of Simple Average of Measures Scores To Calculate Measure Group Scores When Measures Are Not Reported

Measure group score = $[(-1.13 * 0.333) + (0.46 * 0.333) + (0.02 * 0.333)] = -0.22$

TABLE 67: Example of Simple Average of Measure Scores to Calculate Safety of Care Measure Group Score When Measures are not Reported

Measure Name	Example Measure Score	Standardized Measure Score*	Measure Weights	Weighted Standardized Measure Scores*	Safety of Care Measure Group Score*
COMP-HIP-KNEE Hospital-Level Risk Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)	3.22%	-1.13	33.3 %	-0.38	-0.22
HAI-1 Central-Line Associated Bloodstream Infection (CLABSI)	NA	NA	NA	NA	
HAI-2 Catheter-Associated Urinary Tract Infection (CAUTI)	NA	NA	NA	NA	
HAI-3 Surgical Site Infection (SSI) from Colon Surgery	NA	NA	NA	NA	
HAI-4 Surgical Site Infection (SSI) Abdominal Hysterectomy	NA	NA	NA	NA	
HAI-5 Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	NA	NA	NA	NA	
HAI-6 Clostridium Difficile (C. difficile)	0.470	0.46	33.3 %	0.15	
CMS PSI-90 Patient Safety and Adverse Events Composite	0.999	0.02	33.3 %	0.006	

*Please note that measure group scores are continuous and rescaled. Negative and positive scores do not denote good or bad performance.

BILLING CODE 4120–01–C

As previously noted, LVM accounted for measures which are not reported by uniformly assigning the same loading for a measure to hospitals that provide acute inpatient and outpatient care,[249] whereas use of a simple average of measure scores would result in hospitals having varying measure weights depending on differences in the number of measures reported. For example, if a hospital reports three of the eight measures in the Safety of Care measure group, each measure would be weighted at 33 percent within that group. On the other hand, a hospital that reports all eight measures in the Safety of Care measure group would have a different weighting of 12.5 percent for each measure within the measure group. We simulated the possible range of measure weights using the data used for January 2020 Overall Star Rating (October 2019 public reporting data), which included 51 measures. We simulated the results using the measure group weights proposed in section E.5.a.(2) Continue Current Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores of this final rule; outcome and patient experience measure groups were weighted 22 percent and the process group was weighted 12 percent. Taking into account the measure group weights applied later in the methodology, the minimum effective measure weight, or the percentage of the hospital summary score based on a single measure, would be 3 percent for a hospital reporting all 51 measures and the maximum effective measure weight would be 33 percent for another hospital reporting the minimum threshold number of nine measures (at least three measures in at least three groups). Hospitals with more measures will have lower measure weights for each measure, whereas hospitals with fewer measures will have higher measure weights for each measure. The number of measures included in the Overall Star Rating varies for each publication depending on measure removals from and additions for public reporting.

Using a simple average of measure scores to calculate measure group scores would be responsive to stakeholder feedback that requested CMS increase the simplicity of the methods and the predictability of measure emphasis between publications.[250] [251] [252] [253] Using a simple average of measure scores would increase the predictability of measure emphasis by allowing hospitals to anticipate equal measure weights across the measures they report within a given group. While there may be differences in measure emphasis between hospitals that provide acute inpatient and outpatient care based on differences in measure reporting, a simple average of measure scores will be responsive to stakeholder feedback and make the methodology easier for stakeholders to understand, interpret, and explain to patients.

Since measure loadings are an artifact of the LVM approach, they would no longer be calculated under the proposed new method using a simple average of measure scores. In addition, since the point estimates and standard errors used to calculate 95 percent confidence intervals and assign hospital measure group performance to ''above,'' ''same as,'' or ''below the national average'' were products of the LVM approach, measure group performance categories will no longer be available under the proposed new method using a simple average of measure scores. However, we intend to continue to publicly display alternative summaries of hospital performance within measure groups for transparency and patient usability. Should the proposal to use a simple average of measure scores to calculate measure group scores not be finalized, measure group performance categories would still be available in the same manner described above.

In crafting the proposal, we also considered continuing to utilize LVM as we have in the past and as discussed in the section above. Ultimately, we chose to propose to discontinue the use LVM because of the complexity associated with understanding how measure loadings are empirically assigned with the LVM and contribute to the measure group scores. We invited public comment on our proposals to use a simple average of measure scores to calculate measure group scores and to codify this policy at § 412.190(d)(4) as discussed. The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters supported the use of a simple average of measure scores to calculate measure group scores. They appreciated CMS' responsiveness to previous stakeholder input and emphasized advantages of a simple average of measure scores including transparency of methods, predictable and balanced measure emphasis within groups, reduced shifts in measure group scores and star ratings, and alignment with CMS programs. These advantages make the methodology easier for stakeholders to understand and for providers to react to and improve upon measurement and star ratings as well as explain to hospital leadership and patients.

Response: We thank commenters for their support. Being responsive to stakeholder input has been and continues to be a guiding principle of the Overall Star Rating since original development. We agree that the proposals would increase simplicity and predictability of the Overall Star Rating methodology, hopefully providing more transparency and understanding of the methodology for stakeholders, including both providers and patients.

Comment: A few commenters did not support CMS' proposal to use a simple average of measure scores advocated for the continued use of latent variable modeling (LVM) to calculate measure group scores because of the methodological advantages of LVM as a statistical model that accounts for important factors, including the relationship between measures and measure precision. They also pointed out that the original Overall Star Rating TEP favored LVM over other approaches for the same reasons.

Response: We acknowledge the known advantages to the LVM approach that had been favored by the original TEP and have been used to calculate measure group scores, including the ability of the model to account for the relationship between measures, differences in sampling variation, or measure precision, and missing measure scores.[254] However, subsequent application of the LVM approach has also revealed several challenges in implementation as measures and scores have evolved on *Hospital Compare* and its successor websites. Notably, several

[249] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[250] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[251] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[252] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[253] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[254] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

stakeholders,[255] particularly providers, indicated the use of LVM resulted in unpredictable measure loadings. This added greater uncertainty in anticipated changes in star ratings and was challenging for stakeholders to understand, explain to others, and use for quality improvement. A simple average of measure scores would assign equal weights within measure groups, allowing stakeholders to predict, interpret, and easily replicate measure group scores.

Comment: One stakeholder requested that the simple average of measure scores approach be evaluated by a TEP.

Response: The use of a simple average of measure scores was vetted through extensive stakeholder engagement, including TEP,[256] Provider Leadership Work Group, Patient & Patient Advocate Work Group meetings, a public input period,[257] and a CMS listening session.[258] In general, stakeholders supported the use of a simple average of measure scores to calculate measure group scores for a less complex methodology with more predictable measure emphasis that can be easily understood, explained to others, and used to identify areas for quality improvement.

Comment: One commenter recommended that CMS continue to use device days, number of procedures, or patient days as the HAI measure denominators, rather than predicted infections.

Response: One of advantages of LVM was its ability to account for sampling variation, or measure precision, through the use of measure denominator data. In February 2019,[259] we had updated the Overall Star Rating methodology to use alternative HAI denominators of device days, number of procedures, or patient days, instead of predicted infections, to better represent case volume and sampling variation in order to account for measure precision within LVM. It is important to note that the Overall Star Rating has used and will continue to use the HAI Standardized Infection Ratio (SIR) measure scores, as calculated for the HAC Reduction Program, which utilizes predicted infections as the denominator, within the Overall Star Rating methodology. The Overall Star Rating used alternative HAI denominators only to account for measure precision within the LVM. However, the Overall Star Rating methodology will no longer account for measure precision with the use of a simple average of measure scores to calculate measure group scores, therefore negating the need for alternative HAI denominators.

Comment: Some commenters noted disadvantages of a simple average of measure scores to calculate measure group scores and encouraged CMS to continue to consider alternative approaches, including template matching or relative measure weights based on measure volume, evidence, importance to or impact on patients, as the Agency for Health Research and Quality does with harm-based weights within the PSI–90 composite, or opportunity for provider improvement, which could be done through comparisons to the national average.

Response: During development and recent reevaluation of the Overall Star Rating, we considered multiple approaches to the weighting of individual measure scores when calculating measure group scores, including template matching and relative measure weighting. However, given that the Overall Star Rating summarizes aggregate hospital-level measure scores reported through CMS quality programs without the use of underlying patient-level data, approaches such as template matching[260] may be both infeasible as well as not align with the aim for a simple methodology that stakeholders can easily understand and explain to others. Also, relative measure weighting based on volume, in some cases, would result in measure group scores dominated by one measure, such as PSI–90 (81 FR 56761)[261] within the Safety of Care measure group and Hospital-Wide Readmission within the Readmission measure group. During engagement efforts,[262] stakeholders preferred more balanced measure emphasis within measure groups. In addition, relative weighting based on evidence or importance to patients may be subjective and resource intensive for CMS and stakeholders to monitor and maintain. Finally, TEP[263] and work group input also acknowledged that relative measure weighting approaches may have the unintended consequence of creating an incentive for hospitals to focus quality improvement efforts on few measures.

Comment: A few commenters requested impact analyses outlining the impact of the use of a simple average of measure scores on overall and individual hospital star rating results.

Response: We appreciate the commenters' request for impact analyses on the use of a simple average of measure scores to calculate measure group scores. We provided analytic considerations specific to the proposal to use a simple average of measure scores within section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule and we also provided overall impact analyses on hospital star ratings within section 8. Effects of Requirements for the Overall Hospital Quality Star Ratings of the proposed rule (85 FR 49057 through 49077). We simulated impacts using January 2020 Overall Star Rating data (October 2019 public reporting data) and the combined methodology proposals: Regroup measures, use a simple average of measure scores to calculate measure group scores, and update reporting thresholds to require at least three measures in at least three measure groups, one of which must be Mortality of Safety of Care, but not include peer grouping to isolate proposals and allow for informed public comments. As stated in section 8 of 85 FR 49057 through 49077), 1,796 (53 percent) hospitals would receive the same star

[255] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815*.

[256] Centers for Medicare & Medicaid Services. (2019, November). Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6*.

[257] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815*.

[258] Centers for Medicare & Medicaid Services. (2019, November). Overall Hospital Quality Star Rating Listening Session Meeting Summary Report. Retrieved from *https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report*.

[259] Centers for Medicare & Medicaid Services. (2018, November 30). Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report. Retrieved from *www.qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2*.

[260] Silber, J.H., Rosenbaum, P.R., Ross, R.N., Ludwig, J.M., Wang, W., Niknam, B.A., . . . & Fleisher, L.A. (2014). Template matching for auditing hospital cost and quality. Health services research, 49(5), 1446–1474.

[261] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 81 FR 56761 (Aug 22, 2016) (codified at 42 CFR parts 405, 412, 413, and 489).

[262] Centers for Medicare & Medicaid Services. (2019, November). Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6*.

[263] Centers for Medicare & Medicaid Services. (2018, June). Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.

rating. The results showed that 1,468 (43 percent) hospitals would shift up or down one star rating, 135 (4 percent) hospitals would shift up or down two star ratings, 9 (0.3 percent) hospitals would shift up or down three star ratings, and 1 (0.03 percent) hospital would shift up or down four star ratings. Since regrouping measures and updating reporting thresholds primarily resulted in modest impacts to the number of hospitals meeting the reporting thresholds to receive a star rating, the shift in hospital star ratings was primarily due to the use of a simple average of measure scores to calculate measure groups scores. We refer reads to section 8. Effects of Requirements for the Overall Hospital Quality Star Ratings of this final rule for the impact analyses using October 2020 public reporting data for the final Overall Star Rating methodology for 2021 and subsequent years.

After consideration of the public comments received, we are finalizing our proposals as proposed.

c. Standardize Measure Group Scores

Standardizing [264] scores is a way to make varying scores directly comparable by putting them on a common scale. While standardization is used in other parts of the methodology, particularly to standardize measure scores within the first step of methodology, it was previously not necessary to standardize measure group scores when using statistical modeling, such as LVM. In the absence of statistical modeling, under the use of a simple average of measure scores as discussed in section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule, the distributions and interpretations of measure group scores may differ. For example, a 0.5 measure group score in Safety of Care may not conceptually be similar to a 0.5 measure group score in Patient Experience, exaggerating the influence of some measure groups when calculating a weighted average of measure group scores.

Therefore, for the Overall Star Rating beginning with CY 2021 and subsequent years (85 FR 48996 through 49027), we proposed to standardize measure group scores. More specifically, we proposed to standardize measure group scores by calculating Z-scores for each measure group. As mentioned in section E.2.d. Measure Score Standardization of this final rule, a Z-score [265] is a standard deviation [266] score which relays the amount of variation in a dataset, or in this case, the variation in hospital measure scores. Z-scores would be calculated by subtracting the national average measure group scores from each hospital's measure group score and dividing by the standard deviation across hospitals. Standardization of measure group scores would occur prior to combining measure group scores through a weighted average to calculate summary scores, and would result in all measure group scores centered near zero with a standard deviation [267] of one. We also proposed to codify this policy at § 412.190(d)(4)(i).

See Table 68 for an example of how measures would be combined through a simple average of measure scores to calculate measure group scores and then how the measure group scores would be standardized. The standardization of measure group scores would not impact hospital performance within the measure group or the natural distribution of scores. As a result of standardization,[268] mean group scores and standard deviations would become more similar across measure groups. We simulated the potential effects of standardization using data from the January 2020 publication of Overall Star Rating and found that hospital summary scores with and without standardization of measure group scores are highly correlated with a Pearson correlation of 0.975, indicating that standardizing measure group scores does not substantially alter hospital performance assessment. We note that, should the proposal to use a simple average of measure scores to calculate measure group scores not be finalized, we would not need to standardize measure group scores.

We invited public comment on our proposals to standardize measure group scores and codify this policy at § 412.190(d)(4)(i). However, we did not receive any comments on these proposals. We are finalizing our proposals as proposed.

d. Stratify Readmission Measure Group Scores

(1) Current Measure Group Scores Without Stratification

In the past, we have not stratified or adjusted any of the measures, measure groups, summary scores, or star ratings by social risk factor variables within the Overall Star Rating methodology, primarily based on the original guiding principles of the Overall Star Rating. The Overall Star Rating is meant to summarize the existing quality measure information that is publicly reported through CMS programs, including Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, on *Hospital Compare* or its successor websites. Individual measures undergo rigorous development and reevaluation processes under each program that include extensive analytic testing and stakeholder engagement. As such, individual measure methodologies as specified under each program, including approaches to risk adjustment, are included within the Overall Star Rating. As measure data and methodologies are updated under each of the programs, they are subsequently reflected within the Overall Star Rating methodology. CMS' Overall Star Rating development contractor has engaged stakeholders in discussion regarding the comparability of hospital star ratings for over five years throughout the development and reevaluation of the Overall Star Rating. Throughout that engagement, some stakeholders, primarily providers, requested incorporation of social risk factor adjustment within the Overall Star Rating, while other stakeholders expressed concerns regarding adjustment in general or the specific variables available for adjustment.[269] Specifically, some stakeholders have requested social risk factor adjustment of the readmission measures or the Readmission measure group.[270] [271] Recently a HHS Report to Congress has

[264] Illowsky, B., & Dean, S. (2013). *Introductory Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[265] DeVore, G.R. (2017, January 17). ''Computing the Z score and centiles for cross-sectional analysis: a practical approach.'' Journal of Ultrasound in Medicine 36.3: 459–473.

[266] Illowsky, B., & Dean, S. (2013). *Introductory Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[267] Ibid.

[268] Ibid.

[269] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[270] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.orgs http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

[271] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

set forth a broad range of recommendations regarding social risk factors and Medicare's value-based purchasing programs, and the report does not recommend adjusting quality measures for social risk for public reporting.[272] We sought comment on our proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients, and an alternative not to stratify the Readmission measure group based on the proportion of dual-eligible patients.

(2) Proposal To Stratify Only the Readmission Measure Group Scores

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to stratify only the Readmission measure group score by hospitals' proportion of dual-eligible patients and codify this at § 412.190(d)(4)(v). We proposed to specifically stratify only the Readmission measure group, and not other measure groups, based on hospitals' proportion of dual-eligible hospital discharges, to be responsive to select stakeholder concerns that some hospitals providing acute inpatient and outpatient care face unique challenges preventing readmissions among patients with complex social risk factors,[273] and to align with the payment adjustment recently implemented for HRRP payment determination (82 FR 38231 through 38237). We proposed to utilize and repurpose the same peer group quintiles assigned by the HRRP annually. We proposed to assign hospitals that do not participate in the HRRP, but have their proportion of dual-eligible patients available, to HRRP designated peer groups, as they would not have already been assigned to a peer group through the HRRP. We also proposed that in the event a hospital's proportion of dual-eligible patient data is missing, CMS would not adjust that hospital's Readmission measure group score and that hospital would retain its original, unadjusted Readmission measure group score, as calculated through a simple average of their measure scores.

The proposed stratification of the Overall Star Rating Readmission measure group score would use the same dual-eligible variable and a similar peer grouping approach as is used in the HRRP for payment determinations (82 FR 38231 through 38237). To be clear, the Overall Star Rating is not used to determine hospital payments. Dual-eligible[274] patients are those that are dually eligible for Medicare and full-benefit Medicaid among a hospital's total Medicare Fee-for-Service and Medicare Advantage patient discharges (42 U.S. Code 1315b(f)). Dual-eligible status is consistently captured for patients and available through enrollment files, which are updated annually, and does not require extrapolation from area of residence variables, such as census or community surveys.

In 2016, the 21st Century Cures Act mandated that CMS determine hospital penalties for readmissions that account for social risk factors through a transitional methodology that calculates excess readmissions ratios within hospital peer groups defined by the percentage of dual-eligible patients served by the hospital within the HRRP (Pub. L. 114–255). Section 15002 of the 21st Century Cures Act, adding a new section 1886(q)(3)(D) and (E) to the Act, also indicated this methodology could be characterized as a ''transitional adjustment'' and that the Secretary may revise the stratification methodology, taking into account recommendations made on risk-adjustment methodologies for HRRP based on the studies conducted under the IMPACT Act by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) on the role of socioeconomic status in Medicare's value-based purchasing program.

In the FY 2018 IPPS/LTCH PPS rule, we finalized our HRRP proposal to implement a methodology that categorizes participating hospitals that provide acute inpatient care into five peer groups by quintiles, based on the proportion of dual-eligible patients to total patients served by the hospital. The methodology uses the median excess readmission ratio of hospitals within each of the five peer groups as the threshold to assess hospital performance on each measure (82 FR 38231 through 38237). The excess readmission ratio measures a hospital's relative performance and is the ratio of predicted-to-expected readmissions.[275] This methodology was implemented within HRRP in FY 2019 as announced in the associated correction notification (82 FR 46138). The individual readmission measures included within HRRP and publicly reported on *Hospital Compare* or its successor websites are not adjusted for social risk factors.

The proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients is intended to provide consistency between the current stratification method used for the HRRP and the Overall Star Rating methodology. It is not in any way intended to suggest a new policy direction for the more general question of whether CMS programs should employ social risk factor adjustment methods of any kind. The rationale for this proposal is based on alignment between the two CMS efforts. If changes are made in the future to the HRRP stratification approach, CMS may consider similar changes to the Overall Star Rating methodology through future rulemaking. Recently a HHS Report to Congress has set forth a broad range of recommendations regarding social risk factors and Medicare's value-based purchasing programs, which do not recommend adjusting quality measures for social risk for public reporting.[276] The stratification approach in the HRRP has been recommended for removal based on HHS recommendations in a second Report to Congress, mandated by the IMPACT Act of 2014, titled ''Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs'' submitted by ASPE on June 29, 2020.[277] The report recommends not adjusting outcome measures for social risk factors in CMS programs and recommends that,

[272] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

[273] National Quality Forum. (2014, August). Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors. Retrieved from: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=77474.*

[274] Centers for Medicare & Medicaid Services. (2018, May). *Dual Eligible Beneficiaries Under Medicare and Medicaid.* Retrieved from *www.cms.gov: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf.*

[275] Centers for Medicare & Medicaid Services. (2019, Novemebr 19). *Hospital Readmissions Reduction Program (HRRP).* Retrieved from *www.cms.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HRRP/Hospital-Readmission-Reduction-Program.*

[276] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

[277] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

eventually, stratification of hospitals by the proportion dual-eligible patients should be removed from the HRRP. CMS is currently reviewing the report recommendations and considering how to incorporate these recommendations within CMS programs.

The Overall Star Rating uses individual measure scores, as calculated under the quality programs and reported on *Hospital Compare* or its successor website, to calculate measure group scores. Individual measure methodologies, including current and future approaches to risk adjustment for each measure, as specified in the measures, are inherently included within the Overall Star Rating. Since the Overall Star Rating utilizes the individual measure scores as publicly reported, it is not appropriate to apply social risk factor adjustment to the individual measure scores for the purpose of the Overall Star Rating. In addition, stakeholders have agreed that social risk factor adjustment is not appropriate for all measure types, such as measures capturing healthcare-associated infections where the onset of adverse events occur in the hospital setting should not be influenced by a patient's socioeconomic status.[278] [279] The proposed stratification approach would stratify only the Readmission measure group scores based on a comparison to other hospitals with similar proportions of dual-eligible patients, as opposed to in comparison to all hospitals.

Since the Overall Star Rating is not used to determine hospital payment, we proposed calculating the readmission measure group score within each dual-eligible peer group. In the formula below, α_h is the readmission group score for hospital h, $\bar{\alpha}$ is the national average of readmission group score, $\bar{\alpha}_{peer\ group\ j}$ is the average readmission group score for dual-eligible peer group j (j = 1, 2, . . ., 5).

$$\tilde{\alpha}_{h|peer\ group\ j} = \alpha_h * \left\{1 + \frac{\bar{\alpha}}{\alpha_h}\left(1 - \frac{\bar{\alpha}_{peer\ group\ j}}{\bar{\alpha}}\right)\right\}$$
$$= \alpha_h + \bar{\alpha} - \bar{\alpha}_{peer\ group\ j}$$

During public input periods,[280] CMS' contractor received feedback from stakeholders, specifically providers, encouraging alignment between Overall Star Rating and CMS programs, with specific mention of alignment with HRRP's approach to peer grouping by dual-eligibility. In response to stakeholder feedback to promote alignment between programs and provide consistent measurement standards for providers, we proposed to utilize the same dual-eligible quintiles as HRRP for the Readmission measure group. Applying stratification to the Readmission measure group scores based on proportion of dual-eligible patients would align with HRRP (82 FR 38231 through 38237). Consistent with HRRP, stratifying the Overall Star Rating Readmission measure group would assign hospitals to one of five peer groups based on the proportion of dual-eligible patients. For FY 2019, the range of proportion of dual-eligible patients within each of the hospital peer group quintiles for HRRP are as follows: 0 to 13.69 percent, 13.70 to 18.40 percent, 18.41 to 23.23 percent, 23.24 to 30.98 percent, 30.99 to 100 percent for peer groups one, two, three, four, five, respectively. We proposed to utilize and repurpose the same peer group quintiles assigned by the HRRP, annually. Peer groups for the Overall Star Rating would not be exact quintiles, as a greater number of hospitals are included in Overall Star Rating than those participating in HRPP. The Overall Star Rating includes hospitals providing acute inpatient and outpatient care, including both subsection (d) hospitals and CAHs, whereas HRRP only includes subsection (d) hospitals. We refer readers to section A.1.b. Subsection (d) Hospitals and B. Critical Access Hospitals in the Overall Star Rating of this final rule for more information on the hospitals included within the Overall Star Rating. For the 2020 Overall Star Rating release, 4,384 hospitals received a Readmission group score, while 3,077 hospitals participated in HRRP received a readmission score. Since the hospitals within the Overall Star Rating that do not participate in HRRP would not already be assigned to a peer group by the HRRP methodology, we proposed to calculate their proportion of dual-eligible patients and assign them to one of the five peer groups based on the HRRP designated peer groups.

As stated above, we proposed to assign hospitals that do not participate in the HRRP, but have their proportion of dual-eligible patients available, to HRRP designated peer groups, as they would not have already been assigned to a peer group through the HRRP. This is necessary to maintain alignment with HRRP so that hospitals in HRRP are assigned to the same peer group within both HRRP and the Overall Star Rating. As also stated above, we proposed to not adjust a hospital's Readmission measure group score if that hospital has missing dual-eligible patient data. This is necessary because we would not have the dual-eligible data necessary to produce an adjusted score.

(i) Other Methods Considered

In developing our proposal, we also considered recalculating the peer group quintiles based on all hospitals in the Overall Star Rating dataset, and not solely based on those participating in HRRP. Using all hospitals to calculate peer group quintiles would be more consistent with other aspects of the methodology that use all hospital data, such as the calculation of measure group scores and weighted average of measure groups scores to calculate summary scores. However, calculating quintiles based on all hospitals would create potential misalignment between quintiles, and therefore peer group

[278] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

[279] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[280] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

assignment, for HRRP and the Overall Star Rating Readmission measure group. More specifically, if dual-eligible quintiles were recalculated based on all hospitals within the Overall Star Rating, some hospitals that are within both HRRP and the Overall Star Rating would be assigned to different peer groups in each of the two methodologies based on the different dual-eligible quintile cutoffs.

Using January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*), we simulated calculation of quintiles based on all hospitals, 155 (5.04 percent) of the 3,174 HRRP hospitals would move down a peer group quintile; that is, they would move to a quintile with a lower proportion of patients that are dual-eligible, indicating their patient case mix has lower social risk. Under this simulation, specifically, 23 (3.67 percent) hospitals assigned dual-eligible quintiles in HRRP would move from peer group two to peer group one, with the lowest proportion of dual-eligible patients, 40 (6.46 percent) hospitals would move from peer group three to peer group two, 48 (7.74 percent) hospitals would move from peer group four to peer group three, and 44 (7.28 percent) hospitals would move from peer group five, with the highest proportion of dual-eligible patients, to peer group four.

For the January 2020 Overall Star Rating publication, 4,384 hospitals received a Readmission group score, while 1,307 hospitals did not participate in HRRP. Similarly, using the same simulated calculation of quintiles based on all hospitals, 90 (6.89 percent) of the 1,307 non-HRRP hospitals would move down a peer group quintile if calculating based on all hospitals than they would have if using only HRRP hospitals. Specifically, 9 (0.69 percent) hospitals would move from peer group two to peer group one, with the lowest proportion of dual-eligible patients, 31 (2.37 percent) hospitals would move from peer group three to peer group two, 27 (2.07 percent) hospitals would move from peer group four to peer group three, and 23 (1.76 percent) hospitals would move from peer group five, with the highest proportion of dual-eligible patients, to peer group four.

After calculation, mean Readmission measure group scores would be the same for each hospital peer group, resulting in more similar measure group scores across hospital peer groups. While stratifying results in more comparable measure group scores across peer groups of proportions of dual-eligible patients, the effect on the Overall Star Rating Readmission measure group is modest; our simulations showed a 0.967 correlation between unadjusted and adjusted Readmission measure group scores using January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*).

In developing our proposal, as discussed in section a. Alternatives Considered, we also considered not stratifying the Readmission measure group and retaining the current measure group without stratification based on proportion of dual-eligible patients within the calculation of the Overall Star Rating. CMS' Overall Star Rating development contractor engaged stakeholders in discussion regarding the comparability of hospital star ratings for over 5 years throughout the development and reevaluation of the methodology. Throughout that engagement, some stakeholders expressed concerns regarding adjustment for social risk factors in general, adjustment for social risk factors within the Overall Star Rating methodology, or use of specific social risk factor variables that are currently available for adjustment.[281] Most stakeholders agreed that social risk factor adjustment is not appropriate for all measure types, such as measures capturing healthcare-associated infections, and therefore, not appropriate to be applied at aggregated levels, such as the Overall Star Rating.[282] [283] Some stakeholders, including patients and patient advocates, expressed concern that stratifying the Readmission measure group by the proportion of dual-eligible patients would result in a misrepresentation of quality of care at hospitals, particularly for dual-eligible patients, and would be confusing to patients as consumers of the Overall Star Rating.[284] [285] [286] Furthermore, the effect of stratifying the Overall Star Rating Readmission measure group score is negligible, as shown through a 0.967 correlation between unadjusted and adjusted Readmission measure group scores using January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*).

CMS is also considering recommendations on risk-adjustment recently submitted to Congress. On behalf of the Secretary, ASPE recently submitted a HHS Report to Congress on *Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs* that includes recommendations on risk-adjustment for CMS programs and quality efforts, including the Overall Star Rating. For publicly reported quality measures, recommendations are that ''*Quality measures, resource use measures, and composite scores should not be adjusted for social risk factors for public reporting.*'' Instead, recommendations are for quality and resource use measures to be reported separately for dual-eligible beneficiaries and other beneficiaries in order to monitor disparities and improvements over time. The report indicates for public reporting, it is also important to hold providers accountable for outcomes, regardless of social risk. Overall, the report lays out a comprehensive approach for CMS programs to move towards incentivizing providers and initiatives to improve health outcomes by rewarding and supporting better outcomes for beneficiaries with social risk factors. The report indicates proposed solutions that address only the measures or programs, without considering the broader delivery system and policy context, are unlikely to mitigate the full implications of the relationship between social risk factors and outcomes.

However, we ultimately proposed to stratify the Readmission measure group based on the proportion of dual-eligible patients to align with HRRP and to be responsive to stakeholder feedback, particularly from healthcare providers. Considering inconsistent feedback received from stakeholders and HHS

[281] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[282] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

[283] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[284] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[285] Centers for Medicare & Medicaid Services. (2019, October 24) Patient and Patient Advocate Work Group Minutes—October 2019.

[286] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

recommendations for CMS programs, we also sought comment on an alternative to retain the Readmission measure group calculation without stratification based on the proportion of dual-eligible patients.

We invited public comment on our proposals to: (1) Stratify only the Readmission measure group score based on the proportion of dual-eligible patients by using peer groups annually designated by the HRRP, (2) assign hospitals that do not participate in the HRRP, but have their proportion of dual-eligible patients available, to HRRP designated peer groups, as they would not have already been assigned to a peer group through the HRRP, (3) not adjust a hospital's Readmission measure group score if that hospital has missing dual-eligible patient data, and (4) codify this policy at § 412.190(d)(4)(v). We refer readers to section a. Alternatives Considered of this final rule where we sought comment on the alternative to not stratify the Readmission measure group score based on the proportion of dual-eligible patients.

The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters opposed the proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients, primarily noting concerns with the use of dual-eligibility for adjustment. Commenters expressed concern about Medicaid coverage varying by state and that Medicare Advantage might not be accurately captured in the adjustment. One commenter noted that the dual-eligible quintile used within HRRP are subjective and that hospitals with similar proportions of dual-eligible patients that are near a cut point of quintiles may end up in different peer groups.

Response: We acknowledge commenters' concerns with stratifying the Readmission measure group based on the proportion of dual-eligible patients, which are patients that are dually eligible for Medicare and full-benefit Medicaid among a hospital's total Medicare Fee-for-Service and Medicare Advantage patient discharges.[287] While we have heard from stakeholders that dual-eligibility doesn't fully address patient social risk factors at a hospital, few social risk variables are available and consistently captured.

Most of the measures included within CMS hospital quality programs and subsequently, the Overall Star Rating, include data from beneficiaries 65 years of age and older. The Affordable Care Act Medicaid coverage expansion, adopted by most states, did not directly impact coverage for seniors since the newly created optional eligibility pathway extended Medicaid eligibility for those under 65 years of age.[288] Thus, we disagree with concerns about variability in Medicaid by state.

However, we also acknowledge that stratifying the Readmission measure group based on the proportion of dual-eligible patients may be confusing and misleading to patients, especially dual-eligible patients. In addition, analyses reveal the stratification may not result in the intended effect, with a strong correlation of 0.967 between the unadjusted and adjusted measure group scores (see section E.4.d.(2) Proposal to Stratify Only the Readmission Measure Group Scores of this final rule) and significantly more hospitals losing a star rating than gaining a star rating as a result of stratification (see section 8. Effects of Requirements for the Overall Hospital Quality Star Ratings of the proposed rule (85 FR 49057 through 49077)).

Furthermore, we stated in the proposed rule that on behalf of the Secretary, ASPE recently submitted a HHS Report to Congress on *Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs* that includes recommendations not to adjust publicly reported quality measures and information, including composite scores such as the Overall Star Rating, for social risk.[289] Specifically, the report recommends that the stratification of hospitals by the proportion of dual-eligible patients be removed from HRRP, which served as the precedent and inspiration for the Overall Star Rating Readmission stratification proposal. The report indicates it is important to hold providers accountable for outcomes, regardless of social risk, indicates proposed solutions that address only the measures or programs, without consideration of the broader delivery system and policy context, are unlikely to mitigate the full implications of the relationship between social risk factors and outcomes, and outlines a comprehensive approach to incentivize providers and initiatives to improve health outcomes by rewarding and supporting better outcomes for beneficiaries with social risk factors.

As a result of analyses that indicate stratification of the Readmission measure group would not have the intended effect, ASPE's recent report to Congress, and continued stakeholder concerns with dual-eligibility as a variable and stratification potentially causing confusion for patients and caregivers, we are not finalizing our proposal to stratify the Readmission measure group score based on the proportion of dual-eligible patients. However, we will continue to evaluate approaches for increasing the comparability of hospital star ratings.

Comment: Many commenters recommended improved risk adjustment for or incorporation of sociodemographic factors, such as housing, food insecurity, social support, transportation, patient behavior, or functional status within the underlying individual measures or Overall Star Rating methodology. Some commenters recommended CMS utilize alternative forms of accounting for social risk factors, such as inclusion of health disparity reductions measures, reporting of patient social and behavioral risk data, and social risk factor variables, including zip code, Area Deprivation Index, U.S. Census, or American Community Survey data.

Response: We appreciate commenters' request for improved and alternative forms of social risk factor adjustment. The Overall Star Rating is a summary of certain existing quality measures reported as part of CMS quality programs, which undergo rigorous development and reevaluation processes, including but not limited extensive measure testing, stakeholder vetting, and evaluation by the NQF. When measure methodologies, including risk adjustment approaches, are updated within CMS quality programs, they are subsequently updated within the Overall Star Rating. Unfortunately, few patient social risk factors are available and consistently captured for use in quality measurement. As stated above, ASPE recently submitted a HHS Report to Congress on *Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs* that includes recommendations not to adjust publicly reported quality measures and

[287] Centers for Medicare & Medicaid Services. (2018, May). *Dual Eligible Beneficiaries Under Medicare and Medicaid.* Retrieved from *www.cms.gov: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf.*

[288] Patient Protection and Affordable Care Act of 2010, Public Law 111–148, 124 Stat. 119 (2010). See: Section 2001.

[289] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs. Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

composite scores for social risk.[290] The report indicates it is important to hold providers accountable for outcomes, regardless of social risk, indicates proposed solutions that address only the individual measures or programs, without consideration of the broader delivery system and policy context, are unlikely to mitigate the full implications of the relationship between social risk factors and outcomes, and outlines a comprehensive approach to incentivize providers and initiatives to improve health outcomes by rewarding and supporting better outcomes for beneficiaries with social risk factors. As stated above, we are not finalizing our proposal to stratify the Readmission measure group score based on the proportion of dual-eligible patients. We are currently reviewing the report recommendations and considering how to incorporate these recommendations within our programs and initiatives. We will continue to evaluate approaches to increasing the comparability hospital star ratings.

Comment: One commenter specifically requested social risk factor adjustment for the Overall Star Rating measure groups, including Mortality.

Response: We acknowledge the commenter's request, but disagree that social risk factor adjustment should be applied to all of the Overall Star Rating measure groups, including the Mortality measure group. In general, stakeholders have agreed that social risk factor adjustment is not appropriate for all measure types, such as measures capturing healthcare-associated infections or surgical complications, including in-hospital death for example, where the outcome or adverse events occurs within the hospital setting without evidence-based rationale for differences in outcomes based on a patient's socioeconomic status. The proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients would have only applied to the Readmission measure group, which measures returns to the hospital within 30 days of discharge and may be more likely to be influenced by factors outside of hospital control.

Comment: Many stakeholders commented on the proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients, most of whom supported the proposal and appreciated the attempt to increase comparability of hospital star ratings and adjust for social risk factors that may influence readmissions and may be outside of hospital control. Some commenters noted that the proposal would allow for the Overall Star Rating to more accurately reflect the quality of care provided by safety-net, teaching, and hospitals receiving the highest DSH support. Several commenters also stated that the proposal would align with CMS programs and supported the use of the same dual-eligible groupings used within HRRP. Several commenters stated that the proposal would allow dual-eligible patients to make more informed decisions about where to seek care and provide a more accurate portrayal of a hospital's patient population.

Response: We acknowledge the support for our proposal to consider stratifying the Readmission measure group based on the proportion of dual-eligible patients. This proposal would not necessarily increase comparability as it would have improved alignment with the dual-eligible stratification within HRRP. However, this proposal would also reduce alignment, and, in turn, comparability, with public reporting of the individual measures on *Hospital Compare* or its successor website since the HRRP applies dual-eligible adjustment on the program-level, for payment purposes only, and the underlying readmission measure scores reported on *Hospital Compare* or its successor websites are not stratified (82 FR 38231 through 38237). Furthermore, ASPE's recent HHS Report to Congress specifically recommends that the stratification of hospitals by the proportion of dual-eligible patients be removed from HRRP. The Overall Star Rating is intended to summarize and reflect existing measures scores reported through CMS quality programs and reporting on *Hospital Compare* or its successor websites, which undergo rigorous development and reevaluation processes, and while analyses have indicated modest differences in star ratings based on hospital types, such as those receiving highest DSH support (see section 8. Effects of Requirements for the Overall Hospital Quality Star Ratings of the proposed rule (85 FR 49057 through 49077)), these analyses have not indicated that the summary of measure scores in the Overall Star Rating is an inaccurate representation of quality. We disagree that the proposal would have facilitated care decisions for dual-eligible patients. If implemented, the proposal may have obscured hospital quality results specifically for dual-eligible beneficiaries, as stated by the TEP[291] and work groups. As stated above, we are not finalizing our proposal to stratify the Readmission measure group score based on the proportion of dual-eligible patients. We will continue to evaluate approaches to increasing the comparability of hospital star ratings.

After consideration of the public comments received, we are not finalizing our proposals related to stratification of the readmission measure group scores.

5. Step 4: Calculation of Hospital Summary Scores as a Weighted Average of Group Scores

a. Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores

(1) Current Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores

In the past, we have calculated hospital summary scores as a weighted average of measure group scores. That is, each measure group score is multiplied by the assigned weight for that group, and then the weighted measure group scores are summed to calculate the hospital summary score. The measure group weights were based on CMS policy, stakeholder feedback, and similarities to that of the Hospital VBP Program[292] in that outcome measures are given more weight than process measures. Specifically, the Mortality, Safety of Care, Readmission, and Patient Experience measure groups are each weighted 22 percent and the Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging measure groups are each weighted 4 percent. In 2015, CMS' contracted development team engaged stakeholders for input on the measure group weights through the TEP,[293] the Patient & Advocate Work Group, and a public input period.[294] In general,

[290] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs. Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

[291] Centers for Medicare & Medicaid Services. (2019, November). Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[292] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 80 FR 49567 (Aug 17, 2015) (to be codified at 42 CFR part 412).

[293] Centers for Medicare & Medicaid Services. (2015, February). Summary *of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[294] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star*

Continued

stakeholders supported the current measure group weights and agreed that outcome measures should have more weight since they represent strong indicators of quality and are most important to patients in making healthcare decisions. The development contractor included this topic in several past public input periods,[295] [296] wherein some stakeholders suggested different measure group weightings; however, little consensus has been reached on an appropriate alternative weighting scheme.

(2) Continue Current Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to continue to calculate hospital summary scores through a weighted average of measure group scores with a similar weighting scheme that continues to assign more weight to the outcome and patient experience measure groups and less weight to the process measure group. Specifically, for Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to weight each of the outcome and patient experience measure groups—Mortality, Safety of Care, Readmission, and Patient Experience—at 22 percent, and the proposed combined process measure group, Timely and Effective Care (we refer readers to section E.3.b. New Measure Group and Continuation of Certain Groups of this final rule), at 12 percent. We also proposed that hospital summary scores would then be calculated by multiplying the standardized measure group scores by the assigned measure group weight and then summed. We refer readers to an example equation and Table 68. We also proposed to codify the measure group weightings at § 412.190(d)(6)(i) and summary score calculations at § 412.190(d)(6).

Example of Weighted Average of Measure Group Scores To Calculate Summary Scores

$$\text{Summary score} = [(-0.70*0.22) + (0.23*0.22) + (-0.76*0.22) + (-1.13*0.22) + (-0.25*0.12)] = -0.55$$

TABLE 68: Example of Summary Score Calculation and Star Rating Assignment

Measure Groups	Example Group Scores*	Standardized Example Group Scores*	Measure Group Weights	Weighted Standardized Example Group Scores*	Summary Score Calculation*
Mortality	-0.45	-0.70	22 %	-0.15	-0.55
Safety of Care	0.16	0.23	22 %	0.05	
Readmission	-0.35	-0.76	22 %	-0.17	
Patient Experience	-0.93	-1.13	22 %	-0.25	
Timely and Effective Care	-0.07	-0.25	12 %	-0.03	

*Please note that measure group scores are continuous and rescaled. Negative and positive scores do not denote good or bad performance.

In developing our proposal, we also considered equal measure weights across all the measure groups, such that each measure group would be weighted 20 percent. We ultimately chose to propose to weight outcome measures more, because this was vetted and supported by stakeholders and is consistent with past and current stakeholder feedback that outcome measures capture important aspects of quality and are more important to patients.[297] [298]

We invited public comment on our proposals to: (1) Continue to calculate hospital summary scores by multiplying the standardized measure group scores by the assigned measure group weights and then summing the weighted measure group scores; (2) continue to weight outcome and patient experience measure groups, (that is, Mortality, Safety of Care, Readmission, and Patient Experience groups) at 22 percent; (3) weight the proposed Timely and Effective Care process measure group at 12 percent; and (4) codify these policies at § 412.190(d)(6) introductory text and (d)(6)(i). The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters supported the proposed measure group weights to calculate summary scores through a weighted average of measure group scores. Some commenters expressed specific support that the outcome and patient experience measure groups be weighted more than process measure groups, given the importance of patient outcomes. Many commenters supported measure group reweighting, in which the new process measure group, Timely and Effective Care, is weighted 12 percent.

Response: We appreciate the commenters' support for our proposals to calculate summary scores through a weighted average of measure group scores with Mortality, Safety of Care, Readmission, and Patient Experience each weighted 22 percent and Timely and Effective Care weighted 12 percent. We agree and have consistently heard

Rating on Hospital Compare Public Input Summary Report.

[295] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[296] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[297] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[298] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

from stakeholders[299] [300] that outcome and patient experience measures represent a strongly quality signal, are more important to patients, and therefore should be weighted more than process measures within the Overall Star Rating methodology.

Comment: Some commenters supported the notion of measure group weighting but recommended alternative weighting schemes with more weight on Mortality than Readmission, for example.

Response: We thank commenters for their support for weighting in general. As discussed in our proposal, the measure group weighting scheme was determined based on CMS policy, stakeholder feedback, and similarities to that of the Hospital VBP Program.[301] In 2015, CMS' development contractor engaged stakeholders for input on the measure group weights through the TEP,[302] the Patient & Advocate Work Group, and a public input period.[303] In general, stakeholders supported the current measure group weights and agreed that outcome measures should have more weight since they represent strong indicators of quality and are most important to patients in making healthcare decisions. The development contractor included this topic in several past public input periods,[304] [305] wherein some stakeholders suggested different measure group weightings; however, little consensus has been reached on an appropriate alternative weighting scheme. We will continue to evaluate weighting as CMS quality programs evolve and measures are added or removed.

After consideration of the public comments received, we are finalizing our proposals as proposed.

b. Reweighting Measure Group Scores To Calculate Summary Scores

(1) Current Reweighting Measure Group Scores To Calculate Summary Scores

In the past, if a hospital did not report or have sufficient measures for a given measure group under the Overall Star Rating methodology, the weights of those measure groups would be redistributed proportionally across the measure groups for which the hospital did report sufficient measures. Generally, the four outcome measure groups were weighted at 22 percent each, and the three process measure groups were weighted at 4 percent each. The approach to proportioning weights when a hospital did not report enough measures for one or more measure groups was similar to the Hospital VBP Program where the weighting of groups is redistributed where one or more groups are not reported,[306] and was vetted by stakeholders for the Overall Star Rating through TEP [307] engagement and a public input period.[308]

(2) Reweight Measure Group Scores To Calculate Summary Scores Beginning in CY 2021 and Subsequent Years

Moving forward, we proposed to continue to reweight measure group scores. Taking into consideration the new measure grouping (we refer readers to section 5 E.3.b. New Measure Group and Continuation of Certain Groups of this final rule) and the Timely and Effective Care process measure group weighting of 12 percent (we refer readers to section E.5.a. Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores of this final rule), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to re-distribute measure group weights for measure groups which a hospital does not have sufficient measures within the Overall Star Rating methodology. Once a hospital meets the reporting threshold to receive a star rating, which is having at least three measure groups each with at least three measures, any additional measures and measure groups contribute to their star rating (we refer readers to section E.6.b. Minimum Reporting Thresholds for Receiving a Star Rating of this final rule). In other words, once the reporting thresholds are met, a hospital would need to report at least one measure in each group and the weight of any measure group that does not have at least one measure will be re-distributed amongst the other measure groups. Specifically, we proposed to re-distribute the weights for measure groups which are not reported proportionally across the remaining measure groups, to ensure the relative weight between groups is preserved. We would calculate this by subtracting the standard weight percentage of the group that does not meet the minimum threshold from 100 percent; the standard weight percentage of each of the remaining groups would then be divided by the resulting percentage giving new re-proportioned weights. If a hospital does not meet the threshold for two groups, then those two groups' standard weight percentages are added together before subtracting from 100 percent; the standard weight percentage of each of the remaining groups would then be divided by the resulting percentage giving new re-proportioned weights. We also proposed to codify this at § 412.190(d)(6)(ii). These calculations are illustrated in the three examples below.

For example, if a hospital does not report at least one measure within the Timely and Effective Care measure group, the group's 12 percent weight would be subtracted from the total of 100 (100 − 12 = 88) and then each of the measure group weights for that hospital would be determined using the new total of 88 (Mortality weight: 22/88 = 25 percent, Safety of Care weight: 22/88 = 25 percent, Readmission weight: 22/88 = 25 percent, and Patient Experience weight: 22/88 = 25 percent). This example is illustrated in Table 69.

[299] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[300] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[301] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 80 FR 49567 (Aug 17, 2015) (to be codified at 42 CFR part 412).

[302] Centers for Medicare & Medicaid Services. (2015, February). Summary *of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[303] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[304] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[305] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[306] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 77 FR 53606 (August 31, 2012) (to be codified at 42 CFR parts 412, 413, 424, and 476).

[307] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[308] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

TABLE 69: Example of Reweighting for a Hospital Which Does Not Report Timely and Effective Care Measure Group

Measure Group	Standard Weight	Re-Proportioned Weight
Mortality	22%	25%
Safety of Care	22%	25%
Readmission	22%	25%
Patient Experience	22%	25%
Timely and Effective Care	12%	--

As another example, if a hospital does not report at least one measure within the Readmission measure group, the group's 22 percent weight would be subtracted from the total of 100 (100 − 22 = 78) and then each of the measure group weights for that hospital would be determined using the new total of 78 (Mortality weight: 22/78 = 28.2 percent, Safety of Care weight: 22/78 = 28.2 percent, Patient Experience weight: 22/78 = 28.2 percent, and Timely and Effective Care weight: 12/78 = 15.4 percent). This example is illustrated in Table 70.

TABLE 70: Example of Reweighting for a Hospital Which Does Not Report Readmission Measure Group

Measure Group	Standard Weight	Re-Proportioned Weight
Mortality	22%	28.2%
Safety of Care	22%	28.2%
Readmission	22%	--
Patient Experience	22%	28.2%
Timely and Effective Care	12%	15.4%

This same principle would apply if a hospital did not have at least one measure reported in two measure groups. We proposed that a hospital must report at least three measure groups, each with at least three measures, one of which must be Mortality of Safety of Care, in order to receive a star rating; once both the minimum measure and measure group thresholds are met, any additional measures a hospital reports would be included in the Overall Star Rating calculation, including measures groups with as few as one measure (we refer readers to section E.6.b. Minimum Reporting Thresholds for Receiving a Star Rating of this final rule). If a hospital does not report at least one measure within both the Safety of Care and Timely and Effective Care measure groups, the groups' 22 and 12 percent weights would be subtracted from the total of 100 (100 − 22 − 12 = 66) and then each of the measure group weights would be determined using the new total of 66 (Mortality weight: 22/66 = 33.3 percent, Readmission weight: 22/66 = 33.3, and Patient Experience weight: 22/66 = 33.3 percent). This example is illustrated in Table 71.

TABLE 71: Example of Reweighting for a Hospital Which Does Not Report Safety of Care and Timely and Effective Care Measure Groups

Measure Group	Standard Weight	Re-Proportioned Weight
Mortality	22%	33.3%
Safety of Care	22%	--
Readmission	22%	33.3%
Patient Experience	22%	33.3%
Timely and Effective Care	12%	--

We invited public comment on our proposals to reweight measure group scores and codify at § 412.190(d)(6)(ii). The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters supported the proposal to continue to proportionally reweight measure group scores when hospitals have too few measures with one or more measure groups.

Response: We appreciate the commenters' support for our proposal to continue to proportionally reweight measure group scores when hospitals have too few measures within one or measure groups.

Comment: One commenter expressed concern with measure group reweighting if the remaining measure groups are calculating using less than three measures, in which case a measure group scores could be calculated using as few as one measure.

Response: In section E.6.b. Minimum Reporting Thresholds for Receiving a Star Rating of this final rule, we are finalizing that once the reporting thresholds are met, any additional measures or measure groups a hospital reports contribute to their star ratings. We acknowledge that this may result in occasional instances in which a hospital has only one or two measures in a group, and therefore the rare circumstance in which one measure contributes to a substantial portion of a hospital's summary score. However, incorporating all measures for which a hospital has scores aligns with one of the guiding principles of inclusivity of measure information (see section A.1.a. Purpose of this final rule). Using October 2020 public reporting data, of the 3,356 hospitals with an Overall Star Rating, 320 hospitals (10 percent) reported on a single measure in at least one measure group. Of these hospitals, the very rare circumstance in which a hospital reported a single measure in two measure groups only occurred for 10 hospitals (0.3 percent). The median contribution of a single measure score on hospitals' Overall Star Rating was below 5 percent for all measure groups. The maximum that a single measure score contributed to a hospital's Overall Star Rating was 28 percent for the Mortality, Safety or Care, or Readmission measure groups. This number was 5 percent for the Patient Experience group and 15 percent for the Timely and Effective Care group. For 76 percent of hospitals, no individual measure accounted for more than 10 percent of their Overall Star Rating. Thus, only in rare circumstances would a hospital meeting the reporting thresholds to receive a star rating have only one measure in a measure group contributing a high weight towards their star rating.

After consideration of the public comments received, we are finalizing our proposals as proposed.

6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating

a. Current Minimum Measure and Group Thresholds for Receiving a Star Rating

In the past, in order to receive a star rating, hospitals that provide acute inpatient and outpatient care had to publicly report sufficient measures to receive a star rating. Specifically, a minimum threshold was set to require at least three measure groups (one being an outcome group—that is, Mortality, Safety of Care, or Readmission), with at least three measures in each of the three groups. Additionally, in the past, once a hospital met the minimum measure and measure group thresholds, any additional measures and groups, including groups with as few as one measure, the hospital reported were included in the calculation of their star rating. These reporting thresholds were applied based on the guiding principle of information inclusivity, in that it allowed as many hospitals as possible to receive a star rating while also maintaining face validity [309] and reliability of the Overall Star Rating methodology, and were vetted through TEP and public comment stakeholder engagement.[310] [311]

In 2017, the CMS' Overall Star Rating development contractor vetted the minimum reporting thresholds through the TEP and public input.[312] In December 2017,[313] we updated the order of steps in the methodology for which minimum thresholds are applied; instead of applying minimum thresholds in step 6, after the assignment of hospitals to star ratings, we applied them in step 5, prior to the assignment of hospitals to star ratings so only hospitals meeting the threshold were included in the relative k-means

[309] Face validity refers to the notion that an instrument measures what it intends to measure at face value.

[310] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6*

[311] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[312] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[313] Centers for Medicare & Medicaid Services. (2017, December 20). Quarterly Updates and Specifications Report (v2.3). Retrieved from qualitynet.org: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

clustering algorithm.[314] K-means clustering [315] is the algorithm used to assign hospital summary scores to one of five star ratings. An overview of k-means clustering is provided in section E.8. Step 6: Application of Clustering Algorithm to Obtain a Star Rating of this final rule.

b. Minimum Reporting Thresholds for Receiving a Star Rating

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to continue a similar threshold as previously used, but with modification. We proposed that hospitals must report at least three measures for three measures groups, however, one of the groups must specifically be the Mortality or Safety of Care outcome groups. We believe this would increase the comparability of hospitals through the requirement of specific measure groups to receive a star rating. We also believe that this would ensure that, in order to receive a star rating, hospitals have information available on important indicators of acute inpatient and outpatient quality of care—mortality and safety of care—that reflect survival and preventable complications or infections following care and are, therefore, important to patients in making healthcare decisions, as indicated by the Patient & Patient Advocate Work Group. We also proposed to codify this minimum measure group threshold at § 412.190(d)(5).

However, we are aware that a requirement for at least three measures within the Mortality or Safety of Care groups would simultaneously limit the number of hospitals eligible to receive a star rating, particularly reducing the number of small, low volume hospitals with too few cases to report the individual measures. Furthermore, certain entities, such as CAHs, are not required to report safety measures (for example, healthcare-associated infections and PSI–90) as part of HAC Reduction Program (78 FR 50725 to 50728).[316] In January 2020, 125 hospitals did not report at least three measures in either the Mortality or Safety of Care groups. Of those 125 hospitals without at least three measures in either the Mortality or Safety of Care groups, 48 were safety-net hospitals, 68 were CAHs, and 16 were specialty hospitals. However, the TEP still recommended this change because Mortality and Safety of Care are aspects of quality that are most important to patients and reflective of performance under a hospital's control.[317] Once both the minimum measure and measure group thresholds are met, any additional measures a hospital reports would be included in the star rating calculation.

We invited public comment on our proposals to require that hospitals must report at least three measures groups, one of which must specifically be the Mortality or Safety of Care outcome group, each with at least three measures. Once this reported threshold is met, any additional measures and measure groups would contribute to hospital star ratings. We also proposed to codify these policies at § 412.190(d)(5).

We invited public comment on our proposals as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters supported CMS' proposal to require that hospitals report at least three measures in at least three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating. Multiple commenters acknowledged the importance that hospital star ratings reflect performance on the Mortality and Safety of Care measure groups.

Response: We appreciate the commenters' support for the proposal to require that hospitals report at least three measures in at least three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating. We agree that requiring at least three measures in either Mortality or Safety of Care will ensure that hospital star ratings reflect important aspects of care for patients.

Comment: Some commenters opposed the proposed reporting threshold based on concerns that it would dramatically limit the number of hospitals eligible to receive a star rating. Such commenters specifically opposed the removal of the Readmission measure group as an option for meeting the reporting requirement for a Star Rating. They suggested CMS conduct further analyses to understand how no longer requiring the measure group would affect hospital reporting. One commenter supported the proposed reporting threshold based on their own analysis which confirmed that a very small proportion of hospitals in the January 2020 *Hospital Compare* dataset would not receive a rating due to the proposed threshold. One commenter did not support the proposal because select hospital characteristics may be disproportionally ineligible to receive star ratings, therefore questioning the value of the Overall Star Rating as a comparison tool.

Response: We disagree with commenters that this would dramatically limit the number of hospitals eligible to receive star ratings. As stated in the proposed rule, we simulated the proposed reported threshold in section 8. Effects of Requirements for the Overall Hospital Quality Star Ratings (85 FR 49057 through 49077). Using data from the January 2020 Overall Star Rating (October 2019 public reporting data), when requiring at least three measures in at least three measure groups, one of which must be Mortality or Safety of Care, and thus no longer specifying Readmission as a requirement option, only 125 fewer hospitals would receive a star rating, consisting of 48 safety-net hospitals, 68 CAHs, and 16 specialty hospitals. In addition, using data from January 2020 Overall Star Rating, the proposal to combine the three process measure groups into one measure group, Timely and Effective Care, resulted in 180 more hospitals, of which 157 were CAHs, receiving a star rating with the current reporting threshold of three measures in at least three measure groups, one of which must be an outcome measure group. As discussed in section 8. Effects of Requirements for the Overall Hospital Quality Star Ratings of this final rule using October 2020 public reporting data, the final methodology, combining both the effects of regrouping and updating the reporting thresholds, for CY 2021 and subsequent years actually results in slightly more hospitals receiving a star rating than the current methodology. While the proposed reporting threshold, when isolated, modestly limits the number of hospitals eligible to receive a star rating, the final combined methodology results in more hospitals receiving a star rating than previous. In addition, the proposed threshold increases the face validity of the Overall Star Rating as a representation of quality of care at a hospital since it is guaranteed to reflect mortality or safety outcomes, which are most meaningful to patients and consumers, as advised by

[314] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[315] Ibid.

[316] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 50496 (Aug 19, 2013) (to be codified at 42 CFR parts 412, 413, 414, 419, 424, 482, 485, and 489).

[317] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

the TEP and Patient & Patient Advocate Work Group.

We also disagree that the proposed threshold will result in changes to hospital reporting levels since the Overall Star Rating uses measures as required for reporting under CMS quality programs and reported on *Hospital Compare* or its successor websites.

After consideration of the public comments received, we are finalizing our proposals as proposed.

7. Approach to Peer Grouping Hospitals

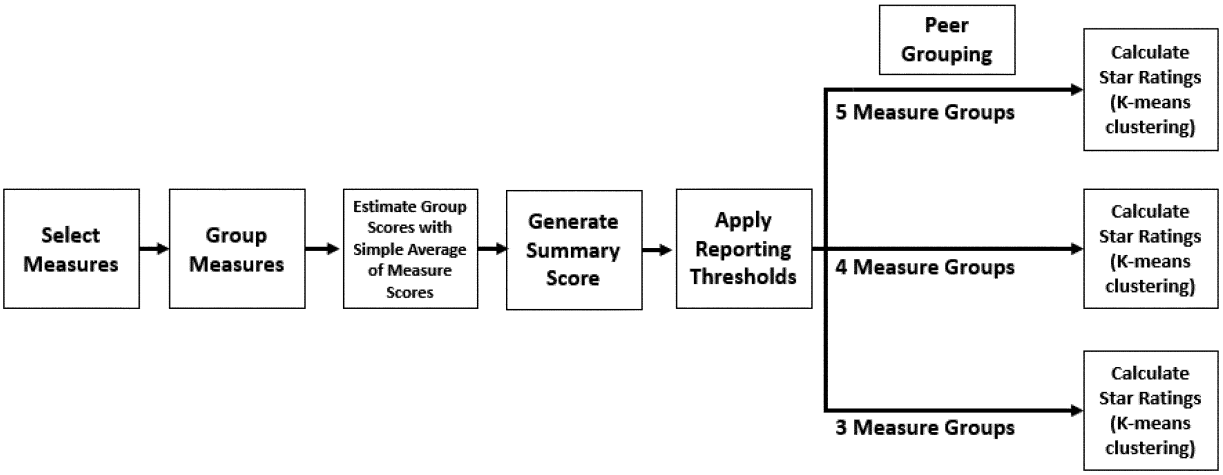
a. Background

We have not previously grouped hospitals by peers within the Overall Star Rating methodology. However, as part of our discussion with stakeholders about the comparability of the Overall Star Rating, peer grouping and potential peer grouping variables were discussed in two TEP meetings (March 2018 [318] and November 2019 [319]), two Provider Leadership Work Group meetings (February and November 2019), two Patient & Advocate Work Group meetings (December 2017 and October 2019), and presented during two public comment periods (August 2017 [320] and March 2019 [321]). Through stakeholder engagement activities, we presented data on peer grouping variables including number of measures or measure groups a hospital reports, teaching designation, specialty designation, critical access designation, and number of beds at a hospital, among others. While there was no consensus among stakeholders regarding which hospital characteristic variable would be most appropriate for peer grouping,[322] CMS focused on the number of measure groups reported as a peer grouping variable based on analyses for many possible variables that assessed similarities among hospitals within peer groups and predictability of hospitals assignments to peer groups over time. Larger hospitals, for example, generally submit the most measures and smaller hospitals submit the fewest. Peer grouping by number of measure groups provides alignment with hospital size.

b. Peer Grouping

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for Overall Star Rating beginning with CY 2021 and subsequent years, we proposed to group hospitals that provide acute inpatient and outpatient care by the number of measure groups for which they have at least three measures as shown in Figure 2. Specifically, after the minimum reporting thresholds are applied, hospitals would be grouped into one of three peer groups based on the number of measure groups for which they report at least three measures—three measure groups, four measure groups, and five measure groups. Once grouped, k-means clustering would be applied within each peer group to assign hospital summary scores to star ratings. We also proposed to codify this policy at § 412.190(d)(7).

Figure 2. Approach to Peer Grouping



Peer grouping hospitals based on the number of measure groups for which they report at least three measures is responsive to stakeholder concerns about the comparability of hospital star ratings and allows hospitals to be assigned to star ratings relative only to other similar hospitals in the same peer group.

We proposed to group hospitals by measure group reporting to capture key differences that are important to stakeholders, such as differences in size, patient volume, case mix,[323] and services provided (service mix [324]). For example, larger hospitals with more diverse case mix and service mix, such as large urban teaching hospitals, report a greater number of measures, and therefore measure groups, and would be grouped separately from smaller

[318] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[319] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[320] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[321] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[322] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[323] Centers for Medicare & Medicaid Services. (2019). *Frequently Asked Questions for the Risk-Standardized Outcome and Payment Measures.* Retrieved from *qualitynet.org: https://www.qualitynet.org/files/5d0d374c764be766b010136d?filename=2019_IQR_CBMsrs_FAQs.pdf.*

[324] Ibid.

hospitals with less diverse patient cases and service mix, which tend to report fewer measures and measure groups.

Hospital summary scores would be placed into three peer groups after calculation of the weighted average of measure group scores and before the assignment of hospitals to star ratings using k-means clustering.[325] This proposal is dependent on a sufficient number of hospitals that provide acute inpatient and outpatient care reporting three, four, and five measure groups to form the three peer groups. We simulated effects of this policy based on January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*): 348 (10 percent) hospitals reported at least 3 measures in 3 groups, 583 (17 percent) reported 4 groups, and 2,509 (73 percent) reported all 5 groups. These group sizes were vetted with the TEP [326] and work groups and considered adequately sized for clustering into peer grouped star ratings.

Of note, this proposal was contingent on the participation of CAHs, as outlined in section B.2. Inclusion of Critical Access Hospitals in the Overall Star Rating of this final rule, since CAHs make up approximately half of the hospitals in the three measure group peer group and their exclusion from the Overall Star Rating would not produce peer groups with a sufficient amount of hospitals for comparison. Because many CAHs currently report the minimum three measure groups required by the reporting threshold, as discussed in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating of this final rule, and make up approximately half of the hospitals within the three measure group peer group, there would likely be an insufficient number of hospitals in the three measure group peer group to produce adequate variation through k-means clustering [327] if CAHs were not included in the calculation. If CAHs were not included, the difference in summary score between a two-star and three-star hospital may be modest and not truly reflective of differences in hospital quality.

After peer grouping, we would then assign star ratings using k-means clustering [328] (discussed in section E.8. Step 6: Application of Clustering Algorithm to Obtain a Star Rating of this final rule) among hospitals within a single group, that is, relative only to hospitals in the same group. Specifically, hospitals would be grouped based on whether they have at least three measures for three measure groups, four measure groups, or five measure groups. The approach to peer grouping would retain the method used for assigning star ratings. Currently, the Overall Star Rating methodology uses a k-means clustering algorithm to assign hospitals to one of five star rating categories based on the distribution of hospital summary scores. This method aims to make hospital summary scores more similar within one star rating category and more different than hospital summary scores in other star rating categories. The proposed approach to peer grouping would be to also apply k-means clustering [329] to assign hospitals to one of five star ratings based only on hospitals in that peer group. For example, hospitals with three measure groups would be assigned to star ratings based on their summary score relative to other hospital summary scores with three measures groups, but not with respect to hospital summary scores among hospitals with four or five measure groups. Since hospitals in a peer group are being compared only to each other and k-means clustering is a comparative approach to assigning star ratings,[330] hospitals with the same summary score but different peer groups could receive different star ratings. In other words, a hospital with three measure groups could have the same summary score as a hospital with four measure groups; however, that summary score could fall within the four-star cluster for the three measure group peer group and the five-star cluster for the four measure group peer group. In addition, peer grouping hospitals would increase the comparability of star ratings within peer groups but decrease the comparability of star ratings across peer groups for patients. For example, once summary scores are calculated through the weighted average of measure group scores, a hospital within the three measure group peer group would not be assigned to a star rating relative to hospitals within the four or five measure group peer groups in the same geography or service line to whom that hospital is being compared by patients and consumers.

Applying peer grouping after the calculation of summary scores and before the assignment of hospitals to star ratings, allows: (1) Hospital summary scores to be equivalent and comparable among all hospitals, regardless of peer grouping; (2) transparency and the ability for stakeholders to review measure group and summary score results comparable to all other hospitals in the nation for quality improvement efforts within their confidential hospital-specific reports during the 30-day confidential preview period or the *Hospital Compare* or its successor websites' downloadable database upon public release; (3) minimal sensitivity of measure-level differences between peer groups on star ratings; and (4) hospitals' final star ratings to only be in comparison to ''like'' hospitals that have a similar number of measure groups.

We have conducted several analyses to inform decision making regarding peer grouping. To determine whether peer grouping not only supports CMS efforts to improve the comparability of star ratings, but also the predictability of hospital assignments to peer groups, we simulated potential effects of this proposal and assessed the stability of peer groups over time. Hospitals tend to report the same number of measure groups over time and therefore are often assigned to the same peer group each reporting period. Using historical data over five previous years, hospitals would have been assigned to the same peer groups of three, four, or five measure groups 96 to 98 percent of the time, indicating a high level of consistency over time. Furthermore, peer grouping hospitals based on the number of measure groups for which they report at least three measures creates similar within peer group hospital reporting profiles. Using January 2020 reporting data (from October 2019 publicly reported measure data on *Hospital Compare*), hospitals with three measure groups tend to almost always report at least three measures in the Mortality (86 percent), Readmission (86 percent), and Timely and Effective Care (96 percent) measure groups but tend to seldom report at least three measures in the Safety of Care (15 percent) and Patient Experience (17 percent) measures groups. Hospitals with four measure groups tend to always report at least three measures in the Readmission (100 percent) measure

[325] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[326] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[327] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[328] Ibid.

[329] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[330] Ibid.

group, tend to almost always report at least three measures in the Mortality (92 percent), Patient Experience (98 percent), and Timely and Effective Care (99 percent) measure groups, and tend to seldom report at least three measures in the Safety of Care (11 percent) measure group. Hospitals with five measure groups report at least three measures in all five measure groups. Hospitals with three and four measure groups are more likely to be critical access hospitals (58 percent in the peer group with three measure groups and 52 percent in the peer group with four measure groups) while hospitals in the peer group with five measure groups tend to be safety-net (19 percent of the peer group) and teaching (56 percent of the peer group) hospitals. These results confirm that peer grouping results in the grouping of hospitals with similar reporting profiles and characteristics and may address stakeholder concerns about the comparability of hospital star ratings.

Peer grouping hospitals by the number of measure groups for which they report at least three measures for the assignment of hospital summary scores to star ratings addresses stakeholder concerns about the comparability of hospitals with fundamental differences, such as measure reporting, hospital size or volume, patient case mix, and service mix. However, we note that peer grouping hospitals would decrease the comparability of all hospitals for patients and change the historical, conceptual comparative nature of the Overall Star Rating.

In developing our proposal, we also considered not peer grouping and continuing to apply k-means clustering amongst all hospitals meeting the minimum reporting thresholds to assign hospitals to star ratings. However, we ultimately decided to propose to peer group hospitals based on the number of measure groups to be responsive to stakeholder feedback and increase comparability of hospital star ratings. Should we not finalize our proposal to include CAHs, we will not peer group the Overall Star Rating by number of measure groups.

We invited public comment on our proposal to peer group hospitals by number of measure groups and to codify this policy at § 412.190(d)(7). The following is a summary of the comments we received and our responses to those comments.

Comment: Many stakeholders commented on peer grouping, most of whom supported CMS' proposal to peer group hospitals by the number of measure groups reported because it provides more equitable comparisons among hospitals. They agreed that number of measure groups serves as a proxy for hospital size, patient volume, case mix, and services, especially considering the analyses that demonstrate hospitals tend to report the same number of measure groups over time. One commenter recommended that CMS finalize the proposal to peer group hospitals, regardless of the inclusion of CAHs.

Response: We appreciate support for our proposal to peer group hospitals by the number of measure groups for which they have at least three measures. We refer readers to section B.2. Inclusion of Critical Access Hospitals in the Overall Star Rating of this final rule where we are finalizing our proposal to include CAHs resulting in a sufficient amount of hospitals in each peer group.

Comment: Some commenters did not support the proposal to peer group hospitals by the number of measure groups, with many of the commenters expressing concerns that peer grouping, as proposed, does not address stakeholder concerns about comparing hospitals with different characteristics, such as safety-net, specialty, hospital size, and patient case mix, and encouraged CMS to continue to evaluate approaches of more direct adjustment within the Overall Star Rating methodology. Many commenters recommended that CMS continue to evaluate other approaches to and options for peer grouping hospitals. They suggested alternative peer grouping variables, including CAH designation, teaching status, hospital size, services provided, and other hospital characteristics.

Response: One of the guiding principles of the Overall Star Rating is responsiveness to stakeholders, from whom we heard concerns that the Overall Star Rating attempts to compare all hospitals that are fundamentally different in terms of services provided, patients treated, and other characteristics. We have evaluated many variables, including but not limited to CAH designation, teaching status, bed size, and other hospital characteristics, and our development contractor solicited input from a TEP, Provider Leadership Work Group, Patient and Patient Advocate Work Group, and the general public through multiple public input periods. Stakeholder engagement consistently results in no consensus, particularly among providers, regarding which variable is most suitable for peer grouping hospitals within the Overall Star Rating methodology. In addition, few variables are available and consistently captured for all hospitals in the nation. While peer grouping hospitals by the number of measure groups may not directly address differences in hospital characteristics, we believe it does distribute hospitals in a way that indirectly accounts for differences in hospital size, case mix, and services provided, as demonstrated through the number and type of measures they report. For example, as stated in section E.7. Approach to Peer Grouping Hospitals of this final rule, hospitals with three or four measure groups report fewer measures and tend to be CAHs while hospitals with all five measure groups tend to be safety-net and teaching hospitals. The recent TEP and work groups supported peer grouping hospitals by the number of measure groups, acknowledging the availability and usability of other characteristics.

We acknowledge that for many commenters this approach did not fully address interest in creating comparable groups of hospitals. However, we believe that peer grouping by the number of measure groups reported would distribute hospitals in a way that indirectly accounts for differences in hospital size, case mix, and services provided, as demonstrated through the number and type of measures they report. As stakeholder input evolves and data becomes available, we will continue to examine alternative approaches to peer grouping both for the calculation as well as display of the Overall Star Rating.

Comment: Some commenters raised concerns that peer grouping would limit meaningfulness and usefulness to patients, such as the ability to compare hospitals based on their needs, result in inconsistent peer group assignments from year to year, create different star rating category cutoffs thereby preventing comparable scores and star ratings between peer groups, and prevent some measure groups important to patients, such as Safety of Care and Patient Experience, and rural and CAHs from being included within the Overall Star Rating.

Response: The Overall Star Rating is intended to summarize and complement individual measure scores reported through CMS quality programs and on *Hospital Compare* or its successor website. The Overall Star Rating and individual measure scores can be viewed together for patients and stakeholders seeking hospital quality information specific to their clinical needs, values, or interests and peer grouping hospitals within the Overall Star Rating would not impede access to that information. Peer grouping hospitals based on the number of

measure groups for which they report at least three measures is intended to improve comparability of hospital star ratings by accounting for differences in measure information. Peer grouping is applied independent of the measure and measure group reporting threshold and would therefore not result in any reduction in the number or type of hospitals receiving star ratings or the number or type of measures or measure groups contributing to hospital scores.

While peer grouping will result in slightly different summary score cutoffs for star rating assignments between groups, reevaluation analyses presented to the TEP [331] and work groups reveal those differences are modest. As outlined in section E.7. Approach to Peer Grouping Hospitals of this final rule, analyses using historical data have confirmed that hospitals tend to report a similar number and type of measures over time, resulting in hospitals assigned to the same peer group 96 to 98 percent of the time over 5 years of data. We plan to make public the summary score cutoffs for each peer group along with each publication of the Overall Star Ratings.

To clarify, peer grouping itself would not prevent measures or measure groups from being included within hospital star ratings nor prevent any specific hospitals from receiving a star rating. In section E.6. of this final rule, we are finalizing a policy about the minimum reporting thresholds for receiving a star rating which details that to receive a star rating, hospitals must report at least three measures within at least three measure groups, one of which must be Mortality of Safety of Care. Once that reporting threshold is met, any additional measures and measure groups a hospital reports contribute to their star rating. Therefore, all measures for which a hospital meets the specified measure threshold will be included within their star rating. We do note that, using data from January 2020 Overall Star Ratings, the proposed reporting threshold does result in 125 fewer hospitals receiving a star rating, consisting of 48 safety-net hospitals, 68 CAHs, and 16 specialty hospitals. These hospitals did not meet the minimum reporting threshold of at least three measures within at least three measure groups, one of which must be Mortality or Safety of Care.

Comment: One commenter stated that the peer grouping proposal does not account for geographic characteristics, especially in light of variations in COVID–19 hospitalizations in certain regions.

Response: The Overall Star Rating summarizes certain existing measure scores reported within CMS quality programs and on *Hospital Compare* or its successor website, which do not make geographical distinction within specifications. The impact of variation in COVID–19 hospitalizations, and healthcare broadly, is under active surveillance by CMS and any updates to the individual measures as a result of COVID–19 will subsequently be incorporated within the Overall Star Rating. We also refer readers to section G. Overall Star Rating Suppressions of this final rule where we are finalizing suppression of star ratings under certain circumstances, including when a Public Health Emergency substantially affects the underlying measure data.

Comment: Regardless of support, several commenters recommended that CMS make transparent on *Hospital Compare* or its successor websites the details of and information regarding peer grouping, including the hospital characteristics within each peer group, to educate stakeholders, including patients.

Response: Historically, we have publicly posted the Overall Star Rating comprehensive methodology report, input file, and SAS pack at the time of the Overall Star Rating publication so that stakeholders may review and replicate the methodology. Using the input file and SAS pack, coupled with hospital characteristic data, stakeholders would have the ability to review the types of hospitals assigned to each peer group. We plan to continue to publicly post, for each publication of the Overall Star Rating, the Overall Star Rating input file and SAS pack on QualityNet and Overall Star Rating results on *data.cms.gov,* which will include all specifications and results of the Overall Star Rating, including peer grouping.

Comment: One commenter suggested that peer grouping be applied earlier in the methodology so that measure group scores and summary scores are also only calculated relative to hospital peers.

Response: In early evaluation of peer grouping, application of peer grouping hospitals as early as measure group score calculation and as late as prior to clustering within the Overall Star Rating methodology were considered. Empirical analyses and stakeholder engagement efforts consistently favored the proposed approach of peer grouping hospitals after summary score calculation and before clustering, because it ensures the most valid comparisons of hospital measure and measure group scores prior to peer grouping. Also, given that peer grouping is based on an aggregate variable of measure group reporting, application of peer grouping at an earlier stage would be less impractical and transparent to stakeholders, potentially confusing stakeholders and patients.

After consideration of the public comments we received, we are finalizing our proposals as proposed.

8. Step 6: Application of Clustering Algorithm To Assign Star Rating

a. K-Means Clustering

(1) Current Application of K-Means Clustering

In the past, in order to assign hospitals to star ratings, we used an approach called k-means clustering to categorize hospitals' summary scores. K-means clustering is a clustering algorithm that groups entities, in this case hospitals, into a specified number of categories,[332] in this case five star rating categories in which one star is the lowest and five stars is the highest, by grouping values, in this case hospital summary scores, so that they are more similar within groups and more different between groups. In other words, for each publication of the Overall Star Rating, k-means clustering establishes cutoffs, or a range of summary scores, for each of the star rating categories so that summary scores in one star rating category would be more similar to each other and less similar to summary scores in other star rating categories.

We considered multiple approaches to assigning hospitals to star ratings, including percentiles, statistically significant cutoffs, and clustering algorithms. Each option was presented to the TEP[333] [334] and during a public input period [335] by the Overall Star Rating development contractor. While any approach to assigning hospitals to star ratings will result in some hospitals with summary scores near the cutoffs of two star rating categories, at that time, we chose to use k-means clustering

[331] Centers for Medicare & Medicaid Services. (2019, November). Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[332] Ibid.

[333] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[334] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[335] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

because it applied a data-driven approach to specification of five categories, minimized the within-category differences and maximized the between-category differences in summary scores, and was similar to the clustering algorithm used to calculate the HCAHPS Star Rating.[336] Stakeholders have generally supported the use of k-means clustering to assign star ratings over arbitrary percentiles and statistically significant cutoffs.[337] [338] [339]

In December 2017, we applied a minor update to the application of k-means clustering by running the summary scores through the clustering algorithm multiple times, a statistical method called complete convergence,[340] to provide more reliable and stable star rating assignments. Prior to December 2017, we performed Winsorization [341] of hospital summary scores to limit the influence of extreme outliers. Winsorization is a common strategy used to set extreme outliers to a specified percentile of the data.[342] While k-means clustering has been used within the methodology since implementation in July 2016, the update to run k-means clustering to complete convergence results in a broader distribution of star ratings and negates the need for Winsorization of hospital summary scores.[343]

(2) Continuation of K-Means Clustering

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to continue to use k-means clustering with complete convergence without Winsorization of hospital summary scores, to group hospitals into five clusters to assign star ratings so that one star is the lowest and five stars is the highest. We also proposed to codify this policy at § 412.190(d)(8). We believe use of k-means clustering is most appropriate because it aligns with the clustering algorithm used for the HCAHPS Star Rating [344] and maximizes the within star rating category similarities and between star rating category differences.

We invited public comment on our proposal to continue to use k-means clustering to complete convergence to assign hospitals to star ratings, where one star is the lowest and five stars is the highest, and to codify this policy at § 412.190(d)(8). The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters supported CMS' proposal to continue use of k-means clustering to assign hospitals to star ratings. Some commenters supported alignment with the clustering algorithm used within the HCAHPS Star Ratings.

Response: We appreciate the commenters' support for our proposal to continue use of k-means clustering to assign hospitals to star ratings and agree that it aligns with the clustering algorithm used within the HCAHPS Star Ratings.[345]

Comment: Some commenters opposed CMS' approach to continue use of k-means clustering because it may not be transparent for or reproducible by stakeholders. Commenters specifically noted that the relative methodology of k-means clustering makes it difficult for hospitals on the border of star rating categories to evaluate and predict their performance from one publication to the next. Some commenters recommended that CMS assign hospital star ratings through fixed cutoffs, which could be initially determined by k-means clustering but remain static over time, in order to increase predictability of star rating assignments and help inform quality improvement efforts.

Response: The use of k-means clustering was originally implemented as a result of testing and stakeholder engagement through a TEP and public input. While k-means clustering may not be as predictable as fixed cutoffs, it clusters hospitals so that summary scores in one star rating category are more similar to each other and more different than summary scores in other star rating categories, effectively minimizing within-category and maximizing between-category differences in summary scores. Historically, we have publicly posted the Overall Star Rating comprehensive methodology report, input file, and SAS pack at the time of the Overall Star Rating publication so that stakeholders may review and replicate the methodology. With any approach to assigning hospitals to star ratings, there will be some hospitals with summary scores at the border of star rating categories that have the potential to increase or decrease star ratings between publications. In addition, k-means clustering aligns with the clustering approach used for the HCAHPS Star Ratings [346] and, at the time of development, resulted in a broader distribution of star rating that alternative approaches. Furthermore, the primary goal of the Overall Star Rating is to summarize existing hospital quality information for patients. For targeted quality improvement efforts, we refer hospitals to their detailed measure rates under each individual CMS hospital quality program.

After consideration of the public comments received, we are finalizing our proposals as proposed.

F. Preview Period

1. Background

In the past, similar to the process in place for multiple CMS quality programs prior to public reporting of measure scores, hospitals providing acute inpatient and outpatient care that are included in the Overall Star Rating had the opportunity to confidentially review their star rating as well as the measures and measure group scores that contribute to their star rating during the confidential preview period a few months prior to the public release of the Overall Star Rating. We provided hospitals with a confidential report and at least 30 days to preview their results prior to releasing the Overall Star Rating. During the confidential preview period, hospitals received a confidential

[336] Centers for Medicare and Medicaid Services (2019, April). *Technical Notes for HCAHPS Star Ratings.* Retrieved from *www.hcahpsonline.org: https://www.hcahpsonline.org/globalassets/hcahps/star-ratings/tech-notes/april_2019_star-ratings_tech-notes.pdf.*

[337] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[338] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[339] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[340] Hsu, P.L., & Robbins, H. (1947). Complete Convergence and the Law of Large Numbers. *Proceedings of the National Academy of Sciences of the United States of America, 33*(2), 25–31. doi:10.1073/pnas.33.2.25.

[341] Kwak, S.K., & Kim, J.H. (2017, July 27). ''Statistical data preparation: management of missing values and outliers.'' Korean journal of anesthesiology 70.4: 407.

[342] Ibid.

[343] Centers for Medicare & Medicaid Services. (2017, December). Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0). Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[344] Centers for Medicare and Medicaid Services (2019, April). *Technical Notes for HCAHPS Star Ratings.* Retrieved from *www.hcahpsonline.org: https://www.hcahpsonline.org/globalassets/hcahps/star-ratings/tech-notes/april_2019_star-ratings_tech-notes.pdf.*

[345] Centers for Medicare and Medicaid Services (2019, April). *Technical Notes for HCAHPS Star Ratings.* Retrieved from *www.hcahpsonline.org: https://www.hcahpsonline.org/globalassets/hcahps/star-ratings/tech-notes/april_2019_star-ratings_tech-notes.pdf.*

[346] Centers for Medicare and Medicaid Services (2019, April). *Technical Notes for HCAHPS Star Ratings.* Retrieved from *www.hcahpsonline.org: https://www.hcahpsonline.org/globalassets/hcahps/star-ratings/tech-notes/april_2019_star-ratings_tech-notes.pdf.*

hospital-specific report (HSR), which detailed their measure performance and measure group scores with comparisons to the national average, as well as their summary score and star rating. The HSRs also provided information about how the measures' scores contribute to measure group scores, how measure group scores are weighted to calculate summary scores, and the range of summary scores for each star rating category. The Overall Star Rating preview period allowed hospitals to review, understand, and ask CMS questions about how the star rating was calculated.

2. Preview Period

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for Overall Star Rating beginning with the CY 2021 and subsequent years, we proposed to continue our current process regarding the preview period. Specifically, a few months prior to public release of the Overall Star Rating, we would issue a confidential HSR, which would detail measure and measure group scores as well as their summary score and star rating. The HSRs would also provide information about how the measures' scores contribute to measure group scores, how measure group scores are weighted to calculate summary scores, and the range of summary scores for each star rating category. During this preview period, hospitals would have at least 30 days to preview their results, and if necessary, reach out to CMS via the QualityNet Question and Answer tool, or additional contact information provided within preview period resources with questions about the methodology and their star ratings results. We also proposed to codify this policy at § 412.190(e). This proposal as well as the proposal to report Overall Star Rating annually using data publicly reported on *Hospital Compare* or its successor websites from a quarter within the prior year would allow hospitals more time to review and understand the methodology and their results, as well as reach out with questions.

We invited public comment on our proposals to: (1) Establish a 30-day confidential preview period, and (2) codify the confidential preview period at § 412.190(e). The following is a summary of the comments we received and our responses to those comments.

Comment: Commenters supported the Overall Star Rating preview period and CMS' provision of Hospital-Specific Reports. One commenter suggested that the confidential preview period be 60 days, rather than 30 days.

Response: We appreciate the commenters' support for our proposal to continue providing a preview period during which providers have the opportunity to confidentially review their measure, measure group, summary score, and star rating results prior to publication. We believe a 30-day preview period is sufficient because it allows hospitals to preview their Overall Star Rating results while maintaining timely publication on *Hospital Compare* or its successor website. In addition, a 30-day preview period is consistent with the standard amount of time provided for hospitals to review their results for the individual measures reported on *Hospital Compare* or its successor website under various CMS hospital quality programs.[347]

After consideration of the public comments received, we are finalizing our proposals as proposed.

G. Overall Star Rating Suppressions

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed separate suppression policies for subsection (d) hospitals and CAHs given that subsection (d) hospitals are subject to CMS quality programs and CAHs voluntarily submit measure data.

1. Subsection (d) Hospitals

a. Background

In the past, we would have only suppressed Overall Star Rating for subsection (d) hospitals when there were errors within the Overall Star Rating calculation or the calculation for individual measures, which would first need to be addressed through CMS programs prior to recalculating star ratings. Furthermore, there is currently no specific corrections process for the Overall Star Rating.

b. Suppression

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), we proposed to continue to allow for suppression, but only in limited circumstances. Specifically, for the Overall Star Rating beginning with the CY 2021 and subsequent years, we proposed to consider suppressing Overall Star Rating only under extenuating circumstances that affect numerous hospitals (as in, not an individualized or localized issue) as determined by CMS or when CMS is at fault, including but not limited to when:

- There is an Overall Star Rating calculation error by CMS;
- There is a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation. For example, there is a CMS quality program level error for one or more measures included within the Overall Star Rating due to incorrect data processing or measure calculations that affects a substantial number of hospitals reporting those measures. We note that we would strive to first correct systemic errors at the program level per program policies and then recalculate the Overall Star Rating, if possible; or
- A Public Health Emergency substantially affects the underlying measure data. We also proposed to codify this policy at § 412.190(f)(1).

As mentioned above, consistent with past practices, we proposed that we would not suppress an individual hospital's Overall Star Rating because the hospital or one of its agents (for example, authorized vendors, representatives, or contractors) submitted inaccurate data to CMS, including inaccurate underlying measure data and claims records. We note that the Overall Star Rating is calculated using individual measures publicly reported on *Hospital Compare* or its successor site via CMS quality programs. Hospitals can utilize established processes under each program in order to review and correct individual measure scores. As policies are specific to each program, we refer readers to the respective hospital program's policies. We also refer readers to the QualityNet website: *https://qualitynet.org/* for additional program-related information.

We invited public comment on our proposals as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: Commenters supported CMS' suppression policy for subsection (d) hospital star ratings but requested that CMS add clear criteria for suppression in the event of data submission error on the part of the provider or calculation error on the part of CMS.

Response: We appreciate the commenters' support for our proposal to

[347] As one example, Section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2) of the Affordable Care Act, requires that the Secretary establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50776 through 50778), we finalized our proposal, for the FY 2014 Hospital IQR Program and subsequent years, to continue our current policy of reporting data from the Hospital IQR Program as soon as it is feasible on CMS websites such as the Hospital Compare website, *http://www.hospitalcompare.medicare.gov,* and/or the interactive *https://data.medicare.gov* website, after a 30- day preview period.

suppress star ratings for subsection (d) hospitals only under extenuating circumstances that affect numerous hospitals as determined by CMS or when CMS is at fault. These extenuating circumstances include: (1) A calculation error on the Overall Star Rating, (2) a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation, or (3) a public health emergency that substantially affects the underlying measure data. We would not suppress an individual hospital's star rating because the hospital or one of its agents submitted inaccurate claims and underlying measure data to CMS.

Comment: Several commenters expressed concern about the impact of COVID–19 on the Overall Star Rating and recommended CMS provide the option to suppress data and ratings possibly affected by COVID–19.

Response: On March 27, 2020, we granted exceptions under certain Medicare quality reporting and value-based purchasing programs.[348] [349] In addition, the Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency Interim Final Rule (IFC) (85 FR 54820) updated the extraordinary circumstances exceptions granted for the Hospital Acquired Condition (HAC) Reduction Program, Hospital Readmissions Reduction Program (HRRP), and Hospital VBP Program for the PHE for COVID–19 as a result of the PHE for COVID–19. This IFC also announced that with respect to the Hospital VBP Program, HRRP, and HAC Reduction Program, if, as a result of a decision to grant a new nationwide ECE without request or a decision to grant a substantial number of individual ECE requests, we do not have enough data to reliably compare national performance on measures, we may propose to not score facilities, hospitals based on such limited data or make the associated payment adjustments for the affected program year.

We are currently analyzing how our exemptions granted and the COVID–19 pandemic impact the measures within various CMS quality programs. We note that the Overall Star Rating is calculated using individual measures publicly reported through CMS quality programs and on *Hospital Compare* or its successor website. The Overall Star Rating uses data publicly reported through CMS quality programs and thus, data excluded from those CMS quality programs, will be subsequently excluded from the Overall Star Rating. Hospitals can also utilize established processes under each program in order to review and correct individual measure scores. We refer readers to the QualityNet website: *https://qualitynet.org/* for additional program-related information. We may also consider suppression of the Overall Star Rating if we determine that due to a public health emergency underlying measure data were substantially affected.

After consideration of the public comments received, we are finalizing our proposals as proposed.

(1) CAHs

(a) Background

As discussed in section B. Critical Access Hospitals in the Overall Star Rating of this final rule, CAHs voluntarily submit measure data consistent with certain CMS programs. These measure results are then publicly reported on *Hospital Compare* or its successor websites. In the past, since the Overall Star Rating summarizes available measure information on *Hospital Compare* or its successor websites, CAHs with publicly reported measures results on *Hospital Compare* that also met the reporting thresholds to receive a star rating were assigned a star rating.

CAHs that did not want their voluntarily submitted measure data publicly reported on *Hospital Compare* could submit a form (''Request Form for Withholding/Footnoting Data for Public Reporting'' available on QualityNet) per the forms' instructions during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh used to calculate the Overall Star Rating. We note that this preview period is distinct from the Overall Star Rating preview period. If the measure data itself was withheld on *Hospital Compare,* it subsequently could not be included in the Overall Star Rating. Generally, upon public release of the Overall Star Rating, we also provide a public input file containing aggregate hospital measure scores, measure group scores, and summary scores along with the Overall Star Rating SAS pack for transparency and to allow stakeholders the opportunity to replicate the calculation of star ratings. If a CAH withheld its data from *Hospital Compare* at this stage, that data was excluded from both the Overall Star Rating calculation and the public input file.

Furthermore, because CAHs voluntarily reported measures, CAHs that would otherwise receive an Overall Star Rating could request to withhold their star rating during the Overall Star Rating preview period. However, at this stage, individual measure scores were still included in the public input file due to time and process constraints.

(b) Withholding

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to (1) continue to allow CAHs to withhold their Overall Star Rating; and (2) to codify this at § 412.190(f)(2). These proposals, discussed in more detail below, align with the guiding principles of transparency and inclusivity of hospitals, as outlined within section A. Background of this final rule, while allowing CAHs to voluntarily withhold their Overall Star Rating.

i. Withholding Star Ratings

Beginning with CY 2021 and for subsequent years, we proposed that CAHs may request to withhold their Overall Star Rating from public release on *Hospital Compare* or its successor websites as long as the request for withholding is made, at the latest, during the Overall Star Rating preview period as finalized in section F.2. Proposed Preview Period of this final rule. We also proposed to codify this policy at § 412.190(f)(2)(i). CAHs may make this request by submitting the ''Request Form for Withholding/Footnoting Data for Public Reporting'' form [350] available on QualityNet by midnight of the last day of the Overall Star Rating preview period. This is the same form used for withholding data from CMS programs. If CAHs request withholding of any of the measures included within the Overall Star Rating from public reporting on *Hospital*

[348] CMS Press Release, dated March 22, 2020, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19. Located at *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[349] CMS Guidance Memo, dated March 27, 2020, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19. Located at *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

[350] The ''Request Form for Withholding/Footnoting Data for Public Reporting'' form is in the process of being updated for use in CY21.

Compare or its successor websites through completion of this form, all of their measure scores will be withheld from the Overall Star Rating calculation. However, individual measure scores would still be included in the public input file. By the time the Overall Star Rating preview period begins, there would not be sufficient time for CMS to remove a CAH's data from the public input file and then recalculate the Overall Star Rating for all affected hospitals. As an example, for a January 2021 Overall Star Rating publication based on data publicly reported on *Hospital Compare* or its successor websites using October 2020 data, CAHs would need to submit their withholding request during the Overall Star Rating preview period, which would occur a few months prior to the January 2021 publication, in order to withhold their Overall Star Rating (but their data would still remain in the public input file).

ii. Withholding Star Ratings and Public Input File Data

We proposed that CAHs may request to have their Overall Star Rating withheld from public release on *Hospital Compare* or its successor website, as well as their data from the public input file, which is posted upon the public release of the Overall Star Rating and used by stakeholders to replicate the calculation of star ratings, so long as the request is made during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh used to calculate the Overall Star Rating. We also proposed to codify this policy at § 412.190(f)(2)(ii). As an example, we refer readers to our discussion in the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51608) for more information about this preview period in one of CMS' quality programs. CAHs may request that CMS withhold their measure and star rating results from public posting on *Hospital Compare* or its successor websites and the Overall Star Rating public input file by submitting a form (''Request Form for Withholding/Footnoting Data for Public Reporting'' [351] available on QualityNet) per the forms' instructions. This is the same form used for withholding from CMS programs. If CAHs request withholding of any of the measures included within the Overall Star Rating from public reporting on *Hospital Compare* or its successor websites through completion of this form during this stated timeframe, all of their measures scores would be withheld from the Overall Star Rating calculation and public input file.

As an example, for a January 2021 Overall Star Rating publication based on data publicly reported on *Hospital Compare* or its successor websites using October 2020 data, CAHs would need to submit their withholding request during the CMS quality program-level 30-day confidential preview period, which would generally occur a few months prior to the October 2020 *Hospital Compare* refresh in order to withhold both their Overall Star Rating and data from the public input file.

We invited public comment on our proposals as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: Some commenters supported the ability for CAHs to choose to withhold their Overall Star Rating from publication.

Response: We thank commenters for their support. We believe this proposal is consistent with the ability for CAHs to voluntarily report measures within CMS quality programs.[352]

Comment: Some commenters did not support CAHs having the option to withhold their rating. These commenters expressed concerns that allowing CAHs to withhold their Overall Star Rating from publication after they have an opportunity to preview their data decreases transparency and allows CAHs to choose to share positive ratings and withhold negative ratings.

Response: We disagree that this policy would actually decrease transparency. As discussed in section B. Critical Access Hospitals in the Overall Star Rating above in this final rule, many CAHs are located in remote areas that face unique challenges in resources and are often one of the only options for patients to seek care.[353] We believe it is important to include CAH data when available because it aligns with CMS goals of healthcare transparency, consumer choice, and the guiding principle of the Overall Star Rating, which is to be inclusive of measure and hospital information. The inclusion of CAHs in the Overall Star Rating has been supported by the Health Resources and Services Administration (HRSA) through their ongoing work with rural hospitals and facilities that provide acute inpatient and outpatient care, including CAHs. HRSA encourages CAHs to report quality measure data as part of quality improvement and public reporting and supports the inclusion of publicly reported measure scores for CAHs within the Overall Star Rating. Additionally, as part of ongoing stakeholder engagement activities, we have heard from some CAHs that they are interested in receiving a star rating and that voluntary measure reporting places no additional burden on CAHs. Furthermore, CMS historical data shows that as few as zero and as many as two CAHs actually exercise the ability to request withholding of their measure data and star rating for a given publication. Many CAHs voluntarily submit measure data for certain CMS quality programs, which are then subsequently displayed on *Hospital Compare* or its successor websites selecting Optional Public Reporting Notice of Participation through their QualityNet account. If CAHs elect to voluntarily submit measure data and report their measure scores on *Hospital Compare* or its successor website, they are subsequently eligible to receive a star rating, should they meet the Overall Star Rating reporting thresholds. The inclusion of CAHs within the Overall Star Rating provides patients with transparency on the hospital performance for hospitals that may be providing acute inpatient and outpatient care in their area.

After consideration of the public comments received, we are finalizing our proposals as proposed.

XVII. Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

A. Background

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Social Security Act (the Act), which allows the Secretary to develop ''a method for controlling unnecessary increases in the volume of covered OPD services'' (84 FR 61142, November 12, 2019).[354] The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

[351] The ''Request Form for Withholding/Footnoting Data for Public Reporting'' form is in the process of being updated for use in CY21.

[352] Centers for Medicare & Medicaid Services. (2020, November 15). Participation. Retrieved from *www.qualitynet.org*: *https://www.qualitynet.org/inpatient/public-reporting/public-reporting/participation.*

[353] Centers for Medicare & Medicaid Services. (2013, April 9). *Critical Access Hospitals.* Retrieved from *www.cms.gov*: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CAHs.*

[354] See also Correction notification issued January 3, 2020 (85 FR 224).

In addition to codifying the basis and scope of subpart I, Prior Authorization for Outpatient Department Services, the regulations include definitions associated with the prior authorization process, provide that prior authorization must be obtained as a condition of payment for the listed service categories, and include the process by which hospitals must obtain prior authorization. Paragraph (a)(1) of § 419.83 lists the specific service categories for which prior authorization must be obtained, which are: (i) Blepharoplasty, (ii) Botulinum toxin injections, (iii) Panniculectomy, (iv) Rhinoplasty, and (v) Vein ablation. Paragraph (b) states that CMS will update this list through formal notice-and-comment rulemaking, paragraph (c) describes the circumstances under which CMS may elect to exempt a provider from the prior authorization process, and paragraph (d) states that CMS may suspend the prior authorization process requirements generally or for a particular service at any time by issuing a notification on the CMS website.

B. Controlling Unnecessary Increases in the Volume of Covered OPD Services

1. Proposed Addition of Two New Service Categories

In accordance with § 419.83(b), we proposed to require prior authorization for two new service categories: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. We also proposed to add those service categories to § 419.83(a). We proposed that the prior authorization process for these two additional service categories will be effective for dates of services on or after July 1, 2021. As explained more fully below, the proposed addition of these service categories is consistent with our authority under section 1833(t)(2)(F) and is based upon our determination that there has been an unnecessary increase in the volume of these services. Based on the different implementation dates for the original five service categories and the two proposed service categories, we proposed to add a reference to the July 1, 2020 implementation date to the end of paragraph (a)(1) to reflect the implementation date for the original five service categories. Specifically, we proposed that paragraph (a)(1) would read, ''[t]he following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2020.'' We also proposed to add a new paragraph (a)(2), which would read: ''[t]he following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021.'' We proposed that the two proposed service categories would be added as new paragraphs (a)(2)(i) through (ii) to new paragraph (a)(2) as follows: (i) Cervical Fusion with Disc Removal and (ii) Implanted Spinal Neurostimulators. We also proposed that existing paragraph (a)(2) would be renumbered as paragraph (a)(3).

We proposed that the list of covered OPD services that would require prior authorization are those identified by the CPT codes in Table 72. For ease of review, we only included in Table 72 the CPT codes that fell into the two proposed service categories in proposed new § 419.83(a)(2)(i) and (ii). Note that this is the same approach we took in establishing the initial five service categories in § 419.83(a)(1). For ease of reference, we also included the Final List of Outpatient Services that Require Prior Authorization for the five initial service categories in Table 73.[355]

2. Basis for Adding Two New Service Categories

As part of our responsibility to protect the Medicare Trust Funds, we are continuing our routine analysis of data associated with all facets of the Medicare program. This responsibility includes monitoring the total amount or types of claims submitted by providers and suppliers; analyzing the claims data to assess the growth in the number of claims submitted over time (for example, monthly and annually, among other intervals); and conducting comparisons of the data with other relevant data, such as the total number of Medicare beneficiaries served by providers, to help ensure the continued appropriateness of payment for services furnished in the hospital OPD setting.

As we noted in the CY 2020 OPPS/ASC proposed rule,[356] we recognize the need to establish baseline measures for comparison purposes, including, but not limited to, the yearly rate-of-increase in the number of OPD claims submitted and the average annual rate-of-increase in the Medicare allowed amounts. For the CY 2021 OPPS/ASC proposed rule, we updated the analyses undertaken for the CY 2020 OPPS/ASC proposed rule.[357] In proposing the addition of these two service categories, we reviewed over 1.2 billion claims related to OPD services during the 12-year period from 2007 through 2018.[358] We determined that the overall rate of OPD claims submitted for payment to the Medicare program increased each year by an average rate of 2.8 percent. This equated to an increase from approximately 90 million OPD claims submitted for payment in 2007 to approximately 117 million claims submitted for payment in 2018. The 2.8 percent rate reflects a slight decrease when compared to the 3.2 percent rate identified in the CY 2020 OPPS proposed rule. Our analysis also showed an average annual rate-of-increase in the Medicare allowed amount (the amount that Medicare would pay for services regardless of external variables, such as beneficiary plan differences, deductibles, and appeals) of 7.8 percent. Again, this is a slight decrease when compared to the 8.2 percent rate identified in the CY 2020 OPPS/ASC proposed rule. We found that the total Medicare allowed amount for the OPD services claims processed in 2007 was approximately $31 billion and increased to $68 billion in 2018, while during this same 12-year period, the average annual increase in the number of Medicare beneficiaries per year was only 0.9 percent.

In the proposed rule, we described what we believe are the unnecessary increases in volume for each of the categories of services for which we proposed to require prior authorization, which we have also included below.

- *Implanted Spinal Neurostimulators:* Our analysis of Integrated Data Repository (IDR) data showed that, with regard to Implanted Spinal Neurostimulators, claims volume for insertion or replacement of spinal neurostimulator pulse generator or receiver, CPT® [359] code 63685, increased by 174.6 percent between 2007 and 2018, reflecting a 10.2 percent average annual increase, a significantly greater annual increase than the 2.8 percent average annual increase for all OPD services. From 2016 through 2018,

[355] The table appears on pages 61456 and 61457 of the final rule but contains certain technical errors. The table printed here is consistent with our January 3, 2020 correction notification. See 85 FR at 225.

[356] *See* Hospital Outpatient Prospective System/Ambulatory Surgical Center Payment System Proposed Rule, 84 FR 39398 at 39603 (August 9, 2019).

[357] 84 FR 39604.

[358] The data reviewed are maintained in the CMS Integrated Data Repository (IDR). The IDR is a high volume data warehouse integrating Medicare Parts A, B, C, and D, and DME claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html.*

[359] The Current Procedural Technology (CPT) coding system is a registered trademark of the American Medical Association.

the average annual increase in volume was 17 percent. For CPT code 63688, revision or removal of implanted spinal neurostimulator pulse generator or receiver, we observed an increase of 149.7 percent between 2007 and 2018, reflecting a 8.8 percent average annual increase, and for CPT code 63650, implantation of spinal neurostimulator electrodes, accessed through the skin, we observed an increase in volume of 77.9 percent between 2007 and 2018, which was an average annual increase of 6.5 percent; these average annual increases for both codes are higher than the 2.8 percent average annual increase for all OPD services over the same period. When analyzing these data, we fully accounted for changes that occurred in 2014 related to electrodes being incorporated into the CPT code 63650, which did not show a corresponding claims volume change that would explain the large increases noted over time when compared to the rates of change for all OPD services.

• *Cervical Fusion with Disc Removal:* When reviewing CMS data available through the IDR, we determined that claims volume for the initial level of spinal fusion of the cervical spine with removal of the corresponding intervertebral disc, CPT code 22551, had increased by 1,538.9 percent between 2012 and 2018, reflecting a 124.9 percent average annual increase, a substantially greater increase than the 2.8 percent average annual increase for all OPD services over the same period and the 2.1 percent average annual increase for all OPD services from 2007 through 2018. In fact, the increase between 2016 and 2018 for this code was 736 percent. The add-on code, CPT code 22552 (for additional levels), reflected claims volume increases of 3,779.6 percent between 2012 and 2018, reflecting a 174.9 percent average annual increase, again, far eclipsing the 2.8 percent average annual increase for all OPD services. Between 2016 and 2018 alone, the claims volume for this code increased 1,020 percent. These codes were first used in 2011 to better reflect the combination of the cervical fusion and the disc removal procedures. Accordingly, we used data from 2012 forward to allow for the start-up statistics to normalize. Nonetheless, the dramatic increases in volume that we identified persisted well after the initial use of these codes.

A rate of increase higher than the expected rate is not always improper; however, when we considered the data, we believed the increases in the utilization rate for this service were unnecessary. CPT code 22551 began being used in 2011. The use of the code almost tripled in 2012 and significantly increased each year thereafter. The increases became even more dramatic beginning in 2016, when the ambulatory payment classification (APC) for CPT code 22551 was changed to a higher level. Effective January 1, 2016, the CY 2016 OPPS/ASC final rule [360] moved the APC for CPT code 22551 from APC 0208 (Laminectomies and Laminotomies) to APC 0425 (Level II Arthroplasty or Implantation with Prosthesis). APC 0425 has a higher payment than APC 0280, the group to which the codes were originally assigned. APC 0208 had a geometric mean cost of $4,267, but APC 0425 had a geometric mean cost of $10,606. This represents a 149 percent increase in allowed amount as a result of the move to APC 0425, which may have contributed to the unnecessary increase in volume. Again, this represents a 736 percent increase in claims volume between 2016 and 2018 when all outpatient department services demonstrated an 0.4 percent increase overall for the same time period. We stated our belief that the change in the payment rate likely prompted the unnecessary volume increases and may have created a financial motivation to utilize these codes more than may be considered medically necessary. We also noted our belief that prior authorization is an appropriate control method for the unnecessary increase in volume for this service.

Our conclusion that the increases in volume for both Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators are unnecessary was based not only on the data specific to each service category, but also on a comparison of the rate of increase for the service categories to the overall trends for all OPD services. We noted our belief that comparing the utilization rate to the baseline growth rate is an appropriate method for identifying unnecessary increases in volume, particularly where there are no legitimate clinical or coding reasons for the changes. For both services categories, we researched possible causes for the increases in volume that would indicate the services are increasingly necessary, but we did not find any explanations that would cause us to believe the increases were necessary. Moreover, other than the recent changes in the CPT code and APC assignments described above, CMS has not taken any action that would explain the significant increases identified. We also conducted reviews of clinical and industry-related literature and found no indication of changes that would justify the increases observed. After reviewing all available data, we found no evidence suggesting other plausible reasons for the increases, which we believe means financial motivation is the most likely cause. We stated our belief that utilizing codes because of financial motivations, as opposed to medical necessity reasons, has resulted in an unnecessary increase in volume. Therefore, comparing the utilization rate to the baseline growth rate is an appropriate method for identifying unnecessary increases in volume, and prior authorization is an appropriate method to control these volume increases.

We stated in the proposed rule that we continue to believe prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments, without adding onerous new documentation requirements. A broad program integrity strategy must use a variety of tools to best account for potential fraud, waste and abuse, including unnecessary increases in volume. We stated that we believe prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and noted our expectation that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. We requested comments on the addition of these two service categories.

[360] 79 FR 66769 and 80 FR 70297.

BILLING CODE 4120–01–P

TABLE 72: 2021 Proposed List of Additional Outpatient Department Services That Would Require Prior Authorization

	Beginning for service dates on or after July 1, 2021
Code	(i) Cervical Fusion with Disc Removal
22551	Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex, initial
22552	Fusion of spine bones with removal of disc in upper spinal column below second vertebra of neck , anterior approach, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators
63650	Implantation of spinal neurostimulator electrodes, accessed through the skin
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

TABLE 73: 2020 Final List of Outpatient Department Services That Require Prior Authorization

	Beginning for service dates on or after July 1, 2020
Code	(i) Blepharoplasty, Eyelid Surgery, Brow Lift, and related services
15820	Removal of excessive skin of lower eyelid
15821	Removal of excessive skin of lower eyelid and fat around eye
15822	Removal of excessive skin of upper eyelid
15823	Removal of excessive skin and fat of upper eyelid
67900	Repair of brow paralysis
67901	Repair of upper eyelid muscle to correct drooping or paralysis
67902	Repair of upper eyelid muscle to correct drooping or paralysis
67903	Shortening or advancement of upper eyelid muscle to correct drooping or paralysis
67904	Repair of tendon of upper eyelid
67906	Suspension of upper eyelid muscle to correct drooping or paralysis
67908	Removal of tissue, muscle, and membrane to correct eyelid drooping or paralysis
67911	Correction of widely-opened upper eyelid
Code	(ii) Botulinum Toxin Injection
64612	Injection of chemical for destruction of nerve muscles on one side of face
64615	Injection of chemical for destruction of facial and neck nerve muscles on both sides of face
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a
Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services

15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (list separately in addition to code for primary procedure)
15877	Suction assisted removal of fat from trunk
Code	(iv) Rhinoplasty, and related services[361]
20912	Nasal cartilage graft
21210	Repair of nasal or cheek bone with bone graft
30400	Reshaping of tip of nose
30410	Reshaping of bone, cartilage, or tip of nose
30420	Reshaping of bony cartilage dividing nasal passages
30430	Revision to reshape nose or tip of nose after previous repair
30435	Revision to reshape nasal bones after previous repair
30450	Revision to reshape nasal bones and tip of nose after previous repair
30460	Repair of congenital nasal defect to lengthen tip of nose
30462	Repair of congenital nasal defect with lengthening of tip of nose
30465	Widening of nasal passage
30520	Reshaping of nasal cartilage
Code	(v) Vein Ablation, and related services
36473	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36474	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36475	Destruction of insufficient vein of arm or leg, accessed through the skin
36476	Radiofrequency destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36478	Laser destruction of incompetent vein of arm or leg using imaging guidance, accessed through the skin
36479	Laser destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36482	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance
36483	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance

BILLING CODE 4120–01–C

1. Summary of the Public Comments and Responses to Comments on the Proposed Rule

We received over 100 comments on this proposal, including comments from healthcare providers, professional and trade organizations, and device manufacturers. The following is a summary of the comments we received and our responses.

Comment: Several commenters reiterated concerns that we addressed in the CY 2020 OPPS/ASC final rule with comment period that prior authorization processes add burden and costs, can result in unnecessary delays in care, and interfere with the physician-patient care decision or otherwise negatively affect patient care. Other commenters

[361] Code 21235, ''Obtaining ear cartilage for grafting'' was removed on June 10, 2020 in accordance with § 419.83(d). See CMS *http://go.cms.gov/OPD_PA.*

similarly expressed concerns with the prior authorization processes within Medicare Advantage Plans. Some commenters stated that prior authorization is contrary to CMS' Patients Over Paperwork initiative and referenced CMS Administrator Seema Verma's comments related to prior authorization. Other commenters stated that CMS has limited experience with prior authorization in Medicare Fee-For-Service and that there is a lack of administrative structure for implementing the proposed changes and a lack of guidelines about the process by which providers would obtain prior authorization. Commenters also noted that time is needed to develop and maintain the communication logistics between physicians and hospitals. Still other commenters requested information regarding how prior authorization will impact advance beneficiary notices (ABNs) and continued to express concern regarding the inability to appeal the outcome of prior authorization requests.

Response: As we stated in the CY 2020 OPPS/ASC final rule with comment period, the process we are establishing specifically relates to Medicare Fee-For-Service, not Medicare Advantage, and we believe that we have structured the Medicare Fee-For-Service prior authorization processes to effectively account for concerns associated with processing timeframes, patient care, and other administrative concerns. We have implemented prior authorization processes while still preserving access to care and are building upon our already established prior authorization program for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) under 42 CFR 414.234. Similarly, we recently announced the nationwide expansion of the Medicare Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) in light of its success in reducing spending while maintaining quality of care. We remain fully committed to the agency's ''Patients over Paperwork'' initiative to reduce unnecessary burden, and, as explained below, our proposals are not inconsistent with this initiative. Moreover, while we agree that Administrator Verma noted concerns about potential burden related to prior authorization, she also recognized that prior authorization ''is an important utilization management tool.'' [362] More recently in discussing the resounding success of the RSNAT model, Administrator Verma stated that ''[w]hen deployed appropriately, prior authorization can help ensure Medicare requirements are met before a service is provided and the claim is paid, without creating any new documentation requirements for providers.'' [363] We recognize apprehension resulting from problems with prior authorization in other settings related to burden, cost, and patient access, but as with our other Medicare Fee-For-Service prior authorization processes, we believe that the Hospital OPD prior authorization process will not have these problems. We have established timeframes for contractors to render decisions on prior authorization requests, as well as an expedited review process when the regular review timeframe could seriously jeopardize the beneficiary's health, that we believe will enable hospitals to receive timely provisional affirmations. Additionally, we note that our prior authorization policy does not create any new documentation or administrative requirements. Instead, it just requires the same documents that are currently required to be submitted earlier in the process. Hospital OPDs should not need to divert resources from patient care. We note that prior authorization has the added benefit of giving hospitals some assurance of payment for services for which they received a provisional affirmation. In addition, beneficiaries will have information regarding coverage prior to receiving the service and will benefit by knowing in advance of receiving a service if they will incur financial liability for non-covered services.

We also believe that some assurance of payment and some protection from future audits will ultimately reduce burdens associated with denied claims and appeals. We note that because the prior authorization process is not a final determination and a provider has the ability to resubmit a prior authorization request multiple times, it is not necessary to provide appeal rights. Appeal rights still exist once a claim is actually denied.

We note that the prior authorization process does not change a provider's obligation with regard to ABNs. An ABN is used to advise a beneficiary in advance that the provider expects Medicare payment to be denied.

Comment: We received comments in support of prior authorization and our goal of ensuring the appropriateness of payment for Medicare services.

Response: We thank the commenters for their comments. We appreciate the positive responses to our proposed prior authorization process.

Comment: Some commenters continue to question whether section 1833(t)(2)(F) of the Act grants CMS the authority to establish a prior authorization process and again questioned the inclusion of botulinum toxin injections. Still other commenters suggested adding new procedures is arbitrary and capricious because the commenters believed that CMS has not demonstrated that increases in the volume of services for which we proposed to require prior authorization are unnecessary and that we did not demonstrate there are not other clinical reasons for the increases.

Response: As we conveyed in the CY 2020 OPPS/ASC final rule with comment period, we believe section 1833(t)(2)(F) of the Act gives us discretion to determine the appropriate methods to control unnecessary increases in the volume of covered OPD services. We carefully considered all available options in choosing to propose the prior authorization process, which has already been shown to be an effective tool in Medicare Fee-for-Service, and which we believe will be effective at controlling unnecessary increases for both cervical fusion with disk removal and implanted spinal neurostimulators. Our decision to include botulinum toxin injections in the CY 2020 OPPS/ASC final rule is beyond the scope of this CY 2021 rule, but our reasoning is discussed in detail in last year's proposed and final rules. Our extensive data analysis included in this year's proposed rule demonstrates that there have been unnecessary increases for each of the two proposed service categories and that we did not identify other, legitimate reasons for the sustained increases.

Comment: Several commenters again questioned why ambulatory surgical centers (ASCs) and physicians are exempt from this prior authorization process and believe the prior authorization process should cover ASCs and physicians. Commenters also stated that services may shift to ASCs, physicians' offices, or even inpatient hospitals to avoid the OPD prior authorization process.

Response: This prior authorization process is being adopted under section 1833(t)(2)(F) of the Act, which is specific to the OPPS, which provides payment only to hospital outpatient

[362] See Administrator Seema Verma's speech at the American Medical Association National Advocacy Conference at *https://www.cms.gov/newsroom/press-releases/speech-remarks-cms-administrator-seema-verma-american-medical-association-national-advocacy.*

[363] See CMS Press Release, dated September 22, 2020, CMS to Expand Successful Ambulance Program Integrity Payment Model Nationwide located at *https://www.cms.gov/newsroom/press-releases/cms-expand-successful-ambulance-program-integrity-payment-model-nationwide.*

departments. As such, we cannot extend the process to ASCs or other healthcare provider types, including physicians outside of the hospital outpatient department setting. These other entities, such as ASCs, are paid under other payment systems. We thank the commenters for reminding us of the potential for these services to shift to other care settings. We will monitor the data and may consider additional program integrity oversight if such shifts are realized.

Comment: Several commenters stated that CMS is not providing adequate time for training and education that providers will require in learning the new process in relation to the additional procedures. Some commenters suggested that CMS must evaluate the current process and assess the administrative burden, costs, impact on patient care, and effectiveness with regard to program integrity and managing inappropriate utilization prior to expanding the process to include cervical fusion with disk removal and implanted spinal neurostimulators. Other commenters stated that in light of the continuing public health emergency (PHE) resulting from the 2019 Novel Coronavirus (COVID–19) and the resulting serious financial impact, CMS should have delayed the implementation of the process and also delay the implementation date for the current proposal.

Response: No new documentation requirements are created as a result of this process. Instead, currently required documents are submitted earlier in the process. We recognize the impact of the COVID–19 PHE, but because we initially focused this process on elective cosmetic procedures, we believed that the impact of the PHE would be minimal. Further, given the importance of prior authorization activities to CMS' program integrity efforts, we did not believe a delay of the implementation date was warranted. The proposed date for the expansion of the prior authorization process to include the two new service categories is July 1, 2021. We believe this provides CMS and the Medicare Administrative Contractors (MACs) more than adequate lead time to educate and train providers on the addition of the new service categories. While these service categories are not cosmetic procedures, they are still elective and non-emergent, thus we do not believe delaying the expansion beyond July 1, 2021 due to the impact of the COVID–19 PHE is warranted.

Comment: Several commenters suggested that prior authorization is unnecessary and that CMS should focus on using already existing tools, such as National Coverage Decisions (NCDs) and Local Coverage Determinations (LCDs), prepayment and postpayment reviews, and provider outreach and education, since these are more effective methods to control unnecessary increases in volume. One commenter suggested CMS should use the Beneficiary and Family Centered Care Quality Improvement Organization contractor to retrospectively educate providers whose use of these procedures is statistically greater than their peers when adjusted for patient population characteristics. Other commenters referenced the trial period that must be completed with regard to spinal cord stimulation and asserted that this trial period served to prevent overutilization of the device. Still other commenters suggested that CMS should clarify already existing LCDs and NCDs to remedy the overutilization instead of using prior authorization.

Response: We have a variety of tools that can be used in making reasonable and necessary determinations, including NCDs and LCDs. For procedures that do not have specific LCDs or NCDs, contractors may make individual claim determinations to assess whether or not the services are reasonable and necessary under section 1862(a)(1)(A) of the Act. This prior authorization process does not make any changes to current documentation or medical necessity requirements. While we recognize the utility of NCDs and LCDs, the existence of an NCD or an LCD does not, in and of itself, guarantee compliance with the policy. Thus, the need for medical record review. We also believe that a broad program integrity strategy must use a variety of tools to best account for potential fraud, waste and abuse, including unnecessary increases in volume, so we use prior authorization, prepayment review, and postpayment reviews to review medical records and ensure compliance with these policies. Prior authorization entails the review of the same documentation provided when submitting a claim to ensure compliance with coverage policy, for example, NCDs or LCDs. Prior authorization has already proven to be an effective method for controlling improper payments and decreasing the volume of potentially improperly billed services for certain DMEPOS items. Thus, we believe that the use of prior authorization in the OPD context will be an effective tool in controlling unnecessary increases in the volume of covered OPD services by ensuring that the correct payments are made for medically necessary OPD services, while also being consistent with our overall strategy of protecting the Medicare Trust Fund from improper payments, reducing the number of Medicare appeals, and improving provider compliance with Medicare program requirements. Merely clarifying existing NCDs and/or LCDs, if warranted, does not equate to a comprehensive strategy. We will continue to work toward enhancing our overall program integrity strategy in meaningful ways.

Comment: Some commenters again suggested that MACs must have the clinical review capabilities to sufficiently handle prior authorization requests and suggested that CMS require specific credentials of the MAC medical reviewers to ensure the accuracy of MAC decisions. One commenter requested that we follow the principles noted in the *2018 Consensus Statement on Improving the Prior Authorization Process*[364] developed in consensus with various national provider associations and insurer trade organizations, including application of prior authorization to only outliers; adjustment of prior authorization lists to remove low-value services; transparency of requirements; protections of patient continuity of care; and automation to improve process efficiency.

Response: In all Medicare Fee-for-Service medical review programs, we require that MACs utilize clinicians, specifically, registered nurses, when reviewing medical documentation. We also require the oversight of a Medical Director and additional clinician engagement if necessary. We are confident that MACs have the requisite expertise to effectively administer the prior authorization process, and we maintain a robust oversight process to ensure the accuracy and consistency of their review decisions. Further, we believe the prior authorization process we have adopted aligns with the principles outlined by the commenters. We have established review timeframes for both initial and resubmitted prior authorization requests, as well as an expedited process when the regular timeframe could impact the health of the beneficiary. Having established turnaround times allows providers and patients to plan accordingly and reduces provider burden. We have also established an exemption process with specific requirements for providers to demonstrate compliance with Medicare requirements for these services and be exempt from the prior authorization

[364] See *https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.*

process. We are also committed to incorporating automation into our prior authorization processes and recognize the value of automation in shortening the receipt of prior authorization requests and our response time frames. We recognize that not all providers have the same level of technology. With regard to the Hospital OPD prior authorization process, the majority of providers so far continue to submit requests and medical information to the MACs via facsimile. Other providers submit the requests through the United States (U.S.) postal service. We also support a variety of electronic mechanisms used by providers in submitting prior authorization requests. These providers use either the MAC-specific web portals, CMS's electronic submission of medical documentation (esMD) system, and may also send prior authorization requests using the X12 278 standard, though currently, relatively few providers submit prior authorization requests electronically. We continue to monitor other federal and industry initiatives in order to improve the efficiency of our prior authorization processes, increase provider willingness to submit requests electronically, reduce provider burden, decrease delays in patient care and promote high quality, affordable health care.

Comment: We received comments that the growth in utilization of a procedure/product class exceeding the baseline growth rates in the Medicare population is not a sufficient basis for inferring that utilization is inappropriate or that utilization growth is unwarranted. Some commenters suggested that CMS must be more transparent in the analyses undertaken while other commenters suggested that the reduction of inappropriate or unnecessary care does not outweigh the increased burden on providers and the impact on patient care. Still other comments agreed that the rates had increased but suggested that CMS analyze readily available clinical information to explain the changes in utilization before the agency adopts broad-based interventions such as imposing prior authorization on outpatient hospitals. Some commenters stated that the increase in cervical fusion with disc removal can be attributed to its removal from the Inpatient Only List (IPO) list as of January 1, 2012. Some of these commenters questioned whether CMS analyzed only the volume of outpatient claims or if the total number of claims that involved cervical fusions were analyzed, specifically to determine if there was a decline in the volume of inpatient claims. Others suggested that we did not consider efforts to combat the opioid public health emergency as a reason for the increased utilization of implanted spinal neurostimulators, as an alternative to treat chronic pain, along with the comorbidity of the patient population. Several commenters suggested that the proposal to include implanted spinal neurostimulators is not in alignment with the Department of Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force Report, which encourages CMS and other payers to provide timely insurance coverage of such procedures in efforts to reduce opioid dependency for pain management. Some commenters stated that CMS changed its methodology because the initial process focused upon items that were cosmetic, while the new items are being added as a result of overutilization. One commenter indicated that in contrast to our findings, they had experienced a decrease in cervical fusion with disk removal procedures in their area of the country.

Response: We thank the commenters for their input. We continue to believe that comparing the utilization rate to the baseline growth rate is an appropriate method for identifying potentially unnecessary increases in volume. Moreover, we clearly conveyed in the CY 2021 OPPS/ASC proposed rule the precise data and time frames used in our analyses and our efforts to identify potential clinical reasons that would explain the increase. As we have noted, we have endeavored to minimize the burden associated with this prior authorization process and this burden is more than outweighed by the need to control unnecessary increases in the volume of these services. We believe that the 10-day timeframe for obtaining a decision on a prior authorization request is not significant considering that these are non-emergency procedures that require the beneficiary to undergo conservative treatment prior to the procedure. While we are aware that the cervical fusion codes were removed from the Inpatient Only List in 2012, the more significant increases in volume occurred years later, when the reimbursement changed for the procedure. This supports our conclusion that financial reasons may have factored into the utilization increases. In confirming our conclusion, we looked at data across both inpatient and outpatient settings for the total volume of cervical fusions, and considered the change in inpatient procedure coding from ICD–9 to ICD–10. The conversion from ICD–9 to ICD–10 makes an exact comparison difficult, but based on our assessment, we do not believe that the 1,538.9 percent increase between 2012 and 2018 for cervical fusion with disc removal is due to its removal from the IPO as of January 1, 2012.

Similarly, we do not agree that the 174.6 percent increase between 2007 and 2018 for implanted spinal neurostimulators is due solely to efforts to avoid opioids. As we noted in the proposed rule, the claims volume that formed the basis of our conclusions regarding implanted neural stimulators was based on data from the time period 2007 through 2018. The opioid crisis affecting our Nation was not declared a PHE until October, 26, 2017. While the crisis certainly existed prior to the declaration of a PHE, most of the data forming the basis of our conclusion that implanted spinal neurostimulators demonstrated unnecessary increases in volume pre-dates the PHE and any federally coordinated efforts to reduce the use of opioids. Thus, most of the data forming the basis of our conclusion pre-dates that PHE and any substantial or coordinated efforts to reduce the use of opioids. We also believe the proposal is in alignment with the Department of Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force Report that encourage CMS and other payers to provide timely insurance coverage of such procedures. We believe that the 10-day timeframe for obtaining a decision on a prior authorization request is not significant considering that these are non-emergency procedures that require the beneficiary to undergo conservative treatment prior to the procedure. Additionally, providers may request an expedited review, and ultimately providers can be exempt from the prior authorization process should a provider demonstrate compliance with Medicare coverage, coding, and payment rules. With regard to our methodology, we again compared the utilization rate to the baseline growth rate and believe that this is an appropriate method for identifying potentially unnecessary increases in volume. We also looked at the overall rates from a national perspective and believe that this approach is warranted, despite the commenter's observation about its area of the country.

Comment: One commenter disagreed with the average hourly rate used by CMS in calculating the average practice labor costs and noted that rather than using clerical employees, clinical staff, from nurses up to and including

physicians, are often involved in completing the documentation required for prior authorization. This same commenter also stated that there is a time burden associated with determining which services require prior authorization and the documentation required associated with a particular procedure code.

Response: We thank the commenter for the comment. We typically use a clerical staff rate because the documentation being submitted is the same documentation that should be regularly maintained in support of claims submitted for payment. The prior authorization process does not require anything new with regard to documentation. The prior authorization process merely requires the documentation be provided earlier in the process. With regard to the time burden, we include 3 hours of training in our burden estimate for each provider. During this time, the staff can be educated on the services that require prior authorization under this program and what documentation is needed as part of the prior authorization request. Moreover, we include the 3 hours each year so that new staff can be trained and current staff can have a refresher course. Given that this process does not create any new documentation requirements and merely necessitates the submission of the documentation earlier in the claims process, we believe the amount estimated is more than sufficient.

Comment: Some commenters indicated that implanted spinal neurostimulators are nothing like the devices CMS originally considered when drafting the NCD in light of advancements in technology. Commenters noted that the process should treat rechargeable and non-rechargeable neurostimulators differently and only include non-rechargeable neurostimulators in the prior authorization process because of the reduced product life of the non-rechargeable neurostimulators.

Response: We thank the commenters for the information. While we recognize that there have been advancements in technology, the NCD does not distinguish the coverage between different types of implanted spinal neurostimulators. Additionally, although our initial review of the data looked solely at unnecessary increases in procedure codes and did not distinguish between the type of product, we have since reviewed our data for any distinctions based on the type of implanted spinal neurostimulators. Both types showed unnecessary increases in volume. As such, we have determined that segmenting the implanted spinal neurostimulators and only including the non-rechargeable neurostimulators in the prior authorization process is not warranted.

Comment: We received several comments that the MACs have not demonstrated the ability to handle the volume of prior authorization requests since the OPD process begin July 1, 2020. These commenters stated that MACs have taken longer than the 10 days specified for communicating the results of prior authorization requests.

Response: We thank the commenters for sharing this concern. While we require prior authorization decisions to be made within 10 days of the request, we acknowledge that there have been occasions when a few of the MACs were not able to issue decisions within this timeframe, as they adjusted to this new workload. When concerns with missed timeframes were brought to CMS' and the MAC's attention, we worked diligently to ensure that outstanding requests were resolved as soon as possible. As this prior authorization process as finalized in last years' rule has only recently been implemented for services furnished beginning July 1, 2020, we have minimal data to track this issue. However, experience with our other prior authorization programs has shown that the MACs are able to meet their established timeframes the vast majority of the time. In the prior authorization process for certain DMEPOS items, the MACs exceeded their required review timeframe only 16 times out of over 62,000 initial prior authorization requests submitted in FY 2020 (less than 0.01 percent). Response times for our Prior Authorization Model for Repetitive, Scheduled Non-emergent Ambulance Transports are similar. As this program continues, we will continue tracking MAC timeliness metrics and are confident that the MACs will be able to meet the required review and decisions timeframes so as not to cause additional burden for OPD providers or delay medically necessary services.

In sum, we continue to believe prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments, without adding onerous new documentation requirements. A broad program integrity strategy must use a variety of tools to best account for potential fraud, waste and abuse, including unnecessary increases in volume. We believe prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. We will continue to monitor and report on the effect of this policy on beneficiary access to services.

We are finalizing our proposal without modification to add these two new service categories to the list of hospital outpatient department services requiring prior authorization and finalizing the proposed changes to the regulation text at 42 CFR 419.83(a)(2)(i) and (ii) to add these categories. Table 74 includes the overall list of services with the effective dates for each.

BILLING CODE 4120–01–P

TABLE 74: 2021 Final List of Outpatient Department Services That Require Prior Authorization

The following is the list of codes associated with the list of hospital outpatient department services contained in 42 CFR 419.83(a)(1) and (2).	
The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after *July 1, 2020*: (i) Blepharoplasty. (ii) Botulinum toxin injections. (iii) Panniculectomy. (iv) Rhinoplasty. (v) Vein ablation.	
Code	(i) Blepharoplasty, Eyelid Surgery, Brow Lift, and related services
15820	Removal of excessive skin of lower eyelid
15821	Removal of excessive skin of lower eyelid and fat around eye
15822	Removal of excessive skin of upper eyelid
15823	Removal of excessive skin and fat of upper eyelid
67900	Repair of brow paralysis
67901	Repair of upper eyelid muscle to correct drooping or paralysis
67902	Repair of upper eyelid muscle to correct drooping or paralysis
67903	Shortening or advancement of upper eyelid muscle to correct drooping or paralysis
67904	Repair of tendon of upper eyelid
67906	Suspension of upper eyelid muscle to correct drooping or paralysis
67908	Removal of tissue, muscle, and membrane to correct eyelid drooping or paralysis

67911	Correction of widely-opened upper eyelid
Code	(ii) Botulinum Toxin Injection
64612	Injection of chemical for destruction of nerve muscles on one side of face
64615	Injection of chemical for destruction of facial and neck nerve muscles on both sides of face
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a
Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (list separately in addition to code for primary procedure)
15877	Suction assisted removal of fat from trunk
Code	(iv) Rhinoplasty, and related services
20912	Nasal cartilage graft
21210	Repair of nasal or cheek bone with bone graft
30400	Reshaping of tip of nose
30410	Reshaping of bone, cartilage, or tip of nose
30420	Reshaping of bony cartilage dividing nasal passages
30430	Revision to reshape nose or tip of nose after previous repair
30435	Revision to reshape nasal bones after previous repair
30450	Revision to reshape nasal bones and tip of nose after previous repair
30460	Repair of congenital nasal defect to lengthen tip of nose
30462	Repair of congenital nasal defect with lengthening of tip of nose
30465	Widening of nasal passage
30520	Reshaping of nasal cartilage
Code	(v) Vein Ablation, and related services
36473	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36474	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36475	Destruction of insufficient vein of arm or leg, accessed through the skin
36476	Radiofrequency destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36478	Laser destruction of incompetent vein of arm or leg using imaging guidance, accessed through the skin

36479	Laser destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36482	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance
36483	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance
The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021: (i) Cervical Fusion with Disc Removal. (ii) Implanted Spinal Neurostimulators.	
Code	(i) Cervical Fusion with Disc Removal
22551	Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex, initial
22552	Fusion of spine bones with removal of disc in upper spinal column below second vertebra of neck , anterior approach, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators
63650	Implantation of spinal neurostimulator electrodes, accessed through the skin
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

BILLING CODE 4120–01–C

XVIII. Clinical Laboratory Fee Schedule: Revisions to the Laboratory Date of Service Policy

A. Background on the Medicare Part B Laboratory Date of Service Policy

The date of service (DOS) is a required data field on all Medicare claims for laboratory services. However, a laboratory service may take place over a period of time—the date the laboratory test is ordered, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date the laboratory performs the test, and the date results are produced may occur on different dates. In the final rule on coverage and administrative policies for clinical diagnostic laboratory services published in the **Federal Register** on November 23, 2001 (66 FR 58791 through 58792), we adopted a policy under which the DOS for clinical diagnostic laboratory services generally is the date the specimen is collected. In that final rule, we also established a policy that the DOS for laboratory tests that use an archived specimen is the date the specimen was obtained from storage (66 FR 58792).

In 2002, we issued Program Memorandum AB–02–134, which permitted contractors discretion in making determinations regarding the length of time a specimen must be stored to be considered ''archived.'' In response to comments requesting that we issue a national standard to clarify when a stored specimen can be considered ''archived,'' in the Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services final notice, published in the **Federal Register** on February 25, 2005 (70 FR 9357), we defined an ''archived'' specimen as a specimen that is stored for more than 30 calendar days before testing. Specimens stored for 30 days or less continued to have a DOS of the date the specimen was collected.

B. Medicare DOS Policy and the ''14-Day Rule''

In the final rule with comment period entitled, in relevant part, ''Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B'' published in the **Federal Register** on December 1, 2006 (December 1, 2006 MPFS final rule) (71 FR 69705 through 69706), we added a new § 414.510 in title 42 of the CFR regarding the clinical laboratory DOS requirements and revised our DOS policy for stored specimens. We explained in that MPFS final rule that the DOS of a test may affect payment for the test, especially in situations in which a specimen that is collected while the patient is being treated in a hospital setting (for example, during a surgical procedure) is later used for testing after the patient has been discharged from the hospital. We noted that payment for the test is usually bundled with payment for the hospital service, even when the results of the test did not guide treatment during the hospital stay. To address concerns raised for tests related to cancer recurrence and therapeutic interventions, we finalized modifications to the DOS policy in § 414.510(b)(2)(i) for a test performed on a specimen stored less than or equal to 30 calendar days from the date it was collected (a non-archived specimen), so that the DOS is the date the test was

performed (instead of the date of collection) if the following conditions are met:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

As we stated in the December 1, 2006 MPFS final rule, we established these five criteria, which we refer to as the ''14-day rule,'' to distinguish laboratory tests performed as part of posthospital care from the care a beneficiary receives in the hospital. When the 14-day rule applies, laboratory tests are not bundled into the hospital stay, but are instead paid separately under Medicare Part B (as explained in more detail below).

We also revised the DOS requirements for a chemotherapy sensitivity test performed on live tissue. As discussed in the December 1, 2006 MPFS final rule (71 FR 69706), we agreed with commenters that these tests, which are primarily used to determine posthospital chemotherapy care for patients who also require hospital treatment for tumor removal or resection, appear to be unrelated to the hospital treatment in cases where it would be medically inappropriate to collect a test specimen other than at the time of surgery, especially when the specific drugs to be tested are ordered at least 14 days following hospital discharge. As a result, we revised the DOS policy for chemotherapy sensitivity tests, based on our understanding that the results of these tests, even if they were available immediately, would not typically affect the treatment regimen at the hospital. Specifically, we modified the DOS for chemotherapy sensitivity tests performed on live tissue in § 414.510(b)(3) so that the DOS is the date the test was performed if the following conditions are met:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

We explained in the December 1, 2006 MPFS final rule that, for chemotherapy sensitivity tests that meet this DOS policy, Medicare would allow separate payment under Medicare Part B; that is, separate from the payment for hospital services.

C. Billing and Payment for Laboratory Services Under the OPPS

As noted previously, the DOS requirements at 42 CFR 414.510 are used to determine whether a hospital bills Medicare for a clinical diagnostic laboratory test (CDLT) or whether the laboratory performing the test bills Medicare directly. Separate regulations at 42 CFR 410.42(a) and 411.15(m) generally provide that Medicare will not pay for a service furnished to a hospital patient during an encounter by an entity other than the hospital unless the hospital has an arrangement (as defined in 42 CFR 409.3) with that entity to furnish that particular service to its patients, with certain exceptions and exclusions. These regulations, which we refer to as the ''under arrangements'' provisions in this discussion, require that if the DOS falls during an inpatient or outpatient stay, payment for the laboratory test is usually bundled with the hospital service.

Under our current rules, if a test meets all DOS requirements in § 414.510(b)(2)(i) or (b)(3) or (5), the DOS is the date the test was performed. In this situation, the laboratory would bill Medicare directly for the test and would be paid under the Clinical Laboratory Fee Schedule (CLFS) directly by Medicare. However, if the test does not meet the DOS requirements in § 414.510(b)(2)(i) or (b)(3) or (5), the DOS would be the date the specimen was collected from the patient. In that case, the hospital would bill Medicare for the test and then would pay the laboratory that performed the test, if the laboratory provided the test under arrangement.

In previous rulemakings, we have reviewed appropriate payment under the OPPS for certain diagnostic tests that are not commonly performed by hospitals. In CY 2014, we finalized a policy to package certain CDLTs under the OPPS (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17) and 419.22(l)). In CYs 2016 and 2017, we made some modifications to this policy (80 FR 70348 through 70350 and 81 FR 79592 through 79594). Under our current policy, certain CDLTs that are listed on the CLFS are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. Specifically, we package most CDLTs under the OPPS. However, when a CDLT is listed on the CLFS and meets one of the following four criteria, we do not pay for the test under the OPPS, but rather, we pay for it under the CLFS when it is: (1) The only service provided to a beneficiary on a claim; (2) considered a preventive service; (3) a molecular pathology test; or (4) an advanced diagnostic laboratory test (ADLT) that meets the criteria of section 1834A(d)(5)(A) of the Act (78 FR 74939 through 74942; 80 FR 70348 through 70350; and 81 FR 79592 through 79594). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70348 through 70350), we excluded all molecular pathology laboratory tests from packaging because we believed these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.

For similar reasons, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592 through 79594), we extended the exclusion to also apply to all ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. We stated that we will assign status indicator ''A'' (Separate payment under the CLFS) to ADLTs once a laboratory test is designated an ADLT under the CLFS. Laboratory tests that meet one of the four criteria above and that are listed on the CLFS are paid under the CLFS, rather than being packaged and paid for under the OPPS.

D. ADLTs Under the New Private Payor Rate-Based CLFS

Section 1834A of the Act, as established by section 216(a) of Public Law 113–93, the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. Section 216(a) of PAMA also established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. In the CLFS final rule published in the **Federal Register** on June 23, 2016, entitled ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System Final

Rule'' (81 FR 41036), we implemented the requirements of section 1834A of the Act.

As defined in § 414.502, an ADLT is a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory, and cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. Also, an ADLT must meet either Criterion (A), which implements section 1834A(d)(5)(A) of the Act, or Criterion (B), which implements section 1834A(d)(5)(B) of the Act, as follows:

- *Criterion (A):* The test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins; when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies); provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and may include other assays.

Or:

- *Criterion (B):* The test is cleared or approved by the FDA.

Generally, under the revised CLFS, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, updates to ADLT payment rates occur annually instead of every 3 years. The payment methodology for ADLTs is detailed in the June 23, 2016 CLFS final rule (81 FR 41076 through 41083). For additional information regarding ADLTs, we refer readers to the CMS website: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html*.

E. Additional Laboratory DOS Policy Exception for the Hospital Outpatient Setting

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59393 through 59400), we established an additional exception at § 414.510(b)(5) so that the DOS for molecular pathology tests and certain ADLTs that are excluded from the OPPS packaging policy is the date the test was performed (instead of the date of specimen collection) if certain conditions are met. Under the exception that we finalized at § 414.510(b)(5), in the case of a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502, the DOS of the test must be the date the test was performed only if:

- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59397), we explained that we believed the laboratory DOS policy in effect prior to CY 2018 created administrative complexities for hospitals and laboratories with regard to molecular pathology tests and laboratory tests expected to be designated by CMS as ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. We noted that under the laboratory DOS policy in effect prior to CY 2018, if the tests were ordered less than 14 days following a hospital outpatient's discharge from the hospital outpatient department, laboratories generally could not bill Medicare directly for the molecular pathology test or ADLT. In those circumstances, the hospital had to bill Medicare for the test, and the laboratory had to seek payment from the hospital. We noted that commenters informed us that because ADLTs are performed by only a single laboratory and molecular pathology tests are often performed by only a few laboratories, and because hospitals may not have the technical ability to perform these complex tests, the hospital may be reluctant to bill Medicare for a test it would not typically (or never) perform. The commenters also stated that as a result, the hospital might delay ordering the test until at least 14 days after the patient is discharged from the hospital outpatient department, or even cancel the order to avoid the DOS policy, which may restrict a patient's timely access to these tests. In addition, we noted that we had heard from commenters that the laboratory DOS policy in effect prior to CY 2018 may have disproportionately limited access for Medicare beneficiaries under Medicare Parts A and B, because Medicare Advantage plans under Medicare Part C and other private payors allow laboratories to bill directly for tests they perform.

We also recognized that greater consistency between the laboratory DOS rules and the current OPPS packaging policy would be beneficial and would address some of the administrative and billing issues created by the DOS policy in effect prior to CY 2018. We noted that we exclude all molecular pathology tests and ADLTs under section 1834A(d)(5)(A) of the Act from the OPPS packaging policy because we believe these tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged, and we had already established exceptions to the DOS policy that permit the DOS to be the date of performance for certain tests that we believe are not related to the hospital treatment and are used to determine posthospital care. We stated that we believed a similar exception is justified for the molecular pathology tests and ADLTs excluded from the OPPS packaging policy, which we understood are used to guide and manage the patient's care after the patient is discharged from the hospital outpatient department. We noted that we believed that, like the other tests currently subject to DOS exceptions, these tests can legitimately be distinguished from the care the patient receives in the hospital, and thus we would not be unbundling services that are appropriately associated with hospital treatment. Moreover, we reiterated that these tests are already paid separately outside of the OPPS at CLFS payment rates. Therefore, we agreed with the commenters that the laboratory performing the test should be permitted to bill Medicare directly for these tests, instead of relying on the hospital to bill Medicare on behalf of the laboratory under arrangements.

Following publication of the CY 2018 OPPS/ASC final rule with comment period, we issued Change Request (CR) 10419, Transmittal 4000, the claims processing instruction implementing the laboratory DOS exception at § 414.510(b)(5), with an effective date of January 1, 2018 and an implementation date of July 2, 2018. After issuing CR 10419, we heard from stakeholders that many hospitals and laboratories were having administrative difficulties implementing the DOS exception set forth at § 414.510(b)(5). On July 3, 2018, we announced that, for a 6-month period, we would exercise enforcement discretion with respect to the laboratory DOS exception at § 414.510(b)(5). We explained that stakeholder feedback suggested many providers and suppliers would not be able to implement the laboratory DOS exception by the July 2, 2018 implementation date established

by CR 10419, and that such entities required additional time to develop the systems changes necessary to enable the performing laboratory to bill for tests subject to the exception. We noted that this enforcement discretion would apply to all providers and suppliers with regard to ADLTs and molecular pathology tests subject to the laboratory DOS exception policy, and that during the enforcement discretion period, hospitals may continue to bill for these tests that would otherwise be subject to the laboratory DOS exception.

We then extended the enforcement discretion period for two additional, consecutive 6-month periods, after learning that there were still many entities needing additional time to come into compliance. The final enforcement discretion announcement as well as CR 10419, Transmittal 4000 is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html*. The enforcement discretion period ended on January 2, 2020.

During the period of enforcement discretion, we continued to gage the industry's readiness to implement the laboratory DOS exception at § 414.510(b)(5). In particular, we heard from stakeholders that some entities performing molecular pathology testing subject to the laboratory DOS exception, such as blood banks and blood centers, may not be enrolled in the Medicare program and may not have established a mechanism to bill Medicare directly. In the CY 2020 OPPS/ASC proposed rule (84 FR 39603), we sought comments on excluding blood banks and blood centers from the laboratory DOS exception at § 414.510(b)(5). Based on concerns raised by stakeholders, we stated that we believe blood banks and centers perform molecular pathology testing for patients to enable hospitals to prevent adverse conditions associated with blood transfusions, rather than perform molecular pathology testing for diagnostic purposes. Given the different purpose of molecular pathology testing performed by the blood banks and centers, that is, blood compatibility testing, we questioned whether the molecular pathology testing performed by blood banks and centers is appropriately separable from the hospital stay, given that it typically informs the same patient's treatment during a future hospital stay. We stated that we were concerned that our current policy may unbundle molecular testing performed by a blood bank or center for a hospital patient.

For these reasons, and based on the support received from commenters, in the CY 2020 OPPS/ASC final rule (84 FR 61444), we finalized a revision to the laboratory DOS policy to exclude molecular pathology tests when performed by laboratories that are blood banks or centers from the laboratory DOS exception at 42 CFR 414.510(b)(5). We also finalized a definition for ''blood bank or center'' at § 414.502 as an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation.

A list of the specific laboratory tests currently subject to the laboratory DOS exception at § 414.510(b)(5) is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html*.

F. Revisions to the Laboratory DOS Policy for Cancer-Related Protein-Based MAAAs

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61438 through 61439), we explained that protein-based Multianalyte Assays with Algorithmic Analyses tests (MAAAs) that are not considered molecular pathology tests and are not designated as ADLTs under paragraph (1) of the definition of ADLT in § 414.502, were packaged under the OPPS at that time. Though they did not qualify for the DOS exception at § 414.510(b)(5) solely because they were MAAAs, we noted that several stakeholders had suggested that the pattern of clinical use of some of these protein-based MAAAs make them relatively unconnected to the primary hospital outpatient service.

In particular, stakeholders suggested that certain protein-based MAAAs, specifically, those described by CPT codes 81490, 81503, 81535, 81536, 81538, and 81539, are generally not performed in the HOPD setting and have similar clinical patterns of use as other tests that are not paid under the OPPS and are paid separately under the CLFS, and so should be treated similarly (82 FR 59299). Consequently, the stakeholders believed that protein-based MAAAs should be excluded from OPPS packaging and paid separately under the CLFS. Notably, with one exception (CPT code 81490), each of those tests described by the CPT codes identified by stakeholders was a cancer-related protein-based MAAA. We did not establish an exception to the laboratory DOS policy for protein-based MAAAs in the CY 2020 OPPS/ASC final rule with comment period, but we did note that a protein-based MAAA that is designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502 would be eligible for the DOS exception at § 414.510(b)(5). We indicated in that rule that we intended to consider policies regarding the application of the DOS policy to MAAAs for future rulemaking (84 FR 61439).

In the CY 2021 OPPS/ASC proposed rule (85 FR 49032 through 49036), we stated that after further consideration of this issue, we now believe certain MAAAs, specifically, cancer-related protein-based MAAAs, which stakeholders identified, as discussed above, have a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected because the results of these tests are typically used to determine posthospital care. We stated that these tests are distinguishable from the care the patient receives in the hospital, similar to molecular pathology tests and tests designated as ADLTs under paragraph (1) of the definition of ADLT in § 414.502, which are currently excluded from the OPPS packaging policy and subject to the laboratory DOS exception at § 414.510(b)(5). Therefore, we proposed to exclude cancer-related protein-based MAAAs from the OPPS packaging policy, as discussed in section II.a.3. of the CY 2021 OPPS/ASC proposed rule, and create an exception to the laboratory DOS rule for them. We noted that these proposals, if finalized, would mean that Medicare would pay for cancer-related protein-based MAAAs under the CLFS instead of the OPPS and the performing laboratory would bill Medicare directly for the test if the test meets all the laboratory DOS requirements specified in § 414.510(b)(5).

We further explained in the CY 2021 OPPS/ASC proposed rule (85 FR 49036) that we understand that, similar to molecular pathology tests and ADLTs under paragraph (1) of the definition of an ADLT in § 414.502, cancer-related protein-based MAAAs are typically used to guide and manage the patient's care after the patient is discharged from the hospital outpatient department because the test results are used to determine potential future oncologic surgical and chemotherapeutic interventions; they would almost never affect the treatment regimen during the same hospital outpatient service in which the specimen was collected, even if the results were available immediately. In other words, decisions as to particular therapies and/or surgical procedures, as guided by the results of

the test, are not made during the same hospital outpatient encounter during which the specimen was collected.

For these reasons, we proposed to add cancer-related protein-based MAAAs to our current laboratory DOS exception rule at § 414.510(b)(5). Under this proposed revision, the DOS for a cancer-related protein-based MAAA would be the date the test was performed if: (1) The test was performed following a hospital outpatient's discharge from the hospital outpatient department; (2) the specimen was collected from a hospital outpatient during an encounter (as both are defined in § 410.2); (3) it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (4) the results of the test do not guide treatment provided during the hospital outpatient encounter; and (5) the test was reasonable and medically necessary for the treatment of an illness.

We noted that this proposed revision to our laboratory DOS policy would require laboratories performing cancer-related protein-based MAAAs, that are excluded from the OPPS packaging policy and meet the DOS requirements at § 414.510(b)(5), to bill Medicare directly for those tests instead of seeking payment from the hospital. We stated that, similar to molecular pathology tests and ADLTs under paragraph (1) of the definition of ADLT in § 414.502, we believe that cancer-related protein-based MAAAs are distinguishable from the care the patient receives during the primary hospital outpatient encounter because, as noted above, the results of the test would almost never affect the treatment regimen during the same hospital outpatient encounter in which the specimen was collected. Therefore, we noted, if we were to finalize our proposal, we believe we would not be unbundling laboratory tests that are appropriately associated with the primary hospital outpatient service.

As discussed in section II.a.3. of the CY 2021 OPPS/ASC proposed rule, the AMA CPT 2020 manual describes a MAAA, in part, as ''procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid based assays (for example, proteins, polypeptides, lipids, carbohydrates).'' Additionally, the AMA CPT 2020 manual provides a MAAA code descriptor format that includes several specific characteristics, including but not limited to disease type (for example, oncology, autoimmune, tissue rejection), and material(s) analyzed (for example, DNA, RNA, protein, antibody). We noted in the proposed rule that, because the AMA CPT 2020 manual describes a MAAA, and the code descriptor of each MAAA distinguishes MAAAs that are cancer-related assays from those that test for other disease types, the AMA CPT manual is a potentially instructive tool to identify cancer-related MAAA tests that are ''protein-based''. Accordingly, we stated that using the AMA CPT 2020 manual criteria to identify MAAA tests that are cancer-related, and, of those tests, identifying the ones whose test analytes are proteins, we have determined there are currently six cancer-related protein-based MAAAs: CPT codes 81500, 81503, 81535, 81536, 81538 and 81539. We also noted that CPT code 81538 has been designated as an ADLT under section 1834A(d)(5)(A) of the Act as of December 21, 2018, and therefore, is currently already subject to the laboratory DOS exception in § 414.510(b)(5). Therefore, the cancer-related protein-based MAAAs that we proposed to exclude from the OPPS packaging policy and subject to an exception from the laboratory DOS policy under our proposals are CPT codes 81500, 81503, 81535, 81536 and 81539. We stated that these tests have not been designated by CMS as ADLTs under paragraph (1) of the definition of ADLT in § 414.502 and so were not currently subject to the laboratory DOS exception in § 414.510(b)(5). We proposed to apply this policy to cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future.

We received approximately 40 public comments on the proposed modification to the laboratory DOS policy for cancer-related protein-based MAAAs. The following is a summary of the comments we received and our responses.

Comment: Generally, most commenters supported the proposed revisions to the laboratory DOS policy, expressing that changes to this policy will lead to improved beneficiary access to precision diagnostic tests and targeted treatment by removing barriers that once led to delayed and canceled laboratory test orders while also reducing hospital administrative burden. Commenters noted that excepting cancer-related protein-based MAAAs from the DOS policy and allowing laboratories to bill Medicare for them directly, will minimize delays in testing and enable patient diagnosis, treatment decision-making, and initiation of care to proceed without interruption or unnecessary delay.

Additionally, some commenters stated that cancer-related protein-based MAAA test codes almost never impact the treatment regimen during the same hospital outpatient service in which the specimen is collected, and the commenters therefore believe it is appropriate to exclude these services from the OPPS packaging policy, as discussed in section II.A. of this final rule, and include these test codes on the list of codes subject to the laboratory DOS exception.

Response: We appreciate the support from commenters for our proposed revisions to the laboratory DOS policy for cancer-related protein-based MAAAs. We agree that the expansion of the laboratory DOS policy exception at § 414.510(b)(5) to include cancer-related protein-based MAAAs is beneficial and appropriate, as these tests have a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected and the results of these tests are typically used to determine post-hospital care and generally reduces delay with respect to access to these tests and subsequent results.

Comment: Some commenters suggested that CMS consider expanding the list of codes excluded from OPPS packaging and adding to the list of tests included in the laboratory DOS exception at § 414.510(b)(5). Specifically, commenters recommended adding all AMA CPT Proprietary Laboratory Analysis (PLA) test codes that may have similar characteristics to AMA CPT MAAA test codes but are not currently categorized as AMA CPT MAAA test codes. Some commenters asserted that the AMA CPT Committee has clearly stated that MAAAs can be assigned PLA codes, and therefore the assignment of a PLA code by the AMA CPT, as opposed to a Category 1 CPT code under the MAAA section of the CPT Manual, should not dictate whether the code is included under the laboratory DOS exception at § 414.510(b)(5). Additionally, commenters suggested that CMS identify the protein-based MAAAs in the PLA section of the AMA CPT manual by determining which codes' descriptors include both multiple proteins and reference to an algorithm.

Commenters also noted that while PLA test codes are not automatically included under § 414.510(b)(5) and the outpatient laboratory packaging exclusion, some tests described by PLA codes are often included under these policies if they qualify as a molecular pathology test or Criterion A ADLT. Therefore, the commenters stated that CMS should continue its historical practice in applying the laboratory DOS policy and OPPS laboratory packaging exclusion to PLA test codes as occurs

with molecular pathology tests and ADLTs that have been assigned PLA codes.

One commenter also requested that CMS include in the laboratory DOS exception under § 414.510(b)(5) MAAA cancer tests of proteins or metabolites. The commenter stated that metabolite biomarkers such as increased levels of metanephrines in the blood or urine are used to diagnose adrenal cancers, such aspheochromocytoma, and represent new and ''under development'' diagnostic MAAA tests. Another commenter requested that CMS evaluate tests for diseases other than cancer to determine if the tests have a distinct pattern of clinical use that make them relatively unconnected to a patient's hospital encounter and therefore should be considered for policy modifications in future rulemaking. Another commenter suggested that CMS modify the regulatory language for the laboratory DOS to include both cancer-related protein-based or metabolite-based MAAA tests, stating that there is a continuum between proteins, amino acids, amino acid modifications or dimers, and metabolites, and drawing fine lines between these biochemical classes is not relevant for this policy.

Response: We appreciate the commenters' suggestions about other test codes that CMS should consider including under the laboratory DOS exception policy at § 414.510(b)(5). We note that our proposal in the CY 2021 OPPS/ASC proposed rule focused on certain protein-based MAAA tests identified by stakeholders. As we discuss previously, we started with the 6 MAAA tests brought to our attention and concluded that the subset of cancer-related protein-based MAAA tests are distinguishable from the care the patient receives during the primary hospital outpatient encounter because the results of the test would almost never affect the treatment regimen during the same hospital outpatient encounter in which the specimen was collected. Further, we explained that the AMA CPT manual easily identifies these tests, which made it straightforward to ensure we captured all cancer-related protein-based MAAA tests currently available.

With regard to PLA tests, according to the AMA CPT Committee, PLA codes ''are alpha-numeric CPT codes with a corresponding descriptor for labs or manufacturers that want to more specifically identify their test. Tests with PLA codes must be performed on human specimens and must be requested by the clinical laboratory or the manufacturer that offers the test.'' [365] We understand PLA codes were created by the AMA CPT Committee so laboratories and manufacturers could have corresponding descriptors to more specifically identify their test as required by PAMA. The PLA category as a whole does not address the clinical use of the test. Therefore, in order for CMS to consider certain PLA tests as potential additions to the DOS exception policy, CMS would need to establish that, like the molecular pathology tests and ADLTs currently excepted from the DOS policy under § 414.510(b)(5), the nature and function of all PLA tests are such that they are appropriately separable from the hospital outpatient encounter and therefore laboratory services for which the performing laboratory must bill Medicare. At this time, CMS cannot establish that every PLA test, MAAA test, or ''MAAA-like'' PLA test, including those that are protein-based, are generally used to guide treatment outside of the outpatient clinical encounter and have a distinct pattern of clinical use that make them relatively unconnected to a patient's hospital encounter. For example, there are currently over 240 codes in the PLA category. In contrast to non-PLA codes which are categorized into groups such as immunoassays, chemistry, molecular pathology tests, MAAAs, etc., PLAs are not separated in separate categories like Category 1 CPT codes. Additions to the PLA code list are frequent and the array of tests included in the PLA category is varied. As such, inclusion in the category of PLA codes alone does not provide sufficient basis for payment policy decisions categorically. However, we note that a protein-based MAAA test that is designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502 would be eligible for the laboratory DOS exception at § 414.510(b)(5).

Therefore, CMS does not believe that all PLA tests, MAAA tests, or ''MAAA-like'' PLA test codes, as a group, should be considered for the laboratory DOS exception at § 414.510(b)(5) at this time. However, we plan to continue to evaluate the laboratory DOS policy and consider whether any additional changes may be merited, and may consider proposing future changes to the laboratory DOS policy through notice-and-comment rulemaking.

Nevertheless, we continue to believe that cancer-related protein-based MAAA tests have a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected because the results of these tests are typically used to determine post-hospital care. In previous rulemakings, commenters have identified certain protein-based MAAAs and informed us that the cancer-related tests are typically used to guide and manage the patient's care after the patient is discharged from the hospital outpatient department and the test results generally are used to determine potential future oncologic surgical and chemotherapeutic interventions. We understand the results would almost never affect the treatment regimen during the same hospital outpatient service in which the specimen was collected, even if the results were available immediately. Consequently, decisions as to particular therapies and/or surgical procedures, as guided by the results of the test, generally are not made during the same hospital outpatient encounter during which the specimen was collected.

Consequently, we believe that cancer-related protein-based MAAA tests should be excluded from OPPS packaging and paid separately under the CLFS and included under the laboratory DOS exception policy at § 414.510(b)(5).

Comment: Commenters requested that we add several specific PLA codes to the laboratory DOS policy exception at § 414.510(b)(5) because they believe these tests meet the AMA CPT description of MAAA tests, analyze proteins, and/or are cancer-related, while also meeting the DOS standard of having a pattern of clinical use that is unrelated to the primary outpatient service when the specimen is collected at an outpatient encounter. Specifically, commenters recommended adding the OVERA test from Aspira Labs (CPT 0003U), EPI assay by Bio-Techne (CPT 0005U), TissueCypher assay from Cernostics (CPT 0108U), and KidneyIntelX (0105U).

Commenters asserted that the results of these tests are used to determine a longer-term care treatment for the patient, and the results are typically discussed at a follow up appointment with the ordering physician. Additionally, the commenters noted that the clinical use of these tests is similar to the clinical use of the cancer-related protein-based MAAA tests. Commenters stated that it would be inconsistent for CMS to require hospitals to bill Medicare for the PLA tests that commenters believe meet the AMA CPT description of MAAA tests, analyze proteins, and/or are cancer-related, and also demonstrate a pattern of clinical use that is unrelated to the

[365] *https://www.ama-assn.org/practice-management/cpt/cpt-pla-codes.*

primary outpatient service when the specimen is collected at an outpatient encounter, while requiring the performing laboratory to bill Medicare for the non-PLA cancer-related protein based MAAAs.

Response: We appreciate the commenters' suggestion that we consider adding the OVERA test from Aspira Labs (CPT 0003U), TissueCypher assay from Cernostics (CPT 0108U), EPI assay by Bio-Techne (CPT 0005U), and KidneyIntelX (CPT 0105U), to the laboratory DOS exception at § 414.510(b)(5). These PLA tests are relatively new, with none to minimal Medicare utilization, and at this time we do not have a sufficient understanding regarding how these tests may be used to guide treatment outside of the outpatient encounter and whether they should be unpackaged under OPPS. The tests would need to demonstrate a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected and the results of these tests are typically used to determine post-hospital care. At this time, we cannot establish that these tests would generally be utilized for guiding treatment outside of the hospital encounter. Nevertheless, we intend to continue to study the laboratory DOS policy and determine whether any additional changes are warranted and may consider proposing changes to the laboratory DOS policy through notice-and-comment rulemaking in the future.

Comment: Commenters also recommended the inclusion of a particular protein-based MAAA test, CPT code 81490, in the laboratory DOS exception at § 414.510(b)(5). Commenters asserted that the use of this rheumatoid arthritis (RA) test is unconnected to the hospital outpatient encounter during which the specimen is collected and is instead used to determine potential future interventions outside of the hospital outpatient encounter; it is used by the rheumatologist to make longer-term changes in RA treatment. The commenters stated that this RA test appears to be generally less tied to a primary service in the hospital outpatient setting and does not appear to be a common or routine laboratory test that would otherwise be packaged into OPPS payment.

Response: In the CY 2021 OPPS/ASC proposed rule (85 FR 48799), we stated that we believed the results for the test described by CPT code 81490 are used to determine disease activity in rheumatoid arthritis patients, guide current therapy to reduce further joint damage, and may be tied to the primary hospital outpatient service, that is, the hospital outpatient encounter during which the specimen was collected. Therefore, we stated that we believed that payment for CPT code 81490 remains appropriately packaged under the OPPS.

However, given commenter feedback, we are convinced that the pattern of clinical use for CPT code 81490 is generally unconnected to the hospital outpatient encounter during which the specimen is collected, as it is typically used to determine potential interventions outside of the hospital outpatient encounter and is generally used by the rheumatologist to make longer-term changes in RA treatment. Commenters informed us that physicians and patients utilize the objective information provided by the results of the test to make longer-term modifications in treatment, to monitor disease activity, and to prevent joint damage progression, and the results would generally not be utilized for the purposes of the hospital outpatient encounter. The commenters further stated that the output of the test is used to assess disease activity, including evaluating response to therapy, directing choice of second-line treatment in patients with inadequate response to the current first line therapy, and identifying patients in stable remission for therapy reduction. The test results appear to guide longer-term therapies and treatments; therefore, we believe that this test, identified by CPT code 81490, is generally less tied to the primary service the patient receives in the hospital outpatient setting and does not appear to be a common or routine laboratory test that would otherwise be packaged into OPPS payment. Given the similarity in clinical pattern of use, we believe that we have sufficient information to add CPT code 81490 to the list of tests included in the laboratory DOS exception at § 414.510(b)(5) at this time. In conclusion, for the reasons discussed previously in this section, we believe that cancer-related protein-based MAAAs, such as CPT codes 81500, 81503, 81535, 81536 and 81539, appear to have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged. Given the similarity in clinical pattern of use, we believe that CPT code 81490 should also be added to the list of tests in the laboratory DOS exception at § 414.510(b)(5). We believe these tests should therefore be excluded from OPPS packaging policy and subject to the laboratory DOS exception at § 414.510(b)(5) as described in section II.A. of this final rule. We intend to continue to study the list of laboratory tests included the laboratory DOS exception policy and to determine whether any additional changes are warranted and may consider proposing future changes to this policy through notice-and-comment rulemaking.

For these reasons and in light of the commenters' suggestions, we are revising the current laboratory DOS exception at 42 CFR 414.510(b)(5) to include cancer-related protein-based MAAAs, such as CPT codes 81500, 81503, 81535, 81536, 81539, as well as the test described by CPT code 81490. We are also finalizing that we will exclude cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future, from the laboratory DOS policy.

XIX. Physician-Owned Hospitals

A. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless all requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for any improperly referred designated health services. A financial relationship may be an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid.

Section 1877(d) of the Act sets forth exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes designated health services. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers (the ''rural provider exception''). In order to qualify for the rural provider exception, the designated health services must be

furnished in a rural area (as defined in section 1886(d)(2) of the Act), substantially all of the designated health services furnished by the entity must be furnished to individuals residing in a rural area, and, in the case where the entity is a hospital, the hospital meets the requirements of section 1877(i)(1) of the Act no later than September 23, 2011. Section 1877(d)(3) of the Act provides an exception for ownership or investment interests in a hospital located outside of Puerto Rico (the ''whole hospital exception''). In order to qualify for the whole hospital exception, the referring physician must be authorized to perform services at the hospital, the ownership or investment interest must be in the hospital itself (and not merely in a subdivision of the hospital), and the hospital meets the requirements of section 1877(i)(1) of the Act no later than September 23, 2011.

B. Prohibition on Facility Expansion

Section 6001(a)(3) of the Affordable Care Act amended the rural provider and whole hospital exceptions to provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the effective date of such provider agreement). Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act, which required the Secretary to establish and implement an exception process to the prohibition on expansion of facility capacity for hospitals that qualify as an ''applicable hospital.'' Section 1106 of the Health Care and Education Reconciliation Act of 2010 (HCERA) amended section 1877(i)(3)(A)(i) of the Act to require the Secretary to establish and implement an exception process to the prohibition on expansion of facility capacity for hospitals that qualify as either an ''applicable hospital'' or a ''high Medicaid facility.'' These terms are defined at sections 1877(i)(3)(E) and 1877(i)(3)(F) of the Act.

The requirements for qualifying as an applicable hospital are set forth at § 411.362(c)(2) and the requirements for qualifying as a high Medicaid facility are set forth at § 411.362(c)(3). An applicable hospital means a hospital: (1) That is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by the Bureau of the Census; (2) whose annual percent of total inpatient admissions under Medicaid is equal to or greater than the average percent with respect to such admissions for all hospitals in the county in hospital is located during the most recent 12-month period for which data are available (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity); (3) that does not discriminate against beneficiaries of federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries; (4) that is located in a state in which the average bed capacity in the state is less than the national average bed capacity; and (5) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located. The regulations at § 411.362(c)(2)(ii), (iv), and (v) specify acceptable data sources for determining whether a hospital qualifies as an applicable hospital. A ''high Medicaid facility'' means a hospital that: (1) Is not the sole hospital in a county; (2) with respect to each of the three most recent 12-month periods for which data are available, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and (3) does not discriminate against beneficiaries of federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. Section 411.362(c)(3)(ii) specifies the acceptable data sources for determining whether a hospital qualifies as a high Medicaid facility. In the CY 2012 OPPS/ASC final rule, we issued regulations setting forth the process for a hospital to request an exception from the prohibition on facility expansion (the exception process) at § 411.362(c) and related definitions at § 411.362(a) (76 FR 74122).

Section 1877(i)(3)(B) of the Act provides that the exception process shall permit an applicable hospital to apply for an exception to the prohibition on expansion of facility capacity up to once every 2 years. In the CY 2012 OPPS/ASC final rule, we extended this provision to high Medicaid facilities using our authority under sections 1871 and 1877(i)(3)(A)(1) of the Act (76 FR 74525). There, we stated that, although the statute provides that an applicable hospital may request an exception up to once every 2 years, we believe that providing a high Medicaid facility the opportunity to request an exception once every 2 years (while also limiting its total growth) balances the Congress' intent to prohibit expansion of physician-owned hospitals with the purpose of the exception to the prohibition on expansion of facility capacity (76 FR 74524). We did not receive any public comments regarding the frequency of exception requests. Under current § 411.362(c)(1), both applicable hospitals and high Medicaid facilities may request an exception to the prohibition on expansion of facility capacity up to once every 2 years from the date of a CMS decision on the hospital's most recent request.

Section 1877(i)(3)(C)(ii) of the Act provides that the Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed to the extent such increase would result in the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital. In the CY 2012 OPPS/ASC final rule, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we adopted a parallel limit in the increase in the number of operating rooms, procedure rooms, and beds for which a high Medicaid facility may request an exception to the prohibition on expansion of facility capacity (76 FR 74524). There, we noted that, in response to our request for comment on whether the 200 percent limit would be sufficient to balance the intent of the general prohibition on facility expansion with the purpose of the exception process, which is to provide the opportunity to expand in areas where a sufficient need for access to high Medicaid facilities is demonstrated, commenters supported our proposal regarding the amount of permitted increase and at least one commenter specifically supported the parallel treatment of high Medicaid facilities (76 FR 74524). Under current § 411.362(c)(6)(i), a 200 percent limitation applies to both applicable hospitals and high Medicaid facilities.

Section 1877(i)(3)(D) of the Act provides that any increase in the number of operating rooms, procedure rooms, and beds for which an applicable

hospital is licensed may occur only in facilities on the main campus of the applicable hospital. In the CY 2012 OPPS/ASC final rule, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we extended this limitation on the location of expanded facility capacity to high Medicaid facilities, explaining that we believe that applying the same limitation to applicable hospitals and high Medicaid facilities will result in an efficient and consistent process (76 FR 74524). We did not receive any public comments regarding the location of the permitted increase. Under current § 411.362(c)(6)(ii), expanded facility capacity may occur only in facilities on the hospital's main campus.

In 2017, CMS launched the Patients over Paperwork initiative, a crosscutting, collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience. This effort emphasizes a commitment to removing regulatory obstacles to providers spending time with patients. As part of this initiative, we reviewed the regulations at § 411.362(c) as they apply to high Medicaid facilities. Certain of the statutory provisions regarding expansion of facility capacity apply only to applicable hospitals and their extension to high Medicaid facilities was effectuated using the Secretary's authority under sections 1871 and 1877(i)(3)(A)(i) of the Act. We continue to believe that our current regulations, for which the Secretary appropriately used his authority and which treat high Medicaid facilities the same as applicable hospitals, are consistent with the Congress' intent to prohibit expansion of physician-owned hospitals generally. Nevertheless, the Congress did not mandate this treatment of high Medicaid facilities and, in light of the Patients over Paperwork initiative, we reconsidered our policies. As we stated in the proposed rule, we believe that our current regulations impose unnecessary burden on high Medicaid facilities, which, by definition, serve significant numbers of Medicaid patients relative to other hospitals in the counties in which they are located (85 FR 49038). Because the statute does not apply to high Medicaid facilities those requirements related to the frequency of permitted requests for exceptions to the prohibition on expansion of facility capacity, the total amount of permitted expansion of facility capacity, or the location of permitted expanded facility capacity, using the Secretary's authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we proposed to remove certain regulatory requirements for high Medicaid facilities that are not included in the statute. Specifically, we proposed to revise § 411.362(c)(1) to permit a high Medicaid facility to request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years. To preserve CMS resources and to continue to maintain an orderly and efficient exception process, we proposed that a high Medicaid facility may submit only one exception request at a time. Under proposed § 411.362(c)(1), a high Medicaid facility could request an exception to the prohibition on expansion of facility capacity at any time, provided that it has not submitted another request for an exception to the prohibition on facility expansion for which CMS has not issued a decision. We also proposed to revise § 411.362(c)(6), with respect to high Medicaid facilities only, to remove the restriction that permitted expansion of facility capacity may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds, as well as the restriction that permitted expanded facility capacity must occur only in facilities on the hospital's main campus. Under proposed § 411.362(c)(6), these restrictions would apply only to applicable hospitals.

Section 1877(i)(3)(A)(ii) requires CMS to provide an opportunity for community input when an applicable hospital applies for an exception to the prohibition on expansion of facility capacity. Through regulation, we made the community input opportunity applicable to facility expansion requests submitted by high Medicaid facilities (76 FR 74523). However, the statute does not expressly require CMS to furnish an opportunity for community input when a high Medicaid facility has applied for such an exception. In the proposed rule, we stated that we are considering whether we should eliminate the opportunity for community input in the review process with respect to high Medicaid facilities (85 FR 49038). We noted specific interest in comments regarding the importance of community input, which allows for confirmation of (or disagreement with) the data provided by a high Medicaid facility seeking an exception to the prohibition on expansion of facility capacity, and how CMS could obtain independent confirmation of the data provided by a high Medicaid facility in the absence of the community input opportunity (see 76 FR 74523). We also noted that obtaining independent confirmation of the data furnished by a high Medicaid facility could delay or add complexity to the review process. We solicited comments regarding whether the additional delay and complexity caused by the elimination of the community input opportunity for requests by high Medicaid facilities would result in greater burden or cause greater harm to high Medicaid facilities than continuing to permit community input on the expansion exception requests submitted by these hospitals.

We are finalizing without modification our proposals to remove the limitations on high Medicaid facilities with respect to the frequency of exception requests, permitted amount of facility expansion, and location of expansion capacity. We are not revising our regulations regarding community input on the expansion requests submitted by hospitals that qualify as high Medicaid facilities.

We received the following comments regarding our proposals and our responses follow:

Comment: Many commenters supported our proposals to eliminate from regulation any limitations on the expansion of facility capacity for high Medicaid facilities not mandated in section 1877 of the Act. Some of the commenters stated that removing existing regulatory limitations would allow physician-owned hospitals to serve greater numbers of Medicaid patients. One commenter suggested that expanded capacity of physician-owned hospitals could increase competition and choice, as well as patient access to high-quality care. Another commenter stated that, if finalized, the removal of the restrictions on high Medicaid facilities that receive an exception to the prohibition on expansion of facility capacity would help increase access to vital health care services for the most vulnerable patients.

In contrast, numerous commenters opposed our proposals to remove limitations on expansion of facility capacity imposed on high Medicaid facilities by regulation. Some commenters noted that certain physician-owned hospitals that qualify as high Medicaid facilities have Medicaid discharge percentages that are extremely low and potentially significantly lower than that of hospitals in surrounding counties where they could locate the large facility expansion capacity permitted under our proposals. Another commenter stated that, if we finalize our proposals, physician-owned

hospitals could expand and move into markets without large Medicaid patient populations, creating additional campuses far away from the patients the expansion is intended by statute to serve. This commenter also asserted that removing the restrictions on high Medicaid facilities could incentivize physician-owned hospitals to ''game the limited exception'' by working to temporarily meet the high Medicaid facility threshold, then, once an exception from the prohibition on expansion of facility capacity is obtained, return to rejecting Medicaid patients because there is no requirement for a physician-owned hospital to maintain its status as a high Medicaid facility following the approval of an exception request.

Response: The plain language of the statute does not impose the same limitations on the expansion of high Medicaid facilities as it does the expansion of applicable hospitals. Therefore, the Secretary is not required under section 1877(b)(4) of the Act to retain the limitations imposed on high Medicaid facilities by regulation. As we explained in the proposed rule, we believe that the existing regulations impose unnecessary burden on high Medicaid facilities. In alignment with our Patients over Paperwork initiative, we are finalizing our proposals to remove this unnecessary burden.

To determine whether a hospital qualifies as a high Medicaid facility, the statute requires a relativity analysis based on the location of the existing hospital; that is, a hospital that has the highest Medicaid discharge percentage relative to the hospitals in the same county will qualify as a high Medicaid facility even if the overall number of Medicaid discharges in the county is low. Although we understand the commenters' concerns regarding actions that a hospital may take after the Secretary grants an exception to the prohibition on facility expansion, as one of the commenters noted, neither the statute nor our regulations require that a hospital maintain its qualification as a high Medicaid facility for any minimum period of time after it requests or receives an exception to the prohibition on expansion of facility capacity. Similarly, the statute does not require the Secretary to compare a high Medicaid facility to the hospitals in the county where it plans to locate the expansion capacity (if approved). However, we emphasize that any expansion of facility capacity must be part of the hospital for which the exception is approved. Medicare rules and regulations regarding the location of hospital facilities, including the expansion capacity, such as distance limitations related to the location of off campus facilities and provider-based departments remain applicable. (See section 1833(t)(B)(i) of the Act and § 413.65(e)(3)(v)(F).) With respect to the concern that a hospital granted an exception would ''return to rejecting Medicaid patients,'' we note that a hospital that rejects (or otherwise discriminates against Medicaid beneficiaries) does not qualify as an applicable hospital or a high Medicaid facility and, thus, would not qualify for an exception to the prohibition on expansion of facility capacity. Under § 411.362(c)(2)(iii) and (c)(3)(iii), to qualify as an applicable hospital or a high Medicaid facility, respectively, which is the prerequisite to the approval of an exception to the prohibition on the expansion of facility capacity, a hospital may not discriminate against beneficiaries of federal health care programs and may not permit physicians practicing at the hospital to discriminate against such beneficiaries. Further, other federal and state laws and regulations, such as the Emergency Medical Treatment and Labor Act (EMTALA) and State Medicaid program rules and regulations, prohibit a hospital from refusing to care for or otherwise discriminate against Medicaid patients.

Comment: Several commenters cited studies that they asserted indicate that physician-owned hospitals present a risk of program or patient abuse. Other commenters cited studies that they asserted show the benefits of physician ownership of hospitals. The commenters that opposed our proposals highlighted various studies, including studies by the Congressional Budget Office, Medicare Payment Advisory Commission.[366] The aforementioned studies concluded that physician self-referral to facilities in which they have an ownership stake leads to greater *per capita* utilization of services and higher costs for the Medicare program. Two of these commenters also shared data from a 2017 study that found physician-owned hospitals cherry-pick patients by avoiding Medicaid and uninsured patients, treat fewer medically complex patients and have margins nearly three times those of nonphysician-owned hospitals.[367] The commenters stated that finalizing the proposals could lead to these abuses of the Medicare program and its beneficiaries. Some of the commenters who supported our proposals cited to a British Medical Journal study that concluded that physician-owned hospitals have similar quality and costs of care when compared to nonphysician-owned hospitals [368] and a study published by the Journal of the American College of Surgeons that concluded that physician-owned surgical hospitals outperform other hospitals in the Medicare value-based purchasing program.[369] One of these commenters quoted the December 2018 HHS report titled ''Reforming America's Healthcare System Through Choice and Competition'' in support of finalizing our proposals, noting HHS' statement that concerns about self-referral and cherry-picking ''may have been overstated, considering that many studies suggest physician-owned hospitals provide higher quality care and that patients benefit when traditional hospitals have greater competition.'' [370]

Response: As we understand the research into the risks and benefits of physician ownership in hospitals that was cited by the commenters, the studies' authors have differed in their conclusions regarding whether physician ownership in hospitals poses a risk of program or patient abuse and, thus, whether further or less regulation of physician-owned hospitals is warranted. Although we appreciate the concerns discussed in the studies cited by the commenters in opposition to our proposals, as discussed in the response to the previous comment, the plain language of the statute does not impose the same limitations on the expansion of high Medicaid facilities as it does the expansion of applicable hospitals, and we believe that the existing regulations impose unnecessary burden on high Medicaid facilities. In alignment with our Patients over Paperwork initiative, we are finalizing our proposals to remove this unnecessary burden.

Comment: Many commenters, including some that supported the proposals to eliminate other restrictions

[366] *https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/kylltrsec651ofhr3162.pdf* and *http://www.medpac.gov/docs/default-source/reports/Mar05_SpecHospitals.pdf?sfvrsn=0.*

[367] *https://www.fah.org/blog/analysis-highlights-need-to-maintain-law-banning-self-referral-to-physician.*

[368] Blumenthal, D., et al., ''Access, quality, and costs of care at physician owned hospitals in the United States: observational study'', British Medical Journal, 2015;351:h4466 (September 2, 2015); available at *http://www.bmj.com/content/bmj/351/bmj.h4466.full.pdf.*

[369] Ramirez AG, Tracci MC, Stukenborg GJ, Turrentine FE, Kozower BD, Jones RS. Physician-owned surgical hospitals outperform other hospitals in Medicare value-based purchasing program. J Am Coll Surg. 2016 Oct; 223(4):559–567; available at *https://www.journalacs.org/article/S1072-7515(16)30720-7/fulltext.*

[370] *https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.*

on high Medicaid facilities, recommended that CMS maintain the requirement for community input related to the request of a high Medicaid facility for an exception to the prohibition on expansion of facility capacity. The comments stated that community input is a valuable part of the expansion exception process. One commenter supported eliminating the community input requirement for high Medicaid facilities, noting that, according to a study entitled ''Specialty Versus Community Hospitals: Referrals, Quality, And Community Benefits,'' physician-owned specialty hospitals exhibit higher levels of net community benefits.[371] Neither this commenter, nor any other commenter, shared an alternative method for CMS to obtain independent confirmation of data provided by a high Medicaid facility in the absence of community input.

Response: We agree with the commenters that community input is vital to the expansion exception process and that it was the Congress' intent to include it. Moreover, we believe that it would significantly lengthen the expansion exception process to eliminate community input, as CMS would need to engage in additional independent verification activities, which is not in line with our burden reduction efforts and our Patients over Paperwork initiative. Therefore, we are not revising our regulations to eliminate the requirement for community input related to the request of a high Medicaid facility for an exception to the prohibition on expansion of facility capacity.

C. Deference to State Law for Purposes of Determining the Number of Beds for Which a Hospital Is Licensed

In order to qualify for the rural provider or whole hospital exception to the physician self-referral law, a hospital may not increase the aggregate number of operating rooms, procedure rooms, and beds above that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of March 23, 2010, but did have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless the Secretary has granted an exception to the prohibition on expansion of facility capacity under section 1877(i)(3) of the Act and § 411.362(c). The statute and our regulations refer to this number as the hospital's ''baseline number of operating rooms, procedure rooms, and beds.'' Thus, at the time a hospital wishes to qualify for the rural provider or whole hospital exception, it may not have an aggregate number of operating rooms, procedure rooms, and beds that exceeds its baseline number of operating rooms, procedure rooms, and beds (unless the Secretary has granted an exception).

Because the availability of the rural provider and whole hospital exceptions turns on whether a hospital has exceeded its baseline number of operating rooms, procedure rooms, and beds at the time of a physician's referral, a clear understanding of how to calculate the hospital's baseline number of operating rooms, procedure rooms, and beds is critical. Stakeholders have asked what CMS would consider the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement) under various state licensure schemes. We responded to formal advisory opinion requests in August 2019 (*https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2019-01-Redacted.pdf*) and March 2020 (*https://www.cms.gov/files/document/cms-ao-2020-01.pdf*) regarding the inclusion of certain operating rooms, procedure rooms, and beds in a hospital's baseline number of operating rooms, procedure rooms, and beds. In March 2020, we also published a Frequently Asked Question addressing stakeholder inquiries regarding the determination of the number of beds for which a hospital was licensed on March 23, 2010 (*https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf*).

The March 2020 Frequently Asked Question states:

Q: If a state's hospital licensure laws and regulations provide that a hospital may increase its licensed bed complement by a certain amount without prior approval of the state's licensing agency, what would CMS consider the number of beds for which the hospital was licensed on March 23, 2010 for purposes of section 1877(i)(1)(B) of the Social Security Act (the Act'') and 42 CFR 411.362(b)(2)?

A: As a general matter, neither section 1877 of the Act nor the physician self-referral regulations (42 CFR 411.350 through 411.389) preempt state licensure laws and regulations. In interpreting and applying the physician self-referral law, CMS defers to state law with respect to the determination of whether a bed is licensed as of a certain date. If the state would consider a bed to be ''licensed'' or within a hospital's ''bed complement'' on March 23, 2010, CMS would also consider the bed to be ''licensed'' or within a hospital's ''bed complement'' as of that date, regardless of the exact number printed on the hospital's physical license. To illustrate, assume that a state does not require prior approval from its licensing agency for a hospital to increase its bed complement by not more than ten beds or 10 percent of the total bed capacity, whichever is less, during a period of a license. However, the state requires notification of the change and that the hospital must at all times meet the physical plant, staffing, and all other requirements set forth in state law and regulations if additional beds are added. The license issued to the hospital on January 1, 2009 indicated that the hospital's bed complement was 100 beds. If the hospital increased its bed complement by 9 beds (to 109 beds) on January 1, 2010 and made no further changes to its bed complement prior to March 23, 2010, its baseline number of licensed beds on March 23, 2010 would be 109 for purposes of section 1877(i)(1)(B) of the Act and 42 CFR 411.362(b)(2), provided that the hospital made the appropriate notification to the state and the hospital at all times met the physical plant, staffing, and all other requirements set forth in state law and regulations after increasing its bed complement. The same would apply to any beds that a state considered to be licensed under its specific licensure scheme on March 23, 2010. Section 1877(i)(1)(B) of the Act limits the expansion of facility capacity of a hospital that wishes to qualify for the rural provider or hospital exceptions to the law's ownership or investment prohibition. (See section 1877(d)(2) and (3); 42 CFR 411.356(c)(1) and (3).) Specifically, section 1877(i)(1)(B) of the Act states that, among other things, to qualify for the rural provider or hospital exceptions, the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after March 23, 2010 is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010. For purposes of applying this provision of the physician self-referral law, we refer to the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 as the hospital's ''baseline.'' As stated

[371] *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.25.1.106.*

previously, we defer to state law with respect to the determination of whether a bed is licensed as of a certain date. However, in extraordinary circumstances, we may include additional beds when determining a hospital's ''baseline'' for purposes of section 1877 of the Act. See, for example, CMS–AO–2020–01 (*https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions*).

In order to ensure stakeholders' awareness of our interpretation regarding the determination of the number of beds for which a hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), we proposed to revise the definition of ''baseline number of operating rooms, procedure rooms, and beds'' at § 411.362(a) to include a statement that, for purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of state licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the state. We sought comments on our proposal to include this language in regulation text at § 411.362(a) generally, and specifically whether the inclusion of this language is necessary or could be perceived as inadvertently limiting the definition of ''baseline number of operating rooms, procedure rooms, and beds.'' We are finalizing our proposal to revise the definition of ''baseline number of operating rooms, procedure rooms, and beds.'' We received the following comment and our response follows.

Comment: A few commenters supported our proposal to codify the policy articulated in our existing Frequently Asked Question into regulation at § 411.362(a). We received no comments in opposition.

Response: Based on the comments and to facilitate stakeholder awareness of our policy that, for purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of state licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the state, we are finalizing our proposal. Under revised § 411.362(a), the definition of ''baseline number of operating rooms, procedure rooms, and beds'' states: baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). For purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of state licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the state.

XX. Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots

A. Background Section

Section 5506 of the Affordable Care Act (Pub. L. 111–148) added subsection (vi) to section 1886(h)(4)(H) of the Social Security Act (the Act) and modified language at section 1886(d)(5)(B)(v) of the Act, to instruct the Secretary of the Department of Health and Human Services (the Secretary) to establish a process to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Specifically, the Secretary is instructed to increase the full-time equivalent (FTE) resident caps for teaching hospitals based upon the FTE resident caps in teaching hospitals that closed ''on or after a date that is 2 years before the date of enactment'' (that is, March 23, 2008). In the CY 2011 OPPS final rule with comment period (75 FR 72212), we established regulations at 42 CFR 413.79(o) and an application process for qualifying hospitals to apply to CMS to receive direct graduate medical education (DGME) and indirect medical education (IME) FTE resident cap slots from the hospital that closed. We made certain modifications to those regulations in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50134). The procedures we established apply both to teaching hospitals that closed on or after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that close after August 3, 2010.

B. Notice of Closure of Westlake Community Hospital, Located in Melrose Park, IL, and the Application Process—Round 18

CMS has learned of the closure of Westlake Community Hospital, located in Melrose Park, IL (CCN 140240). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round of the section 5506 application and selection process. This round will be the 18th round (''Round 18'') of the application and selection process. Table 75 contains the identifying information and IME and DGME FTE resident caps for the closed teaching hospital, which are part of the Round 18 application process under section 5506 of the Affordable Care Act.

TABLE 75. IME and DGME FTE Resident Caps for Westlake Community Hospital

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap (including +/- MMA Sec. 422[1])	Direct GME FTE Resident Cap (including +/- MMA Sec. 422[1])
140240	Westlake Community Hospital	Melrose Park, IL	16984	August 14, 2019	36.87 - 0.54 = 36.33[2]	41.24 - 1.96 = 39.28[3]

[1] Section 422 of the MMA, Pub. L. 108-173, redistributed unused IME and DGME residency slots effective July 1, 2005.
[2] Westlake Community Hospital's 1996 IME FTE resident cap is 36.87. Under section 422 of the MMA, the hospital received a reduction of 0.54 to its IME FTE resident cap: 36.87 – 0.54 = 36.33
[3] Westlake Community Hospital's 1996 DGME FTE resident cap is 41.24. Under section 422 of the MMA, the hospital received a reduction of 1.96 to its DGME FTE resident cap: 41.24 – 1.96 = 39.28

C. Notice of Closure of Astria Regional Medical Center, Located in Yakima, WA, and the Application Process—Round 19

CMS has learned of the closure of Astria Regional Medical Center, located in Yakima, WA (CCN 500012). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round of the section 5506 application and selection process. This round will be the 19th round (''Round 19'') of the application and selection process. Table 76 contains the identifying information and IME and DGME FTE resident caps for the closed teaching hospital, which are part of the Round 19 application process under section 5506 of the Affordable Care Act.

TABLE 76. IME and DGME FTE Resident CAPS for Astria Regional Medical Center

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap (including +/- MMA Sec. 422[1])	Direct GME FTE Resident Cap (including +/- MMA Sec. 422[1])
500012	Astria Regional Medical Center	Yakima, WA	49420	January 15, 2020	3.74 + 8.29 = 12.03[2]	8.18 – 0.16 + 5.00 = 13.02[3]

[1] Section 422 of the MMA, Pub. L. 108-173, redistributed unused IME and DGME residency slots effective July 1, 2005.
[2] Astria Regional Medical Center's 1996 IME FTE resident cap is 3.74. Under section 422 of the MMA, the hospital received an increase of 8.29 to its IME FTE resident cap: 3.74 + 8.29 = 12.03. Note that the slots associated with an IME cap increase under section 422 of the MMA are paid under 42 CFR 412.105(d)(4) using a special multiplier of 0.66.
[3] Astria Regional Medical Center's 1996 DGME FTE resident cap is 8.18. Under section 422 of the MMA, the hospital received a reduction of 0.16 and an increase of 5.00 to its DGME FTE resident cap: 8.18 – 0.16 + 5.00 = 13.02. Note that the slots associated with a DGME cap increase under section 422 of the MMA are paid under 42 CFR 413.77(g) using the appropriate locality-adjusted national average per resident amount (PRA).

D. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days following notice to the public of a hospital closure (77 FR 53436). Therefore, hospitals that wish to apply for and receive slots from the above hospitals' FTE resident caps, must submit applications (Section 5506 Application Form posted on DGME website as noted at the end of this section) directly to the CMS Central Office no later than March 29, 2021. The mailing address for the CMS Central Office is included on the application form. Applications must be received by the CMS Central Office by the March 29, 2021 deadline date. It is not sufficient for applications to be postmarked by this date.

After an applying hospital sends a hard copy of a section 5506 slot application to the CMS Central Office mailing address, the hospital is encouraged to notify the CMS Central Office of the mailed application by sending an email to: *ACA5506application@cms.hhs.gov*. In the email, the hospital should state: ''On behalf of [insert hospital name and Medicare CCN#], I, [insert your name], am sending this email to notify CMS that I have mailed to CMS a hard copy of a section 5506 application under Round [18 or 19] due to the closure of [Westlake Community Hospital or Astria Regional Medical Center]. If you have any questions, please contact me at [insert phone number] or [insert your email address].'' An applying hospital should not attach an electronic copy of the application to the email. The email will only serve to notify the CMS Central Office to expect a hard copy

application that is being mailed to the CMS Central Office.

We have not established a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received by the deadline and notify applicants of our determinations as soon as possible. We refer readers to the CMS DGME website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME* to download a copy of the section 5506 application form (Section 5506 Application Form) that hospitals must use to apply for slots under section 5506 of the Affordable Care Act. Hospitals should also access this same website for a list of additional section 5506 guidelines for the policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

XXI. Radiation Oncology (RO) Model

A. Revised Model Performance Period for the Radiation Oncology Model

On September 29, 2020, we published a final rule in the **Federal Register** (85 FR 61114) entitled ''Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' that finalized the Radiation Oncology Model (RO Model, the Model). Since the publication of that rule, we have received feedback from stakeholders requesting that the RO Model be delayed due to concerns around implementing the RO Model during the public health emergency (PHE) for the Coronavirus disease 2019 (COVID–19) pandemic. These concerns included revenue losses for RO participants due to decreased patient volumes and lay-offs or staff reallocations due to the PHE. Specifically, RO participants have limited capacity to operationalize RO Model requirements this year because of the unprecedented PHE that continues to strain health care resources. To ensure that participation in the RO Model does not further strain RO participants' capacity, potentially hindering the delivery of safe and efficient health care to beneficiaries receiving radiotherapy (RT) services, we are finalizing the RO Model's Model performance period to begin on July 1, 2021. We believe that this will give RO participants an additional 6 months necessary to learn the RO billing requirements and train staff on new procedures for 2021, and as a consequence of the revised Model performance period, an additional 12 months to prepare for required quality measure and clinical data element reporting beginning in 2022. Additionally, under this delay, RO participants will have more time to understand their participant-specific case mix and historical experience adjustments and the payment they expect to receive under the RO Model.

The September 29, 2020 final rule's effective date is November 30, 2020 (85 FR 61114). This interim final rule with comment period revises the following regulations at 42 CFR part 512, which are to become effective on December 4, 2021: Number 25 amending definitions of Model performance period and Performance year (PY) at 42 CFR 512.205; number 26 amending 42 CFR 512.210(a) and (c); number 27 amending 42 CFR 512.217 (c); number 28 amending 42 CFR 512.220(b); number 29 amending 42 CFR 512.245(a); number 30 amending 42 CFR 512.255(c)(10); and number 31 amending 42 CFR 512.285(d).

This interim final rule with comment period revises the following RO Model policies. The Model performance period will be 4.5 years, beginning on July 1, 2021, and ending December 31, 2025. PY1 will be 6 months, beginning on July 1, 2021, and ending on December 31, 2021; each subsequent PY will be a full calendar year, beginning on January 1 and ending on December 31. Revising the Model performance period requires revising other components of the RO Model including: How episodes and RO episodes are used to determine eligibility for the low volume opt-out for PY3 and RO episodes are used to determine eligibility for the low volume opt-out for PY4 through PY5; Certified Electronic Health Record Technology (CEHRT) requirements; submission of quality measures and clinical data elements; the quality withhold; quality reconciliation amount; and the status of the RO Model as an Advanced APM and MIPS APM.

We finalized at § 512.205 the RO Model's Model performance period to last five performance years, beginning January 1, 2021 and ending December 31, 2025 (with each performance year being the 12-month period beginning on January 1 and ending on December 31 of each year during the Model performance period. In this interim final rule with comment period, we are revising the Model performance period to be 4.5 years beginning July 1, 2021 and ending December 31, 2025.

A 4.5-year Model performance period will still be sufficient to test the proposed prospective payment approach, stimulate the development of new evidence-based knowledge, acquire additional knowledge related to patterns of inefficient utilization of health care services, and formulate methods to incentivize the improvement of high-quality delivery of RT services. A Model performance period of 4.5 years will provide RO participants an additional 6 months to address implementation issues prior to the start of the Model performance period. It will also provide sufficient time for the Model evaluation pursuant to section 1115A(b)(4) of the Social Security Act (the Act) to obtain sufficient data to compute a reliable impact estimate and to determine next steps regarding potential expansion or extension of the Model. Based upon the updated savings projection (see section XXVI.C.10) and accounting for the reduced number of cumulative episodes accrued in PY1 since the final rule was published (85 FR 61149), CMS determined that the Model savings will be able to reach the 3.75 percent level that is the threshold indicated by the Model power analysis enabling the evaluation to detect with statistical significance that level of impact. Starting the Model performance period on July 1, 2021 will not require a re-randomization of participation and will not affect the list of participating ZIP Codes posted on the RO Model website. Notably, the RO Model's evaluation will analyze data on the impact of the RO Model on an ongoing basis. To the extent that evaluation results are definitive sooner than the end of the RO Model, we will consider next steps at that time rather than waiting until the RO Model ends.

Because we are revising the Model performance period to begin July 1, 2021, both episodes and RO episodes from 2021 will determine eligibility for the low volume opt-out for PY3. To clarify the type of episodes used to determine eligibility for the low volume opt-out in each performance year, 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. We are revising our regulations at §§ 512.210(c) and 512.245(a) to reflect this clarification.

Because we finalized the specifications for the RO Model quality measure reporting to be based on a calendar year of data (85 FR 61220 through 61223), the RO Model quality

measures requirements will be delayed to PY2 (January 1, 2022 through December 31, 2022). RO participants will submit quality measure data finalized in the 2020 Specialty Care Models to Improve Quality of Care and Reduce Expenditures final rule (85 FR 61215 through 61220), unless CMS specifies different individual measure specifications.

The revised Model performance period requires modifications to the RO Model's form, manner, and timing policy for data reporting. We finalized that, beginning in PY1, RO participants must submit quality measure data annually by March 31 following the end of the previous PY to the RO Model secure data portal, with the first annual submission in March 2022 and continuing thereafter (85 FR 61220 through 61223). This interim final rule with comment period revises this policy so that RO participants must, beginning in PY2, submit in March 2023 quality measures data from January 1, 2022, through December 31, 2022.

For PY2, three measures will be pay-for-performance: (1) Plan of Care for Pain; (2) Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan. The fourth measure, Treatment Summary Communication—Radiation Oncology, will be a pay-for-reporting measure. Data collected for this measure will be used to propose a benchmark to re-specify it as a pay-for-performance measure, for PY4. All four measures will still be scored in accordance with our Aggregate Quality Scoring Methodology (85 FR 61226 through 61231).

We also finalized to 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). This interim final rule with comment period revises this policy so that a CMS-approved contractor will administer the CAHPS® Cancer Care Survey for Radiation Therapy beginning in October 2021.

We finalized under the Model's clinical data collection policy that RO participants must collect certain clinical information not available in claims or quality measures, with data collecting starting in PY1 (85 FR 61223 through 61226). This interim final rule with comment period revises this policy so that the collection period for clinical data elements (CDEs) will begin on January 1, 2022. The first submission of the clinical data elements for January 1, 2022, through June 30, 2022, will be due in July 2022.

We finalized at § 512.255(c)(10) to 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. RO participants may earn back this withhold, in part or in full, based on their AQS. Since this interim final rule with comment period delays the reporting of quality measures (QM) and CDEs until PY2, there will be no quality withhold in PY1. Beginning in PY2, a 2 percent quality withhold for the PC will be applied to the applicable trended national base rates after the case mix and historical experience adjustments. Accordingly, § 512.255(c)(10) is revised.

Revising the quality reporting requirements and quality withhold requires revising the reconciliation payment and the repayment amounts calculations for PY1, as described at § 512.285(d). Since submission of QMs and CDEs will begin in PY2, the AQS will be applied beginning in PY2, and Professional participants and Dual participants will not have a quality reconciliation amount for PY1. The reconciliation amount for PY1 will be based solely on the incorrect episode payment reconciliation amount and any stop-loss reconciliation amount, if applicable. Professional participants and Dual participants will have a quality reconciliation amount only for PY2 through PY5. Accordingly, § 512.285(d) is revised.

We have previously stated that we expect the RO Model will meet the criteria to be an Advanced Alternative Payment Model (APM) and a Merit-based Incentive Payment System (MIPS) APM under the Quality Payment Program beginning in PY1 (85 FR 61231 through 61238). Because we are revising the quality measure policy so that quality measure data will not be collected in PY1, the RO Model will not meet the criteria to be either an Advanced APM or a MIPS APM under the Quality Payment Program in PY1. We anticipate 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 (January 1, 2022). Effective January 1, 2022, at least one of the quality measures upon which the RO Model bases payment will meet at least one of the following criteria: (a) Finalized on the MIPS final list of measures, as described in 42 CFR 414.1330; (b) endorsed by a consensus-based entity; or (c) determined by CMS to be evidenced-based, reliable, and valid. 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/*.

For PY1, all requirements concerning the review and certification of the individual practitioner list codified at § 512.217 will remain in effect, but because the RO Model will not meet the criteria to be either an Advanced APM or a MIPS APM under the Quality Payment Program in PY1, the individual practitioner list will not be used for Qualifying APM Participant determinations or for determining participants in a MIPS APM for purposes of MIPS reporting and scoring rules in PY1. The individual practitioner list will 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. Starting in PY2 (January 1, 2022), the individual practitioner list will be used to identify the relevant eligible clinicians for purposes of making Qualifying APM Participant (QP) determinations and for certain aspects of MIPS under the Quality Payment Program. Dual participants and Professional participants must review and certify the individual practitioner list within 30 days of receipt of the individual practitioner list that is created and provided by CMS. Accordingly, § 512.217(c) is revised.

We finalized at § 512.220(b) that the requirement that RO participants must use CEHRT in a manner sufficient to meet the applicable requirements of the Advanced APM criteria before each PY. Due to the revised Model performance period, this requirement that RO participants must use CEHRT in a manner sufficient to meet the applicable requirements of the Advanced APM criteria will now begin in PY2, on January 1, 2022, and be required for PY2 through PY5. RO participants must annually certify their use of CEHRT for PY2 through PY5, and RO participants will be required to certify their use of CEHRT within 30 days of the start of PY2. Delaying the quality reporting and CEHRT use requirements until PY2 means that the RO Model will not meet the criteria to be considered an Advanced APM in PY1. Therefore, RO participants will not be eligible for the 5 percent APM Incentive Payment for QPs in PY1 based on their participation in the RO Model.

We note that there is a 60-day public comment period following publication of this final rule for the public to comment on these final amendments to our regulations. We refer readers to the **ADDRESSES** section of the final rule for instructions on submitting public comments. Comments are due by the

''Comment date'' specified in the **DATES** section of this rule.

B. Waiver of Proposed Rulemaking

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of proposed rulemaking that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved in the **Federal Register** before the provisions of a rule take effect. Section 553(c) of the APA further requires the agency to give interested parties opportunity to participate in the rulemaking through public comments before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary of the Department of Health and Human Services (Secretary) to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize the agency to waive these procedures if the agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

At the time of this publication, the U.S. continues to respond to a PHE of unprecedented magnitude. Specifically, the nation is responding to an outbreak of ''severe acute respiratory syndrome coronavirus 2'' (SARS–CoV–2), the disease it causes has been named ''coronavirus disease 2019'' (COVID–19).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of International Concern''.[372] On January 31, 2020, pursuant to section 319 of the Public Health Services Act (42 U.S.C. 247d), the Secretary declared a PHE for the U.S., retroactively effective from January 27, 2020, to aid the nation's health care community in responding to COVID–19.[373] On March 11, 2020, the WHO publicly declared COVID–19 a pandemic.[374] On March 13, 2020, President Donald J. Trump declared the COVD–19 pandemic a national emergency.[375] Effective July 25, 2020, the Secretary renewed the January 31, 2020 determination that was previously renewed on April 21, 2020, that a PHE for COVID–19 exists and has existed since January 27, 2020.[376] October 2, 2020, the Secretary renewed the January 31, 2020, PHE for COVID–19 determination effective October 23, 2020.[377] As with each PHE declaration, this renewal of the PHE for COVID–19 determination lasts until the Secretary declares that the PHE no longer exists or upon the expiration of the 90-day period beginning on the date the Secretary declared a PHE exists, whichever occurs first.

On September 29, 2020, we published a final rule entitled ''Specialty Care Models To Improve Quality of Care and Reduce Expenditures'' (Specialty Care Models Rule) in the **Federal Register** (85 FR 61114). In the Specialty Care Models Rule, we adopted a Model performance period that begins on January 1, 2021. At the time of the Specialty Care Models Rule publication, had the Secretary's renewal of the PHE effective July 25, 2020 lasted 90 days, it would have ended prior to the beginning of the Model's performance period.

The COVID–19 pandemic continues to strain health care resources, and CMS understands that those selected for participation in the RO Model may have limited capacity to continue normal operations while also preparing to meet the requirements set forth in the RO Model. We understand that many RO participants have had to furlough or cut staff. Revising the Model performance period to begin July 1, 2021, would provide RO participants with an additional 6 months prior to the start of the Model performance period to operationalize the RO Model while continuing to respond to the COVID–19 pandemic.

We do not presume to know when the Secretary will declare that the PHE no longer exists, but we are erring on the side of caution that this most recent renewal of the PHE for COVID–19 will most likely extend for the entire 90-day period. By erring on the side of caution, this most recent renewal period by the Secretary will likely overlap with the beginning of the RO Model's Model performance period, January 1, 2021. Because of the current state of the pandemic, this most recent renewal of the PHE for COVID–19, and the effect of the PHE on RO participants, we are revising the RO Model's Model performance period to begin on July 1, 2021 and to now be 4.5 years instead of 5 years. As we are still in the midst of the PHE, we find good cause to waive notice and comment rulemaking as we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment rulemaking procedures, as that would delay giving RO participants adequate time to respond to the ongoing impacts of COVID–19 while also preparing for participation in the RO Model.

Revising the Model performance period to begin on July 1, 2021, will require modifying other RO Model requirements, including those related to the types of episodes used to determine eligibility for the low volume opt-out for PY3, CEHRT requirements, submission of quality measures and clinical data elements, the quality withhold, quality reconciliation amount, eligibility for the low volume opt-out, and the status of the RO Model as an Advanced APM and MIPS APM.

We find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act. We find the notice and comment procedure impracticable and contrary to the public interest because, based on the Secretary's recent renewal of the PHE for the COVID–19, it is in the public's interest to revise the Model performance period in order to provide RO participants an additional 6 months prior to the start of the Model performance period to prepare for participation in the RO Model to ensure that the RO Model does not potentially hinder delivery of safe and efficient delivery of RT services to RO beneficiaries. Therefore, we find good cause to waive notice-and-comment procedures and to issue this interim final rule with comment period. We are providing a 60-day public comment period as specified in the **DATES** section of this document.

[372] *https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).*

[373] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[374] *https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.*

[375] *https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.*

[376] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx; https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx.*

[377] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx.*

XXII. COVID–19 Therapeutic Inventory and Usage Data Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) and Reporting Requirements for Hospitals and CAHs To Report Acute Respiratory Illness During the PHE for COVID–19 Interim Final Rule With Comment Period (IFC)

A. Conditions of Participation (CoP) Requirements for Hospitals and CAHs To Report COVID–19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness Data As Specified by the Secretary During the PHE for COVID–19

Under sections 1866 and 1902 of the Social Security Act (the Act), providers of services seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary or the state Medicaid agency, as appropriate. Hospitals (all hospitals to which the requirements of 42 CFR part 482 apply, including short-term acute care hospitals, long-term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, cancer hospitals, and children's hospitals) and CAHs seeking to be Medicare and Medicaid providers of services must be certified as meeting federal participation requirements. Our conditions of participation (CoPs), conditions for coverage (CfCs), and requirements for long term care facilities set out the patient health and safety protections established by the Secretary for various types of providers and suppliers. The specific statutory authority for hospital CoPs is set forth in section 1861(e) of the Act; section 1820(e) of the Act provides similar authority for CAHs. The hospital provision authorizes the Secretary to issue any regulations he or she deems necessary to protect the health and safety of patients receiving services in those facilities; the CAH provision authorizes the Secretary to issue such other criteria as he or she may require. The CoPs are codified in the implementing regulations at part 482 for hospitals, and at 42 CFR part 485, subpart F, for CAHs.

Our CoPs at 42 CFR 482.42 for hospitals and § 485.640 for CAHs, require that hospitals and CAHs, respectively, have active facility-wide programs for the surveillance, prevention, and control of healthcare-associated infections (HAIs) and other infectious diseases and for the optimization of antibiotic use through stewardship. Additionally, the programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable; and to best practices for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the required hospital and CAH programs must also be addressed in coordination with facility-wide quality assessment and performance improvement (QAPI) programs.

Infection prevention and control is a primary goal of hospitals and CAHs in their normal day-to-day operations, and these programs have been at the center of initiatives in hospitals and CAHs during the PHE for COVID–19. Our regulations at §§ 482.42(a)(3) and 485.640(a)(3) require infection prevention and control program policies to address any infection control issues identified by public health authorities. On March 4, 2020, we issued guidance (*https://www.cms.gov/files/document/qso-20-13-hospitalspdf.pdf-2*) stating that hospitals should inform infection prevention and control services, local and state public health authorities, and other healthcare facility staff as appropriate about the presence of a person under investigation for COVID–19. We followed this guidance with an interim final rule with comment (IFC),[378] published in the September 2, 2020 **Federal Register** (85 FR 54820), that requires hospitals and CAHs to report important data critical to support the fight against COVID–19. The CoP provisions require that hospitals and CAHs report this information in accordance with a frequency as specified by the Secretary on COVID–19, as well as in a standardized format specified by the Secretary. Examples of data elements that may be required to be reported include: The number of staffed beds in a hospital and the number of those that are occupied; information about its ventilator and personal protective equipment (PPE) supplies; and a count of patients currently hospitalized who have laboratory-confirmed COVID–19. This list is not exhaustive of those data items that we may require hospitals and CAHs to submit, as specified by the Secretary (see *https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf* for the current list of data items specified). In fact, as new therapeutics are issued Emergency Use Authorizations by the Food and Drug Administration, and because these new therapeutics are in very scarce supply in the United States, HHS is actively working with manufacturers to ensure that they are distributed efficiently and effectively. Effective distribution methods use a variety of indicators, tailored to the specific therapeutic, to estimate the geographic distribution that is recommended for that particular therapeutic. However, without a real-time and real-world understanding of the usage patterns specific to each new therapeutic and lacking accurate information on the current inventory on hand for that therapeutic, scarce therapeutic supplies might be sent to areas that already have adequate inventories on hand. An inefficient and uninformed distribution strategy for these therapeutics such as this negatively and severely impacts areas of the nation that already have inadequate supplies and creates an untenable situation as new therapeutics are introduced.

Therefore, we are revising our current COVID–19 PHE hospital and CAH CoP reporting requirements at 42 CFR 482.42(e) for hospitals and at 42 CFR 485.640(d) for CAHs, to now require hospitals and CAHs to report data elements that must include, but not be limited to, the following: (1) The hospital's (or the CAH's) current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the hospital (or CAH) under the authority and direction of the Secretary; and (2) the hospital's (or the CAH's) current usage rate for any COVID–19-related therapeutics that have been distributed and delivered to the CAH under the authority and direction of the Secretary.

All participating hosptials and CAHs will now track their inventory supplies and usage rates in real time for those COVID–19-related therapeutics that have been distributed and delivered by HHS so that public health officials will have a more robust and accurate database in order to efficiently and effectively manage the distribution and delivery ofthese therapeutics, particularly to those regions of the country that might be experiencing shortages of these crucial supplies. The importance of this particular data reporting, along with the information provided, cannot be overestimated as we continue to make advances to more effectively address the continuing COVID–19 PHE and to greatly diminish its negative impact on the nation.

In this IFC, we are also now requiring hospitals and CAHs to report information with a frequency, and in such standardized format as specified by the Secretary during the COVID–19 PHE, on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness,

[378] *https://www.govinfo.gov/content/pkg/FR-2020-09-02/pdf/2020-19150.pdf.*

and Severe Acute Respiratory Infection). Examples of data elements that we would ask to be reported include things such as diagnoses, admissions, and counts of patients currently hospitalized who have diagnoses of Acute Respiratory Illnesses (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection). In addition, as with the current COVID–19 reporting requirements, we firmly believe these elements are essential for planning, monitoring, and resource allocation during the PHE for COVID–19, especially as the nation enters the seasonal influenza season, when hospitals and CAHs are likely to see an increase in the number of patients presenting with the signs and symptoms of a variety acute respiratory illnesses along with a continuing and unknown number of patients presenting with both suspected and confirmed COVID–19. The new rules make reporting a requirement of participation in the Medicare and Medicaid programs and the required reporting is needed to support broad surveillance of COVID–19 in conjunction with other acute respiratory illnesses that may further burden and strain hospital and CAH resources.

We believe that universal acute respiratory illness reporting, in tandem with the current COVID–19 reporting, by all hospitals and CAHs, will be an important tool for supporting surveillance of COVID–19, as well as for future planning to prevent the spread of these respiratory viruses and infections, especially to those most vulnerable and at-risk. As with the current COVID–19 reporting requirements, we are cognizant of the crucial need for acute respiratory illness data reporting options to reduce duplicative and competing reporting requests and associated burden on hospitals and CAHs whose resources are already stressed during this PHE for COVID–19.

We expect that the new reporting data that will be requested by the Secretary would include reporting channel options similar to, if not the same as, those currently in place for COVID–19, to make submission of data as user-friendly as possible to reduce the potential strain and burden on hospitals and CAHs. The new standards will ask hospitals and CAHs to report information on Acute Respiratory Illness in a standardized format, frequency, and manner specified by the Secretary.

We believe that a streamlined approach to reporting data will greatly assist the White House Coronavirus Task Force (COVID–19 Task Force) in tracking the movement of these respiratory viruses and infections, along with the continuing movement of COVID–19. Similarly, this data may help identify potential problems in the healthcare delivery system as we continue to deal with COVID–19 cases along with potentially concurrent cases of respiratory viruses and infections. The completeness, accuracy, and timeliness of the data will inform the COVID–19 Task Force decisions on capacity and resource needs to ensure a fully coordinated effort across the nation. Furthermore, we believe that consistent processes and streamlined methods for the reporting of acute respiratory illness data in conjunction with the reporting of COVID–19 information will possibly reduce future, urgent requests for such data.

We note here that the new reporting requirements at §§ 482.42(f) and 485.640(e) do not relieve a hospital or a CAH, respectively, of its obligation to continue to comply with § 482.42(a)(3) or § 485.640(a)(3), each of which requires a facility to address any infection prevention and control issues identified by public health authorities. We believe that the requirements, as described in this IFC, to collect and transmit these data, will also encourage greater awareness and promotion of best practices in infection prevention and control within these facilities.

This reporting requirement supports our responsibility to protect and ensure the health and safety of hospital and CAH patients through, for example, ensuring that these facilities follow infection prevention and control protocols based on recognized standards of practice. We believe that these reporting requirements are necessary for CMS to monitor whether individual hospitals and CAHs are appropriately tracking, responding to, and mitigating the spread and impact of acute respiratory illnesses coupled with COVID–19 on patients, the staff who care for them, and the general public. We believe that this action reaffirms our commitment to protecting the health and safety of all patients who receive care at the approximately 6,200 Medicare- and Medicaid-participating hospitals and CAHs nationwide.

As discussed in section XXV.B of this IFC, ''Waiver of Proposed Rulemaking for Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report Acute Respiratory Illness During the PHE for COVID–19 Interim Final Rule with Comment Period (IFC),'' we believe the urgency of this PHE for COVID–19 and the impending and traditional seasonal influenza virus (and acute respiratory illness) season constitutes good cause to waive the normal notice-and-comment process under the Administrative Procedure Act (APA) and section 1871(b)(2)(C) of the Act. Waiving notice and comment is in the public interest because as it is necessary to expeditiously track the continuing incidence and impact of COVID–19 in conjunction with the impending incidence and impact of other acute respiratory illnesses in hospitals and CAHs; such information will assist public health officials in detecting outbreaks and responding appropriately in order to save lives.

The applicability date for § 482.42(e) and (f) for hospitals and for § 485.640(d) and (e) for CAHs is the date of the publication of this rule as noted in the **DATES** section of this IFC.

B. Enforcement of Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report Acute Respiratory Illness (Including, but Not Limited to, Seasonal Influenza Virus, Influenza-Like Illness, and Severe Acute Respiratory Infection) Data

We believe reporting by hospitals and CAHs is an important tool for supporting surveillance of both COVID–19 and other acute respiratory illness cases that are likely to present simultaneously in hospitals and CAHs. We will enforce violations of reporting requirements to the extent permitted by law. Should a hospital or CAH consistently fail to report data related to patient diagnoses of Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) throughout the duration of the PHE for COVID–19, it will be non-compliant with the hospital and the CAH CoPs set forth at §§ 482.42(f) and 485.640(e), respectively, and subject to termination as defined at 42 CFR 489.53(a)(3). We have taken a position on the importance of COVID–19 reporting in other provider areas, including use of civil money penalties (CMPs) for nursing homes that fail to report, and find it prudent to enact penalties for hospitals and CAHs that similarly fail to report Acute Respiratory Illness data. We currently lack the statutory authority to impose CMPs against hospitals and CAHs. However, we will continue to utilize all enforcement and payment authorities available to incentivize and promote compliance with all health and safety requirements, as allowed by statute and regulation.

XXIII. 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 2021, we are retaining these columns, updated to reflect the amount of the 2021 inpatient deductible. For CY 2021, we proposed to add a new column to the OPPS Addenda, A, B, and C, entitled ''Drug Pass-Through Expiration during Calendar Year'' where we would flag through the use of an asterisk, each drug for which pass-through payment is expiring prior to December 31 of the calendar year. We requested public comments on this proposed change to the OPPS Addenda A, B, and C for CY 2021.

We did not receive any public comments regarding the proposed CY 2021 format changes for the OPPS Addenda A, B, and C. Therefore, for CY 2021, we are finalizing our proposal to add an additional column entitled ''Drug Pass-Through Expiration during Calendar Year'' where we would flag through the use of an asterisk, each drug for which pass-through payment is expiring prior to December 31 of the calendar year.

To view the Addenda to the CY 2021 OPPS/ASC final rule with comment period, pertaining to CY 2021 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–1736–FC'' from the list of regulations. All OPPS Addenda to the CY 2021 OPPS/ASC final rule with comment period, are contained in the zipped folder entitled ''2021 NFRM OPPS Addenda'' at the bottom of the page. To view the Addenda to the CY 2021 OPPS/ASC final rule with comment period, pertaining to CY 2021 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–1736–FC'' from the list of regulations. The ASC Addenda to the CY 2021 OPPS/ASC final rule with comment period, 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.

XXIV. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the final rule with comment period, we are soliciting comments 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 IQR Program. We refer readers to the CY 2011 through CY 2020 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; and 84 FR 61468 through 61469, 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. Below we discuss only the changes in burden that will result from the finalized policies in this final rule with comment period.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59477), 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 (May 2019) from the BLS reflects a median hourly wage of $19.40 per hour for a Medical Records and Health Information Technician professional.[379] We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 59477). 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 ($19.40 × 2 = $38.80) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

2. *Summary*

We are finalizing our proposals to: (1) Codify the statutory authority for the Hospital OQR Program; (2) revise and codify the previously finalized public display of measure data policy that hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes; (3) revise existing § 419.46(a)(2) by replacing the term ''security administrator'' with the term ''security official'' and codifying this language; (4) move all deadlines falling on nonwork days forward consistent with section 216(j) of the Social Security Act (the Act), 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days,'' beginning with the effective date of this rule; (5) revise our policy regarding submission deadlines at

[379] Occupational Employment and Wages, May 2019. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm*. Accessed March 30, 2020.

existing § 419.46(c)(2) to reflect the finalized deadlines policy consistent with section 216(j) of the Act, 42 U.S.C. 416(j); (6) expand the existing review and corrections policy for chart-abstracted data 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; (7) codify at 42 CFR 419.46 the review and corrections period policy for measure data submitted to the Hospital OQR Program for chart-abstracted measure data, as well as for the newly finalized policy for measure data submitted directly to CMS via the CMS web-based tool; (8) codify the previously finalized Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures; (9) revise existing § 419.46(b) (redesignated § 419.46(c)) by removing the phrase ''submit a new participation form'' to align with previously finalized policy; and (10) update internal cross-references as a result of the redesignations.

We note that our finalized policies for the CY 2021 OPPS/ASC final rule will not yield a change in burden for the hospitals participating in the Hospital OQR Program as our policies seek only to refine existing regulatory text for current processes or to codify existing processes. As such, we note that the burden hours for the CY 2023 payment determination will be consistent with the previously finalized burden for the CY 2022 payment determination. We refer readers to the information collection request that has been approved by OMB control number 0938–1109 (expiration date March 31, 2023).[380]

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, and CY 2020 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; and 84 FR 61469, 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.

2. Summary

We are finalizing our proposals to: (1) Use the term ''security official'' instead of ''security administrator'' and revise § 416.310(c)(1)(i) by replacing the term ''security administrator'' with the term ''security official;'' (2) remove the phrase ''data collection time period'' in all instances where it appears in § 416.310 and replace it with the phrase ''data collection period''; (3) move forward all program deadlines falling on a nonwork day consistent with section 216(j) of the Act, 42 U.S.C. 416(j) and codify this policy; and (4) formalize the process by which ASCs identify errors and resubmit data before the established submission deadline by creating a review and corrections period that aligns with the Hospital OQR Program as finalized in section XIV.D.7. and that runs concurrent with the existing ASCQR data submission period, and codify this policy. We note that our finalized proposals for the CY 2021 OPPS/ASC final rule with comment period will not yield a change in burden for the facilities participating in the ASCQR Program as our policies seek only to refine existing regulatory text for current processes or to codify existing processes. As such, we note that the burden hours for the CY 2023 payment determination will be consistent with the previously finalized burden for the CY 2022 payment determination. We refer readers to the currently approved information collection request (OMB control number 0938–1270).[381]

D. ICRs for Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services. (84 FR 61142).[382] The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with paragraph (b) of 42 CFR 419.83, we are finalizing our proposal to add two new service categories to § 419.83(a): Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. The ICR associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by providers. The prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and the request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the prior authorization process for the two new categories, Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators, will be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation. We expect that this information will generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task will be 30 minutes, which is equivalent to that for normal prepayment or post payment medical review. We anticipate that most prior authorization requests will be sent by means other than mail. However, we estimate a cost of $5 per request for mailing medical records. Due to the July 1, 2021 start date, the first year of prior authorization for the two new service categories will only include 6 months. Based on CY 2018 data, we estimate that for those first 6 months there will be 6,808 initial requests mailed during the year. In addition, we estimate there will be 2,234 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $45,210 (9,042 mailed requests × $5). Based on CY 2018 data for the two new service categories, we estimate that annually there will be 13,615 initial requests mailed during a year. In addition, we estimate there will be 4,468 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total annual mailing cost is estimated to be $90,415 (18,083 mailed requests × $5). We also

[380] CY 2020 Final Rule Hospital OQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911-0938-015.*

[381] CY 2020 Final Rule ASCQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911-0938-016.*

[382] See also Correction notification issued January 3, 2020 (85 FR 224).

estimate that an additional 3 hours will be required for attending educational meetings, training staff on what services require prior authorization, and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS). Based on the BLS information, we estimate an average clerical hourly rate of $16.63 with a loaded rate of $33.26. The prior authorization program for these two service categories will not create any new documentation or administrative requirements. Instead, it will just require the same documents needed to support claim payments to be submitted earlier in the claim process. The estimate uses the clerical rate since we do not believe that clinical staff will need to spend more time on completing the documentation than will be needed in the absence of the prior authorization policy. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. CMS believes providers will have provided education to their staff on what services are included in the prior authorization process. Following this education, the staff will know which services will need prior authorization and will not need additional time or resources to determine if a service requires prior authorization. We estimate that the total number of submissions for the first year (6 months) will be 30,140 (21,098 submissions through fax or electronic means + 9,042 mailed submissions). Therefore, we estimate that the total burden for the first year (6 months) for the two new service categories, allotted across all providers, will be 24,820 hours (.5 hours × 30,140 submissions plus 3 hours × 3,250 providers for education). The burden cost for the first year (6 months) is $870,723 (24,820 hours × $33.26 plus $45,210 for mailing costs). In addition, we estimate that the total annual number of submissions will be 60,277 (42,194 submissions through fax or electronic means + 18,083 mailed submissions). The annual burden hours for the two new service categories, allotted across all providers, will be 39,889 hours (.5 hours × 60,277 submissions plus 3 hours × 3,250 providers for education). The annual burden cost will be $1,417,107 (39,889 hours × $33.26 plus $90,416 for mailing costs). For the total burden and associated costs for the two new service categories, we estimate the annualized burden to be 34,866 hours and $1,234,979. The annualized burden is based on an average of 3 years, that is, 1 year at the 6-month burden and 2 years at the 12-month burden. The ICR approved under OMB control number 0938–1368 will be revised and submitted to OMB for approval.

Below is a chart reflecting the total burden and associated costs for the provisions included in the CY 2021 OPPS/ASC proposed rule.

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Overall Star Rating[4]	0.0	0.0
Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process	+34,866	+$1.2 million

* Numbers rounded.

[1] Burden changes for the Hospital IQR Program reflect total changes over a four-year period from the CY 2021 reporting period/FY 2023 payment determination through the CY 2024 reporting period/FY 2026 payment determination.

[2] Because the FY 2022 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare fee-for-service claims data that hospitals are already submitting to CMS for payment purposes, the program does not anticipate any change in burden associated with this final rule.

[3] Because the Hospital Readmissions Reduction Program measures are all collected via Medicare fee-for service- claims that hospitals are already submitting to CMS for payment purposes, there is no unique information collection burden associated with the program.

[4] Because the Overall Star Rating uses measure data already collected and reported by other programs, the burden is captured in the respective programs and represents no increased burden.

E. ICRs for the Overall Hospital Quality Star Rating

The Overall Star Rating uses measures that are publicly reported on Hospital Compare or its successor websites under the public reporting authority of each individual hospital program furnishing measure data. We believe the burden associated with measures included in the Overall Star Rating, including requesting withholding of measures from public reporting, is already captured in the respective hospital programs' ICRs and represents no increased information collection burden to hospitals.

F. ICRs for Physician-Owned Hospitals

As discussed in section XIX. of this final rule with comment period, we are finalizing our proposal to modify the physician-owned hospital expansion exception process under the rural provider and hospital ownership exceptions to the physician self-referral law. Specifically, we are modifying the frequency of submission such that a high Medicaid facility could request an exception to the prohibition on expansion of facility capacity at any time, provided that it has not submitted another request for an exception to the prohibition on facility expansion to CMS for which CMS has not issued a decision. We continue to believe this modification will not result in any changes in burden under the PRA. First, we do not anticipate any changes in the annual number of respondents. Although a high Medicaid facility would be permitted to request an expansion exception more frequently than under current regulations, we believe that removing the cap on the size of an expansion would make more

frequent expansion exception requests unlikely. Also, we are not changing the information being collected.

Based on our experience with the expansion exception process to date, we estimate that approximately one physician-owned hospital per year will request an expansion exception on the grounds that it is a high Medicaid facility. This estimate aligns with the total number of expansion exception requests received to date. We estimate that it takes approximately 6 hours and 45 minutes to prepare an expansion exception request and that a request is prepared by a lawyer. To estimate the cost to prepare a request, we use a 2019 wage rate of $69.86 for lawyers from the Bureau of Labor Statistics,[383] and we double that wage to account for overhead and benefits. The total estimated annual cost is $943.11. We received the following comments:

Comment: A few commenters stated that our estimate relating to the number of expansion exception requests we will receive on an annual basis is understated. The commenters stated that, based on their analysis, approximately 25 physician-owned hospitals either currently qualify as high Medicaid facilities or could soon qualify. A commenter recommended that CMS release the data upon which it based its estimate.

Response: We continue to estimate that approximately one physician-owned hospital per year will request an expansion exception on the grounds that it is a high Medicaid facility. The modifications in this rule do not change the definition of a high Medicaid facility and therefore would not change the number of high Medicaid facilities that could seek an expansion exception. We believe it is highly unlikely that every physician-owned hospital that could meet the definition of a high Medicaid facility would seek an expansion exception. Instead, only those physician-owned hospitals that meet the definition and that also have the desire to expand, the resources to expand, and are able to meet any applicable state or local requirements (such as certificate of need) would seek an expansion exception. We believe it is reasonable to use our experience with the expansion exception process to date to estimate the number of requests we may receive in the future. Since the enactment of section 6001 of the Affordable Care Act of 2010, we have received only a handful of expansion exception requests, and only four physician-owned hospitals have been granted expansion exceptions as high Medicaid facilities. All expansion exceptions issued to date have been posted on our website (*https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals*).

G. ICRs for COVID–19 Therapeutic Inventory and Usage Data Reporting and Acute Respiratory Illness (Including, but Not Limited to, Seasonal Influenza Virus, Influenza-Like Illness, and Severe Acute Respiratory Infection) Data Reporting in Hospitals and CAHs

In this IFC, we are revising our current COVID–19 PHE hospital and CAH CoP reporting requirements at 42 CFR 482.42(e) for hospitals and at 42 CFR 485.640(d) for CAHs, to now require hospitals and CAHs to report data elements that must include, but not be limited to, the following: (1) The hospital's (or the CAH's) current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the hospital (or CAH) under the authority and direction of the Secretary; and (2) the hospital's (or the CAH's) current usage rate for any COVID–19-related therapeutics that have been distributed and delivered to the CAH under the authority and direction of the Secretary.

As part of the overall hospital and CAH COVID–19 reporting data, users will most likely report these data on a daily basis, as is currently recommended by the CDC, and that this new data will take users, on average, an additional 15 minutes to complete. As with the other hospital and CAH data elements associated with the PHE that are required through the guidance to be reported, and because OMB PRA approval is requested for 180 days, the total number of responses per respondent is 180 for a six-month period.

We are also revising the regulations by adding provisions to the CoPs (§ 482.42 for hospitals and § 485.640 for CAHs), and are now requiring hospitals and CAHs to report information in accordance with a frequency, and in a standardized format, as specified by the Secretary during the PHE for Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection). The burden associated with these reporting activities will be submitted under OMB control number 0938–NEW. For purposes of burden estimates, we do not differentiate among general acute care and CAHs, as they all complete the same data collection.

We have estimated that the Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) forms will take an average of 90 minutes to complete, with the acknowledgement that the reporting burden includes surveillance and data entry. We further estimate that users will most likely report these data on a daily basis, as is currently recommended by the CDC for COVID–19 data, and will most likely use a data collection channel and format similar, if not identical, to that currently being used for the hospital and CAH COVID–19 reporting data, as recommended in the most current (as of October 6, 2020) COVID–19 Guidance for Hospital Reporting document (*https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf*) and (*https://healthdata.gov/covid-19_hospital_reporting*). Because OMB PRA approval is requested for 180 days, the total number of responses per respondent is 180 for a six month period.

This PRA package will then be merged with the HHS PRA package for Teletracking that is currently seeking OMB approval and was announced in the **Federal Register** on September 23, 2020 (85 FR 59809). Details of these burden estimates and the costs can be found in Tables 77 and 78.

[383] U.S. Department of Labor, Bureau of Labor Statistics, May 2019 National Occupational Employment and Wage Estimates United States, *https://www.bls.gov/oes/current/oes_nat.htm.*

TABLE 77: Hospital and CAH Reporting of Acute Respiratory Illness/Tracking of COVID-19 Therapeutic Inventory and Usage Estimated Burden Hours

Type of respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average burden per response (in hours)	Total burden hours
Hospitals and CAHs	HHS Teletracking COVID–19 Portal	6,200	180	1.5	1,674,000
Hospitals and CAHs	HHS Teletracking COVID–19 Portal	6,200	180	0.25	279,000

TABLE 78: Hospital and CAH Reporting of Acute Respiratory Illness/Tracking of COVID-19 Therapeutic Inventory and Usage Estimated Costs

Type of respondent: Hospital Staff—Registered Nurses	Total burden hours	Hourly wage rate	Total respondent costs
	1,674,000	*$70.48	$117,983,520
	279,000	*$70.48	$19,663,920
Total	1,953,000	*$70.48	$137,647,440

* The hourly wage rate (Accessed at https://www.bls.gov/oes/current/oes291141.htm) includes overhead and fringe benefits.

XXV. Waiver of the 30-Day and 60-Day Delayed Effective Dates for the Final Rule With Comment Period and Waiver of Proposed Rulemaking for the COVID–19 Therapeutic Inventory and Usage Reporting Requirements and for the Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report Acute Respiratory Illness During the PHE for COVID–19 Interim Final Rule With Comment Period (IFC)

A. Waiver of the 30-Day and 60-Day Delayed Effective Dates for the Final Rule With Comment Period

We are committed to ensuring that we fulfill our statutory obligation to update the OPPS as required by law and have worked diligently in that regard. We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued in accordance with the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)). However, section 808(2) of the CRA provides that, if an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the rule shall take effect at such time as the agency determines.

In addition, the Administrative Procedure Act, (5 U.S.C. 553(d)), ordinarily requires a 30-day delay in the effective date of a final rule from the date of its public availability in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Section 1871(e)(1)(B)(ii) of the Act, also permits a substantive rule to take effect less than 30 days after its publication if the Secretary finds that waiver of the 30-day period is necessary to comply with statutory requirements or that the 30-day delay would be contrary to the public interest.

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named ''SARS–CoV–2'' and the disease it causes has been named ''coronavirus disease 2019'' (abbreviated ''COVID–19'').

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of international concern'' (PHEIC). On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation's healthcare community in responding to COVID–19. On March 11, 2020, the WHO publicly characterized COVID–19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID–19 outbreak a national emergency.

The COVID–19 PHE has required the agency to divert energy and personnel resources that would otherwise have been used to complete this OPPS/ASC payment system final rule with comment period to other priority matters, including four interim final rules necessary because of the PHE. (See 85 FR 19230 (April 6, 2020); 85 FR 27550 (May 8, 2020); 85 FR 54820 (September 2, 2020); 85 FR 71142 (November 6, 2020)). Although we have devoted significant resources to completing the OPPS/ASC payment system final rule with comment period, it was impracticable for CMS to complete the work needed on the rule in accordance with our usual schedule for this rulemaking or in sufficient time to ensure a full 60-day period of public notice prior to the next calendar year that begins on January 1, 2021. The OPPS/ASC payment system final rule with comment period is necessary to annually review and update the payment systems, and it is critical to ensure that the payment policies for these systems are effective on the first day of the calendar year to which they are intended to apply. Therefore, in

light of the COVID–19 PHE, and the resulting strain on CMS's resources, it was impracticable for CMS to publish this final rule either 30 or 60 days prior to the beginning of the upcoming year, and CMS has determined that, for good cause, it would be contrary to the public interest to delay the effective date of this final rule with comment period beyond January 1, 2021, and we are waiving both the 30-day and 60-day delayed effective date requirements for this final rule with comment period.

B. Waiver of Proposed Rulemaking for the COVID–19 Therapeutic Inventory and Usage Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) and for the Reporting Requirements for Hospitals and CAHs To Report Acute Respiratory Illness During the PHE for COVID–19 Interim Final Rule With Comment Period (IFC)

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the provisions of the rule are finalized, either as proposed or as amended in response to public comments, and take effect, in accordance with the APA (Pub. L. 79–404), 5 U.S.C. 553, and, where applicable, section 1871 of the Act. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of the proposed rule in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Further, 5 U.S.C. 553 requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and a period of not less than 60 days for public comment for rulemaking carrying out the administration of the insurance programs under title XVIII of the Act. Section 1871(b)(2)(C) of the Act and 5 U.S.C. 553 authorize the agency to waive these procedures, however, if the agency for good cause finds that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

Section 553(b)(B) of title 5 of the U.S. Code ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Section 1871(e)(1)(B)(i) of the Act also prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date the rule is issued or published. However, section 1871(e)(1)(B)(ii) of the Act permits a substantive rule to take effect before 30 days have passed, if the Secretary finds that a waiver of the 30-day period is necessary to comply with statutory requirements or that the 30-day delay would be contrary to the public interest. Furthermore, section 1871(e)(1)(A)(ii) of the Act permits a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act to be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the change retroactively would be contrary to the public interest. Finally, the Congressional Review Act (CRA) (Pub. L. 104–121, Title II) requires a delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. 5 U.S.C. 801(a)(3), 808(2).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of international concern.'' On January 31, 2020, pursuant to section 319 of the PHSA, the Secretary determined that a PHE exists for the United States to aid the nation's healthcare community in responding to COVID–19. On March 11, 2020, the WHO publicly declared COVID–19 a pandemic. On March 13, 2020, the President declared the COVID–19 pandemic a national emergency. Effective July 25, 2020, the Secretary renewed the January 31, 2020 determination that was previously renewed on April 21, 2020, that a PHE exists and has existed since January 27, 2020. This declaration, along with the Secretary's January 30, 2020 declaration of a PHE, conferred on the Secretary certain waiver authorities under section 1135 of the Act. On March 13, 2020, the Secretary authorized waivers under section 1135 of the Act, effective March 1, 2020.

On March 4, 2020, we issued guidance (*https://www.cms.gov/files/document/qso-20-13-hospitalspdf.pdf-2*) stating that hospitals should inform infection prevention and control services, local and state public health authorities, and other healthcare facility staff as appropriate about the presence of a person under investigation for COVID–19. CMS followed this guidance with an interim final rule with comment (IFC), published on September 2, 2020 (85 FR 54820), that now requires hospitals and CAHs to report important data critical to support the fight against COVID–19. The CoP provisions require that hospitals and CAHs report this information in accordance with a frequency as specified by the Secretary on COVID–19 as well as in a standardized format specified by the Secretary. Examples of data elements that may be required to be reported include things such as the number of staffed beds in a hospital and the number of those that are occupied, information about its supplies, and a count of patients currently hospitalized who have laboratory-confirmed COVID–19. This list is not exhaustive of those data items that we may require hospitals and CAHs to submit, as specified by the Secretary (see *https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf* for the current list of data items specified). These elements are essential for planning, monitoring, and resource allocation during the COVID–19 Public Health Emergency (PHE). The new rules make reporting a requirement of participation in the Medicare and Medicaid programs. This reporting is needed to support broader surveillance of COVID–19.

As we discussed in Section XXII., promising new COVID–19-related therapeutics are being issued Emergency Use Authorizations by the Food and Drug Administration. Because these new therapeutics are in very scarce supply in the United States, HHS is actively working with manufacturers to ensure that they are distributed efficiently and effectively. Effective distribution methods use a variety of indicators, tailored to the specific therapeutic, to estimate the geographic and regional distribution that is recommended for that particular therapeutic. However, as we previously noted, analysing and understanding the usage patterns specific to each new therapeutic requires real-world information in real time. Lacking accurate information on the usage rates and current inventory on hand for a particualr therapeutic, can possibly result in scarce therapeutic supplies being sent to areas that already have adequate inventories on hand. Such an inefficient and ill-informed distribution strategy for these therapeutics could

very quickly lead to a situation that could negatively impact areas of the nation that already have inadequate supplies and resources.

In response to this situation and as a pre-emptive means of avoiding the disastrous consequences of inadequate planning, we are revising our current COVID–19 PHE hospital and CAH CoP reporting requirements at 42 CFR 482.42(e) for hospitals and at 42 CFR 485.640(d) for CAHs, to now require hospitals and CAHs to report data elements that must include, but not be limited to, the following: (1) The hospital's (or the CAH's) current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the hospital (or CAH) under the authority and direction of the Secretary; and (2) the hospital's (or the CAH's) current usage rate for any COVID–19-related therapeutics that have been distributed and delivered to the CAH under the authority and direction of the Secretary. The importance of this particular data reporting, along with the information provided, cannot be overestimated as we continue to make advances to more effectively address the continuing COVID–19 PHE and to greatly diminish its negative impact on the nation.

Therefore, we believe that the lack of real data on hospital and CAH inventory supplies and usage rates of COVID–19-related therapeutics, coupled with the overarching and continuing urgency of the PHE for COVID–19, constitutes good cause to waive notice and comment rulemaking as we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment rulemaking procedures. For the same reasons, because we cannot afford any delay in effectuating this IFC, we find good cause to waive the 30-day delay in the effective date and, moreover, to establish these policies in this IFC applicable as of the date this rule is published.

Ensuring the health and safety of all Americans, including Medicare beneficiaries, Medicaid recipients, and healthcare workers, is of primary importance. This IFC directly supports that goal by requiring, in addition to the current COVID–19 reporting by hospitals and CAHs as well as the new COVID–19-related therapeutic inventory and usage data reporting requirements discussed here, the additional reporting of Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) data. It is critically important that we implement the policies in this IFC as quickly as possible. As we are already in the midst of the PHE for the COVID–19 pandemic, we now find our nation also fully entering the seasonal influenza season for North America, which will include increased patient case presentations of a variety of respiratory infections and viral diseases, the most significant of which will be cases of seasonal influenza virus and influenza-like illness as well as cases of other acute respiratory illness as defined by the Centers for Disease Control and Prevention (CDC) (*https://www.cdc.gov/flu/about/glossary.htm*).

According to *Scientific American,* (*https://www.scientificamerican.com/article/coronavirus-and-the-flu-a-looming-double-threat/*), the ''overlap of COVID–19 and influenza has epidemiologists and some policy makers concerned,'' and that, ''the U.S. may soon face two epidemics at the same time,'' precipitating ''a crisis unlike any other.'' The article further states that, ''the worst-case scenario is both [the coronavirus and the flu] are spreading fast and causing severe disease, complicating diagnoses and presenting a double burden on the health care system.'' The most recent data from the CDC regarding the 2017–2018 influenza season and hospitalizations show that, ''30,453 laboratory-confirmed influenza-related hospitalizations were reported through the *Influenza Hospitalization Surveillance Network* (FluSurv-NET), which covers approximately 9% of the U.S. population,'' and that, ''people 65 years and older accounted for approximately 58% of reported influenza-associated hospitalizations,'' and that ''overall hospitalization rates (all ages) during 2017–2018 were the highest ever recorded in this surveillance system, breaking the previously recorded high recorded during 2014–2015'' (*https://www.cdc.gov/flu/about/season/flu-season-2017-2018.htm#anchor_1534865852732*). We believe that these reporting requirements are necessary for CMS to monitor whether individual hospitals and CAHs are appropriately tracking, responding to, and mitigating the spread and impact of acute respiratory illnesses coupled with COVID–19 on patients, the staff who care for them, and the general public. We believe that this action reaffirms our commitment to protecting the health and safety of all patients who receive care at the approximately 6,200 Medicare- and Medicaid-participating hospitals and CAHs nationwide.

Therefore, we believe that the impending seasonal influenza virus (and acute respiratory illness) season with its potential for increased hospitalizations, coupled with the continuing urgency of the PHE for COVID–19, constitutes good cause to waive notice and comment rulemaking as we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment rulemaking procedures. For the same reasons, because we cannot afford any delay in effectuating this IFC, we find good cause to waive the 30-day delay in the effective date and, moreover, to establish these policies in this IFC applicable as of the date this rule is published.

XXVI. 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 final rule with comment period and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXVII. Economic Analyses

A. Statement of Need

This final rule with comment period is necessary to update the Medicare hospital OPPS rates and to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2021. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are revising 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 updated cost report information.

This final rule with comment period also is necessary to update the ASC payment rates for CY 2021 and make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2021. 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 Final Rule With Comment Period

We have examined the impacts of this final rule with comment period, 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 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). This section of this final rule with comment period contains the impact and other economic analyses for the provisions we are finalizing for CY 2021.

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 final rule with comment period has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Congressional Review Act. Accordingly, this final rule with comment period 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 final rule with comment period. We solicited public comments on the regulatory impact analysis in the proposed rule, and we address any public comments we received in this final rule, as appropriate.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2021, compared to CY 2020, due only to the changes to the OPPS in this final rule with comment period, will be approximately $1.49 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2021, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2021 would be approximately $83.9 billion, which is approximately $7.5 billion higher than estimated OPPS expenditures in CY 2020. Because the provisions of the OPPS are part of a final 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 79 of this final rule with comment period displays the distributional impact of the CY 2021 changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that under our CY 2021 policy, drugs and biologicals that are acquired under the 340B Program will continue to be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable. We also note that in the impact tables as displayed in this impact analysis, we have modeled current and prospective payments as if separately payable drugs acquired under the 340B program from hospitals not excepted from the policy are paid under the OPPS in CY 2021 at ASP minus 22.5 percent.

We estimate that the final rule update to the conversion factor, the CY 2021 frontier wage index adjustment, and other adjustments (not including the effects of outlier payments or the pass-through payment estimates) will increase total OPPS payments by 0.2 percent in CY 2021. The changes to the APC relative payment weights, the changes to the wage indexes, the continuation of a payment adjustment for rural SCHs, including EACHs, and the payment adjustment for cancer hospitals will not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2020 and CY 2021, considering all final budget neutral payment adjustments, changes in estimated total outlier payments, pass-through payments, 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, will increase total estimated OPPS payments by 2.4 percent.

We estimate the total increase (from changes to the ASC provisions in this final rule with comment period 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 2021 compared to CY 2020, to be approximately $120 million. Because the provisions for the ASC payment system are part of a final 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 final rule with comment period. Tables 80 and 81 of this final rule with comment period display the redistributive impact of the CY 2021 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 Final Rule With Comment Period

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2021 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2021 with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS website at: *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–1736–FC'' 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

final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 79. 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 final rule with comment period 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 the 340B Program Payment Policy

In section V.B. of this final rule with comment period with comment period, we discuss our policy to adjust the payment amount for nonpass-through, separately payable drugs acquired by certain 340B participating hospitals through the 340B Program. We are finalizing that rural SCHs, children's hospitals, and PPS-exempt cancer hospitals will continue to be excepted from this payment policy in CY 2021 and subsequent years. Specifically, in this final rule with comment period for CY 2021, for hospitals paid under the OPPS (other than those that are excepted for CY 2021), we are not finalizing our proposal 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 28.7 percent. Instead, we are finalizing our alternative proposal that we will continue the current Medicare payment policy for CY 2021. Under our alternative proposal, we will pay for separately payable drugs and biologicals acquired under the 340B program, excluding those on pass-through payment status and vaccines, at ASP minus 22.5 percent. Because we are continuing current Medicare payment policy for CY 2021, there is no change to the budget neutrality adjustment as a result of the 340B drug payment policy.

c. Estimated Effects of OPPS Changes on Hospitals

Table 79 shows the estimated impact of this final rule with comment period 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 79, 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 2021, we are continuing 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 final rule with comment period.

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 IPPS market basket percentage increase for FY 2021 is 2.4 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 2.4 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. However, the most recent MFP estimated from the IGI June 2020 macroeconomic forecast for FY 2021 is estimated to be −0.1 percentage point. This MFP value would have led to an increase in the IPPS market basket. Section 1886(b)(3)(B)(xi)(I) of the Act requires the Secretary to reduce (not increase) the hospital market basket percentage increase by changes in economy-wide productivity. That means the MFP adjustment for the OPPS as described by section 1833(t)(3)(F)(i) of the Act is set to 0.0 percentage points (which is also the MFP adjustment for FY 2021 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58797)). Accordingly, we are applying a 0.0 percentage point MFP adjustment to the CY 2021 market basket percentage increase for the OPPS, which causes the OPD fee schedule increase factor to be 2.4 percent. We are using the OPD fee schedule increase factor of 2.4 percent in the calculation of the CY 2021 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 CY 2020 estimates in Table 79 of this final rule with comment period.

To illustrate the impact of the CY 2021 changes, our analysis begins with a baseline simulation model that uses the CY 2020 relative payment weights, the FY 2020 final IPPS wage indexes that include reclassifications, and the final CY 2020 conversion factor. Table 79 shows the estimated redistribution of the increase or decrease in payments for CY 2021 over CY 2020 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2020 and CY 2021 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 2.4 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated impact taking into account all payments for CY 2021 relative to all payments for CY 2020, including the impact of changes in estimated outlier payments, and changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2021. 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 2021 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 final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between

CY 2020 and CY 2021 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2021 will increase Medicare OPPS payments by an estimated 2.4 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 2.4 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 79 shows the total number of facilities (3,665), 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 2020 and CY 2021 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 2020 or CY 2021 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 final rule with comment period. 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 (3,558), 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 79) 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 0.4 percent to an increase of 0.3, depending on the number of beds. Rural hospitals will experience no change overall. Major teaching hospitals will see an expected decrease of 0.5 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the FY 2021 IPPS post-reclassification wage indexes; the rural adjustment; the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2020 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 final updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the CY 2021 final changes in wage index policy discussed in section II.C. of this CY 2021 OPPS/ASC final rule with comment period. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2021, as described in section II.E. of this final rule with comment period. We also did not model a budget neutrality adjustment for the final cancer hospital payment adjustment because the payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2021 is 0.89, the same as the ratio that was reported for the CY 2020 OPPS/ASC final rule with comment period (84 FR 61191). 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 are applying in section II.F. of this final rule with comment period.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2021 scaled weights and a CY 2020 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2020 and CY 2021.

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 2.4 percent. Overall, these changes will increase payments to urban hospitals by 2.6 percent and to rural hospitals by 2.9 percent. The increase for classes of rural hospitals will vary with sole community hospitals receiving a 3.0 percent increase and other rural hospitals receiving an increase of 2.7 percent.

Column 5: All Changes for CY 2021

Column 5 depicts the full impact of the final CY 2021 policies on each hospital group by including the effect of all changes for CY 2021 and comparing them to all estimated payments in CY 2020. 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 final rule with comment period; 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 final rule with comment period); and the difference in total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2020 update (and assumed, for modeling purposes, to be the same number for CY 2021), we included 18 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 final changes for CY 2021 will increase payments to all facilities by 2.4 percent for CY 2021. We modeled the independent effect of all changes in Column 5 using the final relative payment weights for CY 2020 and the final relative payment weights for CY 2021. We used the final conversion factor for CY 2020 of $80.793 and the final CY 2021 conversion factor of $82.797 discussed in section II.B. of this final rule with comment period.

Column 5 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the

FY 2021 IPPS/LTCH PPS final rule (85 FR 59039) of 6.4 percent (1.06404) to increase individual costs on the CY 2019 claims, and we used the most recent overall CCR in the October 2020 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2020. Using the CY 2019 claims and a 6.4 percent charge inflation factor, we currently estimate that outlier payments for CY 2020, using a multiple threshold of 1.75 and a fixed-dollar threshold of $5,075, will be approximately 0.97 percent of total payments. The estimated current outlier payments of 0.97 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 13.2 percent (1.13218) and the CCRs in the October 2020 OPSF, with an adjustment of 0.974495, to reflect relative changes in cost and charge inflation between CY 2019 and CY 2021, to model the final CY 2020 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $5,300. The charge inflation and CCR inflation factors are discussed in detail in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039).

Overall, we estimate that facilities will experience an increase of 2.4 percent under this final rule with comment period in CY 2021 relative to total spending in CY 2020. This projected increase (shown in Column 5) of Table 79 reflects the 2.4 percent OPD fee schedule increase factor, minus 0.04 percent for the change in the pass-through payment estimate between CY 2020 and CY 2021, minus the difference in estimated outlier payments between CY 2020 (0.97 percent) and CY 2021 (1.0 percent). We estimate that the combined effect of all final changes for CY 2021 will increase payments to urban hospitals by 2.4 percent. Overall, we estimate that rural hospitals will experience a 2.4 percent increase as a result of the combined effects of all the final changes for CY 2021.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 1.9 percent for major teaching hospitals and an increase of 2.7 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 2.6 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 2.3 percent, proprietary hospitals will experience an increase of 3.2 percent, and governmental hospitals will experience an increase of 2.2 percent.

BILLING CODE 4120–01–P

TABLE 79—ESTIMATED IMPACT OF THE CY 2021 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 *	3,665	0.0	0.2	2.6	2.4
ALL HOSPITALS	3,558	0.0	0.2	2.7	2.4
(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS	2,806	0.0	0.2	2.6	2.4
LARGE URBAN	1,449	0.0	0.2	2.6	2.4
(GT 1 MILL.)					
OTHER URBAN	1,357	0.1	0.2	2.7	2.4
(LE 1 MILL.)					
RURAL HOSPITALS	752	0.0	0.4	2.9	2.5
SOLE COMMUNITY	367	0.0	0.5	3.0	2.6
OTHER RURAL	385	0.0	0.2	2.7	2.4
BEDS (URBAN)					
0 - 99 BEDS	961	0.2	0.3	2.9	2.6
100-199 BEDS	786	0.3	0.3	2.9	2.6
200-299 BEDS	447	0.3	0.2	2.9	2.7
300-499 BEDS	386	0.2	0.2	2.8	2.5
500 + BEDS	226	-0.4	0.0	2.1	2.0
BEDS (RURAL)					
0 - 49 BEDS	330	0.0	0.5	2.9	2.5
50- 100 BEDS	256	0.1	0.5	3.1	2.6
101- 149 BEDS	90	0.0	0.3	2.6	2.3
150- 199 BEDS	38	-0.1	0.4	2.8	2.6
200 + BEDS	38	0.0	0.2	2.6	2.5
REGION (URBAN)					
NEW ENGLAND	132	-0.3	1.0	3.1	2.0
MIDDLE ATLANTIC	327	-0.2	0.1	2.4	2.3
SOUTH ATLANTIC	455	0.1	0.1	2.6	2.6
EAST NORTH CENT.	440	-0.1	-0.1	2.3	2.2
EAST SOUTH CENT.	163	0.0	-0.1	2.3	2.3
WEST NORTH CENT.	186	0.0	0.5	2.9	1.9
WEST SOUTH CENT.	474	0.5	0.1	3.0	3.0
MOUNTAIN	213	0.2	0.1	2.8	2.1
PACIFIC	368	0.1	0.2	2.8	2.7
PUERTO RICO	48	0.2	-0.2	2.4	2.3
REGION (RURAL)					

NEW ENGLAND	20	-0.3	0.1	2.2	2.1
MIDDLE ATLANTIC	50	-0.2	0.1	2.4	2.4
SOUTH ATLANTIC	113	0.0	-0.2	2.2	2.1
EAST NORTH CENT.	120	0.2	0.6	3.3	3.2
EAST SOUTH CENT.	146	0.0	0.0	2.5	2.4
WEST NORTH CENT.	91	0.0	1.1	3.5	2.4
WEST SOUTH CENT.	141	0.5	0.0	2.9	2.8
MOUNTAIN	48	-0.2	2.2	4.4	2.4
PACIFIC	23	-0.2	-0.2	2.0	2.0
TEACHING STATUS					
NON-TEACHING	2,391	0.3	0.2	2.9	2.7
MINOR	792	0.2	0.3	3.0	2.6
MAJOR	375	-0.5	0.1	2.0	1.9
DSH PATIENT PERCENT					
0	13	0.1	-0.3	2.1	2.0
GT 0 - 0.10	267	0.6	0.0	3.0	2.7
0.10 - 0.16	241	0.4	0.2	3.1	2.8
0.16 - 0.23	579	0.5	0.2	3.1	2.8
0.23 - 0.35	1,101	0.0	0.3	2.7	2.4
GE 0.35	899	-0.3	0.1	2.3	2.1
DSH NOT AVAILABLE **	458	0.0	0.1	2.5	2.3
URBAN TEACHING/DSH					
TEACHING & DSH	1,048	-0.1	0.2	2.5	2.3
NO TEACHING/DSH	1,307	0.4	0.1	2.9	2.7
NO TEACHING/NO DSH	13	0.1	-0.3	2.1	2.0
DSH NOT AVAILABLE2	438	0.0	0.1	2.5	2.3
TYPE OF OWNERSHIP					
VOLUNTARY	1,976	0.0	0.2	2.6	2.3
PROPRIETARY	1,132	0.9	0.3	3.5	3.2
GOVERNMENT	450	-0.3	0.1	2.2	2.2
CMHCs	39	9.7	-0.1	12.2	11.9

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all final CY 2021 OPPS policies and compares those to the CY 2020 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the final FY 2021 hospital inpatient wage index and the non-budget neutral frontier adjustment. The final 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 in CY 2021 the final target payment-to-cost ratio is the same as that of CY 2020 (0.90 and reduced to 0.89 in accordance with the 21st Century Cures Act)

Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.4 percent OPD fee schedule update factor (2.4 percent reduced by 0.0 percentage point for the productivity adjustment).

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have the frontier adjustment to Column 3 in this table.

These 3,665 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 79 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2020, 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 final 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 11.9 percent increase in payments from CY 2020 (shown in Column 5). We note that this includes the trimming methodology as well as the final CY 2021 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 final FY 2021 wage index values will result in a decrease of 0.1 percent to CMHCs. Column 4 shows that combining this final OPD fee schedule increase factor, along with final changes in APC policy for CY 2021 and the final FY 2021 wage index updates, will result in an estimated increase of 12.2 percent. Column 5 shows that adding the final changes in outlier and pass-through payments will result in a total 11.9 percent increase in payment for CMHCs. This reflects all finalized changes for CMHCs for CY 2021.

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 2021 OPPS/ASC final rule with comment period. 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 18.3 percent for all services paid under the OPPS in CY 2021. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the final CY 2021 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 final changes in the final 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 $1.49 billion in program payments for OPPS services furnished in CY 2021. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in this final rule would increase these Medicaid beneficiary payments by approximately $105 million in CY 2021. 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 thirty 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 $105 million Medicaid increase, approximately $60 million will be from the federal government and $45 million would be from state government.

h. Alternative OPPS Policies Considered

• Column 3—Estimated CY 2021 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 updates to ASC payment rates for CY 2021 compared to CY 2020.

As shown in Table 80, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the update to ASC payment rates for CY 2021 will result in a 3-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 2-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, a 2-percent increase in aggregate payment amounts for cardiovascular system procedures, and a 5-percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and changes in policy. In general, spending in each of these categories of services is increasing due to the 2.4 percent payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 2.4-percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 4-percent increase in aggregate gastrointestinal procedure payments due to an increase in hospital reported costs for Level 1 and Level 2 upper and lower gastrointestinal payment categories under the OPPS. The increases in payment weights for gastrointestinal procedure payments is further increased by the 2.4 percent ASC rate update for these procedures. For estimated changes for selected procedures, we refer readers to Table 81 provided later in this section.

BILLING CODE 4120–01–P

TABLE 80: ESTIMATED IMPACT OF THE CY 2021 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2021 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2020 ASC Payments (in Millions) (2)	Estimated CY 2021 Percent Change (3)
Total	$5,455	2
Eye and ocular adnexa	$1,815	3
Nervous system	$1,180	2
Digestive system	$909	4
Musculoskeletal system	$695	4
Cardiovascular system	$274	2
Genitourinary system	$201	5

Table 81 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2021. The table displays 30 of the procedures receiving the greatest estimated CY 2020 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2020 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2020 ASC Payments were calculated using CY 2019 ASC utilization (the most recent full year of ASC utilization) and the CY 2020 ASC payment rates. The estimated CY 2020 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2021 Percent Change reflects the percent differences between the estimated ASC payment for CY 2020 and the estimated payment for CY 2021 based on the update.

TABLE 81: ESTIMATED IMPACT OF THE FINAL CY 2021 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2020 ASC Payment (in millions) (3)	Estimated CY 2021 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,228	3
63685	Insrt/redo spine n generator	$285	2
45380	Colonoscopy and biopsy	$240	4
63650	Implant neuroelectrodes	$186	-1
43239	Egd biopsy single/multiple	$180	4
45385	Colonoscopy w/lesion removal	$178	4
0191T	Insert ant segment drain int	$121	4
64483	Inj foramen epidural l/s	$118	2
66982	Xcapsl ctrc rmvl cplx wo ecp	$90	3
64635	Destroy lumb/sac facet jnt	$85	1
64493	Inj paravert f jnt l/s 1 lev	$78	2
36902	Intro cath dialysis circuit	$78	1
29827	Sho arthrs srg rt8tr cuf rpr	$73	5
66821	After cataract laser surgery	$67	0
64590	Insrt/redo pn/gastr stimul	$59	4
C9740	Cysto impl 4 or more	$56	2
62323	Njx interlaminar lmbr/sac	$54	2
22869	Insj stablj dev w/o dcmprn	$52	3
G0105	Colorectal scrn; hi risk ind	$51	4
15823	Revision of upper eyelid	$39	6
G0121	Colon ca scrn not hi rsk ind	$38	4
45378	Diagnostic colonoscopy	$37	4
64721	Carpal tunnel surgery	$37	1
63655	Implant neuroelectrodes	$31	5
65820	Relieve inner eye pressure	$29	3
64561	Implant neuroelectrodes	$28	-2
67042	Vit for macular hole	$27	2
64490	Inj paravert f jnt c/t 1 lev	$27	2
62362	Implant spine infusion pump	$27	3
29881	Knee arthroscopy/surgery	$27	4

BILLING CODE 4120–01–C

c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2021 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 are adding to the ASC list of covered surgical procedures and for those we designate as office-based for CY 2021. For example, using 2019 utilization data and CY 2021 OPPS and ASC payment rates, we estimate that if 10 percent of colpopexy procedures migrate from the hospital outpatient setting to the ASC setting as a result of this policy, Medicare payments will be reduced by approximately $7 million in CY 2021 and total beneficiary copayments will decline by approximately $1.4 million in CY 2021. 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 designate as office-based in CY 2021, 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).

Alternatives to the OPPS changes we are finalizing and the reasons for our selected alternatives are discussed throughout this final rule with comment period.

- Alternatives Considered for the Payment Adjustment for Separately Paid Drugs Acquired through the 340B Program.

We refer readers to section V.B.6. of this final rule with comment period for a discussion of our final policy to apply a payment adjustment of ASP minus 22.5 percent for separately paid non-pass through drugs acquired under the 340B Program, which was originally adopted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59350 through 59369). We also proposed but did not finalize a policy to pay ASP minus 28.7 percent for 340B drugs in CY 2021, based on hospital survey data. We note that the effects of this proposal, which was not finalized, and its corresponding budget neutrality adjustment compared to our finalized proposal were provided in Column 4 of Table 55 of the CY 2021 OPPS/ASC proposed rule (85 FR 49047 through 49049).

2. Estimated Effects of CY 2021 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 final rule with comment period, we are setting the CY 2021 ASC relative payment weights by scaling the CY 2021 OPPS relative payment weights by the ASC scalar of 0.8591. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 80 and 81.

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 are requiring that the CY 2021 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which is the hospital market basket for CY 2021. We calculated the CY 2021 ASC conversion factor by adjusting the CY 2020 ASC conversion factor by 1.0012 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2020 and CY 2021 and by applying the CY 2021 MFP-adjusted hospital market basket update factor of 2.4 percent (which is equal to the projected hospital market basket update of 2.4 percent minus an MFP adjustment of 0.0 percentage point). The CY 2021 ASC conversion factor is $48.952 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the changes for CY 2021 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 2021 with precision. We believe the net effect on Medicare expenditures resulting from the CY 2021 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 update to the CY 2021 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 CY 2021 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 80 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2020 payments to estimated CY 2021 payments, and Table 81 shows a comparison of estimated CY 2020 payments to estimated CY 2021 payments for procedures that we estimate will receive the most Medicare payment in CY 2020.

In Table 80, 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 80.

- 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 2020 ASC Payments were calculated using CY 2019 ASC utilization data (the most recent full year of ASC utilization) and CY 2020 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2020 ASC payments.

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 final rule with comment period and the impact of the changes to the RO Model in this interim final rule with comment period. The first accounting statement, Table 82, illustrates the classification of expenditures for the CY 2021 estimated hospital OPPS incurred benefit impacts associated with the final CY 2021 OPD fee schedule increase. The second accounting statement, Table 83, illustrates the classification of expenditures associated with the 2.4 percent CY 2021 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. The third accounting statement, Table 84, shows the classification of expenditures, which represent savings associated with the RO Model, which are classified as transfers. The estimated costs of ICR Burden and Regulatory Familiarization are included in Table 84.

BILLING CODE 4120–01–P

TABLE 82: ACCOUNTING STATEMENT: CY 2021 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2020 TO CY 2021 ASSOCIATED WITH THE FINAL CY 2020 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$1,490 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS
Total	$1,490 million

TABLE 83: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2020 TO CY 2021 AS A RESULT OF THE FINAL CY 2021 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$100 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$100 million

TABLE 84: Accounting Statement Estimated Impacts for the Radiation Oncology Model

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized ($million/year)	-$38 million	2019	7%	2021 – 2025
	-$40 million	2019	3%	2021 – 2025
From Whom to Whom	From the federal government to healthcare providers			

TABLE 85: ESTIMATED COSTS IN CY 2021

CATEGORY	Costs
ICR Burden	$139 million*
Regulatory Familiarization	$1.195 million**

*The annual estimates are in 2019 year dollars which includes the impact of hospital outpatient QRP, prior authorization process and requirements for certain OPD services, and flu reporting provisions.
** Regulatory familiarization costs occur upfront only.

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 2020 payment determinations. Of the 3,144 hospitals that met eligibility requirements for the CY 2020 payment determination, we determined that 78 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. We did not propose to add or remove any quality measures to the Hospital OQR Program measure set for the CY 2022 or CY 2023 payment determinations.

b. Impact of CY 2021 Finalized Policies

We do not anticipate that any of the CY 2021 Hospital OQR Program finalized policies will impact the number of facilities that will receive payment reductions. In this final rule with comment period, we are finalizing our proposals to: (1) Codify the statutory authority for the Hospital OQR Program; (2) revise and codify the previously finalized public display of measure data policy that hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes; (3) revise existing § 419.46(a)(2) by replacing the term ''security administrator'' with the term ''security official'' and codify this language; (4) move all deadlines falling on nonwork days forward consistent with section 216(j) of the Social Security Act (the Act), 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days,'' beginning with the effective date of this rule; (5) revise our policy regarding submission deadlines at existing § 419.46(c)(2) to reflect the proposed deadlines policy consistent with section 216(j) of the Act, 42 U.S.C. 416(j); (6) expand the existing review and corrections policy for chart-abstracted data 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; (7) codify at § 419.46 the review and corrections period policy for measure data submitted to the Hospital OQR Program for chart-abstracted measure data, as well as for the proposed policy for measure data submitted directly to CMS via the CMS web-based tool; (8) codify the previously finalized Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures; (9) revise existing § 419.46(b) (redesignated § 419.46(c)) by removing the phrase ''submit a new participation form'' to align with previously finalized policy, and (10) update internal cross-references as a result of the redesignations.

We do not anticipate that the requirements affecting the Hospital OQR Program in this final rule with comment period will impact the number of hospitals that will receive payment reductions.

5. Effects of Requirements for the ASCQR Program

a. Background

In section XV.B. of this final rule with comment period, we discuss our finalized policies affecting the Ambulatory Surgical Centers Quality Reporting (ASCQR) Program. For the CY 2020 payment determination, of the 6,651 ASCs that met eligibility requirements for the ASCQR Program, 195 ASCs did not meet the requirements to receive the full annual payment update. We did not propose any quality measure additions or removals for the ASCQR Program measure set for future calendar year payment determinations.

b. Impact of CY 2021 Finalized Policies

In sections XV.C. and XV.D. of this final rule with comment period, we are finalizing our proposals to: (1) Use the term ''security official'' instead of ''security administrator'' and revise § 416.310(c)(1)(i) by replacing the term ''security administrator'' with the term ''security official;'' (2) remove the phrase ''data collection time period'' in all instances where it appears in § 416.310, replace it with the phrase ''data collection period,'' and use the phrase ''data collection period'' wherever the phrase ''data collection time period'' is found in the preamble of this final rule with comment period; (3) move forward all program deadlines falling on a nonwork day consistent with the section 216(j) of the Act, 42 U.S.C. 416(j) and codify this policy; and (4) formalize the process by which ASCs identify errors and resubmit data before the established submission deadline by creating a review and corrections period similar to that finalized for the Hospital OQR Program in section XIV.D.7. of this final rule with comment period that runs concurrent with the existing data submission period from January 1 through May 15 and codify this policy.

We do not anticipate that the finalized policies affecting the ASCQR Program in this final rule with comment period will impact the number of ASCs that will receive payment reductions.

6. Effects of Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

a. Overall Impact

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop ''a method for controlling unnecessary increases in the volume of covered OPD services'' (84 FR 61142).[384] The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we are finalizing our proposal requiring prior authorization for two new service categories: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. We are adding those service categories to § 419.83(a). We are requiring that the prior authorization process for these two additional service categories will be effective for dates of services on or after July 1, 2021. The addition of these service categories is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services.

The overall economic impact on the health care sector to require prior authorization for two additional service categories is dependent on the number of claims affected. Table 86, Overall Economic Impact to the Health Sector, lists an estimate for the overall economic impact to the health sector for the two new service categories combined. The values populating this table were obtained from the cost reflected in Table 87, Annual Private Sector Costs, and Table 88, Estimated Annual Administrative Costs to CMS. Together, Tables 87 and 88 combine to convey the overall economic impact to the health sector for the two new service categories, which is illustrated in Table 86. It should be noted that due to the July start date for prior authorization for these two new service categories, year one includes only 6 months of prior authorization requests.

Based on the estimate, the overall economic cost impact is approximately $2.9 million in the first year based on 6 months for the two new service categories. The 5-year impact is approximately $22.9 million, and the 10-year impact is approximately $47.9 million. The 5- and 10-year impacts account for year one including only 6 months. Additional administrative paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create the financial impact; however, this impact is offset by Medicare savings. Annually, we estimate an overall Medicare savings of $31,844,388. We believe there are likely to be other benefits that result from the prior authorization requirement for the two new service categories, though many of those benefits are difficult to quantify. For instance, we expect to see savings in the form of reduced fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (we note that not all improper payments are fraudulent). We solicited public comments on the potential increased costs and benefits associated with the proposed provision for the two new service categories. As part of a larger comment on a previous section of this rule, one commenter stated that our costs and hours were under-estimated. The response to this part of the comment is included in the overall response to the comment in the previous section.

TABLE 86: Overall Economic Cost Impact to the Health Sector

	Year 1	5 Years	10 Years
Private Sector Costs	$870,723	$6,539,151	$13,624,686
Administrative Costs to CMS	$2,017,317	$16,349,353	$34,264,398
Total Economic Impact to Health Sector	$2,888,040	$22,888,504	$47,889,084

According to the RFA's use of the term, most suppliers and providers are small entities. Likewise, the vast majority of physician and nurse practitioner (NP) practices are considered small businesses according to the SBA's size standards of having total revenues of $10 million or less in any 1 year. While the economic costs and benefits are substantial in the aggregate, the economic impact on individual entities compliant with Medicare program coverage and utilization rules and regulations will be relatively small. We estimate that 90 to 95 percent of providers who provide these services are small entities under the RFA definition. The rationale behind requiring prior authorization is to control unnecessary increases in the volume of covered OPD services. The impact on providers not in compliance with Medicare coverage, coding, and payment rules and regulations could be significant, as the finalized rule will change the billing practices of those providers. We believe that the purpose of the statute and this rule is to avoid unnecessary increases in utilization of OPD services. Therefore, we do not view decreased revenues from the two additional OPD services categories subject to unnecessary utilization by providers to be a condition that we must mitigate. We believe that the effect will be minimal on providers who are compliant with Medicare coverage, coding, and payment rules and requirements. Adding these two services will offer an additional protection to a provider's cash flow as the provider will know in advance if the Medicare requirements are met.

b. Anticipated Specific Cost Effects

1. Private Sector Costs

We do not believe that this rule will significantly affect the number of legitimate claims submitted for these new service categories. However, we do expect a decrease in the overall amount paid for the services resulting from a reduction in unnecessary utilization of the services requiring prior authorization.

We estimate that the private sector's per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request for the two additional service categories is equivalent to that of submitting

[384] See also Correction notification issued January 3, 2020 (85 FR 224).

documentation and clerical activities associated for prepayment review, which is 0.5 hours. We apply this time burden estimate to initial submissions and resubmissions.

TABLE 87: Year 1 (6 Month) Private Sector Costs

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests-Initial Submissions	15,884	0.5	7,942	$264,158
Fax and Electronic Submitted Requests-Resubmissions	5,214	0.5	2,607	$86,702
Mailed in Requests-Initial Submissions	6,808	0.5	3,404	$113,210
Mailed in Requests-Resubmissions	2,234	0.5	1,117	$37,158
Mailing Costs	9,042	$5	NA	$45,210
Provider Demonstration-Education	3,250	3	9,750	$324,285
Total			24,820	$870,723

2. Administrative Costs to CMS

CMS will incur additional costs associated with processing the prior authorization requests for the two new service categories. We use the range of potentially affected cases (submissions and resubmissions) and multiply it by $50, the estimated cost to review each request. The combined cost also includes other elements such as appeals, education and outreach, and system changes.

TABLE 88: Year 1 (6 Month) Estimated Administrative Costs to CMS

Cervical Fusion with Disc Removal	Implanted Spinal Neurostimulators	Combined
$489,916	$1,077,401	$2,017,317

3. Estimated Beneficiary Costs

We expect a reduction in the utilization of the two new Medicare OPD service categories when such utilization does not comply with one or more of Medicare's coverage, coding, and payment rules. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, we are unable to quantify that burden. Although the rule is designed to permit utilization that is medically necessary, OPD services that are not medically necessary may still provide convenience or usefulness for beneficiaries; any rule-induced loss of such convenience or usefulness constitutes a cost of the rule that we lack data to quantify. Additionally, beneficiaries may have out-of-pocket costs for those services that are determined not to comply with Medicare requirements and thus, are not eligible for Medicare payment. We lack the data to quantify these costs as well.

c. Estimated Benefits

There will be quantifiable benefits for this rule because we expect a reduction in the unnecessary utilization of those two new Medicare OPD service categories subject to prior authorization. It is difficult to project the exact

decrease in unnecessary utilization; however, based on other prior authorization programs, we estimate our savings based on a 50 percent reduction in improper payments, using a 10 percent improper payment rate. We estimate that for the first 6 months, there would be savings of $15,922,194 overall. Annually, we estimate an overall gross savings of $31,844,388. This savings represents a Medicare benefit from a more efficient use of health care resources while still maintaining the same health outcomes for necessary services. We will closely monitor utilization and billing practices. The expected benefits would also include changed billing practices that would also enhance the coordination of care for the beneficiary. For example, requiring prior authorization for the two additional OPD services categories would ensure that the primary care practitioner recommending the service and the facility collaborate more closely to provide the most appropriate OPD services to meet the needs of the beneficiary. The practitioner recommending the service would evaluate the beneficiary to determine what services are medically necessary based on the beneficiary's condition. This would require the facility to collaborate closely with the practitioner early on in the process to ensure the services are truly necessary and meet all requirements and that their supporting documentation is complete and correct. Improper payments made because the practitioner did not evaluate the patient or the patient does not meet the Medicare requirements would likely be reduced by the requirement that a provider submit clinical documentation created as part of its prior authorization request.

7. Effects of Revision to the Laboratory Date of Service Policy

In section XVIII. of this final rule with comment period, we discuss our policy to include cancer-related protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) and the test described by CPT code 81490 in the laboratory date of service (DOS) exception at § 414.510(b)(5). We are also excluding these tests from the OPPS packaging policy, which is discussed in section II.a.3 of this final rule with comment period. Under these policies, Medicare will pay for certain protein-based MAAAs under the CLFS instead of the OPPS and the performing laboratory will bill Medicare directly for the test if the test meets all the laboratory DOS requirements specified in § 414.510(b)(5). While there may be some impact under the hospital OPPS resulting from additional tests being excluded from OPPS packaging policy and paid at the CLFS rate instead of the OPPS bundled rate, we expect this change to be budget neutral for scoring purposes. Accordingly, the discussion in sections II.a.3. and XVIII of this final rule with comment period is not reflected in Table 79 in the regulatory impact analysis under section XXVII of this final rule with comment period.

8. Effects of Requirements for the Overall Hospital Quality Star Ratings

In section E. Current and Proposed Overall Star Rating Methodology of this final rule with comment period, we discussed our proposal as it relates to the Overall Star Rating methodology. The Overall Star Rating uses measures that are publicly reported on *Hospital Compare* or its successor websites under the public reporting authority of each individual hospital program furnishing measure data. The burden associated with measures included in the Overall Star Rating, including forms used to request withholding of publicly reported measure data and the Overall Star Rating (for Critical Access Hospitals (CAHs)), is already captured in the respective hospital programs' burden estimates and represents no increased information collection burden to hospitals.

In this CY 2021 OPPS/ASC final rule with comment period, however, we are finalizing that hospitals have the opportunity to review confidential reports containing their measure, measure group, and Overall Star Rating results for at least 30 days prior to publication of the Overall Star Rating. We believe that reviewing the Overall Star Rating in confidential reports prior to public reporting represents additional burden to hospitals.

In this CY 2021 OPPS/ASC final rule with comment period, we are using the most recent data from the Bureau of Labor Statistics, which reflects a median hourly wage of $19.40 [385] per hour for a Medical Records and Health Information Technician professional. We calculate the cost of overhead, including fringe benefits, at 100 percent of the hourly wage estimate, consistent with the previous year. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($19.40 × 2 = $38.80) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $38.80 per hour.

We estimate that the non-information collection burden associated with all non-Veterans Health Administration (VHA) hospitals reviewing their Overall Star Rating preview report prior to public reporting to be 2 hours per hospital, which includes time to review the report and ask any questions about the calculation necessary to increase comprehension. Estimating that 4,500 hospitals that will receive an Overall Star Rating hospital specific report (HSR), regardless if they meet the reporting thresholds to be assigned a star rating, we estimate the overall non-information collection burden to be $397,710 annually [$38.80 × 2 hours per preview report × once per year × 4,500 hospitals]. For CAHs specifically, which are included in the estimate above, we estimate that half of CAHs will be eligible for an Overall Star Rating (using an estimate of 1,300 total CAHs in the U.S.), which represents a burden of $100,890 annually [650 CAHs × 2 hours per preview report × once per year × $38.80].

Within this rule, for CY 2021 Overall Star Rating and subsequent years, we are finalizing the continuation of the Overall Star Rating methodology, as currently implemented, with the following modifications: (1) Elimination of measure score Winsorization; (2) grouping measures into five, rather than seven, measure groups, consisting of Mortality, Safety of Care, Readmission, Patient Experience, and Timely and Effective Care; (3) using a simple average of measure scores to calculate measure group scores; (4) standardization of measure group scores; (5) weighting measure groups so that Mortality, Safety of Care, Readmission, and Patient Experience each are weighted 22 percent and Timely and Effective Care is weighted 12 percent with proportional reweighting when hospitals have too few measures in one or more measure groups; (6) requiring three measures in at least three measure groups, one of which must be Mortality or Safety of Care; and (7) peer grouping hospitals based on the number of measure groups for which hospitals reports at least three measures. As a result of continued stakeholder concerns with the dual-eligibility variable and that stratification may be confusing to patients, analyses that indicate stratification of the Readmission measure group would not

[385] Bureau of Labor Statistics. (2019, September 4). *Occupational Outlook Handbook: Medical Records and Health Information Technicians.* Retrieved from *www.bls.gov*: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

have the intended effect, and ASPE's recent report to Congress, we are not finalizing our proposal to stratify the Readmission measure group score based on the proportion of dual-eligible patients.

To simulate the impact of the final Overall Star Rating methodology, we used October 2020 *Hospital Compare* data to describe the overall distribution of star ratings, reclassification of star ratings, and distribution of star ratings across different types of hospitals

The final Overall Star Rating methodology for CY 2021 and subsequent years results in a similar distribution of star ratings but with slightly more hospitals receiving a star rating, primarily due to combining the existing three process measure groups into one measure group, Timely and Effective Care. Specifically, using October 2020 *Hospital Compare* data, the final Overall Star Rating methodology results in 3,350 (74 percent) hospitals receiving a star rating and more three (30 percent) and four (28 percent) star ratings and fewer one (7 percent), two (21 percent), and five (14 percent) star ratings (Table 89).

Given the substantial change in methods, particularly using a simple average of measure scores to calculate measure group scores instead of the LVM, we expect considerable shifts in hospital star ratings from the current methodology to the final methodology for CY 2021 and subsequent years. When comparing the current methodology to the final methodology for CY 2021 and subsequent years, 1,585 (50 percent) hospitals would receive the same star rating, 1,423 (45 percent) hospitals would increase or decrease one star rating, 150 (5 percent) hospitals would increase or decrease two star ratings, 9 (0.3 percent) hospitals would increase or decrease three star ratings, and 0 (0 percent) hospitals would increase or decrease four star ratings (Table 90).

With the final methodology for CY 2021 and subsequent years, most hospital characteristics have a similar distribution of star ratings to that of all hospitals with some variations (Tables 91 and 92). The variations in the distribution of star ratings across hospital characteristics compared to all hospitals are listed below.

- Specialty hospitals have a smaller proportion of one (1 percent specialty, 5 percent non-specialty), two (0 percent specialty, 16 percent non-specialty), three (6 percent specialty, 23 percent non-specialty), and four (6 percent specialty, 22 percent non-specialty) star ratings and a higher proportion of five (15 percent specialty, 10 percent specialty) star ratings than non-specialty hospitals.
- Teaching hospitals have a higher proportion of all star rating categories with a higher proportion of one (10 percent major teaching, 7 percent minor teaching, 3 percent non-teaching), two (21 percent major teaching, 20 percent minor teaching, 12 percent non-teaching), three (26 percent major teaching, 26 percent minor teaching, 20 percent non-teaching), four (28 percent major teaching, 27 percent minor teaching,19 percent non-teaching), and five (14 percent major teaching, 13 percent minor teaching, 8 percent non-teaching) star ratings than non-teaching hospitals.
- Safety net hospitals have a slightly higher proportion of two (21 percent safety net, 18 percent non-safety net) and slightly smaller proportion of four (27 percent safety net, 31 percent non-safety net) star ratings than non-safety net hospitals.
- DSH hospitals have a higher proportion of one (6 percent DSH, 2 percent non-DSH), two (21 percent DSH, 8 percent non-DSH), three (29 percent DSH, 14 percent non-DSH), and four (27 percent DSH, 23 percent non-DSH) and a smaller proportion of five (11 percent DSH, 22 percent non-DSH) star ratings than non-DSH; with increasing DSH quintiles, hospitals have a higher proportions of one (2 percent DSH quintile 1, 3 percent DSH quintile 2, 5 percent DSH quintile 3, 6 percent DSH quintile 4, 15 percent DSH quintile 5), two (11 percent DSH quintile 1, 18 percent DSH quintile 2, 18 percent DSH quintile 3, 25 percent DSH quintile 4, 30 percent DSH quintile 5), and a smaller proportions of four (34 percent DSH quintile 1, 31 percent DSH quintile 2, 30 percent DSH quintile 3, 23 percent DSH quintile 4, 15 percent DSH quintile 5) and five (21 percent DSH quintile 1, 13 percent DSH quintile 2, 11 percent DSH quintile 3, 7 percent DSH quintile 4, 5 percent DSH quintile 5) star ratings.
- CAHs have a smaller proportion of all star rating categories with a smaller proportion of one (2 percent CAHs, 6 percent non-CAHs), two (7 percent CAHs, 19 percent non-CAHs), and three (13 percent CAHs, 27 percent non-CAHs), four (12 percent CAHs, 26 percent non-CAHs), and five (3 percent CAHs, 13 percent non-CAHs) star ratings than non-CAHs.
- Urban hospitals have a higher proportion of one (8 percent large urban, 5 percent other urban, 3 percent rural) and two (19 percent large urban, 18 percent other urban, 20 percent rural) and a smaller proportion of three (25 percent large urban, 27 percent other urban, 29 percent rural) and four (25 percent large urban, 29 percent other urban, 25 percent rural) star ratings than rural hospitals.

BILLING CODE 4120–01–P

TABLE 89: Overall Star Rating Distribution by Current Methodology and Final Methodology for CY 2021 and Subsequent Years (October 2020 Hospital Compare Data)

Star Rating	Current Methodology	Final Methodology
1	208 (6.4%)	230 (6.9%)
2	597 (18.5%)	704 (21.0%)
3	1000 (31.0%)	1005 (30.0%)
4	1049 (32.5%)	947 (28.3%)
5	375 (11.61%)	464 (13.9%)
N/A	1308	1187

TABLE 90: Overall Star Rating Reclassification, Current Methodology vs Final Methodology for CY 2021 and Subsequent Years (October 2020 Hospital Compare Data)

Star Rating (Current Methodology)	Star Rating (Final Methodology)					
	1	**2**	**3**	**4**	**5**	**Total**
1	117	81	10	0	0	208
	56.25%	38.94	4.81	0	0	
2	78	306	180	25	2	591
	13.2	51.78	30.46	4.23	0.34	
3	19	240	462	238	30	989
	1.92	24.27	46.71	24.06	3.03	
4	4	48	296	496	176	1020
	0.39	4.71	29.02	48.63	17.25	
5	0	3	18	134	204	359
	0	0.84	5.01	37.33	56.82	
Total	218	678	966	893	412	3167

TABLE 91: Distribution of Star Ratings by Hospital Characteristics, Current Methodology (October 2020 *Hospital Compare* Data)

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	208 (4.58%)	597 (13.16%)	1000 (22.04%)	1049 (23.12%)	375 (8.27%)	1308 (28.83%)
Specialty	0 (0%)	0 (0%)	4 (3.25%)	8 (6.50%)	27 (21.95%)	84 (68.29%)
Non-Specialty	208 (4.78%)	595 (13.67%)	992 (22.79%)	1038 (23.85%)	344 (7.90%)	1175 (27.00%)
N/A	0 (0%)	2 (3.23%)	4 (6.45%)	3 (4.84%)	4 (6.45%)	49 (79.03%)
Major Teaching	41 (17.52%)	64 (27.35%)	50 (21.37%)	53 (22.65%)	24 (10.26%)	2 (0.85%)
Minor Teaching	119 (7.33%)	288 (17.73%)	464 (28.57%)	410 (25.25%)	185 (11.39%)	158 (9.73%)
Non-Teaching	48 (1.83%)	243 (9.29%)	482 (18.42%)	583 (22.28%)	162 (6.19%)	1099 (41.99%)
N/A	0 (0%)	2 (3.23%)	4 (6.45%)	3 (4.84%)	4 (6.45%)	49 (79.03%)
Safety-Net	3 (3.66%)	17 (20.73%)	17 (20.73%)	25 (30.49%)	9 (10.98%)	11 (13.41%)
Non-Safety-Net	16 (6.35%)	44 (17.46%)	67 (26.59%)	72 (28.57%)	28 (11.11%)	25 (9.92%)
N/A	189 (4.50%)	536 (12.75%)	916 (21.79%)	952 (22.65%)	338 (8.04%)	1272 (30.26%)
Non-DSH	3 (3.66%)	17 (20.73%)	17 (20.73%)	25 (30.49%)	9 (10.98%)	11 (13.41%)
DSH	16 (6.35%)	44 (17.46%)	67 (26.59%)	72 (28.57%)	28 (11.11%)	25 (9.92%)
Quintile 1	189 (4.50%)	536 (12.75%)	916 (21.79%)	952 (22.65%)	338 (8.04%)	1272 (30.26%)
Quintile 2	3 (3.66%)	17 (20.73%)	17 (20.73%)	25 (30.49%)	9 (10.98%)	11 (13.41%)
Quintile 3	16 (6.35%)	44 (17.46%)	67 (26.59%)	72 (28.57%)	28 (11.11%)	25 (9.92%)
Quintile 4	189 (4.50%)	536 (12.75%)	916 (21.79%)	952 (22.65%)	338 (8.04%)	1272 (30.26%)
Quintile 5	3 (3.66%)	17 (20.73%)	17 (20.73%)	25 (30.49%)	9 (10.98%)	11 (13.41%)
N/A	16 (6.35%)	44 (17.46%)	67 (26.59%)	72 (28.57%)	28 (11.11%)	25 (9.92%)
CAH	0 (0%)	15 (1.13%)	108 (8.17%)	217 (16.41%)	42 (3.18%)	940 (71.10%)
Non-CAH	208 (6.47%)	582 (18.10%)	892 (27.74%)	832 (25.88%)	333 (10.36%)	368 (11.45%)
1-99 beds	13 (1.12%)	100 (8.64%)	293 (25.30%)	356 (30.74%)	133 (11.49%)	263 (22.71%)
100-199 beds	48 (5.32%)	209 (23.15%)	281 (31.12%)	228 (25.25%)	81 (8.97%)	56 (6.20%)
200-299 beds	59 (12.29%)	108 (22.50%)	147 (30.63%)	108 (22.50%)	44 (9.17%)	14 (2.92%)

Hospital Characteristic	1	2	3	4	5	N/A
300-399 beds	35 (12.92%)	68 (25.09%)	73 (26.94%)	61 (22.51%)	30 (11.07%)	4 (1.48%)
400 or more beds	53 (14.21%)	95 (25.47%)	98 (26.27%)	79 (21.18%)	45 (12.06%)	3 (0.80%)
N/A	0 (0%)	17 (1.26%)	108 (7.99%)	217 (16.05%)	42 (3.11%)	968 (71.60%)
Large Urban	96 (7.74%)	242 (19.50%)	330 (26.59%)	292 (23.53%)	137 (11.04%)	144 (11.60%)
Other Urban	90 (7.56%)	216 (18.14%)	332 (27.88%)	305 (25.61%)	133 (11.17%)	115 (9.66%)
Rural	22 (2.92%)	122 (16.20%)	230 (30.54%)	235 (31.21%)	63 (8.37%)	81 (10.76%)
N/A	0 (0%)	17 (1.26%)	108 (7.99%)	217 (16.05%)	42 (3.11%)	968 (71.60%)

TABLE 92: Distribution of Star Ratings by Hospital Characteristics, Final Methodology for CY 2021 and Subsequent Years (October 2020 *Hospital Compare* Data)

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	204 (4.50%)	690 (15.21%)	1019 (22.46%)	988 (21.78%)	455 (10.03%)	1181 (26.03%)
Specialty	1 (0.81%)	0 (0%)	7 (5.69%)	7 (5.69%)	18 (14.63%)	90 (73.17%)
Non-Specialty	202 (4.64%)	689 (15.83%)	1008 (23.16%)	977 (22.45%)	435 (10.00%)	1041 (23.92%)
N/A	1 (1.61%)	1 (1.61%)	4 (6.45%)	4 (6.45%)	2 (3.23%)	50 (80.65%)
Major Teaching	24 (10.26%)	49 (20.94%)	60 (25.64%)	66 (28.21%)	33 (14.10%)	2 (0.85%)
Minor Teaching	109 (6.71%)	317 (19.52%)	420 (25.86%)	433 (26.66%)	206 (12.68%)	139 (8.56%)
Non-Teaching	70 (2.67%)	323 (12.34%)	535 (20.44%)	485 (18.53%)	214 (8.18%)	990 (37.83%)
N/A	1 (1.61%)	1 (1.61%)	4 (6.25%)	4 (6.45%)	2 (3.23%)	50 (80.65%)
Safety-Net	1 (1.22%)	17 (20.73%)	22 (26.83%)	22 (26.83%)	10 (12.20%)	10 (12.20%)
Non-Safety-Net	6 (2.38%)	45 (17.86%)	71 (28.17%)	77 (30.56%)	29 (11.51%)	24 (9.52%)
N/A	197 (4.69%)	628 (14.94%)	926 (22.03%)	889 (21.15%)	416 (9.90%)	1147 (27.29%)

Hospital Characteristic	1	2	3	4	5	N/A
Non-DSH	8 (1.68%)	40 (8.39%)	67 (14.05%)	111 (23.27%)	105 (22.01%)	146 (30.61%)
DSH	168 (6.20%)	556 (20.53%)	784 (28.95%)	720 (26.59%)	305 (11.26%)	175 (6.46%)
Quintile 1	11 (2.03%)	62 (11.46%)	148 (27.36%)	184 (34.01%)	114 (21.07%)	22 (4.07%)
Quintile 2	15 (2.76%)	97 (17.86%)	160 (29.47%)	167 (30.76%)	69 (12.71%)	35 (6.45%)
Quintile 3	26 (4.81%)	98 (18.11%)	174 (32.16%)	161 (29.76%)	58 (10.72%)	24 (4.44%)
Quintile 4	34 (6.27%)	134 (25.09%)	172 (31.73%)	129 (23.80%)	38 (7.01%)	33 (6.09%)
Quintile 5	82 (15.16%)	163 (30.13%)	130 (24.03%)	79 (14.60%)	26 (4.81%)	61 (11.28%)
N/A	28 (2.07%)	94 (6.95%)	168 (12.43%)	157 (11.61%)	45 (3.33%)	146 (30.61%)
CAH	26 (1.97%)	94 (7.11%)	166 (12.56%)	157 (11.88%)	45 (3.40%)	834 (63.09%)
Non-CAH	178 (5.54%)	596 (18.54%)	853 (26.53%)	831 (25.85%)	410 (12.75%)	347 (10.79%)
1-99 beds	23 (1.99%)	170 (14.68%)	252 (21.76%)	276 (23.83%)	168 (14.51%)	269 (23.23%)
100-199 beds	44 (4.87%)	164 (18.16%)	266 (29.46%)	270 (29.90%)	112 (12.40%)	47 (5.20%)
200-299 beds	51 (10.63%)	104 (21.67%)	142 (29.58%)	123 (25.63%)	56 (11.67%)	4 (0.83%)
300-399 beds	28 (10.33%)	73 (26.94%)	83 (30.63%)	56 (20.66%)	30 (11.07%)	1 (0.37%)
400 or more beds	30 (8.04%)	85 (22.79%)	108 (28.95%)	106 (28.42%)	44 (11.80%)	0 (0%)
N/A	28 (2.07%)	94 (6.95%)	168 (12.43%)	157 (11.61%)	45 (3.33%)	860 (63.61%)
Large Urban	94 (7.57%)	234 (18.86%)	305 (24.58%)	306 (24.66%)	165 (13.30%)	137 (11.04%)
Other Urban	57 (4.79%)	210 (17.63%)	324 (27.20%)	340 (28.55%)	149 (12.51%)	111 (9.32%)
Rural	25 (3.32%)	152 (20.19%)	222 (29.48%)	185 (24.57%)	96 (12.75%)	73 (9.69%)

Hospital Characteristic	1	2	3	4	5	N/A
N/A	28 (2.07%)	94 (6.95%)	168 (12.43%)	157 (11.61%)	45 (3.33%)	860 (63.61%)

BILLING CODE 4120–01–C

Alternatives Considered

Overall Hospital Quality Star Rating

We considered a number of alternatives to our proposals discussed in section XVI of this final rule with comment period. Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years of the preamble of the CY 2021 OPPS/ASC proposed rule. As described more fully in section E. Current and Proposed Overall Star Rating Methodology of this final rule with comment period, we considered alternatives to measure group weighting, calculation of measure group scores, stratifying the Readmission group based on proportion of dual-eligible patients, and peer grouping by number of measures.

We considered an alternative to equally weight the five measure groups instead of the proposal to weight the four outcome and patient experience measure groups at 22 percent (Morality, Safety of Care, Readmission, and Patient Experience) and the newly proposed Timely and Effective Care process group at 12 percent. Because past stakeholder comments have recommended that outcome groups receive the most weight, we recommended our proposal but are sought comment on the alternative presented.

We considered keeping the Latent Variable Model (LVM) as an alternative to the proposed simple average of measure group scores since it is a data driven model where the measure loadings, or measure contribution to the measure group score, are empirically derived and are able to account for sampling variation and missing data. Because past stakeholder comments have indicated that the use of LVM is difficult to understand and the weights of measures and their subsequent impact on the group score changes depending on the underlying data, we proposed to use a simple average of measure group scores but are seeking comment on the alternative presented.

We also considered not stratifying the Readmission measure group based on dual-eligibility peer groups and retaining the current approach, without stratification. This consideration was based on the premise that, although select stakeholders have requested social risk factor adjustment of the Readmission measure group in alignment with Hospital Readmission Reduction Program (HRRP),[386] other stakeholder groups expressed concern that social risk factor adjustment would be confusing to patients and consumers, resulting in misrepresentation of quality of care at hospitals providing acute inpatient and outpatient care, specifically for dual-eligible patients, while others were concerned that the dual-eligibility variable would not adequately account for social risk in the Overall Star Rating. [387] [388] [389] Furthermore, this consideration was in response to a HHS report titled ''Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs,'' submitted to Congress by ASPE, that sets forth new recommendations regarding social risk factors, wherein ASPE does not recommend adjusting quality measure for social risk in public reporting.[390] Due to these considerations, we sought comment on the alternative to not stratify the Readmission measure group by proportion of dual-eligible patients.

Within the proposal to stratify the Readmission measure group scores based on dual-eligibility peer groups, we also considered recalculating the peer group quintiles based on all hospitals in the Overall Star Rating, and not solely based on those participating in HRRP. However, calculating quintiles based on all hospitals would create potential misalignment between HRRP quintiles and Overall Star Rating quintiles, and therefore peer group assignment. Because of this potential misalignment, we proposed to recalculate peer group quintiles based on those in the HRRP but sought public comment on our proposal and alternative to recalculate the quintiles based on all hospitals included in the Overall Star Rating.

Finally, we considered not peer grouping by number of measures. Because past stakeholder feedback suggested that CMS consider some type of peer grouping to enable more similar comparisons among hospital types, we proposed to peer group by number of measure groups to achieve this aim. This would enable more similar comparisons among hospitals where smaller hospitals that submit the fewest number of measures are more likely to be in the three measure group peer group and larger hospitals that submit the most measures are more likely to be in the five measure group peer group. We also stated that if we did not finalize our proposal to include CAHs in the Overall Star Ratings, we would not be able to peer group since CAHs make up the majority of the three measure group peer group. Ultimately, we decided to propose peer grouping but solicited public comment on our proposal as well as the alterative considered to not peer group. We solicited comment on our alternative considered to not peer group even if we finalized our proposal to include CAHs.

9. Effects of Requirements for the Physician-Owned Hospitals

The physician-owned hospital provisions are discussed in section XIX. of this final rule with comment period. We proposed and are finalizing regulatory updates to the process under which a hospital that qualifies as a high Medicaid facility can request an exception to the prohibition on facility expansion. Specifically, we will permit a high Medicaid facility to request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years. With respect to a hospital that qualifies as a high Medicaid facility, we have

[386] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[387] Ibid.

[388] Centers for Medicare & Medicaid Services. (2019, October 24) Patient and Patient Advocate Work Group Minutes—October 2019.

[389] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org*: *http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

[390] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

removed the restrictions that permitted expansion of facility capacity: (1) May not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and (2) must occur only in facilities on the hospital's main campus. We expect these changes will reduce burden on high Medicaid facilities and give them additional flexibility to expand. As we explained in the proposed rule, we believe that the existing regulations impose unnecessary burden on high Medicaid facilities. In alignment with our Patients over Paperwork initiative, we are finalizing our proposals to remove this unnecessary burden. Finally, are we are codifying in regulations our longstanding policy, currently set forth in a frequently asked question on the CMS website, that explains CMS' deference to state law for purposes of determining the number of beds for which a hospital is licensed. As this final policy reflects current policy, we do not anticipate that it will have an impact.

In the past decade, the Secretary has granted six expansion exception requests. Neither the statute nor our regulations require that a hospital report to the Secretary whether and when it expands its facility capacity. Based on our own review of the websites of the hospitals granted expansion exception requests, it does not appear that any of the hospitals have yet expanded to 200 percent of their baseline capacity (the current regulatory limit). We are unable to predict with certainty whether any hospital qualifying as a high Medicaid facility would request to, or utilize permitted expansion of facility capacity to, expand beyond 200 percent of its baseline facility capacity.

As noted in the ICR section for physician-owned hospitals, we expect the final policies will impact one physician-owned hospital per year. We do not anticipate any impact on Medicare expenditures for several reasons. First, although an expansion of a physician-owned hospital's capacity may increase access to patients seeking care, it does not affect the type of services being received. Second, the regulations will not affect the payment for Medicare covered items and services. The regulations do not permit development of a new hospital, but rather expansion of an existing hospital. All services furnished by the hospital will be paid at the applicable Medicare payment rates for the existing hospital. Further, existing Medicare billing and claims submission requirements, including the requirement that the services are reasonable and necessary, will continue to apply. Although we believe these changes potentially increase access for patients seeking care, we do not believe there would be any impact to the type or range of services sought, or the amount paid for the services furnished.

We received no comments concerning the burden associated with our proposal to codify in regulations the policy in an existing frequently asked question that explains CMS' deference to state law for purposes of determining the number of beds for which a hospital is licensed. This reflects current policy, and we continue to believe that it will not have an impact. We received the following comments regarding the impact of our proposals to remove the regulatory limitations on high Medicaid facilities not imposed in section 1877(i) of the Act. Our response follows:

Comment: We received many comments stating that removing existing regulatory limitations would allow physician-owned hospitals to serve greater numbers of Medicaid patients and allow physicians more options to care for patients in various and appropriate sites of service. Several commenters stated that the restrictions on hospitals that qualify as high Medicaid facilities have hampered economic growth in communities that rely upon them, contributed to inflated prices through reduced competition between providers, limited patient choice, and decreased the ability of specific hospitals to meet the needs of their communities. The commenters added that removal of the restrictions on high Medicaid facilities would help increase access to vital health care services for the most vulnerable patients.

In contrast, some commenters noted that certain hospitals that qualify as high Medicaid facilities have Medicaid discharge percentages that are extremely low and potentially significantly lower than that of hospitals in surrounding counties where they could locate the large facility expansion capacity permitted under our proposals. Another commenter stated that, if we finalize our proposals, physician-owned hospitals could expand and move into markets without large Medicaid patient populations, creating additional campuses far away from the patients the expansion is intended by statute to serve.

Response: As we explained in section XX of this final rule, to determine whether a hospital qualifies as a high Medicaid facility, the statute requires a relativity analysis based on the location of the existing hospital; that is, a hospital that has the highest Medicaid discharge percentage relative to the hospitals in the same county will qualify as a high Medicaid facility even if the overall number of Medicaid discharges in the county is low. The statute does not require the Secretary to compare a high Medicaid facility to the hospitals in the county where it plans to locate the expansion capacity (if approved). However, Medicare rules and regulations regarding the location of hospital facilities, including the expansion capacity, such as distance limitations related to the location of off campus facilities and provider-based departments remain applicable. (See section 1833(t)(B)(i) of the Act and § 413.65(e)(3)(v)(F)).

The physician self-referral law does not prohibit a hospital granted an exception to the prohibition on expansion of facility capacity from relocating operating rooms, procedure rooms, or beds that were licensed on March 23, 2010 (baseline facility capacity) from the hospital's main campus to a remote location in order to make room for the approved expansion facility capacity. (See *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf.*) Therefore, we believe that removing the requirement that permitted expansion of facility capacity must occur only in facilities on the hospital's main campus would have minimal, if any, impact, as developing the permitted expansion of facility capacity in a location other than the hospital's main campus derives generally the same result as relocating baseline facility capacity to a remote location of the hospital and locating expansion capacity on the hospital's main campus.

10. Effects of Requirements for the Radiation Oncology (RO) Model

We have examined the impact of this interim final rule with comment period (IFC) as required by Executive Order 12866 and other laws and Executive Orders requiring economic analysis of the effects of final rules. We are revising the Model performance period that was finalized in 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, and have updated our net estimate of the RO Model impact. Accordingly, we have prepared an RIA that, to the best of our ability, reflects the economic impact of the policies contained in this IFC.

a. 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 61114) remains unchanged with this IFC. However, as described in detail in section XXI.A of this IFC, RO participants will not be required to collect or submit quality measure data or clinical data in PY1 due to the revised Model performance period. Instead, submission of quality measure data and clinical data will begin in PY2 with the final data submission ending in early 2026 (specifically January 2026 for the clinical data, and March 2026 for the quality measure data). Due to the change in the Model performance period, CMS's collection of patient experience surveys will start in October 2021 rather than April 2021 as finalized under 85 FR 61220.

b. Impact of RO Model

Based on the finalized RO Model policies of the Specialty Care Models final rule (see 85 FR 61114), we expected a savings of $230 million for Medicare. We now expect that revising the Model performance period to a July 1, 2021 start date, which shortens the Model performance period to 4.5 years, will reduce savings from $230 million to $220 million for Medicare.

c. Anticipated Effects

(1). Scale of the Radiation Oncology (RO) Model

In the Specialty Care Models final rule (85 FR 61114), we finalized our policy to include 30 percent of radiation oncology episodes (§ 512.210(d)) and a low volume opt-out policy (§ 512.210(c)). We performed a simulation based on our final rule policies. Based on this simulation, we expected to have approximately 500 physician group practices (PGPs) (of which 275 are freestanding radiation therapy centers) and 450 HOPDs furnishing RT services in those simulated selected CBSAs. We further expected the RO Model to include approximately 348,000 RO episodes, 309,000 beneficiaries, and $5.3 billion in total episode spending of allowed charges over the Model performance period. Revising the Model performance period to begin on July 1, 2021, and end on December 31, 2025 does not affect the number of PGPs or HOPDs we expect to furnish RT services in the simulated selected CBSAs. However, we expect the duration of the revised Model performance period, which shortens the Model performance period to 4.5 years, will reduce the number of RO episodes, the number of beneficiaries, and total spending. We expect the revised Model performance period will include approximately 315,000 RO episodes, 279,000 beneficiaries, and $4.8 billion in total episode spending of allowed charges over the Model performance period.

(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 will be a mandatory model designed to test a prospectively determined episode payment for RT services furnished to Medicare beneficiaries during RO episodes initiated between July 1, 2021 and December 31, 2025 (§ 512.245(a)).

(b). Data and Methods

A stochastic simulation based on the policies in this IFC was created to estimate the financial impacts of the RO Model relative to baseline expenditures.

(c). Medicare Estimate

Table 93 summarizes the estimated impact of the RO Model with a revised Model performance period that begins on July 1, 2021 and ends December 31, 2025. We estimate that on net the Medicare program will save $220 million over the Model performance period. 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.

We project that 83 percent of physician participants (measured by unique NPI) will receive the APM incentive payment under the Quality Payment Program at some point (at least one QP Performance Period) during the Model performance period. This assumption is based on applying the 2020 Quality Payment Program final rule qualification criteria to simulated billing and treatment patterns for each Quality Payment Program performance year during the Model performance period. Episode-initiating physicians were assumed to form an APM entity with the TIN(s) under which they bill for RT services. For each APM entity, counts of total treated patients and spending for covered physician services under the RO Model were estimated and applied to Quality Payment Program qualification criteria based on CY 2018 physician billing patterns.

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 with quality data reporting starting in 2022, APM incentive payments will only be made during 2024.

Complete information regarding the data sources and underlying methodology used to determine amounts for reconciliation were not available at the time of this forecast. In the case of the incomplete payment withhold, we assume CMS retains payment only in the event that offsetting payment errors were made elsewhere. Past CMS experience in other value-based payment initiatives that included a penalty for not reporting have shown high rates of reporting compliance. Given the limited spending being withheld, scoring criteria, and specified timeframes involved, we assume that quality and patient experience withholds, on net, have a negligible financial impact to CMS.

A key assumption underlying of the impact estimate is that the volume and intensity (V&I) of the bundled services per episode remains unchanged between the period used for rate setting and when 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 impact of the RO Model to Medicare spending to be approximately budget neutral between July 1, 2021 and December 31, 2025. Similarly if V&I increases by 1.0 percent annually then net outlays would be reduced by $440 million for this projection period as opposed to $470 million for the Specialty Care Models final rule projection period of 5 full performance years between January 1, 2021 and December 31, 2025. Although V&I growth from 2014 through 2018 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 PHE 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 the policy measures taken as a response are variables that are significant but unknown at this time. This forecast assumes that Medicare Fee-for-Service billing and treatment patterns for beneficiaries observed during the 2016–2018 baseline period resume by the

middle of 2021. To the extent that this assumption does not hold, actual experience may vary significantly.

This table summarizes our estimated impacts of this IFC:

TABLE 93. Estimates of Medicare Program Savings (Millions $) for Radiation Oncology Model (Starting July 1, 2021)

	Year of Model					
	2021	2022	2023	2024	2025	Total*
Net Impact To Medicare Program Spending	-10	-40	-50	-50	-60	-220
Changes to Incurred FFS Spending	-10	-30	-40	-40	-50	-170
Changes to MA Capitation Payments	-10	-20	-30	-30	-40	-120
Part B Premium Revenue Offset	10	10	20	20	20	70
Total APM Incentive Payments	0	0	0	10	0	10
Episode Allowed Charges	490	1030	1050	1100	1120	4790
Episode Medicare Payment	390	800	820	860	880	3740
Total Number of Episodes	33,000	68,000	70,000	71,000	72,000	315,000
Total Number of Beneficiaries	33,000	67,000	68,000	69,000	70,000	279,000

*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.

(3). Effects on RO Participants

We believe that the revised Model performance period 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 applies 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 less than or equal to that for small businesses, which we estimate to be approximately $1,845 per entity per year based on 2020 wages. Since we estimate approximately 950 RO participants, the total annual burden estimate for collecting and reporting quality measures and clinical data is approximately $1,752,750 for a total of $7,011,000 over the Model performance period of four and a half years. Since RO participants are not required to collect nor submit quality measure or clinical data in PY1 due to the change in start date, this reduces burden to RO participants by $1,752,750 as compared to a 5-year submission period of quality measure and clinical data finalized under 85 FR 61211 through 61231.

11. Effects of CoP Requirements for Hospitals and CAHS To Report COVID–19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness (Including, but not Limited to, Seasonal Influenza Virus, Influenza-Like Illness, and Severe Acute Respiratory Infection) as Specified by the Secretary During the PHE for COVID–19

Section XXII. of this IFC revises the infection prevention and control requirements for hospitals and CAHs to add new COVID–19 PHE hospital and CAH CoP reporting provisions at 42 CFR 482.42(e)(1) and (2) for hospitals and at 42 CFR 485.640(d)(1) and (2) for CAHs, to now require hospitals and CAHs to report data elements that must include, but not be limited to, the following: (1) The hospital's (or the CAH's) current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the hospital (or CAH) under the authority and direction of the Secretary; and (2) the hospital's (or the CAH's) current usage rate for any COVID–19-related therapeutics that have been distributed and delivered to the CAH under the authority and direction of the Secretary. We currently estimate the cost of these new COVID–19 data elements to total $19,663,920.

Additionally, we are revising the infection prevention and control requirements for hospitals and CAHs to more effectively respond to the specific challenges posed by the impending seasonal influenza virus season in the midst of the COVID–19 pandemic. Specifically, we are adding provisions to require facilities to electronically report information related to Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) cases in a standardized format specified by the Secretary. As detailed in section XXII. of this IFC, we currently estimate the cost of these reporting requirements to total $117,983,520.

These estimates are likely overestimates of the costs associated with reporting because it assumes that all hospitals and CAHs will report manually. Efforts are underway to automate hospital and CAH reporting that have the potential to significantly decrease reporting burden and improve

reliability. We anticipate that the need for reporting will be temporary in direct relationship to the duration of the PHE. Existing guidance on reporting, which may be revised in the future, can be found at *https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf* and at *https://healthdata.gov/covid-19_hospital_reporting*. Data reported to the Secretary is used by federal agencies and states, to provide data for the unified hospital picture, as well as guidance on the distribution of resources.

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 2021 OPPS/ASC proposed rule (1,349) will be the number of reviewers of the CY 2021 OPPS/ASC final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the final rule. It is possible that not all commenters will review the final rule in detail, and it is also possible that some reviewers will choose not to comment on the final rule. Nonetheless, we believe that the number of commenters on the CY 2021 OPPS/ASC proposed rule would be a fair estimate of the number of reviewers of the final rule. We welcomed any comments on the approach in estimating the number of entities that will review the final rule. We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of 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 the final rule. For each facility that reviewed the final rule, the estimated cost is $885.92 (8 hours × $110.74). Therefore, we estimated that the total cost of reviewing the final rule is $1,195,106 ($885.92 × 1,349 reviewers on the CY 2021 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 final rule with comment period. As a result, the Secretary has determined that this final rule with comment period 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 final rule with comment period will 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. That threshold level is currently approximately $156 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments, or for the private sector.

G. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. It has been determined that this final rule with comment period, will be a regulatory action for the purposes of Executive Order 13771. We estimate that this final rule with comment period will generate $7.01 million in annualized cost at a 7-percent discount rate, discounted relative to 2016, over a perpetual time horizon.

H. Conclusion

The changes we are making in this final rule with comment period 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 2021. Table 79 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that will result in a 2.4 percent increase in payments for all services paid under the OPPS in CY 2021, 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 will experience more significant gains or losses in OPPS payments in CY 2021.

The updates we are finalizing to the ASC payment system for CY 2021 will 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 80 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted hospital market basket update factor of 2.4 percent for CY 2021.

XXVIII. 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 final rule with comment period 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 79 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will increase by 2.2 percent under this final rule with comment period. 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 final rule with comment period, in conjunction with the remainder of this document, demonstrate that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This final rule with comment period 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.

Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

List of Subjects

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 2. Section 410.27 is amended by—
■ a. Adding the word ''and'' at the end of paragraph (a)(1)(iv)(C);
■ b. Revising paragraph (a)(1)(iv)(D); and
■ c. Removing paragraph (a)(1)(iv)(E).

The revision reads as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) * * *

(1) * * *

(iv) * * *

(D) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively. Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or December 31, 2021, the presence of the physician includes virtual presence through audio/video real-time communications technology (excluding audio-only); and

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 3. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 4. Section 411.362 is amended—
■ a. In paragraph (a) by revising the definition of ''Baseline number of operating rooms, procedure rooms, and beds''; and
■ b. By revising paragraphs (c)(1) and (6) introductory text.

The revisions read as follows:

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) * * *

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). For purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State.

* * * * *

(c) * * *

(1) *General.* An applicable hospital may request an exception from the prohibition on facility expansion up to

once every 2 years from the date of a CMS decision on the hospital's most recent request. A high Medicaid facility may request an exception from the prohibition on facility expansion at any time, provided that it has not submitted another request for an exception to the prohibition on facility expansion for which CMS has not issued a decision.

* * * * *

(6) *Permitted increase in facility capacity.* With respect to an applicable hospital only, a permitted increase under this section—

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 5. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 6. Section 412.3 is amended by revising paragraph (d)(2) to read as follows:

§ 412.3 Admissions.

* * * * *

(d) * * *

(2) An inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) of this chapter is generally appropriate for payment under Medicare Part A regardless of the expected duration of care. Procedures no longer specified as inpatient only under § 419.22(n) of this chapter are appropriate for payment under Medicare Part A in accordance with paragraph (d)(1) or (3) of this section. Claims for services and procedures removed from the inpatient only list under § 419.22 of this chapter on or after January 1, 2020 are exempt from certain medical review activities.

(i) For those services and procedures removed between January 1 and December 31, 2020, the exemption in this paragraph (d)(2) will last for 2 years from the date of such removal.

(ii) For those services and procedures removed on or after January 1, 2021, the exemption in this paragraph (d)(2) will last until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting.

* * * * *

■ 7. Section 412.190 is added to subpart I to read as follows:

§ 412.190 Overall Hospital Quality Star Rating.

(a) *Purpose.* (1) The Overall Hospital Quality Star Rating (Overall Star Rating) is a summary of certain publicly reported hospital measure data for the benefit of stakeholders, such as patients, consumers, and hospitals.

(2) The guiding principles of the Overall Star Rating are as follows. In developing and maintaining the Overall Star Ratings, we strive to:

(i) Use scientifically valid methods that are inclusive of hospitals and measure information and able to accommodate underlying measure changes;

(ii) Align with *Hospital Compare* or its successor website and CMS programs;

(iii) Provide transparency of the methods for calculating the Overall Star Rating; and

(iv) Be responsive to stakeholder input.

(b) *Data included in Overall Star Rating*—(1) *Source of data.* The Overall Star Rating is calculated based on measure data collected and publicly reported on *Hospital Compare* or its successor site under the following CMS hospital inpatient and outpatient programs:

(i) Hospital Inpatient Quality Reporting (IQR) Program—section 1886(b)(3)(B)(viii)(VII) of the Act.

(ii) Hospital-Acquired Condition Reduction Program—section 1886(p)(6)(A) of the Act.

(iii) Hospital Value-based Purchasing Program—section 1886(o)(10)(A) of the Act.

(iv) Hospital Readmissions Reduction Program—section 1886(q)(6)(A) of the Act.

(v) Hospital Outpatient Quality Reporting (OQR) Program—section 1833(t)(17)(e) of the Act.

(2) *Hospitals included in Overall Star Rating.* Subsection (d) hospitals subject to the CMS quality programs specified in paragraph (b)(1) of this section that also have their data publicly reported on one of CMS' websites are included in the Overall Star Rating.

(3) *Critical Access Hospitals.* Critical Access Hospitals (CAHs) that wish to be voluntarily included in the Overall Star Rating must have elected to—

(i) Voluntarily submit quality measures included in and as specified under CMS hospital programs; and

(ii) Publicly report their quality measure data on *Hospital Compare* or its successor site.

(c) *Frequency of publication and data used.* The Overall Star Rating are published once annually using data publicly reported on *Hospital Compare* or its successor website from a quarter within the prior year.

(d) *Methodology*—(1) *Selection of measures.* Measures are selected from those publicly reported on *Hospital Compare* or its successor website through certain CMS quality programs under paragraph (b)(1) of this section.

(i) From this group of measures, measures falling into one or more of the exclusions in paragaphs (d)(1)(i)(A) through (E) of this section will be removed from consideration:

(A) Measures that 100 hospitals or less publicly report. These measures would not produce reliable measure group scores based on too few hospitals;

(B) Measures that cannot be standardized to a single, common scale and otherwise not amenable to inclusion in a summary score calculation alongside process and outcome measures or measures that cannot be combined in a meaningful way. This includes measures that cannot be as easily combined with other measures captured on a continuous scale with more granular data;

(C) Non-directional measures for which it is unclear whether a higher or lower score is better. These measures cannot be standardized to be combined with other measures and form an aggregate measure group score;

(D) Measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs; or

(E) Measures that overlap with another measure in terms of cohort or outcome, including component measures that are part of an already-included composite measure.

(ii) [Reserved]

(2) *Measure score standardization.* All measure scores are standardized by calculating Z-scores so that all measures are on a single, common scale to be consistent in terms of direction (that is, higher scores are better) and numerical magnitude. This is calculated by subtracting the national mean measure score from each hospital's measure score and dividing the difference by the measure standard deviation in order to standardize measures.

(3) *Grouping measures.* Measures are grouped into one of the five clinical groups as follows:

(i) Mortality.

(ii) Safety of Care.

(iii) Readmission.

(iv) Patient Experience.

(v) Timely and Effective Care.

(4) *Calculate measure group scores.* A score is calculated for each measure group for which a hospital has measure data using a simple average of measure scores, as follows:

(i) Each measure group score is standardized by calculating Z-scores for each measure group so that all measure group scores are centered near zero with a standard deviation of one.

(ii) We take 100 percent divided by the number of measures reported in a measure group to determine the percentage of each measure's weight.

(iii) The measure weight is then multiplied by the standardized measure score to calculate the measure's weighted score.

(iv) Then, all of the individual measure weighted scores within a measure group are added together to calculate the measure group score.

(5) *Reporting thresholds.* In order to receive an Overall Star Rating, a hospital must report at least three measures within at least three measure groups, one of which must specifically be the Mortality or Safety of Care outcome group.

(6) *Hospital summary score.* A summary score is calculated by multiplying the standardized measure group scores by the assigned measure group weights and then summing the weighted measure group scores.

(i) *Standard measure group weighting.* (A) Each of the Mortality, Safety of Care, Readmission, and Patient Experience groups are weighted 22 percent; and

(B) The Timely and Effective Care group is weighted 12 percent.

(ii) *Reweighting.* (A) Hospitals may have too few cases to report particular measures and, in those cases, may not report enough measures in one or more measure groups.

(B) When a hospital does not have enough measures in one or more measure groups due to too few cases CMS may re-distribute one or more of the missing measure group's weight proportionally across the remaining measure groups by subtracting the standard weight percentage of the group or groups with insufficient measures from 100 percent; and then dividing the resulting percentage across the remaining measure groups, giving new re-proportioned weights.

(7) *Peer grouping.* Hospitals are assigned to one of three peer groups based on the number of measure groups for which they report at least three measures: three, four, or five measure groups.

(8) *Star ratings assignment.* Hospitals in each peer group are then assigned between one and five stars where one star is the lowest and five stars is the highest using k-means clustering to complete convergence.

(e) *Preview period prior to publication.* CMS provides hospitals the opportunity to preview their Overall Star Rating prior to publication. Hospitals have at least 30 days to preview their results, and if necessary, can reach out to CMS with questions.

(f) *Suppression of Overall Star Rating*—(1) *Subsection (d) hospitals.* CMS may consider suppressing Overall Star Rating for subsection (d) hospitals only under extenuating circumstances that affect numerous hospitals (as in, not an individualized or localized issue) as determined by CMS, or when CMS is at fault, including but not limited to when:

(i) There is an Overall Star Rating calculation error by CMS;

(ii) There is a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation; or

(iii) If a Public Health Emergency, as defined in § 400.200 of this chapter, substantially affects the underlying measure data.

(2) *CAHs.* (i) CAHs may request to withhold their Overall Star Rating from publication on *Hospital Compare* or its successor website so long as the request for withholding is made, at the latest, during the Overall Star Rating preview period.

(ii) CAHs may request to have their Overall Star Rating withheld from publication on *Hospital Compare* or its successor website, as well as their data from the public input file, so long as the request is made during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh data used to calculate the Overall Star Ratings.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 8. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 9. Section 414.510 is amended by revising paragraph (b)(5) introductory text to read as follows:

§ 414.510 Laboratory date of service for clinical laboratory and pathology specimens.

* * * * *

(b) * * *

(5) In the case of a molecular pathology test performed by a laboratory other than a blood bank or center, a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test in § 414.502, a test that is a cancer-related protein-based Multianalyte Assays with Algorithmic Analyses, or the test described by CPT code 81490, the date of service of the test must be the date the test was performed only if—

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 10. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 11. Section 416.166 is revised to read as follows:

§ 416.166 Covered surgical procedures.

(a) *Covered surgical procedures.* (1) Effective for services furnished on or after January 1, 2008 through December 31, 2020, covered surgical procedures are those procedures that meet the general standards described in paragraph (b)(1) of this section (whether commonly furnished in an ASC or a physician's office) and are not excluded under paragraph (c) of this section; and

(2) Effective for services furnished on or after January 1, 2021, covered surgical procedures are those procedures that meet the requirements described in paragraph (b)(2) of this section (whether commonly furnished in an ASC or a physician's office).

(b) *Requirements for covered surgical procedures*—(1) *General standards.* Effective for services furnished on or after January 1, 2008 through December 31, 2020, 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.

(2) Effective for services furnished on or after January 1, 2021, 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:

(i) Are separately paid under the OPPS; and

(ii) Are not:

(A) Designated as requiring inpatient care under § 419.22(n) of this subchapter as of December 31, 2020;

(B) Only able to be reported using a CPT unlisted surgical procedure code; or

(C) Otherwise excluded under § 411.15 of this chapter.

(c) *General exclusions effective January 1, 2008 through December 31, 2020.* Notwithstanding paragraph (b)(1)

of this section, covered surgical procedures do not include those surgical procedures that—

(1) Generally result in extensive blood loss;

(2) Require major or prolonged invasion of body cavities;

(3) Directly involve major blood vessels;

(4) Are generally emergent or life-threatening in nature;

(5) Commonly require systemic thrombolytic therapy;

(6) Are designated as requiring inpatient care under § 419.22(n) of this subchapter;

(7) Can only be reported using a CPT unlisted surgical procedure code; or

(8) Are otherwise excluded under § 411.15 of this chapter.

(d) *Physician considerations beginning January 1, 2021.* Physicians consider the following safety factors as to a specific beneficiary when determining whether to perform a covered surgical procedure. The covered procedure—

(1) Is not expected to pose a significant safety risk when performed in an ASC;

(2) Is one for which standard medical practice dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure;

(3) Generally results in extensive blood loss;

(4) Requires major or prolonged invasion of body cavities;

(5) Directly involves major blood vessels;

(6) Is generally emergent or life-threatening in nature; and

(7) Commonly requires systemic thrombolytic therapy.

(e) *Additions to the list of ASC covered surgical procedures beginning January 1, 2021.* On or after January 1, 2021, CMS adds surgical procedures to the list of ASC covered surgical procedures as follows.

(1) CMS identifies a surgical procedure that meets the requirements at paragraph (b)(2) of this section.

(2) CMS is notified of a surgical procedure that could meet the requirements at paragraph (b)(2) of this section and CMS confirms that such surgical procedure meets those requirements.

■ 12. Section 416.310 is amended—

■ a. In paragraphs (a)(2) and (b) by removing the phrase ''data collection time period'' and adding in its place ''data collection period'';

■ b. By revising paragraph (c)(1)(i);

■ c. In paragraph (c)(1)(ii) by removing the phrase ''data collection time period'' and adding in its place ''data collection period'' and removing the phrase ''time period'' and adding in its place ''period'';

■ d. By adding paragraph (c)(1)(iii);

■ e. In paragraph (c)(2) by removing the phrase ''data collection time period'' and adding in its place ''data collection period''; and

■ f. By adding paragraph (f).

The revision and additions read as follows:

§ 416.310 Data collection and submission requirements under the ASCQR Program.

* * * * *

(c) * * *

(1) * * *

(i) *QualityNet account for web-based measures.* ASCs, and any agents submitting data on an ASC's behalf, must maintain a QualityNet account in order to submit quality measure data to the QualityNet website for all web-based measures submitted via a CMS online data submission tool. A QualityNet security official is necessary to set up such an account for the purpose of submitting this information.

* * * * *

(iii) *Review and corrections period.* For measures submitted to CMS via a CMS online tool, ASCs have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, ASCs can enter, review, and correct data submitted. After the submission deadline, this data cannot be changed.

* * * * *

(f) *Data submission deadlines.* 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 are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 13. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 14. Section 419.22 is amended by revising paragraph (n) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(n) Services and procedures that the Secretary designates as requiring inpatient care. Effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024.

* * * * *

■ 15. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*11*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*11*) For calendar year 2020 and subsequent years, a multifactor productivity adjustment (as determined by CMS).

* * * * *

■ 16. Section 419.45 is amended by revising paragraphs (b)(1) and (2) to read as follows:

§ 419.45 Payment and copayment reduction for devices replaced without cost or when full or partial credit is received.

* * * * *

(b) * * *

(1) The amount of the reduction to the APC payment made under paragraphs (a)(1) and (2) of this section is calculated as the lesser of the device offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under § 419.66 or the amount of the credit described in paragraph (a)(2) of this section.

(2) The amount of the reduction to the APC payment made under paragraph (a)(3) of this section is calculated as the lesser of the device offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under § 419.66 or the amount of the credit described in paragraph (a)(3) of this section.

* * * * *

■ 17. Section 419.46 is amended—

■ a. By redesignating paragraphs (a) through (h) as paragraphs (b) through (i), respectively;

■ b. By adding a new paragraph (a);

■ c. By revising newly redesignated paragraphs (b)(2), (c), and (d)(1) and (2);

■ d. In newly redesignated paragraphs (d)(3)(ii) and (iii) by removing the cross-reference to ''paragraph (c)(2)'' and adding in its place ''paragraph (d)(2)'';

■ e. By adding paragraphs (d)(4) and (f)(4);
■ f. By revising newly redesignated paragraph (g)(1);
■ g. In newly redesignated paragraph (g)(2)(viii) by removing the cross-reference to ''paragraph (e)(1)'' and adding in its place ''paragraph (f)(1)'';
■ h. In newly redesignated paragraph (i)(1) by removing the cross-reference ''paragraphs (h)(2) and (3)'' and adding in its place ''paragraphs (i)(2) and (3)'';
■ i. In newly redesignated paragraph (i)(3) introductory text by removing the cross-reference ''paragraph (h)(2)'' and adding in its place ''paragraph (i)(2)''; and
■ j. In newly redesignated paragraph (i)(3)(ii) introductory text by removing the cross-reference ''paragraph (h)(3)(i)(A)'' and adding in its place ''paragraph (i)(3)(i)(A)''.

The additions and revisions read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) *Statutory authority.* Section 1833(t)(17) of the Act authorizes the Secretary to implement a quality reporting program in a manner so as to provide for a 2.0 percentage point reduction in the OPD fee schedule increase factor for a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that does not submit data required to be submitted on measures in accordance with the Secretary's requirements in this part.

(b) * * *

(2) Identify and register a QualityNet security official as part of the registration process under paragraph (b)(1) of this section; and

* * * * *

(c) *Withdrawal from the Hospital OQR Program.* A participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet website. The hospital may withdraw any time up to and including August 31 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under paragraph (i) of this section, and is required to renew participation as specified in paragraph (b) of this section in order to participate in any future year of the Hospital OQR Program.

(d) * * *

(1) *General rule.* Except as provided in paragraph (e) of this section, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(t)(17)(C) of the Act in a form and manner, and at a time, specified by CMS. Hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on the QualityNet website. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.

* * * * *

(4) *Review and corrections period.* For both chart-abstracted and web-based measures, hospitals have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, hospitals can enter, review, and correct data submitted. However, after the submission deadline, this data cannot be changed.

* * * * *

(f) * * *

(4) Hospitals that are selected and receive a score for validation of chart-abstracted measures may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation for chart-abstracted measures was incorrectly scored, the corrected quarterly validation score will be used to compute the hospital's final validation score at the end of the calendar year.

(g) * * *

(1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program in paragraph (b) of this section for a particular calendar year. Except as provided in paragraph (e) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet website, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day as defined in paragraph (d)(2) of this section, of the affected payment year as determined using the date the request was mailed or submitted to CMS.

* * * * *

■ 18. Section 419.66 is amended by revising paragraph (c)(2)(ii) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(c) * * *

(2) * * *

(ii) For devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to paragraph (c)(2)(i) of this section, a new device is part of the Food and Drug Administration's (FDA's) Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

* * * * *

■ 19. Section 419.83 is amended by revising paragraph (a) to read as follows:

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) *Service categories for the list of hospital outpatient department services requiring prior authorization.* (1) The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2020:

(i) Blepharoplasty.
(ii) Botulinum toxin injections.
(iii) Panniculectomy.
(iv) Rhinoplasty.
(v) Vein ablation.

(2) The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021:

(i) Cervical Fusion with Disc Removal.
(ii) Implanted Spinal Neurostimulators.

(3) Technical updates to the list of services, such as changes to the name of the service or CPT code, will be published on the CMS website.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 20. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 21. Section 482.42 is amended, effective December 4, 2021, by revising paragraph (e) and adding paragraph (f) to read as follows:

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(e) *COVID–19 reporting.* During the Public Health Emergency, as defined in § 400.200 of this chapter, the hospital must report information in accordance with a frequency as specified by the Secretary on COVID–19 in a standardized format specified by the Secretary. This report must include, but not be limited to, the following data elements:

(1) The hospital's current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the hospital under the authority and direction of the Secretary; and

(2) The hospital's current usage rate for any COVID–19-related therapeutics that have been distributed and delivered to the hospital under the authority and direction of the Secretary.

(f) *Standard: Reporting of Acute Respiratory Illness, including Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection.* During the Public Health Emergency, as defined in § 400.200 of this chapter, the hospital must report information, in accordance with a frequency as specified by the Secretary, on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) in a standardized format specified by the Secretary.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 22. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 23. Section 485.640 is amended, effective December 4, 2021, by revising paragraph (d) and adding paragraph (e) to read as follows:

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(d) *COVID–19 reporting.* During the Public Health Emergency, as defined in § 400.200 of this chapter, the CAH must report information in accordance with a frequency as specified by the Secretary on COVID–19 in a standardized format specified by the Secretary. This report must include, but not be limited to, the following data elements:

(1) The CAH's current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the CAH under the authority and direction of the Secretary; and

(2) The CAH's current usage rate for any COVID–19-related therapeutics that have been distributed and delivered to the CAH under the authority and direction of the Secretary.

(e) *Standard: Reporting of Acute Respiratory Illness, including Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection.* During the Public Health Emergency, as defined in § 400.200 of this chapter, the CAH must report information, in accordance with a frequency as specified by the Secretary, on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) in a standardized format specified by the Secretary.

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 24. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 25. Section 512.205 is amended, effective December 4, 2021, by revising the definitions ''Model performance period'' and ''Performance year (PY)'' to read as follows:

§ 512.205 Definitions.

* * * * *

Model performance period means July 1, 2021, through December 31, 2025, the last date on which an RO episode may end under the RO Model. No new RO episodes may begin after October 3, 2025, in order for all RO episodes to end by December 31, 2025.

* * * * *

Performance year (PY) means 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.

* * * * *

■ 26. Section 512.210 is amended, effective December 4, 2021, by revising paragraphs (a) and (c) to 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 RO participant 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 on or after July 1, 2021, and ends on or before December 31, 2025, must participate in the RO Model.

* * * * *

(c) *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 of RT services across all CBSAs selected for participation in the most recent year with claims data available prior to the applicable PY. At least 30 days prior to the start of each PY, CMS notifies RO participants eligible for the low volume opt-out for the upcoming PY. The RO participant must attest to its intention of opting out of the RO Model prior to the start of the upcoming PY. Low volume opt-out eligibility is determined as follows:

(1) *PY1.* Episodes from January 1, 2019 through December 31, 2019 determine eligibility for the low volume opt-out for PY1.

(2) *PY2.* Episodes from January 1, 2020 through December 31, 2020 determine eligibility for the low volume opt-out for PY2.

(3) *PY3.* Episodes from January 1, 2021 through June 30, 2021 and RO episodes from July 1, 2021 through December 31, 2021 determine eligibility for the low volume opt-out for PY3.

(4) *PY4.* RO episodes from January 1, 2022 through December 31, 2022 determine low volume opt-out eligibility for PY4.

(5) *PY5.* RO episodes from January 1, 2023 through December 31, 2023 determine low volume opt-out eligibility for PY5.

* * * * *

■ 27. Section 512.217 is amended, effective December 4, 2021, by revising paragraph (c)(3) introductory text to read as follows:

§ 512.217 Identification of individual practitioners.

* * * * *

(c) * * *

(3) If the RO participant does not certify the individual practitioner list in PY2 through PY5:

* * * * *

■ 28. Section 512.220 is amended, effective December 4, 2021, by revising paragraph (b) to read as follows:

§ 512.220 RO participant compliance with RO Model requirements.

* * * * *

(b) *CEHRT.* Each RO participant must use CEHRT, and ensure that its individual practitioners use CEHRT, in a manner sufficient to meet the

applicable requirements of the Advanced APM criteria codified in § 414.1415(a)(1)(i) of this chapter. Within 30 days of the start of PY2 and each subsequent PY, each RO participant must certify in the form and manner, and by a deadline specified by CMS, that it uses CEHRT throughout such PY in a manner sufficient to meet the requirements set forth in § 414.1415(a)(1)(i) of this chapter.

■ 29. Section 512.245 is amended, effective December 4, 2021, by revising paragraph (a) to read as follows:

§ 512.245 Included RO episodes.

(a) *General.* Any RO episode that begins on or after July 1, 2021, and ends on or before December 31, 2025, is included in the Model performance period.

* * * * *

■ 30. Section 512.255 is amended, effective December 4, 2021, by revising paragraph (c)(10) to read as follows:

§ 512.255 Determination of participant-specific professional episode payment and participant-specific technical episode payment amounts.

* * * * *

(c) * * *

(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 starting in PY2. RO participants may earn back this withhold, in part or in full, based on their AQS.

* * * * *

■ 31. Section 512.285 is amended, effective December 4, 2021, by revising paragraph (d) to read as follows:

§ 512.285 Reconciliation process.

* * * * *

(d) *Quality reconciliation payment amount.* For Professional participants and Dual participants, CMS determines the quality reconciliation payment amount for PY2 through PY5 by multiplying the participant's AQS (as a percentage) by the total quality withhold amount for all RO episodes initiated during the PY. There is no quality reconciliation payment amount for PY1.

* * * * *

Dated: November 19, 2020.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: November 23, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–26819 Filed 12–4–20; 8:45 am]

BILLING CODE 4120–01–P