DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

[CMS–1695–P]

RIN 0938–AT30

Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2019 to implement changes arising from our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. The proposed rule also includes requests for information on promoting interoperability and electronic health care information exchange, improving beneficiary access to provider and supplier charge information, and leveraging the authority for the Competitive Acquisition Program (CAP) for Part B drugs and biologicals for a potential CMS Innnovation Center model. In addition, we are proposing to modify the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure under the Hospital Inpatient Quality Reporting (IQR) Program by removing the Communication about Pain questions.

DATES: To be assured consideration, comments on this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on September 24, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1695–P when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1695–P, P.O. Box 8013, 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–1695–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

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

FOR FURTHER INFORMATION CONTACT: (We note that public comments must be submitted through one of the four channels outlined in the **ADDRESSES** section above. Comments may not be submitted via email.)

340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital, contact Juan Cortes via email *Juan.Cortes@cms.hhs.gov* or at 410–786–4325.

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 at 410–786–4142.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Blood and Blood Products, contact Joshua McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

Cancer Hospital Payments, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email *Chuck.Braver@cms.hhs.gov* or at 410–786–6719.

CPT Codes, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments, contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

Comment Solicitation to Control for Unnecessary Increases in Volume of Outpatient Services, contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

Comprehensive APCs (C–APCs), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider, contact Juan Cortes via email *Juan.Cortes@cms.hhs.gov* or at 410–786–4325.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson via email

Twi.Jackson@cms.hhs.gov or at 410–786–1159.

Inpatient Only (IPO) Procedures List, contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

No Cost/Full Credit and Partial Credit Devices, contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

OPPS Brachytherapy, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

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 at 410–786–1816 or Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email *Josh.McFeeters@cms.hhs.gov* or at 410–786–9732.

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

OPPS Exceptions to the 2 Times Rule, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

OPPS Packaged Items/Services, contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

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

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email *Marina.Kushnirova@cms.hhs.gov* or at 410–786–2682.

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

Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model, contact the CMS Innovation Center Team Mailbox via email at *CMMIPartBDrugCAP_RFI@cms.hhs.gov.*

Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange, contact Scott Cooper via email at *Scott.Cooper@cms.hhs.gov* or at 410–786–9465.

Request for Information on Requirements for Hospitals To Make Public a List of Their Standard Charges via the internet, contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

Rural Hospital Payments, contact Joshua McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

Skin Substitutes, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

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.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Publishing Office. This database can be accessed via the internet at *https://www.gpo.gov/fdsys/.*

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/index.html.* The Addenda relating to the ASC payment system are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

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 CY 2018 OPPS/ASC Final Rule With Comment Period

II. Proposed Updates Affecting OPPS Payments
- A. Recalibration of APC Relative Payment Weights
- B. Proposed Conversion Factor Update
- C. Proposed Wage Index Changes
- D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)
- E. Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) under Section 1833(t)(13)(B) of the Act
- F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2019
- G. Proposed Hospital Outpatient Outlier Payments
- H. Proposed Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment
- I. Proposed Beneficiary Copayments

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

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

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

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

B. Estimate of Pass-Through Spending
VII. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services
VIII. Proposed Payment for Partial Hospitalization Services
A. Background
B. Proposed PHP APC Update for CY 2019
C. Proposed Outlier Policy for CMHCs
IX. Proposed Procedures That Would Be Paid Only as Inpatient Procedures
A. Background
B. Proposed Changes to the Inpatient Only (IPO) List
X. Proposed Nonrecurring Policy Changes
A. Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments
B. Proposal and Comment Solicitation on Method to Control Unnecessary Increases in the Volume of Outpatient Services
C. Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital
D. Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider
XI. Proposed CY 2019 OPPS Payment Status and Comment Indicators
A. Proposed CY 2019 OPPS Payment Status Indicator Definitions
B. Proposed CY 2019 Comment Indicator Definitions
XII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System
A. Background
B. Proposed Treatment of New and Revised Codes
C. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services
D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services
E. New Technology Intraocular Lenses (NTIOLs)
F. Proposed ASC Payment and Comment Indicators
G. Proposed Calculation of the Proposed ASC Payment Rates and the Proposed ASC Conversion Factor
XIII. 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. Proposed Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2019 Payment Determination
XIV. 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
XV. Requests for Information (RFIs)
A. Request for Information on Promoting Interoperability and Electronic Health Care Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare-Participating and Medicaid-Participating Providers and Suppliers
B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information
C. Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model
XVI. Proposed Additional Hospital Inpatient Quality Reporting (IQR) Program Policies
XVII. Files Available to the Public Via the Internet
XVIII. 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 the Proposed Update to the HCAHPS Survey Measure in the Hospital IQR Program
E. Total Reduction in Burden Hours and in Costs
XIX. Response to Comments
XX. Economic Analyses
A. Statement of Need
B. Overall Impact for the Provisions of This Proposed Rule
C. Detailed Economic Analyses
D. Effects of the Proposed Update to the HCAHPS Survey Measure in the Hospital IQR Program
E. Regulatory Review Costs
F. Regulatory Flexibility Act (RFA) Analysis
G. Unfunded Mandates Reform Act Analysis
H. Reducing Regulation and Controlling Regulatory Costs
I. Conclusion
XXI. Federalism Analysis
Regulation Text

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we are proposing to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) beginning January 1, 2019. 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, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

In this proposed rule, we also are including three Requests for Information (RFIs) on: (1) Promoting interoperability and electronic health care information exchange through possible revisions to the CMS patient health and safety requirements for hospitals and other Medicare-participating and Medicaid-participating providers and suppliers; (2) improving beneficiary access to provider and supplier charge information; and (3) leveraging the authority for the Competitive Acqisition Program (CAP) for Part B drugs and biologicals for a potential CMS Innovation Center model. In addition, we are proposing to modify the HCAHPS Survey measure by removing the Communication about Pain questions from the HCAHPS Survey for the Hospital IQR Program, which are used to assess patients' experiences of care, effective with January 2022 discharges for the FY 2024 payment determination.

2. Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

Regulatory reform and reducing regulatory burden are high priorities for CMS. To reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.[1] This initiative is one component of our agency-wide Patients Over Paperwork Initiative,[2] which is aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve

[1] Meaningful Measures web page: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[2] Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017. Available at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html.*

beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that fosters operational efficiencies, and will reduce costs including, collection and reporting burden while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures framework has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers;
- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

In order to achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in the table below.

Quality priority	Meaningful measure area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections
	Preventable Healthcare Harm
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals
	End of Life Care According to Preferences
	Patient's Experience of Care
	Patient Reported Functional Outcomes
Promote Effective Communication and Coordination of Care	Medication Management
	Admissions and Readmissions to Hospitals
	Transfer of Health Information and Interoperability
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care
	Management of Chronic Conditions
	Prevention, Treatment, and Management of Mental Health
	Prevention and Treatment of Opioid and Substance Use Disorders
	Risk Adjusted Mortality
Work with Communities to Promote Best Practices of Healthy Living	Equity of Care
	Community Engagement
Make Care Affordable	Appropriate Use of Healthcare
	Patient-focused Episode of Care
	Risk Adjusted Total Cost of Care

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers as well as promoting operational efficiencies.

3. Summary of the Major Provisions

- *OPPS Update:* For CY 2019, we are proposing to increase the payment rates under the OPPS by an outpatient department (OPD) fee schedule increase factor of 1.25 percent. This increase factor is based on the proposed hospital inpatient market basket percentage increase of 2.8 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.8 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act. Based on this proposed update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2019 would be approximately $74.6 billion, an increase of approximately $4.9 billion compared to estimated CY 2018 OPPS payments.

We are proposing to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

- *Comprehensive APCs:* For CY 2019, we are proposing to create three new comprehensive APCs (C–APCs). These proposed new C–APCs include ears, nose, and throat (ENT) and vascular procedures. This proposal would increase the total number of C–APCs to 65.

- *Proposed Changes to the Inpatient Only List:* For CY 2019, we are proposing to remove two procedures from the inpatient only list and add one procedure to the list.

- *Proposal and Comment Solicitation on Method to Control Unnecessary Increases in Volume of Outpatient Services:* To the extent that similar services can be safely provided in more than one setting, it is not prudent for the Medicare program to pay more for these services in one setting than another. We believe that capping the OPPS payment at the Physician Fee Schedule (PFS)-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed. In particular, we believe this method of capping payment will control unnecessary volume increases as manifested both in terms of numbers of covered outpatient department services furnished and costs of those services. Therefore, we are proposing to use our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. In addition, we are soliciting public

comments on how to expand the Secretary's statutory authority under section 1833(t)(2)(F) of the Act to additional items and services paid under the OPPS that may represent unnecessary increases in hospital outpatient department utilization.

• *Expansion of Services at Off-Campus Provider-Based Departments (PBDs) Paid under the OPPS (Section 603):* For CY 2019, we are proposing that if an excepted off-campus PBD furnishes a service from a clinical family of services for which it did not previously furnish a service (and subsequently bill for that service) during a baseline period, services from this new clinical family of services would not be covered OPD services. Instead, services in the new clinical family of services would be paid under the PFS.

• *Proposal to Apply 340B Drug Payment Policy to Off-Campus Departments of a Hospital Paid under the Medicare Physician Fee Schedule:* For CY 2019, we are proposing to pay average sales price (ASP) minus 22.5 percent for 340B-acquired drugs furnished by nonexcepted, off-campus provider-based departments (PBDs). This is consistent with the payment methodology adopted in CY 2018 for 340B-acquired drugs furnished in hospital departments paid under the OPPS.

• *Payment Policy for Biosimilar Biological Products without Pass-Through Status That Are Acquired under the 340B Program:* For CY 2019, we are proposing to pay nonpass-through biosimilars acquired under the 340B program at ASP minus 22.5 percent of the biosimilar's own ASP rather than ASP minus 22.5 percent of the reference product's ASP.

• *Payment of Drugs, Biologicals, and Radiopharmaceuticals If Average Sales Price (ASP) Data Are Not Available:* For CY 2019, we are proposing to pay separately payable drugs and biological products that do not have pass-through payment status and are not acquired under the 340B Program at wholesale acquisition cost (WAC)+3 percent instead of WAC+6 percent. If WAC data are not available for a drug or biological product, we are proposing to continue our policy to pay separately payable drugs and biological products at 95 percent of the average wholesale price (AWP). Drugs and biologicals that are acquired under the 340B Program would continue to be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable.

• *Device-Intensive Procedure Criteria:* For CY 2019, we are proposing to modify the device-intensive criteria to allow procedures that involve single-use devices, regardless of whether or not they remain in the body after the conclusion of the procedure, to qualify as device-intensive procedures. We also are proposing to allow procedures with a device offset percentage of greater than 30 percent to qualify as device-intensive procedures. In addition, we are soliciting comments on whether any high-cost devices (other than capital equipment) should be left out of the definition of single-use devices or, alternatively, whether our proposed definition excludes devices that commenters believe should be subject to our device-intensive policy.

• *Device Pass-Through Payment Applications:* For CY 2019, we are evaluating seven applications for device pass-through payments and are seeking public comments in this CY 2019 proposed rule on whether these applications meet the criteria for device pass-through payment status.

• *New Technology APC Payment for Extremely Low-Volume Procedures:* For CY 2019, we are proposing to apply a ''smoothing methodology'' based on multiple years of claims data to establish a more stable rate for services assigned to New Technology APCs with fewer than 100 claims per year under the OPPS. Under the smoothing methodology, we would calculate the geometric mean costs, the median costs, and the arithmetic mean costs for these procedures to promote payment stability. This methodology allows the option to use of one of these methodologies to assign the most representative payment for the service. In addition, we are proposing to exclude low-volume services from bundling into C–APC procedures.

• *Cancer Hospital Payment Adjustment:* For CY 2019, we are proposing to continue to provide additional payments to cancer hospitals so that the cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, we are proposing that a target PCR of 0.88 would be used to determine the CY 2019 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments would be the additional payments needed to result in a PCR equal to 0.88 for each cancer hospital.

• *Rural Adjustment:* For 2019 and subsequent years, we are proposing to continue the 7.1 percent adjustment to OPPS payments for certain rural SCHs, including essential access community hospitals (EACHs). We intend to continue the 7.1 percent adjustment for future years in the absence of data to suggest a different percentage adjustment should apply.

• *Ambulatory Surgical Center (ASC) Payment Update:* For CYs 2019 through 2023, we are proposing to update the ASC payment system using the hospital market basket update instead of the CPI–U. However, we are requesting public comments on ASCs' cost structure to assess whether the hospital market basket is an appropriate proxy for ASC costs. During this 5-year period, we intend to examine whether such adjustment leads to a migration of services from other settings to the ASC setting. Using the hospital market basket methodology, for CY 2019, we are proposing to increase payment rates under the ASC payment system by 2.0 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed increase is based on a proposed hospital market basket percentage increase of 2.8 percent minus a proposed MFP adjustment required by the Affordable Care Act of 0.8 percentage point.

Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2019 would be approximately $4.89 billion, an increase of approximately $300 million compared to estimated CY 2018 Medicare payments to ASCs. We note that the CY 2019 ASC payment update, under our prior policy, would have been 1.3 percent, based on a projected CPI–U update of 2.1 percent minus a MFP adjustment required by the Affordable Care Act of 0.8 percentage point. In addition, we will 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.

• *Proposed Changes to the List of ASC Covered Surgical Procedures:* For CY 2019, we are proposing to revise our definition of ''surgery'' in the ASC payment system to account for certain ''surgery-like'' procedures that are assigned codes outside the Current Procedural Terminology (CPT) surgical range. In addition, we are proposing to add 12 cardiac catheterization procedures to the ASC covered procedures list. We also are soliciting public comments on our proposal to reassess, and soliciting further public comments on, procedures recently

added to the ASC covered procedures list.

• *Payment for Non-Opioid Pain Management Therapy:* For CY 2019, in response to the recommendation from the President's Commission on Combating Drug Addiction and the Opioid Crisis, we are proposing to change the packaging policy for certain drugs when administered in the ASC setting and provide separate payment for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in an ASC. In addition, we are soliciting public comments and peer-reviewed evidence to help determine whether we should pay separately for other non-opioid treatments for pain under the OPPS and the ASC payment system.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are proposing changes for the CY 2019, CY 2020, and CY 2021 payment determinations and subsequent years. Effective upon the final rule, we are proposing to: (1) Update measure removal Factor 7; (2) add a new removal Factor 8; and (3) codify our measure removal policies and factors. We also are providing clarification of our ''topped-out'' criteria. These proposals would align the Hospital OQR Program measure removal factors with those used in the ASCQR Program. In addition, beginning with CY 2019, we are proposing to update the frequency with which we would release a Hospital OQR Program Specifications Manual such that it would occur every 6 to 12 months. We also are proposing for the CY 2020 payment determination and subsequent years: (1) To update the participation status requirements by removing the Notice of Participation (NOP) form; and (2) to extend the reporting period for the OP–32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure to 3 years.

Beginning with the CY 2020 payment determination and subsequent years, we also are proposing to remove the OP–27: Influenza Vaccination Coverage Among Healthcare Personnel measure.

Beginning with the CY 2021 payment determination and subsequent years, we are proposing to remove the following nine measures: (1) OP–5: Median Time to ECG; (2) OP–9: Mammography Follow-up Rates; (3) OP–11: Thorax CT Use of Contrast Material; (4) OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; (5) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT; (6) OP–17: Tracking Clinical Results between Visits; (7) OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients; (8) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (9) OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are proposing changes in policies for the CY 2020 payment determination and CY 2021 payment determination and subsequent years. Effective upon the final rule, we are proposing to: (1) Remove one factor; (2) add two new measure removal factors; and (3) update the regulations to better reflect our measure removal policies. We also are making one clarification to measure removal Factor 1. These proposals would align the ASCQR Program measure removal factors with those used in the Hospital OQR Program.

Beginning with the CY 2020 payment determination and subsequent years, we are proposing to extend the reporting period for the ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure to 3 years. For the CY 2020 payment determination and subsequent years, we also are proposing to remove one measure from the ASCQR Program measure set, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel.

Beginning with the CY 2021 payment determination and subsequent years, we are proposing to remove seven measures: (1) ASC–1: Patient Burn; (2) ASC–2: Patient Fall; (3) ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; (4) ASC–4: All-Cause Hospital Transfer/Admission; (5) ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; (6) ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (7) ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

• *Hospital Inpatient Quality Reporting (IQR) Program Update:* In this proposed rule, we are proposing to modify the HCAHPS Survey measure by removing the Communication about Pain questions from the HCAHPS Survey for the Hospital IQR Program, effective with January 2022 discharges for the FY 2024 payment determination and subsequent years.

4. Summary of Costs and Benefits

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

a. Impacts of the Proposed OPPS Update

(1) Impacts of All Proposed OPPS Changes

Table 42 in section XX. of this proposed rule displays the distributional impact of all the proposed OPPS changes on various groups of hospitals and CMHCs for CY 2019 compared to all estimated OPPS payments in CY 2018. We estimate that policies in this proposed rule would result in a 0.1 percent overall decrease in OPPS payments to providers. We estimate that total OPPS payments for CY 2019, including beneficiary cost-sharing, to the approximate 3,800 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would decrease by approximately $80 million compared to CY 2018 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our proposed OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure we adopted beginning in CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate a 17.9 percent decrease in CY 2019 payments to CMHCs relative to their CY 2018 payments.

(2) Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY 2019 IPPS proposed rule wage indexes would result in no estimated payment change for urban and rural hospitals under the OPPS. These proposed wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data, with updates as discussed in section II.C. of this proposed rule.

(3) Impacts of the Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our proposed CY 2019 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural hospital payment adjustments. While we are implementing the required reduction to the cancer hospital payment adjustment in section 16002 of the 21st Century Cures Act for CY 2019, the proposed target payment-to-cost ratio (PCR) for CY 2019 remains the same as in CY 2018 and therefore does not impact the budget neutrality adjustments.

(4) Impacts of the Proposed OPD Fee Schedule Increase Factor

For the CY 2019 OPPS, we are proposing an OPD fee schedule increase factor of 1.25 percent to the conversion factor for CY 2019. As a result of the proposed OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that rural and urban hospitals would experience increases of approximately 1.3 percent for urban hospitals and 1.5 percent for rural hospitals. Classifying hospitals by teaching status, we estimate nonteaching hospitals would experience increases of 1.4 percent, minor teaching hospitals would experience increases of 1.3 percent, and major teaching hospitals would experience a decrease of 1.1 percent. We also classified hospitals by type of ownership. We estimate that hospitals with voluntary ownership would experience increases of 1.3 percent, hospitals with proprietary ownership would experience increases of 1.4 percent, and hospitals with government ownership would experience decrease of 1.3 percent in payments.

(5) Impacts of the Proposal to Control for Unnecessary Increases in the Volume of Outpatient Services

In section X.B. of this proposed rule, we discuss our CY 2019 proposal to control for unnecessary increases in the volume of outpatient service by paying for clinic visits furnished at an off-campus provider-based department at a PFS-equivalent rate under the OPPS rather than at the standard OPPS rate. As a result of this proposal, we estimated decreases of 1.2 percent to urban hospitals, and estimated decreases of 1.3 percent to rural hospitals, with the estimated effect for individual groups of hospitals depending on the volume of clinic visits provided at off-campus provider-based departments.

b. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the proposed CY 2019 payment rates, compared to estimated CY 2018 payment rates, generally ranges between an increase of 1 to 4 percent, depending on the service, with some exceptions. We estimate the impact of applying the hospital market basket update to proposed ASC payment rates would increase payments by $32 million under the ASC payment system in CY 2019 compared to if we applied an update based on CPI–U.

c. Impact of the Proposed Changes to the Hospital OQR Program

Across 3,300 hospitals participating in the Hospital OQR Program, we estimate that our proposed requirements would result in the following changes to costs and burdens related to information collection for the Hospital OQR Program compared to previously adopted requirements: (1) No change in the total collection of information burden or costs for the CY 2020 payment determination; (2) a total collection of information burden reduction of 1,468,614 hours and a total collection of information cost reduction of approximately $57.3 million for the CY 2021 payment determination due to the proposed removal of six specific measures: OP–5, OP–12, OP–17, OP–29, OP–30, and OP–31.

Further, we anticipate that the proposed removal of a total of 10 measures would result in a reduction in costs unrelated to information collection. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Also, when measures are in multiple programs, maintaining the specifications for those measures, as well as the tools we need to collect, validate, analyze, and publicly report the measure data may result in costs to CMS. In addition, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

d. Impact of the Proposed Changes to the ASCQR Program

Across 3,937 ASCs participating in the ASCQR Program, we estimate that our proposed requirements would result in the following changes to costs and burdens related to information collection for the ASCQR Program compared to previously adopted requirements: (1) No change in the total collection of information burden or costs for the CY 2020 payment determination; (2) a total collection of information burden reduction of 140,585 hours and a total collection of information cost reduction of approximately $5.1 million for the CY 2021 payment determination due to the proposed removal of three specific measures: ASC–9, ASC–10, and ASC–11.

Further, we anticipate that the proposed removal of a total of eight measures would result in a reduction in costs unrelated to information collection. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Also, when measures are in multiple programs, maintaining the specifications for those measures as well as the tools we need to collect, analyze, and publicly report the measure data may result in costs to CMS. In addition, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Social Security 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, and the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this final rule with comment period. 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 (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2) 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 generally 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 and in some cases, provides for a longer period under which transitional pass-through payments are made. 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 Physician Fee Schedule (PFS); 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 include:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under the Maryland All-Payer 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, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and 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 external advisory panel of experts to annually review 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;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 21, 2016, for a 2-year period (81 FR 94378).

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

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 21, 2017. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for Panel membership, to announce new members and to announce 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). Further information on the 2018 summer meeting can be found in the meeting notice titled ''Medicare Program: Announcement of the Advisory Panel on Hospital Outpatient Payment (the Panel) Meeting on August 20–21, 2018'' (83 FR 19785).

In addition, the Panel has established an operational structure that, in part, currently includes the use of three subcommittees to facilitate its required review process. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises 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 subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 21, 2017 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the August 21, 2017 Panel meeting, namely endovascular procedure APCs, blood derived hematopoietic stem cell transplantation, OPPS payment for drugs acquired under the 340B program, and packaging of drug administration services, were discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59216) and the CY 2018 OPPS/ASC correction notice (82 FR 61184), or are included in the sections of this proposed rule that are specific to each 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 on the CY 2018 OPPS/ASC Final Rule With Comment Period

We received approximately 127 timely pieces of correspondence on the

CY 2018 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on December 14, 2017 (82 FR 59216), some of which contained comments on 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 new or replacement Level II HCPCS codes will be set forth in the CY 2019 final rule with comment period under the appropriate subject matter headings.

II. Proposed Updates Affecting OPPS Payments

A. Proposed 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.

In this CY 2019 OPPS/ASC proposed rule, for CY 2019, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2019, and before January 1, 2020 (CY 2019), using the same basic methodology that we described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52367 through 52370), using updated CY 2017 claims data. That is, we are proposing to 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 APC proposed relative payment weights for CY 2019, we began with approximately 163 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, 2017, and before January 1, 2018, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 86 million final action claims to develop the proposed CY 2019 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this CY 2019 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 this proposed rule (which is available via the internet on the CMS website) includes the proposed list of bypass codes for CY 2019. The proposed list of bypass codes contains codes that were reported on claims for services in CY 2017 and, therefore, includes codes that were in effect in CY 2017 and used for billing, but were deleted for CY 2018. We retained these deleted bypass codes on the proposed CY 2019 bypass list because these codes existed in CY 2017 and were covered OPD services in that period, and CY 2017 claims data are used to calculate CY 2019 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we are proposing to add for CY 2019 are identified by asterisks (*) in the fourth column of Addendum N.

We are not proposing to remove any codes from the CY 2019 bypass list.

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

For CY 2019, in this CY 2019 OPPS/ASC proposed rule, we are proposing to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2019 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 2017 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2016. For the proposed CY 2019 OPPS payment rates, we used the set of claims processed during CY 2017. 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. 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.*

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2017 (the year of claims data we used to calculate the proposed CY 2019 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2017 Data Specifications Manual.

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

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74840 through 74847), we finalized our policy of creating new cost centers and distinct CCRs for implantable devices, magnetic resonance imagings (MRIs), computed tomography (CT) scans, and cardiac catheterization. However, in response to the CY 2014 OPPS/ASC proposed rule, commenters reported that some hospitals currently use an imprecise ''square feet'' allocation methodology for the costs of large moveable equipment like CT scan and MRI machines. They indicated that while CMS 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 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 (78 FR 74847). 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 a 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 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), we finalized a policy to extend the transition policy for 1 additional year and 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.

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 below 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 below provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods.

TABLE 1—PERCENTAGE CHANGE IN ESTIMATE COST FOR CT AND MRI APCS WHEN EXCLUDING CLAIMS FROM PROVIDER USING ''SQUARE FEET'' AS THE COST ALLOCATION METHOD

APC	APC descriptor	Percentage change
5521	Level 1 Imaging without Contrast	−3.6
5522	Level 2 Imaging without Contrast	5.5
5523	Level 3 Imaging without Contrast	4.3
5524	Level 4 Imaging without Contrast	4.7
5571	Level 1 Imaging with Contrast	7.7
5572	Level 2 Imaging with Contrast	8.4
5573	Level 3 Imaging with Contrast	2.8
8005	CT and CTA without Contrast Composite	13.9
8006	CT and CTA with Contrast Composite	11.4
8007	MRI and MRA without Contrast Composite	6.6
8008	MRI and MRA with Contrast Composite	7.4

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	0.0377	0.0527	0.0780	0.1046
Square Feet Only	0.0309	0.0475	0.0701	0.0954
Direct Assign	0.0553	0.0645	0.1058	0.1227
Dollar Value	0.0446	0.0592	0.0866	0.1166
Direct Assign and Dollar Value	0.0447	0.0592	0.0867	0.1163

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 17.4 percent to 2,174 providers and the number of valid CT CCRs has increased by 14.8 percent to 2,244 providers. However, as shown in Table 1 above, nearly all imaging APCs would see an increase in payment rates for CY 2019 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 cost allocation method of ''square feet'' as shown in Table 2 above.

In response to provider concerns and to provide added flexibility for hospitals to improve their cost allocation methods, for the CY 2019 OPPS, we are proposing to extend our transition policy and remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs with the APCs for CT and MRI identified in Table 2 above. This proposed extension would mean that CMS would now be providing 6 years for providers to transition from a ''square feet'' cost allocation method to another cost allocation method. We do not believe another extension in CY 2020 will be warranted and expect to determine the imaging APC relative payment weights for CY 2020 using cost data from all providers, regardless of the cost allocation method employed.

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

In this section of this proposed rule, we discuss the use of claims to calculate the proposed OPPS payment rates for CY 2019. The Hospital OPPS page on the CMS website on which this proposed rule is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below 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 2017 claims that were used to calculate the proposed payment rates for the CY 2019 OPPS.

In the history of the OPPS, we have traditionally established the scaled relative weights on which payments are based using APC median costs, which is 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 2019, in this CY 2019 OPPS/ASC proposed rule, we are proposing to continue to use geometric mean costs to calculate the proposed relative weights on which the CY 2019 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the proposed OPPS payment rates for CY 2019 shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

We note that this will be the first year in which claims data containing lines with the modifier ''PN'' will be available, which indicate 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, we are proposing 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 details of the claims process used in this proposed rule, we refer readers to the claims accounting narrative under supporting documentation for this CY 2019 OPPS/ASC proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

a. Proposed Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

(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.

In this CY 2019 OPPS/ASC proposed rule, we are proposing 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, in order to address the differences in CCRs and to better reflect hospitals' costs, we are proposing 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 are proposing to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We are proposing to calculate the costs upon which the proposed CY 2019 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 2019 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that, as discussed in section II.A.2.b. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59234 through 59239), 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. In this CY 2019 OPPS/ASC proposed rule, we are proposing to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C–APCs. Because the costs of blood and blood products would be reflected in the overall costs of the C–APCs (and, as a result, in the proposed payment rates of the C–APCs), we are proposing to not 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 also refer readers to Addendum B to this proposed rule (which is available via the internet on the CMS website) for the proposed CY 2019 payment rates for blood and blood products (which are 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).

(b) Pathogen-Reduced Platelets Payment Rate

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70322 through 70323), we reiterated that we calculate 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. Because HCPCS code P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit), the predecessor code to HCPCS code P9073 (Platelets, pheresis, pathogen-reduced, each unit), was new for CY 2016, there were no claims data available on the charges and costs for this blood product upon which to apply our blood-specific CCR methodology. Therefore, we established an interim payment rate for HCPCS code P9072 based on a crosswalk to existing blood product HCPCS code P9037 (Platelets, pheresis, leukocytes reduced, irradiated, each unit), which we believed provided the best proxy for the costs of the new blood product. In addition, we stated that once we had claims data for HCPCS code P9072, we would calculate its payment rate using the claims data that should be available for the code beginning in CY 2018, which is our practice for other blood product HCPCS codes for which claims data have been available for 2 years.

We stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59232) that, although our standard practice for new codes involves using claims data to set payment rates once claims data become available, we were concerned that there may have been confusion among the provider community about the services that HCPCS code P9072 described. That is, as early as 2016, there were discussions about changing the descriptor for HCPCS code P9072 to include the phrase ''or rapid bacterial tested'', which is a less costly technology than pathogen reduction. In addition, effective January 2017, the code descriptor for HCPCS code P9072 was changed to describe rapid bacterial testing of platelets and, effective July 1, 2017, the descriptor for the temporary successor code for HCPCS code P9072 (HCPCS code Q9988) was changed again back to the original descriptor for HCPCS code P9072 that was in place for 2016.

Based on the ongoing discussions involving changes to the original HCPCS code P9072 established in CY 2016, we believed that claims from CY 2016 for pathogen reduced platelets may have potentially reflected certain claims for rapid bacterial testing of platelets. Therefore, we decided to continue to crosswalk the payment amount for services described by HCPCS code P9073 to the payment amount for services described by HCPCS P9037 for CY 2018 (82 FR 59232), as had been done previously, to determine the payment rate for services described by HCPCS code P9072. In this proposed rule, for CY 2019, we have reviewed the CY 2017 claims data for the two predecessor codes to HCPCS code P9073 (HCPCS codes P9072 and Q9988), along with the claims data for the CY 2017 temporary code for pathogen test for platelets (HCPCS code Q9987), which describes rapid bacterial testing of platelets.

We found that there were over 2,200 claims billed with either HCPCS code P9072 or Q9988. Accordingly, we believe that there are a sufficient number of claims to use to calculate a payment rate for HCPCS code P9073 for CY 2019. We also performed checks to estimate the share of claims that may have been billed for rapid bacterial testing of platelets as compared to the share of claims that may have been billed for pathogen-reduced, pheresis platelets (based on when HCPCS code P9072 was an active procedure code from January 1, 2017 to June 30, 2017). First, we found that the geometric mean cost for pathogen-reduced, pheresis platelets, as reported by HCPCS code Q9988 when billed separately for rapid bacterial testing of platelets, was $453.87, and that over 1,200 claims were billed for services described by HCPCS code Q9988. Next, we found that the geometric mean cost for rapid bacterial testing of platelets, as reported by HCPCS code Q9987 on claims, was $33.44, and there were only 59 claims reported for services described by HCPCS code Q9987, of which 3 were separately paid.

These findings imply that almost all of the claims billed for services reported with HCPCS code P9072 were for pathogen-reduced, pheresis platelets. In addition, the geometric mean cost for services described by HCPCS code P9072, which may contain rapid bacterial testing of platelets claims, was $468.11, which is lower than the geometric mean cost for services described by HCPCS code Q9988 of $453.87, which would not have contained claims for rapid bacterial testing of platelets. Because the geometric mean for services described by HCPCS code Q9987 is only $33.44, it would be expected that if a significant share of claims billed for services described by HCPCS code P9072 were for the rapid bacterial testing of platelets, the geometric mean cost for services described by HCPCS code P9072 would be lower than the geometric mean cost for services described by HCPCS code Q9988. Instead, we found that the geometric mean cost for services described by HCPCS code Q9988 is higher than the geometric mean cost for services described by HCPCS code P9072.

Based on our analysis of claims data, we believe there are sufficient claims available to establish a payment rate for pathogen-reduced pheresis platelets without using a crosswalk. Therefore, we are proposing to calculate the payment rate for services described by HCPCS code P9073 in CY 2019 and in subsequent years using claims payment history, which is the standard methodology used by the OPPS for HCPCS and CPT codes with at least 2 years of claims history. We refer readers to Addendum B of this proposed rule for the proposed payment rate for services described by HCPCS code P9073 reportable under the OPPS. Addendum B is available via the internet on the CMS website.

(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.

In this CY 2019 OPPS/ASC proposed rule, for CY 2019, we are proposing to use the costs derived from CY 2017 claims data to set the proposed CY 2019 payment rates for brachytherapy sources because CY 2017 is the same year of data we are proposing to use to set the proposed payment rates for most other items and services that would be paid under the CY 2019 OPPS. We are proposing to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we are proposing for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also are proposing 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 are proposing 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 are proposing 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 2019 payment rates for brachytherapy sources are included in Addendum B to this proposed rule (which is available via the internet on the CMS website) and are identified with status indicator ''U''. For CY 2019, we are proposing to continue to assign status indicator ''U'' (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and to use external data (invoice prices) and other relevant information to establish the proposed APC payment rate for HCPCS code C2645. Specifically, we are proposing to set the payment rate at $4.69 per mm^2, the same rate that was in effect for CYs 2017 and 2018.

We note that, for CY 2019, we are proposing to assign status indicator ''E2'' (Items and Services for Which Pricing Information and Claims Data Are Not Available) to HCPCS code C2644 (Brachytherapy cesium-131 chloride) because this code was not reported on CY 2017 claims. Therefore, we are unable to calculate a proposed payment rate based on the general OPPS ratesetting methodology described earlier. Although HCPCS code C2644 became effective July 1, 2014, there are no CY 2017 claims reporting this code. Therefore, we are proposing to assign new proposed status indicator ''E2'' to HCPCS code C2644 in the CY 2019 OPPS.

We continue to invite hospitals and other parties to submit recommendations to us for new codes to describe new brachytherapy sources. Such recommendations should be directed 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. Proposed Comprehensive APCs (C–APCs) for CY 2019

(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 one 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, we did not change the total number of C–APCs from 62.

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

Services excluded from the C–APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act;

brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C–APC policy is included in Addendum J to this proposed rule (which is available via the internet on the CMS website).

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'' that is reported with a date of service on the same day or 1 day earlier than the date of service associated with services described by HCPCS code G0378;
- Contains 8 or more units of services described by HCPCS code G0378 (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 referral 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. Therefore, the requirement for functional reporting under the regulations at 42 CFR 410.59(a)(4) and 42 CFR 410.60(a)(4) does not apply. 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 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 2019, in this CY 2019 OPPS/ASC proposed rule, we are proposing to apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code for the primary ''J1'' service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C–APC within the same clinical family of C–APCs. As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C–APC. We list the complexity adjustments proposed for ''J1'' and add-on code combinations for CY 2019, along with all of the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the internet on the CMS website).

Addendum J to this proposed rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code

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

(2) Proposed Additional C–APCs for CY 2019

For CY 2019 and subsequent years, in this CY 2019 OPPS/ASC proposed rule, we are proposing to continue to apply the C–APC payment policy methodology made effective in CY 2015 and updated with the implementation of status indicator ''J2'' in CY 2016. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology and revisions. Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we are proposing to add three C–APCs under the existing C–APC payment policy beginning in CY 2019: proposed C–APC 5163 (Level 3 ENT Procedures); proposed C–APC 5183 (Level 3 Vascular Procedures); and proposed C–APC 5184 (Level 4 Vascular Procedures). These APCs were selected to be included in this proposal because, similar to other C–APCs, these APCs include primary, comprehensive services, such as major surgical procedures, that are typically reported with other ancillary and adjunctive services. Also, similar to other APCs that have been converted to C–APCs, there are higher APC levels within the clinical family or related clinical family of these APCs that have previously been assigned to a C–APC. Table 3 of this proposed rule lists the proposed C–APCs for CY 2019. All C–APCs are displayed in Addendum J to this proposed rule (which is available via the internet on the CMS website). Addendum J to this proposed rule also contains all of the data related to the C–APC payment policy methodology, including the list of proposed complexity adjustments and other information.

TABLE 3—PROPOSED CY 2019 C–APCS

C–APC	CY 2019 APC group title	Clinical family	Proposed 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 & Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery & 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	
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 & Related Services	LAPXX	

TABLE 3—PROPOSED CY 2019 C–APCS—Continued

C–APC	CY 2019 APC group title	Clinical family	Proposed new C-APC
5362	Level 2 Laparoscopy & Related Services	LAPXX	
5373	Level 3 Urology & Related Services	UROXX	
5374	Level 4 Urology & Related Services	UROXX	
5375	Level 5 Urology & Related Services	UROXX	
5376	Level 6 Urology & Related Services	UROXX	
5377	Level 7 Urology & 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	
5462	Level 2 Neurostimulator & Related Procedures	NSTIM	
5463	Level 3 Neurostimulator & Related Procedures	NSTIM	
5464	Level 4 Neurostimulator & 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.

(3) Exclusion of Procedures Assigned to New Technology APCs From the Comprehensive APC (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. When a procedure assigned to a New Technology APC is included on the claim with a primary procedure, identified by OPPS status indicator ''J1'', payment for the new technology service is typically packaged into the payment for the primary procedure. Because the new technology service is not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service is reduced. This is 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.

For example, for CY 2017, there were seven claims generated for HCPCS code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy), which involves the use of the Argus® II Retinal Prosthesis System. However, several of these claims were not available for ratesetting because HCPCS code 0100T was reported with a ''J1'' procedure and, therefore, payment was packaged into the associated C–APC payment. If these services had been separately paid under the OPPS, there would be at least two additional single claims available for ratesetting. As mentioned previously, the purpose of the new technology APC policy is to ensure that there are sufficient claims data for new services, which is particularly important for services with a low volume such as procedures described by HCPCS code 0100T. Another concern is the costs reported for the claims when payment is not packaged for a new technology procedure may not be representative of all of the services included on a claim that is generated, which may also affect our ability to assign the new service to the most appropriate clinical APC.

To address this issue and help ensure that there is sufficient claims data for services assigned to New Technology APCs, we are proposing to exclude payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. This issue is also addressed in section III.C.3.b. of this proposed rule.

c. Proposed Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for

groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. (We note that, in the CY 2018 OPPS/ASC final rule with comment period, we finalized a policy to delete the composite APC 8001 (LDR Prostate Brachytherapy Composite) for CY 2018 and subsequent years.) We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241 through 59242 and 59246 through 52950) for more recent background.

In this CY 2019 OPPS/ASC proposed rule, for CY 2019 and subsequent years, we are proposing to continue our composite APC payment policies for mental health services and multiple imaging services, as discussed below. In addition, as discussed in section II.A.2.b.(3) and II.A.2.c. of the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33577 through 33578 and 59241 through 59242 and 59246, respectively), we are proposing to continue to assign CPT code 55875 (Transperineal placement of needs or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to status indicator ''J1'' and to continue to assign the services described by CPT code 55875 to C–APC 5375 (Level 5 Urology and Related Services) for CY 2019.

(1) Mental Health Services Composite APC

In this CY 2019 OPPS/ASC proposed rule, we are proposing 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.

For CY 2019, we are proposing 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 2019. In addition, we are proposing to set the proposed payment rate for composite APC 8010 at the same payment rate that we are proposing for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the proposed payment rate for composite APC 8010.

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

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, in order 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).

In this CY 2019 OPPS/ASC proposed rule, we are proposing, for CY 2019 and subsequent years, 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 2019 payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) are based on proposed geometric mean costs calculated from a partial year of CY 2017 claims available for this CY 2019 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 2019 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 2019 OPPS/ASC proposed rule.

For this CY 2019 OPPS/ASC proposed rule, we were able to identify approximately 638,902 ''single session'' claims out of an estimated 1.7 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately37 percent of all eligible claims, to calculate the proposed CY 2019 geometric mean costs for the multiple imaging composite APCs. Table 4 of this CY 2019 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 2019.

TABLE 4—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Proposed CY 2019 APC 8004 (ultrasound composite)	Proposed CY 2019 approximate APC geometric mean cost = $300
Family 1—Ultrasound	
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.
Proposed CY 2019 APC 8005 (CT and CTA without contrast composite) *	Proposed CY 2019 approximate APC geometric mean cost = $275
Family 2—CT and CTA with and without Contrast	
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.
74261	Ct colonography, w/o dye.
74176	Ct angio abd & pelvis.
Proposed CY 2019 APC 8006 (CT and CTA with contrast composite)	Proposed CY 2019 approximate APC geometric mean cost = $501
70487	Ct maxillofacial w/dye.
70460	Ct head/brain w/dye.

TABLE 4—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

70470	Ct head/brain w/o & w/dye.
70481	Ct orbit/ear/fossa w/dye.
70482	Ct orbit/ear/fossa w/o & 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.
74262	Ct colonography, w/dye.
75635	Ct angio abdominal arteries.
74177	Ct angio abd & pelv w/contrast.
74178	Ct angio abd & pelv 1+ regns.

* 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.

Proposed CY 2019 APC 8007 (MRI and MRA without contrast composite) *	Proposed CY 2019 approximate APC geometric mean cost = $556
Family 3—MRI and MRA with and without Contrast	
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.
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.
Proposed CY 2019 APC 8008 (MRI and MRA with contrast composite)	Proposed CY 2019 approximate APC geometric mean cost = $871
70549	Mr angiograph neck w/o & w/dye.
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.
70552	Mri brain w/dye.
70553	Mri brain w/o & w/dye.
71551	Mri chest w/dye.
71552	Mri chest w/o & w/dye.
72142	Mri neck spine w/dye.
72147	Mri chest spine w/dye.
72149	Mri lumbar spine w/dye.
72156	Mri neck spine w/o & w/dye.
72157	Mri chest spine w/o & w/dye.
72158	Mri lumbar spine w/o & w/dye.
72196	Mri pelvis w/dye.
72197	Mri pelvis w/o & w/dye.
73219	Mri upper extremity w/dye.
73220	Mri uppr extremity w/o & w/dye.
73222	Mri joint upr extrem w/dye.
73223	Mri joint upr extr w/o & w/dye.
73719	Mri lower extremity w/dye.
73720	Mri lwr extremity w/o & w/dye.
73722	Mri joint of lwr extr w/dye.
73723	Mri joint lwr extr w/o & w/dye.
74182	Mri abdomen w/dye.
74183	Mri abdomen w/o & w/dye.
75561	Cardiac mri for morph w/dye.
75563	Card mri w/stress img & dye.
C8900	MRA w/cont, abd.
C8902	MRA w/o fol w/cont, abd.
C8903	MRI w/cont, breast, uni.
C8905	MRI w/o fol w/cont, brst, un.
C8906	MRI w/cont, breast, bi.
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest.
C8911	MRA w/o fol w/cont, chest.
C8912	MRA w/cont, lwr ext.
C8914	MRA w/o fol w/cont, lwr ext.
C8918	MRA w/cont, pelvis.
C8920	MRA w/o fol w/cont, pelvis.
C8931	MRA, w/dye, spinal canal.
C8933	MRA, w/o&w/dye, spinal canal.
C8934	MRA, w/dye, upper extremity.
C8936	MRA, w/o&w/dye, upper extr.

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

3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular patient. 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 often occurs 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), and the

CY 2018 OPPS/ASC final rule with comment period (82 FR 59250). 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, 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 2019, 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 of 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 this CY 2019 OPPS/ASC proposed rule, for CY 2019, we are proposing to conditionally package the costs of selected newly identified ancillary services into payment with 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 proposed changes to packaging policies beginning in CY 2019.

b. Proposed CY 2019 Packaging Policy for Non-Opioid Pain Management Treatments

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 expressed a variety of views on packaging under the OPPS. In the CY 2018 OPPS/ASC final rule with comment period, we summarized the comments received in response to our request (82 FR 59255). The comments ranged from requests to unpackage most items and services that are either conditionally or unconditionally packaged under the OPPS, including drugs and devices, to specific requests for separate payment for a specific drug or device. We stated in the CY 2018 OPPS/ASC final rule with comment period that CMS would continue to explore and evaluate packaging policies under the OPPS and consider these policies in future rulemaking.

In addition to stakeholder feedback regarding OPPS packaging policies, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission) recently recommended that CMS examine payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments. The Commission was established in 2017 to study ways to combat and treat drug abuse, addiction, and the opioid crisis. The Commission's report [3] included a recommendation for CMS to ''. . . review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain. . . . '' [4] With respect to the packaging policy, the Commission's report states that ''. . . the current CMS payment policy for 'supplies' related to surgical procedures creates unintended incentives to prescribe opioid medications to patients for postsurgical pain instead of administering non-opioid pain medications. Under current policies, CMS provides one all-inclusive bundled payment to hospitals for all 'surgical supplies,' which includes hospital-administered drug products intended to manage patients' postsurgical pain. This policy results in the hospitals receiving the same fixed fee from Medicare whether the surgeon administers a non-opioid medication or not.'' [5] HHS also presented an Opioid Strategy in April 2017 [6] that aims in part to support cutting-edge research and advance the practice of pain management. On October 26, 2017, the opioid crisis was declared a national public health emergency under Federal law [7] and this determination was renewed on April 20, 2018.[8]

In response to stakeholder comments on the CY 2018 OPPS/ASC proposed rule and in light of the recommendations regarding payment policies for certain drugs, we recently evaluated the impact of our packaging policy for drugs that function as a supply when used in a surgical procedure on the utilization of these drugs in both the hospital outpatient department and the ASC setting. Currently, as noted above, drugs that function as a supply are packaged under the OPPS and the ASC payment system, regardless of the costs of the drugs. The costs associated with packaged drugs that function as a supply are included in the ratesetting methodology for the surgical procedures with which they are billed and the payment rate for the associated procedure reflects the costs of the packaged drugs and other packaged items and services to the extent they are billed with the procedure. In our evaluation, we used currently available data to analyze the utilization patterns associated with specific drugs that function as a supply over a 5-year time period (CYs 2013 through 2017) to determine whether this packaging policy has reduced the use of these drugs. If the packaging policy discouraged the use of drugs that function as a supply or impeded access to these products, we would expect to see a significant decline in utilization of these drugs over time, although we note that a decline in utilization could also reflect other factors, such as the availability of alternative products. We did not observe significant declines in the total number of units used in the hospital outpatient department for a majority of the drugs included in our analysis.

In fact, under the OPPS, we observed the opposite effect for several drugs that function as a supply, including Exparel

[3] President's Commission on Combating Drug Addiction and the Opioid Crisis, Report (2017). Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.*

[4] Ibid, at page 57, Recommendation 19.

[5] Ibid.

[6] Available at: *https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html.*

[7] Available at: *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[8] Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

(HCPCS code C9290). Exparel is a liposome injection of bupivacaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. In 2011, Exparel was approved by the FDA for administration into the postsurgical site to provide postsurgical analgesia.[9] Exparel had pass-through payment status from CYs 2012 through 2014 and was separately paid under both the OPPS and the ASC payment system during this 3-year period. Beginning in CY 2015, Exparel was packaged as a surgical supply under both the OPPS and the ASC payment system. Exparel is currently the only non-opioid pain management drug that is packaged as a drug that functions as a supply when used in a surgical procedure under the OPPS and the ASC payment system.

From CYs 2013 through 2017, there was an overall increase in the OPPS Medicare utilization of Exparel of approximately 229 percent (from 2.3 million units to 7.7 million units) during this 5-year time period. The total number of claims reporting Exparel increased by 222 percent (from 10,609 claims to 34,183 claims) over this time period. This increase in utilization continued, even after the 3-year drug pass-through payment period ended for this product in 2014, with 18 percent overall growth in the total number of units used from CYs 2015 through 2017 (from 6.5 million units to 7.7 million units). The number of claims reporting Exparel increased by 21 percent during this time period (from 28,166 claims to 34,183 claims).

Thus, we have not found evidence to support the notion that the OPPS packaging policy has had an unintended consequence of discouraging the use of non-opioid treatment for postsurgical pain management in the hospital outpatient department. Therefore, based on this data analysis, we do not believe that changes are necessary under the OPPS for the packaged drug policy for drugs that function as a surgical supply when used in a surgical procedure in this setting at this time.

In terms of Exparel in particular, we have received several requests to pay separately for the drug rather than packaging payment for it as a surgical supply. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66874 and 66875), in response to comments from stakeholders requesting separate payment for Exparel, we stated that we considered Exparel to be a drug that functions as a surgical supply because it is indicated for the alleviation of postoperative pain. We also stated that we consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59345), we reiterated our position with regard to payment for Exparel, stating that we believed that payment for this drug is appropriately packaged with the primary surgical procedure. In addition, we have reviewed recently available literature with respect to Exparel, including a briefing document[10] submitted for the FDA Advisory Committee Meeting held February 14–15, 2018, by the manufacturer of Exparel that notes that ''. . . Bupivacaine, the active pharmaceutical ingredient in Exparel, is a local anesthetic that has been used for infiltration/field block and peripheral nerve block for decades'' and that ''since its approval, Exparel has been used extensively, with an estimated 3.5 million patient exposures in the U.S.''[11] On April 6, 2018, the FDA approved Exparel's new indication for use as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.[12] Based on our review of currently available OPPS Medicare claims data and public information from the manufacturer of the drug, we do not believe that the OPPS packaging policy has discouraged the use of Exparel for either of the drug's indications. Accordingly, we continue to believe it is appropriate to package payment for Exparel as we do with other postsurgical pain management drugs when it is furnished in a hospital outpatient department. However, we are seeking public comments on whether separate payment would nonetheless further incentivize appropriate use of Exparel in the hospital outpatient setting and peer-reviewed evidence that such increased utilization would lead to a decrease in opioid use and addiction among Medicare beneficiaries.

Although we found increases in utilization for Exparel when it is paid under the OPPS, we did notice different effects on Exparel utilization when examining the effects of our packaging policy under the ASC payment system. In particular, during the same 5-year period of CYs 2013 through 2017, the total number of units of Exparel used in the ASC setting decreased by 25 percent (from 98,160 total units to 73,595 total units) and the total number of claims reporting Exparel decreased by 16 percent (from 527 claims to 441 claims). In the ASC setting, after the pass-through payment period ended for Exparel at the end of CY 2014, the total number of units of Exparel used decreased by 70 percent (from 244,757 units to 73,595 units) between CYs 2015 and 2017. The total number of claims reporting Exparel also decreased during this time period by 62 percent (from 1,190 claims to 441 claims). However, there was an increase of 238 percent (from 98,160 total units to 331,348 total units) in the total number of units of Exparel used in the ASC setting during the time period of CYs 2013 and 2014 when the drug received pass-through payments, indicating that the payment rate of ASP +6 percent for Exparel may have an impact on its usage in the ASC setting. The total number of claims reporting Exparel also increased during this time period from 527 total claims to 1,540 total claims, an increase of 192 percent.

While several variables may contribute to this difference between utilization and claims reporting in the hospital outpatient department and the ASC setting, one potential explanation is that, in comparison to hospital outpatient departments, ASCs tend to provide specialized care and a more limited range of services. Also, ASCs are paid, in aggregate, approximately 55 percent of the OPPS rate. Therefore, fluctuations in payment rates for specific services may impact these providers more acutely than hospital outpatient departments, and therefore, ASCs may be less likely to choose to furnish non-opioid postsurgical pain management treatments, which are typically more expensive than opioids, as a result. Another possible contributing factor is that ASCs do not typically report packaged items and services and, accordingly, our analysis may be undercounting the number of Exparel units utilized in the ASC setting.

In light of the results of our evaluation of packaging policies under the OPPS and the ASC payment system, which showed decreased utilization for certain drugs that function as a supply in the ASC setting in comparison to the hospital outpatient department setting, as well as the Commission's recommendation to examine payment

[9] Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022496s000lbl.pdf.*

[10] Food and Drug Administration, Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee Briefing Document (2018). Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM596314.pdf.*

[11] Ibid, page 9.

[12] Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022496s009lbledt.pdf.*

policies for non-opioid pain management drugs that function as a supply, we believe a change in how we pay for non-opioid pain management drugs that function as surgical supplies may be warranted. In particular, we believe it may be appropriate to pay separately for evidence-based non-opioid pain management drugs that function as a supply in a surgical procedure in the ASC setting to address the decreased utilization of these drugs and to encourage use of these types of drugs rather than prescription opioids. Therefore, we are proposing in section XII.D.3. of this proposed rule 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 for CY 2019.

We have stated previously (82 FR 59250) that our packaging policies are designed to support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. The packaging policies established under the OPPS also typically apply when services are provided in the ASC setting, and the policies have the same strategic goals in both settings. While this proposal is a departure from our current ASC packaging policy for drugs (specifically, non-opioid pain management drugs) that function as a supply when used in a surgical procedure, we believe that this proposed change will incentivize the use of non-opioid pain management drugs and is responsive to the Commission's recommendation to examine payment policies for non-opioid pain management drugs that function as a supply, with the overall goal of combating the current opioid addiction crisis. As previously noted, the proposal for payment of non-opioid pain management drugs in the ASC setting is presented in further detail in section XII.D.3. of this proposed rule. However, we also are interested in peer-reviewed evidence that demonstrates that non-opioid alternatives, such as Exparel, in the outpatient setting actually do lead to a decrease in prescription opioid use and addiction and are seeking public comments containing evidence that demonstrate whether and how such non-opioid alternatives affect prescription opioid use during or after an outpatient visit or procedure.

In addition, as noted in section XII.D.3. of this proposed rule, we are seeking comment on whether the proposed policy would decrease the dose, duration, and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure (especially for beneficiaries at high-risk for opioid addiction) as well as whether there are other non-opioid pain management alternatives that would have similar effects and may warrant separate payment. For example, we are interested in identifying whether single post-surgical analgesic injections, such as Exparel, or other non-opioid drugs or devices that are used during an outpatient visit or procedure are associated with decreased opioid prescriptions and reduced cases of associated opioid addiction following such an outpatient visit or procedure. We also are requesting comments that provide evidence (such as published peer-reviewed literature) 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 separate payment under either or both the OPPS and the ASC payment system. The reduction or avoidance of prescription opioids would be the criteria we would seek to determine whether separate payment is warranted for CY 2019. Should evidence change over time, we would consider whether a reexamination of any policy adopted in the final rule would be necessary.

In addition, we are inviting the public to submit ideas on regulatory, subregulatory, policy, practice, and procedural changes to help prevent opioid use disorders and improve access to treatment under the Medicare program. We are interested in identifying barriers that may inhibit access to non-opioid alternatives for pain treatment and management or access to opioid use disorder treatment, including those barriers related to payment methodologies or coverage. In addition, consistent with our ''Patients Over Paperwork'' Initiative, we are interested in suggestions to improve existing requirements in order to more effectively address the opioid epidemic.

As noted above, we are interested in comments regarding other non-opioid treatments besides Exparel that might be affected by OPPS and ASC packaging policies, including alternative, non-opioid pain treatments, such as devices or therapy services that are not currently separable payable. We are specifically interested in comments regarding whether CMS should consider separate payment for such items and services for which payment is currently packaged under the OPPS and the ASC payment system that are effective non-opioid alternatives as well as evidence that demonstrates such items and services lead to a decrease in prescription opioid use during or after an outpatient visit or procedure in order to determine whether separate payment may be warranted. We intend to examine the evidence submitted to determine whether to adopt a final policy that incentivizes use of non-opioid alternative items and services that have evidence to demonstrate an associated decrease in prescription opioid use and addiction following an outpatient visit or procedure. Some examples of evidence that may be relevant could include an indication on the product's FDA label or studies published in peer-reviewed literature that such product aids in the management of acute or chronic pain and is an evidence-based non-opioid alternative for acute and/or chronic pain management. We would also be interested in evidence relating to products that have shown clinical improvement over other alternatives, such as a device that has been shown to provide a substantial clinical benefit over the standard of care for pain management. This could include, for example, spinal cord stimulators used to treat chronic pain such as the devices described by HCPCS codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), and C1767 (Generator, neurostimulator (implantable), nonrechargeable) which are primarily assigned to APCs 5463 and 5464 (Levels 3 and 4 Neurostimulator and Related Procedures) with proposed CY 2019 payment rates of $18,718 and $27,662, respectively, that have received pass-through payment status as well as other similar devices.

Currently, all devices are packaged under the OPPS and the ASC payment system unless they have pass-through payment status. However, in light of the Commission's recommendation to review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, we are interested in comments from stakeholders regarding whether, similar to the goals of the proposed payment policy for non-opioid pain management drugs that function as a supply when used in a surgical procedure, a policy of providing separate payment (rather than packaged payment) for these products, indefinitely or for a specified period of time, would also incentivize the use of alternative non-opioid pain

management treatments and improve access to care for non-opioid alternatives, particularly for innovative and low-volume items and services.

We also are interested in comments regarding whether we should provide separate payment for non-opioid pain management treatments or products using a mechanism such as an equitable payment adjustment under our 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. For example, we are considering whether an equitable payment adjustment in the form of an add-on payment for APCs that use a non-opioid pain management drug, device, or service would be appropriate. To the extent that commenters provide evidence to support this approach, we would consider adopting a final policy, which could include regulatory changes that would allow for an exception to the packaging of certain nonpass-through devices that represent non-opioid alternatives for acute or chronic pain that have evidence to demonstrate that their use leads to a decrease in opioid prescriptions or addictions, in the final rule for CY 2019 to effectuate such change.

Alternatively, we are interested in comments on whether a reorganization of the APC structure for procedures involving these products or establishing more granular APC groupings for specific procedure and device combinations to ensure that the payment rate for such services is aligned with the resources associated with procedures involving specific devices would better achieve our goal of incentivizing increased use of non-opioid alternatives, with the aim of reducing opioid use and subsequent addiction. For example, we would consider finalizing a policy to establish new APCs for procedures involving non-opioid pain management packaged items or services if such APCs would better recognize the resources involved in furnishing such items and services and decrease or eliminate the need for prescription opioids. In addition, given the general desire to encourage provider efficiency through creating larger bundles of care and packaging items and services that are integral, ancillary, supportive, dependent, or adjunctive to a primary service, we also are seeking comment on how such alternative payment structures would continue to balance the goals of incentivizing provider efficiencies with encouraging the use of non-opioid alternatives to pain management. Furthermore, because patients may receive opioid prescriptions following receipt of a non-opioid drug or implantation of a device, we are interested in identifying any cost implications for the patient and the Medicare program caused by this potential change in policy. The implications of incentivizing non-opioid pain management drugs available for postsurgical acute pain relief during or after an outpatient visit or procedure are also of interest, including for non-opioid drugs. The goal is to encourage appropriate use of such non-opioid alternatives. We note that this comment solicitation is also discussed in section XII.D.3. of this proposed rule.

4. Proposed 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 2018 OPPS/ASC final rule with comment period (82 FR 59255 through 59256), we applied this policy and calculated the relative payment weights for each APC for CY 2018 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 2019, as we did for CY 2018, we are proposing to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2019 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 2019, as we did for CY 2018, we are proposing 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 2019, as we did for CY 2018, we are proposing 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 section X.B. of this proposed rule, we discuss our CY 2019 proposal to control for unnecessary increases in the volume of outpatient service by paying for clinic visits furnished at an off-campus provider-based department at a PFS-equivalent rate under the OPPS rather than at the standard OPPS rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the proposal has only a negligible effect on the scalar. Specifically, under the proposed policy, there would be 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 our proposal, the savings that would result from the change in payments for these clinic visits would not be budget neutral. Therefore, the impact of the proposed policy would generally not be reflected in the budget neutrality adjustments, whether the adjustment is to the OPPS relative weights or to the OPPS conversion factor.

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 2019 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, we are proposing to compare

the estimated aggregate weight using the CY 2018 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2019 unscaled relative payment weights.

For CY 2018, we multiplied the CY 2018 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2017 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 2019, we are proposing to apply the same process using the estimated CY 2019 unscaled relative payment weights rather than scaled relative payment weights. We are proposing to calculate the weight scalar by dividing the CY 2018 estimated aggregate weight by the unscaled CY 2019 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: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* Click on the CY 2019 OPPS proposed rule link and open the claims accounting document link at the bottom of the page.

We are proposing to compare the estimated unscaled relative payment weights in CY 2019 to the estimated total relative payment weights in CY 2018 using CY 2017 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we are proposing to adjust the calculated CY 2019 unscaled relative payment weights for purposes of budget neutrality. We are proposing to adjust the estimated CY 2019 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4553 to ensure that the proposed CY 2019 relative payment weights are scaled to be budget neutral. The proposed CY 2019 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) were scaled and incorporated the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2. of this proposed rule) is included in the budget neutrality calculations for the CY 2019 OPPS.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20381), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2017 forecast of the FY 2019 market basket increase, the proposed FY 2019 IPPS market basket update is 2.8 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(v) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), provide adjustments to the OPD fee schedule increase factor for CY 2019.

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 this proposed rule, the proposed MFP adjustment for FY 2019 is 0.8 percentage point.

We are proposing that if more recent data become subsequently available after the publication of this proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such updated data, if appropriate, to determine the CY 2019 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 2019 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that, for each of years 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 2019, section 1833(t)(3)(G)(v) of the Act provides a 0.75 percentage point reduction to the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act. Therefore, in accordance with sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act, we are proposing to apply a 0.75 percentage point reduction to the OPD fee schedule increase factor for CY 2019.

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 are proposing to apply an OPD fee schedule increase factor of 1.25 percent for the CY 2019 OPPS (which is 2.8 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.8 percentage point MFP adjustment, and less the 0.75 percentage point additional adjustment).

Hospitals that fail to meet the Hospital OQR Program reporting requirements are 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 XIII. of this proposed rule.

In this CY 2019 OPPS/ASC proposed rule, we are proposing to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (*10*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2019, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS, and

to reflect the requirement in section 1833(t)(3)(G)(v) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by an additional 0.75 percentage point for CY 2019.

To set the OPPS conversion factor for this CY 2019 OPPS/ASC proposed rule, we are proposing to increase the CY 2018 conversion factor of $78.636 by 1.25 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing further to adjust the conversion factor for CY 2019 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We are proposing to calculate an overall proposed budget neutrality factor of 1.0004 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2019 IPPS wage indexes to those payments using the FY 2018 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For this CY 2019 OPPS/ASC proposed rule, we are proposing to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment would be 1.0000.

For this CY 2019 OPPS/ASC proposed rule, we are proposing to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule. We are proposing to calculate a CY 2019 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated proposed total CY 2019 payments under section 1833(t) of the Act, including the proposed CY 2019 cancer hospital payment adjustment, to estimated CY 2019 total payments using the CY 2018 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The CY 2019 proposed estimated payments applying the proposed CY 2019 cancer hospital payment adjustment are the same as estimated payments applying the CY 2018 final cancer hospital payment adjustment. Therefore, we are proposing to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 16002(b) of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.89, not the 0.88 target payment-to-cost ratio we are proposing to apply as stated in section II.F. of this proposed rule.

For this CY 2019 OPPS/ASC proposed rule, we estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2019 would equal approximately $126.7 million, which represents 0.17 percent of total projected CY 2019 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.04 percent estimate of pass-through spending for CY 2018 and the 0.17 percent estimate of proposed pass-through spending for CY 2019, resulting in a proposed decrease for CY 2019 of 0.13 percent. Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2019. We estimate for this proposed rule that outlier payments would be 1.02 percent of total OPPS payments in CY 2018; the 1.00 percent for proposed outlier payments in CY 2019 would constitute a 0.02 percent increase in payment in CY 2019 relative to CY 2018.

For this CY 2019 OPPS/ASC proposed rule, we also are proposing 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 are proposing to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of −0.75 percent (that is, the proposed OPD fee schedule increase factor of 1.25 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2019 of $77.955 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.591 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2019, we are proposing to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (*10*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2019 to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(v) of the Act. We are proposing to use a reduced conversion factor of $77.955 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.591 in the conversion factor relative to hospitals that met the requirements).

For CY 2019, we are proposing to use a conversion factor of $79.546 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 1.25 percent for CY 2019, the required proposed wage index budget neutrality adjustment of approximately1.0004, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment of 0.02 percentage point of projected OPPS spending for the difference in the pass-through spending and outlier payments that result in a proposed conversion factor for CY 2019 of $79.546.

C. Proposed Wage Index Changes

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

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We are proposing to continue this policy for the CY 2019 OPPS. We refer readers to section II.H. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting documentation for this proposed rule (which is available via the internet on the CMS website), for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same proposed FY 2019 pre-reclassified wage index that the IPPS uses 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 (c)(3) of our regulations. For the CY 2019 OPPS, we are proposing to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00 (as discussed below, we are proposing not to extend the imputed floor under the OPPS for CY 2019 and subsequent years, consistent with our proposal in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20362 and 20363) not to extend the imputed floor under the IPPS for FY 2019 and subsequent fiscal years). Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the FY 2011 through FY 2018 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; and for FY 2018, 82 FR 38142.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2019 IPPS wage indexes continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). We refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20353 through 20377) for a detailed discussion of all proposed changes to the FY 2019 IPPS wage indexes. We note that, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20362 through 20363), we proposed not to apply the imputed floor to the IPPS wage index computations for FY 2019 and subsequent fiscal years. Consistent with this, we are proposing not to extend the imputed floor policy under the OPPS beyond December 31, 2018 (the date the imputed floor policy is set to expire under the OPPS). We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38138 through 38142) for a detailed discussion of the application of the imputed floor under the IPPS for FY 2018.

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 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), 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. We believe that it is important for the OPPS to use the latest labor market area delineations available as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

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 provide detailed information on the update to the statistical areas since July 15, 2015, and are 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 OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

- Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB Bulletin No. 17–01 is available on the OMB website at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.* In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20354), we noted that we did not have sufficient time to include this change in the computation of the proposed FY 2019 IPPS wage index, ratesetting, and Tables 2 and 3 associated with the FY 2019 IPPS/LTCH PPS proposed rule. We stated that this new CBSA may affect the IPPS budget neutrality factors and wage indexes, depending on whether the area is eligible for the rural floor and the impact of the overall payments of the hospital located in this new CBSA. As we did in the FY 2019 IPPS/LTCH

PPS proposed rule (83 FR 20354), we are providing below an estimate of this new area's wage index based on the average hourly wages for new CBSA 46300 and the national average hourly wages from the wage data for the proposed FY 2019 IPPS wage index (described in section III.B. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule). Currently, provider 130002 is the only hospital located in Twin Falls County, Idaho, and there are no hospitals located in Jerome County, Idaho. Thus, the proposed wage index for CBSA 46300 is calculated using the average hourly wage data for one provider (provider 130002).

Below we provide the proposed FY 2019 IPPS unadjusted and occupational mix adjusted national average hourly wages and the estimated CBSA average hourly wages. Taking the estimated average hourly wage of new CBSA 46300 and dividing by the proposed national average hourly wage results in the estimated wage indexes shown in the table below.

	Estimated unadjusted wage index for new CBSA 46300	Estimated occupational mix adjusted wage index for new CBSA 46300
Proposed National Average Hourly Wage	42.990625267	42.948428861
Estimated CBSA Average Hourly Wage	35.833564813	38.127590025
Estimated Wage Index	0.8335	0.8878

As we stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20354), for the proposed FY 2019 IPPS wage indexes, we would use the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01. We also stated that we would incorporate the revision from OMB Bulletin No. 17–01 in the final FY 2019 IPPS wage index, ratesetting, and tables. Similarly, for the proposed CY 2019 OPPS wage indexes, we are proposing to use the OMB delineations that were adopted beginning with CY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01. We would incorporate the revision from OMB Bulletin No. 17–01 in the final CY 2019 OPPS wage index, ratesetting, and tables.

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. 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 the purposes of crosswalking counties to CBSAs for the OPPS wage index.

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.* In our transition to using only FIPS codes for counties for the IPPS wage index, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), we updated the FIPS codes used for crosswalking counties to CBSAs for the IPPS wage index effective October 1, 2017, to incorporate changes to the counties or county equivalent entities included in the Census Bureau's most recent list. We included these updates to calculate the area IPPS wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59261), we finalized our proposal to implement these FIPS code updates for the OPPS wage index effective January 1, 2018, beginning with the CY 2018 OPPS wage indexes.

For this CY 2019 OPPS/ASC proposed rule, we are proposing to use the FY 2019 hospital 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 standardized amount for CY 2019. Therefore, any adjustments for the FY 2019 IPPS post-reclassified wage index would be reflected in the final CY 2019 OPPS wage index. (We refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20353 through 20377) and the proposed FY 2019 hospital wage index files posted on the CMS website.) As explained above, 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.

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 were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. We are proposing to continue this policy for CY 2019. The following is a brief summary of the major proposed FY 2019 IPPS wage index policies and adjustments that we are proposing to apply to these hospitals under the OPPS for CY 2019. We are inviting public comments on these proposals. We refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20353 through 20377) for a detailed discussion of the proposed changes to the FY 2019 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 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 2019, we are proposing to continue our policy of allowing 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 MMA).

As stated earlier, in the FY 2015 IPPS/LTCH PPS final rule, we adopted the OMB labor market area delineations issued by OMB in OMB Bulletin No. 13–01 on February 28, 2013, based on standards published on June 28, 2010 (75 FR 37246 through 37252) and the 2010 Census data to delineate labor market areas for purposes of the IPPS wage index. For IPPS wage index purposes, for hospitals that were located in urban CBSAs in FY 2014 but were designated as rural under these revised OMB labor market area delineations, we generally assigned them the urban wage index value of the CBSA in which they were physically located for FY 2014 for a period of 3 fiscal years (79 FR 49957 through 49960). To be consistent, we applied the same policy to hospitals paid under the OPPS but not under the IPPS so that such hospitals maintained the wage index of the CBSA in which they were physically located for FY 2014 for 3 calendar years (until December 31, 2017). Because this 3-year transition ended at the end of CY 2017, it was not applied beginning in CY 2018.

In addition, under the IPPS, the imputed floor policy is set to expire effective October 1, 2018. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20362 through 20363), we proposed not to extend the imputed floor policy under the IPPS for FY 2019 and subsequent fiscal years. For purposes of the CY 2019 OPPS, the imputed floor policy is set to expire effective December 31, 2018. Consistent with the FY 2019 IPPS/LTCH PPS proposed rule, as discussed earlier, we are proposing not to extend the imputed floor policy under the OPPS beyond December 31, 2018.

For CMHCs, for CY 2019, we are proposing to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. As with OPPS hospitals and for the same reasons, for CMHCs previously located in urban CBSAs that were designated as rural under the revised OMB labor market area delineations in OMB Bulletin No. 13–01, we finalized a policy to maintain the urban wage index value of the CBSA in which they were physically located for CY 2014 for 3 calendar years (until December 31, 2017). Because this 3-year transition ended at the end of CY 2017, it was not applied beginning in CY 2018. The wage index that would apply to CMHCs for CY 2019 would include the rural floor adjustment, but would not include the imputed floor adjustment because, as discussed above, we are proposing to not extend the imputed floor policy beyond December 31, 2018. Also, the wage index that would apply to CMHCs would not include the out-migration adjustment because that adjustment only applies to hospitals.

Table 2 associated with the FY 2019 IPPS/LTCH PPS proposed rule (available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) identifies counties eligible for the out-migration adjustment and IPPS hospitals that would receive the adjustment for FY 2019. We are including the out-migration adjustment information from Table 2 associated with the FY 2019 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under the CY 2019 OPPS. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At this link, readers will find a link to the proposed FY 2019 IPPS wage index tables and Addendum L.

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

In addition to using CCRs to estimate costs from charges on claims for ratesetting, CMS uses 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. MACs cannot calculate a CCR for some hospitals because there is no cost report available. For these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned earlier until a hospital's MAC is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report. These hospitals include, but are not limited to, 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. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a biased CCR (that is, the CCR falls outside the predetermined ceiling threshold for a valid CCR) or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 4, Section 10.11).

In this CY 2019 OPPS/ASC proposed rule, we are proposing to update the default ratios for CY 2019 using the most recent cost report data. 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 detail on our process for calculating the statewide average CCRs, we refer readers to the CY 2019 OPPS proposed rule Claims Accounting Narrative that is posted on the CMS website. Table 5 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2019, based on proposed rule data.

TABLE 5—PROPOSED CY 2019 STATEWIDE AVERAGE CCRS

State	Urban/Rural	Proposed CY 2019 default CCR	Previous default CCR (CY 2018 OPPS Final Rule)
ALASKA	RURAL	0.655	0.659

TABLE 5—PROPOSED CY 2019 STATEWIDE AVERAGE CCRS—Continued

State	Urban/Rural	Proposed CY 2019 default CCR	Previous default CCR (CY 2018 OPPS Final Rule)
ALASKA	URBAN	0.224	0.218
ALABAMA	RURAL	0.190	0.190
ALABAMA	URBAN	0.154	0.155
ARKANSAS	RURAL	0.193	0.186
ARKANSAS	URBAN	0.195	0.200
ARIZONA	RURAL	0.241	0.232
ARIZONA	URBAN	0.157	0.160
CALIFORNIA	RURAL	0.181	0.181
CALIFORNIA	URBAN	0.188	0.193
COLORADO	RURAL	0.337	0.346
COLORADO	URBAN	0.201	0.204
CONNECTICUT	RURAL	0.322	0.324
CONNECTICUT	URBAN	0.251	0.249
DISTRICT OF COLUMBIA	URBAN	0.273	0.279
DELAWARE	URBAN	0.268	0.295
FLORIDA	RURAL	0.171	0.158
FLORIDA	URBAN	0.136	0.138
GEORGIA	RURAL	0.223	0.222
GEORGIA	URBAN	0.199	0.198
HAWAII	RURAL	0.355	0.332
HAWAII	URBAN	0.321	0.322
IOWA	RURAL	0.288	0.296
IOWA	URBAN	0.242	0.254
IDAHO	RURAL	0.339	0.339
IDAHO	URBAN	0.376	0.369
ILLINOIS	RURAL	0.209	0.214
ILLINOIS	URBAN	0.205	0.208
INDIANA	RURAL	0.256	0.299
INDIANA	URBAN	0.213	0.213
KANSAS	RURAL	0.266	0.264
KANSAS	URBAN	0.195	0.199
KENTUCKY	RURAL	0.179	0.184
KENTUCKY	URBAN	0.190	0.187
LOUISIANA	RURAL	0.211	0.212
LOUISIANA	URBAN	0.193	0.195
MASSACHUSETTS	RURAL	0.314	0.322
MASSACHUSETTS	URBAN	0.343	0.348
MAINE	RURAL	0.423	0.419
MAINE	URBAN	0.419	0.422
MARYLAND	RURAL	0.256	0.258
MARYLAND	URBAN	0.226	0.227
MICHIGAN	RURAL	0.296	0.302
MICHIGAN	URBAN	0.314	0.318
MINNESOTA	RURAL	0.376	0.379
MINNESOTA	URBAN	0.309	0.302
MISSOURI	RURAL	0.216	0.220
MISSOURI	URBAN	0.247	0.240
MISSISSIPPI	RURAL	0.219	0.213
MISSISSIPPI	URBAN	0.157	0.160
MONTANA	RURAL	0.478	0.486
MONTANA	URBAN	0.339	0.350
NORTH CAROLINA	RURAL	0.204	0.206
NORTH CAROLINA	URBAN	0.217	0.212
NORTH DAKOTA	RURAL	0.325	0.366
NORTH DAKOTA	URBAN	0.375	0.369
NEBRASKA	RURAL	0.304	0.313
NEBRASKA	URBAN	0.227	0.233
NEW HAMPSHIRE	RURAL	0.304	0.307
NEW HAMPSHIRE	URBAN	0.247	0.255
NEW JERSEY	URBAN	0.198	0.200
NEW MEXICO	RURAL	0.231	0.224
NEW MEXICO	URBAN	0.280	0.284
NEVADA	RURAL	0.163	0.175
NEVADA	URBAN	0.121	0.114
NEW YORK	RURAL	0.297	0.299
NEW YORK	URBAN	0.310	0.303
OHIO	RURAL	0.277	0.280
OHIO	URBAN	0.204	0.203

TABLE 5—PROPOSED CY 2019 STATEWIDE AVERAGE CCRS—Continued

State	Urban/Rural	Proposed CY 2019 default CCR	Previous default CCR (CY 2018 OPPS Final Rule)
OKLAHOMA	RURAL	0.215	0.215
OKLAHOMA	URBAN	0.166	0.169
OREGON	RURAL	0.277	0.290
OREGON	URBAN	0.327	0.336
PENNSYLVANIA	RURAL	0.264	0.267
PENNSYLVANIA	URBAN	0.177	0.173
PUERTO RICO	URBAN	0.547	0.577
RHODE ISLAND	URBAN	0.276	0.276
SOUTH CAROLINA	RURAL	0.166	0.170
SOUTH CAROLINA	URBAN	0.187	0.191
SOUTH DAKOTA	RURAL	0.338	0.391
SOUTH DAKOTA	URBAN	0.240	0.242
TENNESSEE	RURAL	0.173	0.173
TENNESSEE	URBAN	0.166	0.174
TEXAS	RURAL	0.218	0.205
TEXAS	URBAN	0.169	0.168
UTAH	RURAL	0.288	0.391
UTAH	URBAN	0.304	0.304
VIRGINIA	RURAL	0.177	0.177
VIRGINIA	URBAN	0.215	0.215
VERMONT	RURAL	0.392	0.393
VERMONT	URBAN	0.383	0.378
WASHINGTON	RURAL	0.260	0.256
WASHINGTON	URBAN	0.325	0.323
WISCONSIN	RURAL	0.342	0.348
WISCONSIN	URBAN	0.304	0.308
WEST VIRGINIA	RURAL	0.261	0.253
WEST VIRGINIA	URBAN	0.299	0.297
WYOMING	RURAL	0.397	0.407
WYOMING	URBAN	0.343	0.327

E. Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2019

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, 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 § 419.43(g) of the regulations to clarify that essential access community hospitals (EACHs) also are 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 2018. 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 the CY 2019 OPPS, we are proposing 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. In addition, we are proposing to maintain this 7.1 percent payment adjustment for the years after CY 2019 until we identify data in the future that would support a change to this payment adjustment.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2019

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), 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 for purposes of the cancer hospital payment adjustment was 0.89. 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).

2. Proposed Policy for CY 2019

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 42 CFR 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. For CY 2019, we are proposing 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 are available at the time of the development of this proposed rule, reduced by 1.0 percentage point to comply with section 16002(b) of the 21st Century Cures Act. We are not proposing an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) for CY 2019. To calculate the proposed CY 2019 target PCR, we use the same extract of cost report data from HCRIS, as discussed in section II.A. of this proposed rule, used to estimate costs for the CY 2019 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 2017 claims data that we used to model the impact of the proposed CY 2019 APC relative payment weights (3,676 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2019 OPPS. The cost report data for the hospitals in this dataset were from cost report

periods with fiscal year ends ranging from 2014 to 2017.

We then removed the cost report data of the 43 hospitals located in Puerto Rico from our dataset because we do not believe that their cost structure reflects 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 18 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 3,615 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 89 percent of reasonable cost (weighted average PCR of 0.89). Therefore, after applying the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act, we are proposing 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 0.88 for each cancer hospital.

Table 6 below indicates the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2019 due to the proposed cancer hospital payment adjustment policy. The actual amount of the CY 2019 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2019 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 6—PROPOSED ESTIMATED CY 2019 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider No.	Hospital name	Estimated percentage increase in OPPS payments for CY 2019 due to payment adjustment
050146	City of Hope Comprehensive Cancer Center	37.1
050660	USC Norris Cancer Hospital	13.4
100079	Sylvester Comprehensive Cancer Center	21.0
100271	H. Lee Moffitt Cancer Center & Research Institute	22.3
220162	Dana-Farber Cancer Institute	43.7
330154	Memorial Sloan-Kettering Cancer Center	46.9
330354	Roswell Park Cancer Institute	16.2
360242	James Cancer Hospital & Solove Research Institute	22.6
390196	Fox Chase Cancer Center	8.4
450076	M.D. Anderson Cancer Center	53.6
500138	Seattle Cancer Care Alliance	54.3

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2018, 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 $4,150 (the fixed-dollar amount threshold) (82 FR 59267 through 59268). 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 2017 OPPS payments, using CY 2017 claims available for this proposed rule, is approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2017, we estimate that we paid the outlier target of 1.0 percent of total aggregated OPPS payments.

For this proposed rule, using CY 2017 claims data and CY 2018 payment rates, we estimate that the aggregate outlier payments for CY 2018 would be approximately 1.02 percent of the total CY 2018 OPPS payments. We are providing estimated CY 2019 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. Proposed Outlier Calculation for CY 2019

For CY 2019, we are proposing to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We are proposing 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 this proposed rule, we are proposing to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under APC 5853 (Partial Hospitalization for CMHCs), exceeds 3.40 times the payment rate for proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC 5853 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this proposed rule.

To ensure that the estimated CY 2019 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we are proposing 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 $4,600.

We calculated this proposed fixed-dollar threshold of $4,600 using the standard methodology most recently used for CY 2018 (82 FR 59267 through 59268). For purposes of estimating outlier payments for this proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2018 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 2019 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2017 claims using the same inflation factor of 1.085868 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20581). We used an inflation factor of 1.04205 to estimate CY 2018 charges from the CY 2017 charges reported on CY 2017 claims. The methodology for determining this charge inflation factor is discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 20581). 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 are 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 are proposing to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2019 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2019 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2019, we are proposing to apply an adjustment factor of 0.987842 to the CCRs that were in the April 2018 OPSF to trend them forward from CY 2018 to CY 2019. The methodology for calculating this proposed adjustment is discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20582).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2018 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.987842 to approximate CY 2019 CCRs) to charges on CY 2017 claims that were adjusted (using the proposed charge inflation factor of 1.085868 to approximate CY 2019 charges). We simulated aggregated CY 2019 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 2019 OPPS payments. We estimated that a proposed fixed-dollar threshold of $4,600, 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 are proposing that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

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

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

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2019 OPPS/ASC proposed rule, the proposed payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this proposed rule and the proposed relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the internet on the CMS website) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available via the internet on the CMS website) was calculated by multiplying the proposed CY 2019 scaled weight for the APC by the proposed CY 2019 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 XIII. of this proposed rule.

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

Individual providers interested in calculating the payment amount that they would receive for a specific service from the proposed national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the proposed 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 proposed 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 proposed reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The proposed 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 in order to receive the proposed full CY 2019 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, under the proposed CY 2019 OPPS policy for continuing to use the OMB labor market area delineations based on the 2010 Decennial Census data for the wage indexes used under the IPPS, a hold harmless policy for the wage index may apply, as discussed in section II.C. of this proposed rule. The proposed 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 2019 under the IPPS, reclassifications through the Metropolitan Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Public Law 98–21. For further discussion of the proposed changes to the FY 2019 IPPS wage indexes, as applied to the CY 2019 OPPS, we refer readers to section II.C. of this proposed rule. We are proposing to continue to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act of 2010.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this proposed rule (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the proposed FY 2019 IPPS, which are listed in Table 2 in the FY 2019 IPPS/LTCH PPS proposed rule 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 2019 IPPS Proposed Rule Home Page'' and select ''FY 2019 Proposed Rule Tables.'') This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

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

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

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

$X_a = .60 * (\text{national unadjusted payment rate}) * \text{applicable wage index}$.

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

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

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

Y = .40 * (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 proposed full and reduced national unadjusted payment rates that would apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we used a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The proposed CY 2019 full national unadjusted payment rate for APC 5071 is approximately $581.99. The proposed reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is approximately $570.35. This proposed reduced rate is calculated by multiplying the proposed reporting ratio of 0.980 by the proposed full unadjusted payment rate for APC 5071.

The proposed FY 2019 wage index for a provider located in CBSA 35614 in New York is 1.2850. The labor-related portion of the proposed full national unadjusted payment is approximately $448.71 (.60 * $581.99 * 1.2850). The labor-related portion of the proposed reduced national unadjusted payment is approximately $439.74 (.60 * 570.35* 1.2850). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $232.80 (.40 * $581.99). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $228.14 (.40 * $570.35). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $681.51 ($448.71 + $232.80). The sum of the portions of the proposed reduced national adjusted payment is approximately $667.88 ($439.74 + $228.14).

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in calendar years thereafter, shall not exceed 40 percent of the APC payment rate. Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

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

2. Proposed OPPS Copayment Policy

For CY 2019, we are proposing 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 are proposing 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, 2019 are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

As discussed in section XIII.E. of this proposed rule, for CY 2019, the proposed Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

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

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

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than*

the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).

- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

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

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

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

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, $116.40 is approximately 20 percent of the proposed full national unadjusted payment rate of $581.99. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

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

B is the beneficiary payment percentage.

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

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

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC. The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

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

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

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.980.

The proposed unadjusted copayments for services payable under the OPPS that would be effective January 1, 2019, are shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed CY 2019 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

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

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

A. Proposed OPPS Treatment of New CPT and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, 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 and medical services;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these 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 CPT and Level II HCPCS codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that may more accurately describe items or services furnished and provides payment or more accurate payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on these new codes and finalize our proposals related to 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 status indicators. Certain payment status indicators provide separate payment, while other payment status indicators do not. Section XI. of this proposed rule discusses the various status indicators used under the OPPS.

In Table 7 below, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS.

TABLE 7—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2018	Level II HCPCS Codes	April 1, 2018	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
July 1, 2018	Level II HCPCS Codes	July 1, 2018	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) CPT Codes, Category III CPT codes.	July 1, 2018	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
October 1, 2018	Level II HCPCS Codes	October 1, 2018	CY 2019 OPPS/ASC final rule with comment period.	CY 2020 OPPS/ASC final rule with comment period.
January 1, 2019	Category I and III CPT Codes	January 1, 2019	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
	Level II HCPCS Codes	January 1, 2019	CY 2019 OPPS/ASC final rule with comment period.	CY 2020 OPPS/ASC final rule with comment period.

1. Proposed Treatment of New HCPCS Codes That Were Effective April 1, 2018 for Which we Are Soliciting Public Comments in This CY 2019 OPPS/ASC Proposed Rule

Through the April 2018 OPPS quarterly update CR (Transmittal 4005, Change Request 10515, dated March 20, 2018), we made effective nine new Level II HCPCS codes for separate payment under the OPPS. In this CY 2019 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for these Level II HCPCS codes, which are listed in Table 8 of this proposed rule. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

TABLE 8—NEW LEVEL II HCPCS CODES EFFECTIVE APRIL 1, 2018

CY 2018 HCPCS code	CY 2018 Long descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC
C9462	Injection, delafloxacin, 1 mg	G	9462
C9463	Injection, aprepitant, 1 mg	G	9463
C9464	Injection, rolapitant, 0.5 mg	G	9464
C9465	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose	G	9465
C9466	Injection, benralizumab, 1 mg	G	9466
C9467	Injection, rituximab and hyaluronidase, 10 mg	G	9467
C9468	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u.	G	9468
C9469*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg.	G	9469
C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)	J1	5164

*HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), which was effective April 1, 2018, was deleted June 30, 2018 and replaced with HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) effective July 1, 2018.

In addition, there were several new laboratory CPT Multianalyte Assays with Algorithmic Analyses (MAAA) codes (M codes) and Proprietary Laboratory Analyses (PLA) codes (U codes) that were effective April 1, 2018, but were too late to include in the April 2018 OPPS Update. Because these codes were released on the American Medical Association's (AMA) CPT website in February 2018, they were too late for us to include in the April 2018 OPPS Update CR and in the April 2018 Integrated Outpatient Code Editor (IOCE), and, consequently, were included in the July 2018 OPPS Update with an effective date of April 1, 2018. These CPT codes are listed below in Table 9. In this CY 2019 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for these CPT codes, which are listed in Table 9 of this proposed rule. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

TABLE 9—NEW CPT MAAA AND PROPRIETARY LABORATORY ANALYSES (PLA) CODES EFFECTIVE APRIL 1, 2018

CY 2018 HCPCS code	CY 2018 Long descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC
0012M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma.	A	N/A
0013M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma.	A	N/A
0035U	Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative.	Q4	N/A
0036U	Exome (*i.e.,* somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses.	A	N/A
0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden.	A	N/A
0038U	Vitamin D, 25 hydroxy D2 and D3, by LC–MS/MS, serum microsample, quantitative	Q4	N/A
0039U	Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity	Q4	N/A
0040U	BCR/ABL1 (t(9;22)) (*e.g.,* chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative.	A	N/A
0041U	Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM	Q4	N/A
0042U	Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG	Q4	N/A
0043U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM.	Q4	N/A
0044U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG.	Q4	N/A

2. Proposed Treatment of New HCPCS Codes That Were Effective July 1, 2018 for Which we Are Soliciting Public Comments in This CY 2019 OPPS/ASC Proposed Rule

Through the July 2018 OPPS quarterly update CR (Transmittal 4075, Change Request 1078, dated June 15, 2018), we made 4 new Category III CPT codes and 10 Level II HCPCS codes effective July 1, 2018 (14 codes total), and assigned them to appropriate interim OPPS status indicators and APCs. As listed in Table 10 below, 13 of the 14 HCPCS codes are separately payable under the OPPS while 1 HCPCS code is not. Specifically, HCPCS code QQ994 is assigned to status indicator ''E1'' to indicate that the item is not payable by Medicare. In addition, we note that HCPCS code C9469 was deleted June 30, 2018, and replaced with HCPCS code Q9993 effective July 1, 2018. Because HCPCS code Q9993 describes the same drug as HCPCS code C9469, we are proposing to continue the drug's pass-through payment status and to assign HCPCS code Q9993 to the same APC and status indicators as its predecessor HCPCS code C9469, as shown in Table 10 below.

In this CY 2019 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for CY 2019 for the CPT and Level II HCPCS codes implemented on July 1, 2018, all of which are listed in Table 10 below.

The proposed payment rates and status indicators for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

TABLE 10—NEW HCPCS CODES EFFECTIVE JULY 1, 2018

CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC
C9030	Injection, copanlisib, 1 mg	G	9030
C9031	Lutetium Lu 177, dotatate, therapeutic, 1 mCi	G	9067
C9032	Injection, voretigene neparvovec-rzyl, 1 billion vector genome	G	9070
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	K	9096
Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units	K	9097
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	G	9073
Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	G	9239
Q9993 *	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg.	G	9469
Q9994	In-line cartridge containing digestive enzyme(s) for enteral feeding, each	E1	N/A
Q9995	Injection, emicizumab-kxwh, 0.5 mg	G	9257
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion.	J1	5193
0506T	Macular pigment optical density measurement by heterochromatic flicker photometry, unilateral or bilateral, with interpretation and report.	Q1	5733
0507T	Near-infrared dual imaging (*i.e.,* simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report.	Q1	5733

TABLE 10—NEW HCPCS CODES EFFECTIVE JULY 1, 2018—Continued

CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC
0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia.	S	5522

*HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), which was effective April 1, 2018, was deleted June 30, 2018 and replaced with HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) effective July 1, 2018.

In addition, there are several new PLA codes (U codes) that will be effective July 1, 2018, but were too late to include in the July 2018 OPPS Update. Consequently, these codes will instead be included in the October 2018 OPPS Update with an effective date of July 1, 2018. These CPT codes are listed below in Table 11 along with the proposed APC and status indicator assignment for these CPT codes. In this CY 2019 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for these CPT codes. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

TABLE 11—NEW CPT PROPRIETARY LABORATORY ANALYSES (PLA) CODES EFFECTIVE JULY 1, 2018

CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC
0045U	Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT–PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score.	A	N/A.
0046U	*FLT3* (fms-related tyrosine kinase 3) (*e.g.,* acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative.	A	N/A.
0047U	Oncology (prostate), mRNA, gene expression profiling by real-time RT–PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score.	A	N/A.
0048U	Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s).	A	N/A.
0049U	*NPM1* (nucleophosmin) (*e.g.,* acute myeloid leukemia) gene analysis, quantitative	A	N/A.
0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements.	A	N/A.
0051U	Prescription drug monitoring, evaluation of drugs present by LC–MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service.	Q4	N/A.
0052U	Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation.	Q4	N/A.
0053U	Oncology (prostate cancer), FISH analysis of 4 genes (*ASAP1, HDAC9, CHD1* and *PTEN*), needle biopsy specimen, algorithm reported as probability of higher tumor grade.	A	N/A.
0054U	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service.	Q4	N/A.
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma.	A	N/A.
0056U	Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s).	A	N/A.
0057U	Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank.	A	N/A.
0058U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative.	Q4	N/A.
0059U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative.	Q4	N/A.
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood.	A	N/A.
0061U	Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis.	Q4	N/A.

3. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2018 and January 1, 2019 for Which We Will Be Soliciting Public Comments in the CY 2019 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we will solicit comments on those new Level II HCPCS codes that are effective October 1, 2018 and January 1, 2019 in the CY 2019 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators, APCs, and payment rates for the codes in the CY 2020 OPPS/ASC final rule with comment period. These codes will be released to the public through the October and January OPPS quarterly update CRs and via the CMS HCPCS website (for Level II HCPCS codes).

For CY 2019, we are proposing to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to those new Level II HCPCS codes that are effective October 1, 2018 and January 1, 2019 to indicate that we are assigning them an interim payment status, which is subject to public comment. We will be inviting public comments in the CY 2019 OPPS/ASC final rule with comment period on the status indicator, APC assignments, and payment rates for these codes, if applicable, which would then be finalized in the CY 2020 OPPS/ASC final rule with comment period.

4. Proposed Treatment of New and Revised CY 2019 Category I and III CPT Codes That Will Be Effective January 1, 2019 for Which We Are Soliciting Public Comments in This CY 2019 OPPS/ASC Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid 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 2019 OPPS update, we received the CY 2019 CPT codes from AMA in time for inclusion in this CY 2019 OPPS/ASC proposed rule. The new, revised, and deleted CY 2019 Category I and III CPT codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website). We note that the new and revised 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 assignment and status indicator.

Further, we remind 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 are including the 5-digit placeholder codes and their long descriptors for the new and revised CY 2019 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) so that the public can adequately comment on our proposed APCs and status indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled ''CY 2019 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code,'' to this proposed rule. The final CPT code numbers will be included in the CY 2019 OPPS/ASC final rule with comment period. We note that not every code listed in Addendum O is subject to comment. For the new and revised Category I and III CPT codes, we are requesting comments on only those codes that are assigned to comment indicator ''NP''.

In summary, we are soliciting public comments on the proposed CY 2019 status indicators and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2019. The CPT codes are listed in Addendum B to this proposed rule with short descriptors only. We list them again in Addendum O to this proposed rule with long descriptors. We also are proposing to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2019 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

B. Proposed OPPS Changes—Variations Within APCs

1. Background

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

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a

primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3. of this proposed rule.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2019, we are proposing that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the HOP Panel recommendations for specific services for the CY 2019 OPPS update will be discussed in the relevant specific sections throughout the CY 2019 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 this section of this proposed rule, for CY 2019, we are proposing to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2019 OPPS update, we have identified the APCs with violations of the 2 times rule. Therefore, we are proposing changes to the procedure codes assigned to these APCs in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this CY 2019 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 are proposing 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 2019 included in this proposed rule are related to changes in costs of services that were observed in the CY 2017 claims data newly available for CY 2019 ratesetting. Addendum B to this CY 2019 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we are proposing a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2018 OPPS Addendum B Update (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html*).

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we are proposing to make for CY 2019, 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 2017 claims data available for this CY 2019 proposed rule, we found 16 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we are proposing to make exceptions under the 2 times rule for CY 2019, and found that all of the 16 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2017 claims data available for this proposed rule. We did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have a similar geometric mean costs and do not create a 2 time rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule.

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

and the quality of the claims data used to determine the APC payment rates.

Table 12 of this proposed rule lists the 16 APCs that we are proposing to make an exception for under the 2 times rule for CY 2019 based on the criteria cited above and claims data submitted between January 1, 2017, and December 31, 2017, and processed on or before December 31, 2017. For the final rule with comment period, we intend to use claims data for dates of service between January 1, 2017, and December 31, 2017, that were processed on or before June 30, 2018, and updated CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

TABLE 12—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2019

Proposed CY 2019 APC	Proposed CY 2019 APC title
5071	Level 1 Excision/Biopsy/Incision and Drainage.
5113	Level 3 Musculoskeletal Procedures.
5521	Level 1 Imaging without Contrast.
5522	Level 2 Imaging without Contrast.
5523	Level 3 Imaging without Contrast.
5571	Level 1 Imaging with Contrast.
5612	Level 2 Therapeutic Radiation Treatment Preparation.
5691	Level 1 Drug Administration.
5692	Level 2 Drug Administration.
5721	Level 1 Diagnostic Tests and Related Services.
5724	Level 4 Diagnostic Tests and Related Services.
5731	Level 1 Minor Procedures.
5732	Level 2 Minor Procedures.
5735	Level 5 Minor Procedures.
5822	Level 2 Health and Behavior Services.
5823	Level 3 Health and Behavior Services.

C. Proposed New Technology APCs

1. Background

In the November 30, 2001 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 2018, 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. 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 (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 techniques 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 2019, the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 can be found in Addendum A to this proposed rule (which is available via the internet on the CMS website).

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

Procedures 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. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new procedure so that it can be assigned to an appropriate clinical APC. Some procedures that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. We consider procedures with fewer than 100 claims annually as low-volume procedures because there is a higher probability that the payment data for a procedure 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. For these low-volume procedures, we are concerned that the methodology we use to estimate the cost of a procedure 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 procedure. 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 procedure to a new technology APC allows us to gather claims data to price the procedure 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 believe that it is appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs. We 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 procedures in the past (82 FR 59281). Although we have used this adjustment authority on a case-by-case basis in the past, we believe that it is appropriate to adopt an adjustment for low-volume services assigned to New Technology APCs in order mitigate the wide payment fluctuations that can occur for new technology services with fewer than 100 claims and to provide more predictable payment for these services.

For purposes of this adjustment, 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 consider procedures with fewer than 100 claims annually as low-volume procedures because there is a higher probability that the payment data for a procedure 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. For these low-volume procedures, we are concerned that the methodology we use to estimate the cost of a procedure 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 procedure. 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 believe that using the median or arithmetic mean rather than the geometric mean (which ''trims'' the costs of certain claims out) may 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 believe that 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, we are proposing that, in each of our annual rulemakings, we will seek public comments on which statistical methodology should be used for each low-volume New Technology APC. In the preamble of each annual rulemaking (including this proposed rule), we will 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 would assign the service to the New Technology APC with the cost band that includes its payment rate.

Accordingly, for CY 2019, we are proposing to establish a different payment methodology for services assigned to New Technology APCs with fewer than 100 claims using our equitable adjustment authority under

section 1833(t)(2)(E) of the Act. Under this proposal, we are proposing to use up to 4 years of claims data to establish a payment rate for each applicable service both for purposes of assigning a service to a New Technology APC and for assigning a service to a regular APC at the conclusion of payment for the service through a New Technology APC. The goal of such a policy is to promote transparency and stability in the payment rates for these low-volume new technology procedures and to mitigate wide variation from year to year for such services. We also are proposing to use the geometric mean, the median, or the arithmetic mean to calculate the cost of furnishing the applicable service, present the result of each statistical methodology in our annual rulemaking, and solicit public comment on which methodology should be used to establish the payment rate. The geometric mean may not be representative of the actual cost of a service when fewer than 100 claims are present because the payment amounts for the claims may not be distributed normally. Under this proposal, we would have the option to use the median payment amount or the arithmetic mean to assign a more representative payment for the service. Once we identify the payment rate for a service, we would assign the service to the New Technology APC with the cost band that includes its payment rate.

3. Proposed Procedures Assigned to New Technology APC Groups for CY 2019

As we explained 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 2019, in this CY 2019 OPPS/ASC proposed rule, we are proposing 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).

a. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114, and 5414)

Currently, there are four CPT/HCPCS codes that describe magnetic resonance image-guided, high-intensity focused ultrasound (MRgFUS) procedures, three of which we are proposing to continue to assign to standard APCs, and one that we are proposing to reassign to a different New Technology APC for CY 2019. 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.

As shown in Table 13 of this proposed rule, and as listed in Addendum B to this CY 2019 OPPS/ASC proposed rule, we are proposing to continue to assign the procedures described by CPT codes 0071T and 0072T to APC 5414 (Level 4 Gynecologic Procedures), with a proposed payment rate of approximately $2,410 for CY 2019. We also are proposing to continue to assign the APC to status indicator ''J1'' (Hospital Part B services paid through a comprehensive APC) to indicate that payment for all covered Part B services reported on the claim are packaged with the payment for the primary ''J1'' service for the claim, except for services assigned to OPPS status indicator ''F'', ''G'', ''H'', ''L'', and ''U''; ambulance services; diagnostic and screening mammography; all preventive services; and certain Part B inpatient services. In addition, we are proposing to continue to assign the services described by HCPCS code C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance) to APC 5115 (Level 5 Musculoskeletal Procedures), with a proposed payment rate of approximately $10,936 for CY 2019. We also are proposing to continue to assign HCPCS code C9734 to status indicator ''J1''.

For procedures described by CPT code 0398T, we have only identified one paid claim for a procedure in CY 2016 and two paid claims in CY 2017, for a total of three paid claims. We note that the procedures described by CPT code 0398T were first assigned to a New Technology APC in CY 2016. Accordingly, there are only 2 years of claims data available for the OPPS ratesetting purposes. The payment amounts for the claims vary widely, with a cost of $29,254 for the sole CY 2016 claim and a geometric mean cost of $4,647 for the two CY 2017 claims. We are concerned that the reported geometric mean cost for CY 2017, which we would normally use to determine the proposed payment rate for the procedures described by CPT code 0398T, is significantly lower than the reported cost of the claim received in CY 2016, as well as the payment rate for the procedures for CY 2016 ($9,750.50) and for CY 2017 ($17,500.50). 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, as mentioned in section III.C.2. of this proposed rule, we are proposing 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 establish a payment rate that is more likely to be representative of the cost of the procedures described by CPT code 0398T, despite the low geometric mean costs for procedures described by CPT code 0398T available in the claims data used for this proposed rule. We continue to believe that this situation for the procedures described by CPT code 0398T is unique, given the very limited number of claims for the procedures and the high variability for the cost of the claims which makes it challenging to determine a reliable payment rate for the procedures.

Our analysis found that the arithmetic mean of the three claims is $12,849.11, the geometric mean of the three claims is $8,579.91 (compared to $4,646.56 for CY 2017), and the median of the claims is $4,676.77. Consistent with what we state in section III.C.2. of this proposed rule, we have presented the result of each statistical methodology in this preamble, and we are seeking public comments on which method should be used to establish payment for the

procedures described by CPT code 0398T. We believe that the arithmetic mean is the most appropriate representative cost of the procedures described by CPT code 0398T, which gives consideration to the payment rates established for the procedures in CY 2017 and CY 2018, without any trimming. The arithmetic mean also gives consideration to the range in cost for the three paid claims, which represent 2 years of claims data for the procedures. We are proposing to estimate the proposed payment rate for the procedures described by CPT code 0398T by calculating the arithmetic mean of the three paid claims for the procedures in CY 2016 and CY 2017, and assigning the procedures described by CPT code 0398T to the New Technology APC that includes the estimated cost. Accordingly, we are proposing to reassign the procedures described by CPT code 0398T from APC 1576 (New Technology—Level 39 ($15,001–$20,000)) to APC 1575 (New Technology—Level 38 ($10,001–$15,000)), with a proposed payment rate of $12,500.50. We refer readers to Addendum B to this 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.

TABLE 13—PROPOSED CY 2019 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRgFUS) PROCEDURES

CPT/HCPCS code	Long descriptor	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate	Proposed CY 2019 OPPS SI	Proposed CY 2019 OPPS APC	Proposed CY 2019 OPPS payment rate
0071T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue.	J1	5414	$2,272.77	J1	5414	Refer to OPPS Addendum B.
0072T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue.	J1	5414	2,272.77	J1	5414	Refer to OPPS Addendum B.
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	1576	17,500.50	S	1575	Refer to OPPS Addendum B.
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	J1	5115	5,606.42	J1	5115	Refer to OPPS Addendum B.

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 the Food and Drug Administration (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 includes 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 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 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. 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 changes 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, 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 CY 2017 hospital outpatient claims data used for this CY 2019 OPPS/ASC proposed rule is approximately $152,021, which is $29,520 more than the payment rate for the procedure for CY 2018. We continue to note 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 did not exceed 10 claims for CY 2017. We continue to believe 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 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 want 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.

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, as discussed in section III.C.2. of this proposed rule, we are proposing 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 establish a payment rate that is more representative of the likely cost of the service. We believe the likely cost of the Argus® II procedure is lower than the geometric mean cost calculated from the CY 2017 claims data used for this proposed rule and closer to the CY 2018 payment rate.

We analyzed claims data for the Argus® II procedure using the last 3 years of available data from CY 2015 through CY 2017. These data include claims from the last year (CY 2015) that the Argus® II received transitional device pass-through payments and the first 2 years since device pass-through payment status for the Argus® II expired. We found the geometric mean for the procedure to be $129,891 (compared to $152,021 in CY 2017 alone), the arithmetic mean to be $134,619, and the median to be $133,679. As indicated in our proposal in section III.C.2. of this proposed rule, we have presented the result of each statistical methodology in this preamble, and are requesting public comment on which methodology should be used to establish a payment rate. We are proposing to use the arithmetic mean, which generates the highest payment rate of the three statistical methodologies, to estimate the cost of the Argus® II procedure as a means to balance the fluctuations in the costs of the procedure that have occurred from CY 2015 through CY 2017, while acknowledging the higher payment rates for the procedure in CY 2015 and CY 2017. Therefore, for CY 2019, we are proposing to reassign the Argus® II procedure from APC 1904 (New Technology—Level 50 ($115,001–$130,000)) to APC 1906 (New Technology—Level 51 ($130,001–$145,000)), which would result in a proposed payment rate for the Argus® II procedure of $137,500.50.

As we do each year, we acquired 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 like the Argus® II procedure as they transition into mainstream medical practice (77 FR 68314). We note that this proposed payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841).

The most recent claims data available have shown another payment issue with regard to the Argus® II procedure. We have found that payment for the Argus® II procedure is sometimes bundled into the payment for another procedure. We have identified two possible instances in the CY 2017 claims data in which this may have occurred. The bundling of payment for the Argus® II procedure occurs when the procedure is reported with other eye procedures assigned to a comprehensive APC (C–APC). A C–APC bundles payment for all services related to the primary service into one payment rate. We are concerned that when payment for new technology services is bundled into the payment for comprehensive procedures, there is not complete claims information to estimate accurately the cost of these services to allow their assignment to clinical APCs. Therefore, we are proposing to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a C–APC. This action would allow for separate payment for the Argus® II procedure even when it is performed with another comprehensive service, which would provide more cost information regarding the procedure. This proposal is also discussed in section II.A.2.c. of this proposed rule.

D. Proposed OPPS APC-Specific Policies

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and to revise the APC 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. 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. Although we do not discuss every APC change in the proposed and final rules, these changes are listed in the OPPS Addendum B of the proposed and final rules. Specifically, the procedure and service codes with revised APC and/or status indicator assignments are identified with comment indicator ''CH'' (Active HCPCS code in current year and next

calendar year, status indicator and/or APC assignment has changed) in the OPPS Addendum B payment file.

1. Endovascular Procedures (APCs 5191 Through 5194)

At the annual meeting for the HOP Panel held on August 21, 2017, the HOP Panel recommended that, for CY 2018, CMS examine the number of APCs for endovascular procedures. The HOP Panel also recommended that the appropriate Panel subcommittee review the APCs for endovascular procedures to determine whether more granularity (that is, more APCs) is warranted.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59293 through 59294), we stated that we believed that the current C–APC levels for the Endovascular Procedures C–APC family provide an appropriate distinction between the resource costs at each level and clinical homogeneity. We also stated that we would continue to review the C–APC structure for endovascular procedures to determine if any additional granularity is necessary for this C–APC family.

Using the most recent data available for this proposed rule, we have analyzed the four existing levels of the Endovascular Procedures C–APCs. We did not observe any violations of the 2 times rule within the current Endovascular Procedures C–APC structure. Some stakeholders have suggested that for certain procedures, such as angioplasty procedures involving the use of a drug-coated balloon in addition to a nondrug-coated balloon, resource costs are significantly higher than the geometric mean cost (and associated C–APC payment) for all of the angioplasty procedures combined. We recognize that the costs of a given procedure involving additional devices will be higher than the costs of the procedure when it does not involve such additional devices. However, the OPPS is a prospective payment system based on a system of averages in which the costs of some cases within an APC will be more costly than the APC payment rate, while the costs of other cases will be less costly. While we believe that there is sufficient granularity within the existing Endovascular Procedures C–APC structure and at least one stakeholder agrees, we have also received input from other stakeholders who have suggested alternative structures for this C–APC family that include a five-level structure and a six-level structure. An illustration of these proposed C–APC structure levels is displayed in Table 15 and Table 16, respectively. Because interested stakeholders have suggested a variety of options for the endovascular procedures C–APC structure, including keeping the existing C–APC structure, in this CY 2019 OPPS/ASC proposed rule, we are proposing to maintain the existing four-level structure for this C–APC family listed in Table 14 below. However, we are inviting public comments on our proposal, as well as the stakeholder-requested five-level and six-level structures displayed in the tables below. We note that the approximate geometric mean costs associated with the suggested five-level and six-level C–APC structures shown in Tables 15 and 16 are only estimates and, if either of the suggested structure levels are adopted, they would be subject to change, depending on the final rule with comment period data and the particular services that are assigned to each C–APC.

TABLE 14—PROPOSED CY 2019 C–APC STRUCTURE FOR ENDOVASCULAR PROCEDURES

C-APC	Proposed geometric mean cost
5191—Level 1 Endovascular Procedures	$2,882
5192—Level 2 Endovascular Procedures	4,843
5193—Level 3 Endovascular Procedures	9,945
5194—Level 4 Endovascular Procedures	15,789

TABLE 15—REQUESTED CY 2019 FIVE-LEVEL ENDOVASCULAR C–APC STRUCTURE

C-APC	Potential approximate geometric mean cost
5191—Level 1 Endovascular Procedures	$2,881
5192—Level 2 Endovascular Procedures	4,476
5193—Level 3 Endovascular Procedures	9,207
5194—Level 4 Endovascular Procedures	13,524
5195—New Level 5 Endovascular Procedures	16,926

TABLE 16—REQUESTED CY 2019 SIX-LEVEL ENDOVASCULAR C–APC STRUCTURE

C–APC	Potential approximate geometric mean cost
5191—Level 1 Endovascular Procedures	$2,880

TABLE 16—REQUESTED CY 2019 SIX-LEVEL ENDOVASCULAR C–APC STRUCTURE—Continued

C–APC	Potential approximate geometric mean cost
5192—Level 2 Endovascular Procedures	4,722
5193—New Level 3 Endovascular Procedures	7,743
5194—Level 4 Endovascular Procedures	10,128
5195—New Level 5 Endovascular Procedures	12,216
5196—Level 6 Endovascular Procedures	16,140

2. Imaging Procedures and Services (APCs 5521 Through 5524 and 5571 Through 5573)

Section 1833(t)(2)(G) of the Act requires the Secretary to create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those procedures that do not utilize contrast agents. In CY 2016, as a part of our comprehensive review of the structure of the APCs and procedure code assignments, we restructured the APCs that contain imaging services (80 FR 70392). The purpose of this restructuring was to more appropriately reflect the resource costs and clinical characteristics of the services classified within the Imaging APCs. The restructuring of the Imaging APCs resulted in broader groupings that removed the excessive granularity of grouping imaging services according to organ or physiologic system, which did not necessarily reflect either significant differences in resources or how these services are delivered in the hospital outpatient setting. In CY 2017, in response to public comments on the CY 2017 OPPS/ASC proposed rule, we further consolidated the Imaging APCs from 17 APCs in CY 2016 to 7 APCs in CY 2017 (81 FR 79633). These included four Imaging without Contrast APCs and three Imaging with Contrast APCs.

For CY 2018, we proposed to establish a new Level 5 Imaging without Contrast APC to more appropriately group certain imaging services with higher resource costs and stated that our latest claims data supported splitting the CY 2017 Level 4 Imaging without Contrast APC into two APCs such that the Level 4 Imaging without Contrast APC would include high frequency, low-cost services and the proposed Level 5 Imaging without Contrast APC would include low frequency high-cost services. Therefore, for CY 2018, we proposed to add a fifth level within the

Imaging without Contrast APCs (82 FR 33608). However, based on public comments, we did not finalize this proposal. In general, commenters disagreed with CMS' proposal to add a fifth level within the Imaging without Contrast APC series because they believed that the addition of a fifth level would reduce payment for several imaging services, including vascular ultrasound procedures (82 FR 59309 through 59311). Commenters also noted that the lower payment rates under the OPPS would also apply under the PFS.

For this CY 2019 proposed rule, we reviewed the services assigned to the seven imaging APCs listed below in Table 17. Specifically, we evaluated the resource costs and clinical coherence of the procedures associated with the four levels of Imaging without Contrast APCs and the three levels of Imaging with Contrast APCs, as well as identified for correction any 2 times rule violations, to the extent feasible. Based on the geometric mean cost for each APC, which is listed in Table 17, for CY 2019, we are proposing to maintain the seven Imaging APCs, which consist of four levels of Imaging without Contrast APCs and three levels of Imaging with Contrast APCs, and to make minor reassignments to the HCPCS codes within this series to resolve or mitigate any violations of the 2 times rule, or both.

TABLE 17—PROPOSED CY 2019 IMAGING APCS

CY 2019 APC	CY 2019 APC title	CY 2018 APC geometric mean cost	Proposed CY 2019 APC geometric mean cost
5521	Level 1 Imaging without Contrast	$62.08	$64.02
5522	Level 2 Imaging without Contrast	114.39	115.89
5523	Level 3 Imaging without Contrast	232.17	236.05
5524	Level 4 Imaging without Contrast	486.38	502.75
5571	Level 1 Imaging with Contrast	252.58	206.94
5572	Level 2 Imaging with Contrast	456.08	395.84
5573	Level 3 Imaging with Contrast	681.45	699.02

We are inviting public comments on our proposal to maintain the seven Imaging APCs and the current APC structure level of the imaging APCs. Moreover, we are specifically interested in receiving public comments and recommendations on the proposed HCPCS code reassignments associated with each of the seven Imaging APCs. We refer readers to Addendum B to this proposed rule (which is available via the internet on the CMS website) for the proposed list of specific codes that would be reassigned to each Imaging APC.

3. Musculoskeletal Procedures (APCs 5111 Through 5116)

Prior to the CY 2016 OPPS, payment for musculoskeletal procedures was primarily divided according to anatomy and the type of musculoskeletal procedure. As part of the CY 2016 reorganization to better structure the OPPS payments 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 to provide clinical homogeneity. However, we also indicated that we would continue to review the structure of these APCs to determine whether additional granularity would be necessary.

While we are not proposing any changes to the 2019 OPPS structure of the Musculoskeletal APC series in this proposed rule, we recognize that commenters have previously expressed concerns regarding the granularity of the current APC levels and requested establishment of additional levels. Therefore, we are soliciting comments on the creation of a new APC level between the current Level 5 and Level 6 within the Musculoskeletal APC series.

TABLE 18—PROPOSED CY 2019 MUSCULOSKELETAL PROCEDURES APCS

APC	Group title	HCPCS codes assigned to APC	Proposed APC geometric mean cost
5111	Level 1 Musculoskeletal Procedures	102	$229.40
5112	Level 2 Musculoskeletal Procedures	133	$1,345.93
5113	Level 3 Musculoskeletal Procedures	442	$2,673.08
5114	Level 4 Musculoskeletal Procedures	287	$5,816.78
5115	Level 5 Musculoskeletal Procedures	67	$10,935.83
5116	Level 6 Musculoskeletal Procedures	15	$15,785.37

4. Level 5 Intraocular Procedures (APC 5495)

In prior years, CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) has been 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 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 policy is discussed in more detail in section III.C.2. of this proposed rule.

In reviewing the claims data available for this proposed rule for CY 2019 OPPS ratesetting, there are only two claims containing procedures described by CPT code 0308T. Based on those two claims, APC 5495 would have a proposed geometric mean of $5,438.99 and a proposed median of $8,237.56. Based on its estimated costs in the most recently available claims data, we believe that the procedure described by CPT code 0308T is more appropriately placed in the APC 5493, which has a geometric mean of $9,821.47, which is more comparable to that of CPT code 0308T. Therefore, for CY 2019, we are proposing to reassign the procedure described by CPT code 0308T from APC 5495 to APC 5493 (Level 3 Intraocular Procedures) and to delete APC 5495. We will continue to monitor the volume of claims reporting a procedure described by CPT code 0308T available to us for future ratesetting.

IV. Proposed OPPS Payment for Devices

A. Pass-Through Payments for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

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 have 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 changes to the 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 no device categories eligible for pass-through payment.

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).

As specified in regulations at 42 CFR 419.66(b)(1) through (b)(3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria: (1) If required by FDA, the device must have received FDA approval or clearance (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 another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance 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; (2) 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 (3) 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 costs 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 cryoblation, 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 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).

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html,* in the ''Downloads'' section. In addition, CMS is amenable to meeting with applicants or potential applicants to discuss research trial design in advance of any device pass-through application or to discuss application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Payment for CY 2019

We received seven applications by the March 1, 2018 quarterly deadline, which is the last quarterly deadline for applications to be received in time to be included in this CY 2019 OPPS/ASC proposed rule. We received four of the applications in the second quarter of 2017, one of the applications in the third quarter of 2017, and two of the applications in the first quarter of 2018. None of the seven applications were approved for device pass-through payment during the quarterly review process.

Applications received for the later deadlines for the remaining 2018 quarters (June 1, September 1, and December 1), if any, will be presented in the CY 2020 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 seven applications received by the March 1, 2018 deadline is presented below.

(1) AquaBeam System

PROCEPT BioRobotics Corporation submitted an application for a new device category for transitional pass-through payment status for the AquaBeam System. The AquaBeam System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). The applicant stated that this is a very common condition typically occurring in elderly men. The clinical symptoms of this condition can include diminished urinary stream and partial urethral obstruction.[13] According to the applicant, the AquaBeam system resects the prostate to relieve symptoms of urethral compression. The resection is performed robotically using a high velocity, nonheated sterile saline water jet (in a procedure called Aquablation). The applicant stated that the AquaBeam System utilizes real-time intra-operative ultrasound guidance to allow the surgeon to precisely plan the surgical resection area of the prostate and then the system delivers Aquablation therapy to accurately resect the obstructive prostate tissue without the use of heat. The materials submitted by the applicant state that the AquaBeam System consists of a disposable, single-use handpiece as well as other components that are considered capital equipment.

With respect to the newness criterion at § 419.66(b)(1), FDA granted a De Novo request classifying the AquaBeam System as a class II device under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act on December 21, 2017. The application for a new device category for transitional pass-through payment status for the AquaBeam System was received on March 1, 2018, which is within 3 years of the date of the initial FDA approval or clearance. We are inviting public comments on whether the AquaBeam System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the AquaBeam System 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 the AquaBeam System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. However, in the CY 2000 interim final rule with comment period (65 FR 67804 through 67805), we explained how we interpreted § 419.43(e)(4)(iv). We stated that we consider a device to be surgically implanted or inserted if is surgically inserted or implanted via a natural or surgically created orifice, or inserted or implanted via a surgically created incision. We also stated that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment, not eligible for transitional pass-through payments. We stated that we believe the function of these items is different and distinct from that of devices that are

[13] Chungtai B. Forde JC. Thomas DDM et al. Benign Prostatic Hyperplasia. Nature Reviews Disease Primers 2 (2016) article 16031.

used for surgical implantation or insertion. Finally, we stated that, generally, we would expect that surgical implantation or insertion of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for implanting the device. In the CY 2006 final rule with comment period (70 FR 68329 and 68630), we adopted as final our interpretation that surgical insertion or implantation criteria include devices that are surgically inserted or implanted via a natural or surgically created orifice, as well as those devices that are inserted or implanted via a surgically created incision. We reiterated that we maintain all of the other criteria in § 419.66 of the regulations, namely, that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We are inviting public comments on whether the AquaBeam System meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through payment category that describes the AquaBeam System. The applicant proposed a category descriptor for the AquaBeam System of ''Probe, image guided, robotic resection of prostate.'' We are inviting public comments on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With respect to this criterion, the applicant submitted several articles that examined the use of a current standard treatment for BPH—transurethral prostatectomy (TURP), including complications associated with the procedure and the comparison of the effectiveness of TURP to other modalities used to treat BPH, including holmium laser enucleation of the prostate (HoLEP) [14] and photoselective vaporization (PVP).[15]

The most recent clinical study involving the AquaBeam System was an accepted manuscript describing a double-blind trial that compared men treated with the AquaBeam System versus men treated with traditional TURP.[16] This was a multicenter study in four countries with 17 sites, 6 of which contributed 5 patients or fewer. Patients were randomized to receive either the AquaBeam System or TURP in a two-to-one ratio. With exclusions and dropouts, 117 patients were treated with the AquaBeam System and 67 patients with TURP. The data on efficacy supported the equivalence of the two procedures based upon noninferiority analysis. The safety data were reported as showing superiority of the AquaBeam System over TURP, although the data were difficult to track because adverse consequences were combined into categories. The applicant claimed that the International Prostate Symptom Scores (IPPS) were significantly improved in AquaBeam System patients as compared to TURP patients in men whose prostate was greater the 50 ml in size.

Although there may be some evidence of the improved safety of the AquaBeam System over TURP, we believe that the comparison of the AquaBeam System with TURP does not recognize that there are other treatment modalities available that are likely to have a similar safety profile as the AquaBeam System. No studies comparing other treatment modalities can be cited to show that AquaBeam System is a significant improvement over other available procedures.

Based on the evidence submitted with the application, we have insufficient evidence that the AquaBeam System provides a substantial clinical improvement over other similar products. We are inviting public comments on whether the AquaBeam System meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the AquaBeam System would be reported with CPT code 0421T. CPT code 0421T is assigned to APC 5375 (Level 5 Urology and Related Services). To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5375, which has a CY 2018 payment rate of $3,706.03. 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 0421T had device offset amount of $0.00 at the time the application was received. According to the applicant, the cost of the handpiece for the AquaBeam System 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 the AquaBeam System exceeds 68 percent of the applicable APC payment amount for the service related to the category of devices of $3,706.03 ($2,500/$3,706.03 × 100 = 67.5 percent). Therefore, we believe the AquaBeam System meets the first cost significance test.

The second cost significance test, 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 the AquaBeam System exceeds the cost of the device-related portion of the APC payment amount for the related service of $0.00 by at least 25 percent. Therefore, we believe that the AquaBeam System meets the second cost significance test.

The third cost significance test, at § 419.66(d)(3), requires 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

[14] Montorsi, F. et al. (2004). Holmium Laser Enucleation Versus Transurethral Resection of The Prostate: Results from A 2-Center, Prospective, Randomized Trial In Patients With Obstructive Benign Prostatic Hyperplasia. *J. Urol. 172,* 1926–1929.

[15] Bachmann A, et al. (2014). 180–W XPS GreenLight laser vaporisation versus transurethral resection of the prostate for the treatment of benign prostatic obstruction: 6-month safety and efficacy results of a European Multicentre Randomised Trial—the GOLIATH study. *Eur Urol, 65(5):* 931–42.

[16] Gilling P. Barber M. Anderson P et al.: WATER—A Double-Blind Randomized Controlled Trial of Aquablation vs Transurethal Resection of the Prostate in Benign Prostatic Hyperplasia. *J Urol.* Accepted December 29, 2017 doi 10.1016/j.juro.2017.12.065.

exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,500 for the AquaBeam System and the portion of the APC payment amount for the device of $0.00 exceeds the APC payment amount for the related service of $3,706.03 by 68 percent (($2,500-$0.00)/$3,706.03 × 100 = 67.5 percent). Therefore, we believe that the AquaBeam System meets the third cost significance test.

We are inviting public comments on whether the AquaBeam System meets the device pass-through payment criteria discussed in this section, including the cost criteria.

(2) BioBag® (Larval Debridement Therapy in a Contained Dressing)

BioMonde US, LLC resubmitted an application for a new device pass-through category for the BioBag® (larval debridement therapy in a contained dressing), hereinafter referred to as the BioBag®. The application submitted contained similar information to the previous application received in March 2016 that was evaluated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79650). The only new information provided by the applicant were additional studies completed since the original application addressing the substantial clinical improvement criterion.

According to the applicant, BioBag® is a biosurgical wound treatment (''maggot therapy'') consisting of disinfected, living larvae (Lucilia sericata) in a polyester net bag; the larvae remove dead tissue from wounds. The BioBag® is indicated for debridement of nonhealing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and nonhealing traumatic or postsurgical wounds. Debridement, which is the action of removing devitalized tissue and bacteria from a wound, is required to treat or prevent infection and to allow the wound to progress through the healing process. This system contains disinfected, living larvae that remove the dead tissue from wounds and leave healthy tissue undisturbed. The larvae are provided in a sterile polyester net bag, available in different sizes. The only other similar product is free-range (that is, uncontained) larvae. Free-range larvae are not widely used in the United States because application is time consuming, there is a fear of larvae escaping from the wound, and there are concerns about proper and safe handling of the larvae. The total number of treatment cycles depends on the characteristics of the wound, the response of the wound, and the aim of the therapy. Most ulcers are completely debrided within 1 to 6 treatment cycles.

With respect to the newness criterion at § 419.66(b)(1), the applicant received FDA clearance for BioBag® through the premarket notification section 510(k) process on August 28, 2013, and the first U.S. sale of BioBag® occurred in April 2015. The June 1, 2017 application is more than 3 years after FDA clearance but less than 3 years after its first U.S. sale. We are inviting public comments on whether BioBag® meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), the applicant claimed that the BioBag® is an integral part of the wound debridement, is used for one patient only, comes in contact with human skin, and is applied in or on a wound. In addition, the applicant stated that the BioBag® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, or item for which depreciation and financing expenses are recovered. We had also determined in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79650) that the BioBag® is not a material or supply furnished incident to a service. We are inviting public comments on whether BioBag® meets the eligibility criterion.

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 describes the BioBag®, the applicant suggested a category descriptor of ''Contained medicinal larvae for the debridement of necrotic non-healing skin and soft tissue wounds.'' We have not identified an existing pass-through payment category that describes the BioBag®.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With respect to the substantial clinical improvement criterion, the applicant provided substantial evidence that larval therapy may improve outcomes compared to other methods of wound debridement. However, given the existence of the Medical Maggots®, another form of larval therapy that has been on the market since 2004, the relevant comparison is between the BioBag® and the Medical Maggots®. There are many reasons to suspect that the BioBag® could improve outcomes and be preferable to the Medical Maggots®. In essence, with the latter, the maggots are directly placed on the wound, which may result in escape, leading to infection control issues as well as dosing variability. In addition, there are the issues with patient comfort. With the Biobag®, the maggots are in a sealed container so escape is not an issue. The applicant cited a study showing large decreases in maggot escape with the BioBag® as opposed to the Medical Maggots®. However, the applicant did not provide any data that clinical outcomes are improved using the BioBag® as opposed to the Medical Maggots®. Based on the studies presented, we believe there is insufficient data to determine whether the BioBag® offers a substantial clinical improvement over other treatments for wound care. We are inviting public comments on whether BioBag® 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 device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. With respect to the cost criterion, the applicant stated that the BioBag® would be reported with CPT code 97602 (Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (*e.g.,* wet-to-moist dressings, enzymatic, abrasion, larval therapy), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session). CPT code 97602 is assigned to APC 5051 (Level 1 Skin Procedures), with a proposed CY 2019 payment rate of $178.60, and the device offset is $0.02. The price of the BioBag® varies with the size of the bag ($375 to $435 per bag), and bag size selection is based on the size of the wound.

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 reasonable cost of $435 for the BioBag®

exceeds the applicable APC amount for the service related to the category of devices of $178.60 by 243.56 percent ($435/$178.60 × 100 = 243.56 percent). Thus, the BioBag® appears to meet the first cost significance test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of devices in the category must exceed the cost of the device-related portion of the APC payment amount by at least 25 percent, which means the device cost needs to be at least 125 percent of the device offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $435 for the BioBag® exceeds the device-related portion of the APC amount for the related service of $0.02 by 2,175,000 percent ($435/$0.02 × 100 = 2,175,000 percent). Thus, the BioBag® appears to meet the second cost significance test.

Section 419.66(d)(3), the third cost significance test, requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device exceeds 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $435 for the BioBag® and the portion of the APC payment for the device of $0.02 exceeds 10 percent at 243.55 percent (($435 − $0.02)/$178.60 × 100 = 243.55 percent). Thus, the BioBag® appears to meet the third cost significance test and satisfies the cost significance criterion. We are inviting public comments on whether the BioBag® Wound Matrix meets the device pass-through payment criteria discussed in this section, including the cost criteria.

(3) BlastX™ Antimicrobial Wound Gel

Next Science™ has submitted an application for a new device category for transitional pass-through payment status for BlastX™. According to the manufacturer, BlastX™ is a PEG-based aqueous hydrogel which contains citric acid, sodium citrate, and benzalkonium chloride, buffered to a pH of 4.0 at 2.33 osmolarity. BlastX™ received a 510(k) clearance from the FDA on March 6, 2017. BlastX™ is indicated for the management of wounds such as Stage I–IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, postsurgical wounds, first and second degree burns, and grafted and donor sites.

The manufacturer stated in its application for transitional pass-through payment status that BlastX™ works by disrupting the biofilm matrix in a wound and eliminating the bacteria absorbed within the gel. The manufacturer asserted that disrupting and eliminating the biofilm removes a major barrier to wound healing. The manufacturer also asserted that BlastX™ is not harmful to host tissue and stated that BlastX™ is applied to the wound every other day as a thin layer throughout the entire wound healing process.

When used as an adjunct to debridement, BlastX™ is applied immediately after debridement to eliminate any remaining biofilm and prevent the growth of new biofilm. Based on the evidence provided in the manufacturer's application, BlastX™ is not a skin substitute and cannot be considered for transitional pass-through payment status as a device. To be considered a device for purposes of the medical device pass-through payment process under the OPPS, a skin substitute needs to be applied in or on a wound or other skin lesion based on 42 CFR 419.66(b)(3). It should be a product that is primarily used in conjunction with the skin graft procedures described by CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278 (78 FR 74937). The skin substitute should only be applied a few times during a typical treatment episode. BlastX™, according to the manufacturer, may be used in many other procedures other than skin graft procedures, including several debridement and active wound care management procedures. The manufacturer also stated that BlastX™ would be used in association with any currently available skin substitute product and that the product should be applied every other day, which is not how skin substitute products for skin graft procedures are used to heal wounds. BlastX™ is not a required component of the skin graft service, and is used as a supply that may assist with the wound healing process that occurs primarily because of the use of sheet skin substitute product in a skin graft procedure.

Therefore, with respect to the eligibility criterion at § 419.66(b)(3), we have determined that BlastX™ is not integral to the service provided (which is a skin graft procedure using a sheet skin substitute), is a material or supply furnished incidentally to a service, and is not surgically inserted into a patient. BlastX™ does not meet the basic criterion of being an eligible device for transitional pass-through payment. Therefore, it is not feasible to evaluate the product on the other criteria required for transitional pass-through payment for devices, including the newness criterion, the substantial clinical improvement criterion, and the cost criterion. We are inviting public comments on the eligibility of BlastX™ for transitional pass-through payment for devices.

(4) EpiCord®

MiMedx® submitted an application for a new OPPS device category for transitional pass-through payment status for EpiCord®, a skin substitute product. According to the applicant, EpiCord® is a minimally manipulated, dehydrated, devitalized cellular umbilical cord allograft for homologous use that provides a protective environment for the healing process. According to the applicant, EpiCord® is comprised of the protective elements of the umbilical cord with a thin amnion layer and a thicker Wharton's Jelly mucopolysaccharides component. The Wharton's Jelly contains collagen, hyaluronic acid, and chondroitin sulfate, which are the components principally responsible for its mechanical properties.

The applicant stated that EpiCord® is packaged as an individual unit in two sizes, 2 cm x 3 cm and 3 cm x 5 cm. The applicant asserted that EpiCord® is clinically superior to other skin substitutes because it is much thicker than dehydrated amnion/chorion allografts, which allows for application over exposed bone, tendon, nerves, muscle, joint capsule and hardware. According to the applicant, due to its unique thicker, stiffer structure, clinicians are able to apply or suture EpiCord® for deep, tunneling wounds where other products cannot fill the entire wound bed or dead spaces.

With respect to the newness criterion at § 419.66(b)(1), EpiCord® was added to the MiMedx® registration for human cells, tissues, and cellular and tissue-based products (HCT/Ps) on December 31, 2015. In adding EpiCord, MiMedx® asserted that EpiCord® conformed to the requirements for HCT/Ps regulated solely under section 361 of the Public Health Service Act and the regulations at 21 CFR part 1271. For these products, FDA requires that the manufacturer register and list its HCT/Ps with the FDA's Center for Biologics Evaluation and Research (CBER) within 5 days after beginning operations and update its registration annually, and MiMedx® provided documentation verifying that EpiCord® had been registered. However, no documentation regarding an FDA determination that EpiCord® is appropriate for regulation solely under section 361 of the Public Health Service Act had been submitted. According to

the applicant, December 31, 2015 was the first date of sale within the United States for EpiCord®. Therefore, it appears that market availability of EpiCord® is within 3 years of this application.

We note that a product that is regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR part 1271 is not regulated as a device. The regulations at 21 CFR 1271.20 state that ''If you are an establishment that manufactures an HCT/P that does not meet the criteria set out in § 1271.10(a), and you do not qualify for any of the exceptions in § 1271.15, your HCT/P will be regulated as a drug, device, and/or biological product . . . .''). The Federal Food, Drug, and Cosmetic Act requires that manufacturers of devices that are not exempt obtain marketing approval or clearance for their products from FDA before they may offer them for sale in the United States. We did not receive documentation from the applicant that EpiCord® is regulated as a device by FDA in accordance with Medicare regulations at 42 CFR 419.66(b)(1). We are inviting public comments on whether EpiCord® meets the newness criterion.

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

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through category that describes EpiCord®. There are no present or previously established device categories for pass-through status that describe minimally manipulated, lyophilized, non-viable cellular umbilical membrane allografts. MiMedx® proposed a new device category descriptor of ''Dehydrated Human Umbilical Cord Allografts'' for EpiCord®.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With regard to the substantial clinical improvement criterion, the applicant asserted that EpiCord® reduces the mortality rate with use of the device; reduces the rate of device-related complications; decreases the rate of subsequent diagnostic or therapeutic interventions; decreases the number of future hospitalizations or physician visits; provides more rapid beneficial resolution of the disease process treated because of the use of the device; decreases pain, bleeding, or other quantifiable symptom; and reduces recovery time.

To determine if the product meets the substantial improvement criterion, we compared EpiCord® to other skin substitute products. Compared to NEOX CORD 1K Wound Allograft, EpiCord® has half the levels of Vascular Endothelial Growth Factor (VEGF) and insulin-like growth factor binding protein-4 (IGFBP–4) and lower levels of Glial Cell Line Derived Neurotrophic Factor (GDNF) and Epidermal Growth Factor (EGF). Despite EpiCord® having higher levels of other growth factors, the cumulative effect of these differences has not been sufficiently demonstrated in the application. Moreover, most professional opinions do not compare EpiCord® to specific alternative skin substitutes; the few that do are, for the most part, of limited specificity (in terms of foci of superiority to other skin substitutes). Studies demonstrated 41 percent higher relative rates (4.1 percent higher absolute rates) of severe complications for EpiCord® compared to standard of care. Additionally, the control group was moist dressings and offloading (instead of another umbilical or biologic product). Furthermore, 38 percent of EpiCord® patients in the study were smokers versus 58 percent of control patients (smoking impairs wound healing; thus, this important dissimilarity between intervention and study populations casts doubt on attributing observed benefit to the intervention).

Based on the evidence submitted with the application, we have insufficient evidence that EpiCord® provides a substantial clinical improvement over other treatments for wound care. We are inviting public comments on whether EpiCord® 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. EpiCord® would be reported with CPT code 15271 or 15275. CPT code 15271 describes the 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. CPT code 15275 describes the application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area. Both codes are assigned to APC 5054 (Level 4 Skin Procedures). CPT codes 15271 through 15278 are assigned to either APC 5054 (Level 4 Skin Procedures), with a proposed CY 2019 payment rate of $1,593.38 and a device offset of $4.62, or APC 5055 (Level 5 Skin Procedures), with a proposed CY 2019 payment rate of $2,811.13 and a device offset of $37.11. The price of EpiCord® is $1,595 for the 2 cm x 3 cm and $3,695 for the 3 cm x 5 cm product size. To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $3,695 for the 3 cm x 5 cm product exceeds the applicable APC amount for the service related to the category of devices of $1,593.38 by 231.90 percent ($3,695/$1,593.38 × 100 percent = 231.90 percent). Therefore, it appears that EpiCord® meets the first cost significance test.

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

average reasonable cost of $3,695 for the 3 cm x 5 cm product exceeds the device-related portion of the APC payment amount for the related service of $4.62 by 79,978.35 percent ($3,695/$4.62 × 100 percent = 79,978.35 percent). Therefore, it appears that EpiCord® meets the second cost significance test.

Section 419.66(d)(3), the third cost significance test, requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $3,695 for the 3 cm x 5 cm product and the portion of the APC payment amount for the device of $4.62 exceeds 10 percent at 231.61 percent (($3,695 − $4.62)/$1,593.38) × 100 percent = 231.61 percent). Therefore, it appears that EpiCord® meets the third cost significance test. Based on the costs submitted by the applicant and the calculations noted earlier, it appears that EpiCord® meets the cost criterion at § 419.66(c)(3) for new device categories. We are inviting public comments on whether EpiCord® meets the cost criterion for device pass-through payment.

(5) remedē® System Transvenous Neurostimulator

Respicardia, Inc. submitted an application for a new device category for transitional pass-through payment status for the remedē® System Transvenous Neurostimulator. According to the applicant, the remedē® System is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe central sleep apnea (CSA) in adult patients. The applicant stated that the remedē® System is the first and only implantable neurostimulator to use transvenous sensing and stimulation technology. The applicant also stated that the remedē® System consists of an implantable pulse generator, a transvenous lead to stimulate the phrenic nerve and a transvenous sensing lead to sense respiration via transthoracic impedance. Lastly, the applicant stated that the device stimulates a nerve located in the chest (phrenic nerve) that is responsible for sending signals to the diaphragm to stimulate breathing to restore normal sleep and respiration in patients with moderate to severe central sleep apnea (CSA).

With respect to the newness criterion at § 419.66(b)(1), the applicant received a Category B Investigational Device Exemption (IDE) from FDA on April 18, 2013. Subsequently, the applicant received approval of its premarket approval (PMA) application from FDA on October 6, 2017. The application for a new device category for transitional pass-through payment status for the remedē® System was received on May 31, 2017, which is within 3 years of the date of the initial FDA approval or clearance. We are inviting public comments on whether the remedē® System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the remedē® System 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 the remedē® System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through payment category that describes the remedē® System. The applicant proposed a category descriptor for the remedē® System of ''generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation.'' We are inviting public comments on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With respect to this criterion, the applicant submitted several journal articles that discussed the health effects of central sleep apnea (CSA) which include fatigue, decreased mental acuity, myocardial ischemia, and dysrhythmias. The applicant stated that patients with CSA may suffer from poor clinical outcomes, including myocardial infarction and congestive heart failure.[17]

The applicant claims that the remedē® System has been found to significantly improve apnea-hypopnea index (AHI), which is an index used to indicate the severity of sleep apnea. AHI is represented by the number of apnea and hypopnea events per hour of sleep and was used as the primary effectiveness endpoint in the remedē® System pivotal trial. The applicant noted that the remedē® System was shown to improve AHI in small, self-controlled studies as well as in larger trials.

The applicant reported that in the pivotal study, a large, multicenter, randomized controlled trial of CSA patients, intention-to-treat analysis found that 51 percent (35/68) of CSA patients using the remedē® System had greater than 50 percent reduction of apnea-hypopnea index (AHI) from baseline at 6 months compared to 11 percent (8/73) of the control group ($p < 0.0001$). Per-protocol analysis found that 60 percent (35/58) of remedē® System patients had a greater than 50 percent reduction of AHI and in 74 percent (26/35) of these patients AHI dropped to <20.[18]

According to the applicant, an exploratory post-hoc analysis of patients with CSA and congestive heart failure (CHF) in the Pivotal trial found that, at 6 months, the remedē® System group had a greater percentage of patients with >=50 percent reduction in AHI compared to control group (63 percent versus 4 percent, $p < 0.001$).[19]

The applicant noted that patient symptoms and quality of life were improved with the remedē® System therapy. The mean Epworth Sleepiness Scale (ESS) score significantly decreased in remedē® System patients, indicating less daytime sleepiness.[20] Adverse events associated with remedē® System insertion and therapy included lead dislodgement/dislocation, hematoma, migraine, atypical chest pain, pocket perforation, pocket infection, extra-respiratory stimulation,

[17] Costanzo, M.R., et al., Mechanisms and Clinical Consequences of Untreated Central Sleep Apnea in Heart Failure. *Journal of the American College of Cardiology,* 2015. 65(1): p. 72–84.

[18] Costanzo, M.R., et al. (2016). Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet, 388(10048):* p. 974–982.

[19] Goldberg, L.R., et al. (2017). In Heart Failure Patients with CSA, Stimulation of the Phrenic Nerve Improves Sleep and Quality of Life. *Journal of Cardiac Failure, 23(8):* p. S15.

[20] Costanzo, M.R., et al. (2016). Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet, 388(10048):* p. 974–982.

concomitant device interaction, and elevated transaminases.[21] There were no patient deaths that were related to the device implantation or therapy.

One concern regarding the remedē® System is the potential for complications in patients with coexisting cardiac devices, such as pacemakers or ICDs, given that the remedē® System device requires lead placement and generation of electric impulses. Another concern with the evidence of substantial clinical improvement is that there is limited long-term data on patients with remedē® System implants. The pivotal trial included only 6 months of follow-up. Also, while the applicant reported a reduction in AHI in the treatment group, the applicant did not establish that that level of change was biologically meaningful in the population(s) being studied. The applicant did not conduct a power analysis to determine the necessary size of the study population and the necessary duration of the study to detect both early and late events.

In addition, patients in the pivotal study were not characterized by the use of cardiac devices. Cardiac resynchronization therapy (CRT), in particular, is known to improve chronic sleep apnea in addition to its primary effects on heart failure, and central apnea is a marker of the severity of the congestive heart failure. The applicant did not conduct subset analyses to assess the impact of cardiac resynchronization therapy.

Lastly, while evaluation of AHI and quality of life metrics show improvement with the remedē® System, the translation of those effects to mortality benefit is yet to be determined. Further studies of the remedē® System are likely needed to determine long-term effects of the device, and as well as its efficacy compared to existing treatments of CPAP or medications.

Based on the evidence submitted with the application, we have insufficient evidence that the remedē® System provides a substantial clinical improvement over other similar products. We are inviting public comments on whether the remedē® System meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the remedē® System would be reported with CPT code 0424T. CPT code 0424T is assigned to APC 5464 (Level 4 Neurostimulator and Related Procedures). To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5464, which had a CY 2017 payment rate of $27,047.11 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 0424T had a device offset amount of $11,089 at the time the application was received. According to the applicant, the cost of the remedē® System was $34,500. 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 $34,500 for the remedē® System exceeds 127 percent of the applicable APC payment amount for the service related to the category of devices of $27,047.11 ($34,500/$27,047.11 × 100 = 127.5 percent). Therefore, we believe the remedē® System meets the first cost significance test.

The second cost significance test, 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 $34,500 for the remedē® System exceeds the cost of the device-related portion of the APC payment amount for the related service of $11,089 by 311 percent ($34,500/$11,089) × 100 = 311 percent). Therefore, we believe that the remedē® System meets the second cost significance test.

The third cost significance test, at § 419.66(d)(3), requires 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 $34,500 for the remedē® System and the portion of the APC payment amount for the device of $11,089 exceeds the APC payment amount for the related service of $27,047.11 by 87 percent (($34,500 − $11,089)/$27,047.11 × 100 = 86.6 percent). Therefore, we believe that the remedē® System meets the third cost significance test.

We are inviting public comments on whether the remedē® System meets the device pass-through payment criteria discussed in this section, including the cost criteria for device pass-through payment.

(6) Restrata® Wound Matrix

Acera Surgical, Inc. submitted an application for a new device category for transitional pass-through payment status for Restrata® Wound Matrix. Restrata® Wound Matrix is a sterile, single-use product intended for use in local management of wounds. According to the applicant, Restrata® Wound Matrix is a soft, white, conformable, non-friable, absorbable matrix that works as a wound care management product by acting as a protective covering for wound defects, providing a moist environment for the body's natural healing process to occur. Restrata® Wound Matrix is made from synthetic biocompatible materials and was designed with a nanoscale non-woven fibrous structure with high porosity, similar to native extracellular matrix. Restrata® Wound Matrix allows for cellular infiltration, new tissue formation, neovascularization, and wound healing before completely degrading via hydrolysis. The product permits the ingress of cells and soft tissue formation in the defect space/wound bed. Restrata® Wound Matrix can be used to manage wounds, including: Partial and full-thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (for example, donor site/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds (for example, abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.

With respect to the newness criterion at § 419.66(b)(1), the applicant received FDA clearance for Restrata® Wound Matrix through the premarket notification section 510(k) process on April 26, 2017 and its February 27, 2018 application for pass-through payment status was within 3 years of FDA clearance. We are inviting public

[21] Costanzo, M.R., et al. (2016).Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet, 388(10048):* p. 974–982.

comment on whether Restrata® Wound Matrix meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Restrata® Wound Matrix is a product that is integral to the service provided, is used for one patient only, comes in contact with human skin, and is surgically inserted into the patient. The description of Restrata® Wound Matrix shows the product meets the device eligibility requirements of § 419.66(b)(4) because Restrata® Wound Matrix is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material. We are inviting public comment on whether Restrata® Wound Matrix meets the eligibility criteria.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through category that describes Restrata® Wound Matrix. The applicant proposed a new device category descriptor of ''Nanofiber Skin Substitute'' for Restrata® Wound Matrix. We are inviting public comments on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With regard to the substantial clinical improvement criterion, the applicant submitted three clinical studies about Restrata® to address this criterion. The largest study is non-randomized, non-blinded, uncontrolled single site retrospective analysis of 70 patients with 82 wounds. This study has not been published but has been submitted to a journal. The study included different types of wounds including diabetic wounds, venous wounds, and other wounds. The study asserted that the wounds had not responded to other wound care treatments, but provides little information on the reasons for the failure of previous treatments.

The study had no power analysis of the results. There were no corrections for multiple comparisons or peeks at the data, and the study did not address if participants dropped out or why there was a lack of drop-outs. The conclusions were descriptive statistics and were compared to the findings in another study where the average wound duration was nearly twice as long as in the original study. There was no previously established endpoint for the most important aspect of functionality, which would be the proportion of wounds with total closure that remained closed after six months despite weight bearing.

The other two studies were extremely small. One study was performed on two non-human subjects (pigs) with a competitor skin matrix product compared to Restrata®. The results of the study were mixed with Restrata® performing better on some measures and the competitor product performing better on other measures. The other study was a case series of six patients that was non-randomized without a control group. It was not clear how the results of these non-randomly selected pre-treated patients relate to the larger population of ulcer patients.

Based on the evidence submitted, we believe there is insufficient data to determine whether Restrata® offers a substantial clinical improvement over other treatments for wound care. We are inviting public comments on whether Restrata® meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires CMS to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. Restrata® Wound Matrix would be reported with CPT codes 15271 through 15278, which cover the application of skin substitute grafts to different areas of the body for high-cost skin substitutes. To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. CPT codes 15271 through 15278 are assigned to either APC 5054 (Level 4 Skin Procedures), with a proposed CY 2019 payment rate of $1,593.38 and a device offset of $4.62, or APC 5055 (Level 5 Skin Procedures), with a proposed CY 2019 payment rate of $2,811.13 and a device offset of $37.11. According to the applicant, the highest retail cost of Restrata® Wound Matrix is $11,718.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $11,718 for Restrata® Wound Matrix exceeds the applicable APC amount for the service related to the category of devices of $1,593.38 by 735.42 percent ($11,718/$1,593.38 × 100 percent = 735.42 percent). Therefore, it appears that Restrata® Wound Matrix meets the first cost significance test.

The second cost significance test, 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 the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $11,718 for Restrata® Wound Matrix exceeds the device-related portion of the APC payment amount for the related service of $4.62 by 253,636.36 percent ($11,718/$4.62 × 100 percent = 253,636.36 percent). Therefore, it appears that Restrata® Wound Matrix meets the second cost significance test.

Section 419.66(d)(3), the third cost significance test, requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $11,718 for Restrata® Wound Matrix and the portion of the APC payment amount for the device of $4.62 exceeds 10 percent at 735.13 percent (($11,718 − $4.62)/$1,593.38 × 100 percent = 735.13 percent). Therefore, it appears that Restrata® Wound Matrix meets the third cost significance test. Based on the costs submitted by the applicant and the calculations noted earlier, we believe that Restrata® Wound Matrix appears to meet the cost criterion at § 419.66(c)(3) for new device categories. We are inviting public comments on whether Restrata® Wound Matrix meets the device pass-through payment criteria discussed in this section, including the cost criteria.

(7) SpaceOAR® System

Augmenix, Inc. submitted an application for a new device category for transitional pass-through payment status for the SpaceOAR® System. According to the applicant, the

SpaceOAR® System is a polyethylene glycol hydrogel spacer that temporarily positions the anterior rectal wall away from the prostate to reduce the radiation delivered to the anterior rectum during prostate cancer radiotherapy treatment. The applicant stated that the SpaceOAR® System reduces some of the side effects associated with radiotherapy, which are collectively known as ''rectal toxicity'' (diarrhea, rectal bleeding, painful defecation, and erectile dysfunction, among other conditions). The applicant also stated that the SpaceOAR® is implanted several weeks before radiotherapy; the hydrogel maintains space between the prostate and rectum for the entire course of radiotherapy and is completely absorbed by patient's body within 6 months.

With respect to the newness criterion at § 419.66(b)(1), FDA granted a De Novo request classifying the SpaceOAR® System as a class II device under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act on April 1, 2015. We received the application for a new device category for transitional pass-through payment status for the SpaceOAR® System on June 1, 2017, which is within 3 years of the date of the initial FDA approval or clearance. We are inviting public comments on whether the SpaceOAR® System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the SpaceOAR® System 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 the SpaceOAR® System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through payment category that describes the SpaceOAR® System. The applicant proposed a category descriptor for the SpaceOAR® System of ''Absorbable perirectal spacer''. We are inviting public comments on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With respect to this criterion, the applicant submitted several studies which generally discussed the benefits and techniques for using hydrogel spacers to limit radiation exposure to the rectum in prostate radiotherapy. The applicant also submitted several studies that specifically examined the effect that the SpaceOAR® System had on mitigating outcomes such as rectal dose, toxicity, and quality of life declines after image guided intensity modulated radiation therapy for prostate cancer. Articles by Hamstra et al.[22] and Mariados et al.[23] discussed the results of a single-blind phase III trial of image guided intensity modulated radiation therapy with 3 years of follow up. A total of 222 men were randomized 2:1 to the spacer or control group and received 79.2 Gy in 1.8-Gy fractions to the prostate with or without the seminal vesicles. The results of this study showed that after 3 years, compared with the control group, the participants who received the SpaceOAR® System injection had a statistically significant smaller volume of the rectum receiving a threshold radiation exposure, which was the primary effectiveness endpoint. The results also showed that in an extended follow up period, the control group experienced larger declines in bowel and urinary quality of life compared to participants who received the SpaceOAR® System treatment. Lastly, in an extended follow-up period, the probability of grade ≥1 rectal toxicity was decreased in the SpaceOAR® System arm (9 percent control group, 2 percent SpaceOAR® System group, $p<.03$) and no ≥ grade 2 rectal toxicity was observed in the SpaceOAR® System arm. However, the control arm had low rates of rectal toxicity in general. The results of this 3-year follow-up of these participants showed that the differences identified in the 15-month follow-up study were maintained or increased.[24]

The applicant also included a secondary analysis of the phase III trial data which showed that participants who received lower radiation doses to the penile bulb, associated with the SpaceOAR® System injection, reported similar erectile function compared with the control group based on patient-reported sexual quality of life.[25] A 2017 retrospective cohort study by Pinkawa et al.[26] evaluated quality of life changes up to 5 years after RT for prostate cancer with the SpaceOAR® System and showed that 5 years after radiation therapy, no patients who received the SpaceOAR® System reported moderate/big problems with bowel urgency, losing control of stools, or with bowel habits overall. However, there were no statistically significant differences in mean score changes for urinary, bowel, or sexual bother between the percentage of participants in the SpaceOAR® System and control groups at either 1.5 or 5 years post radiation therapy. Concerns regarding the phase III trial include inclusion of only low to moderate risk prostate cancer in the study population and failing to use a clinical outcome as a primary endpoint, although the purpose of the spacer is to reduce the side effects of undesired radiation to the rectum including bleeding, diarrhea, fistula, pain, and/or stricture. Notwithstanding acknowledgement that rectal complications may be reduced using biodegradable biomaterials placed to increase the distance between the rectum and the prostate, it is not clear that SpaceOAR® System is superior to existing alternative biodegradable biomaterials currently utilized for spacing in the context of prostate radiotherapy.

Based on the evidence submitted with the application, we have insufficient evidence that the SpaceOAR® System provides a substantial clinical improvement over other similar products. We are inviting public comments on whether the SpaceOAR® System meets the substantial clinical improvement criterion.

[22] Hamstra DA, et al. (2017). Continued Benefit to Rectal Separation for Prostate Radiation Therapy: Final Results of a Phase III Trial. *Int J Radiat Oncol Biol PhysApr 1;97(5)*:976–985. Epub 2016 Dec 23. PMID:28209443.

[23] Mariados N, et al. (2015). Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. *Int J Radiat Oncol Biol Phys.92(5)*:971–977. Epub 2015 Apr 23. PMID: 26054865.

[24] Ibid.

[25] Hamstra, DA et al. (2018) Sexual quality of life following prostate intensity modulated radiation therapy (IMRT) with a rectal/prostate spacer: secondary analysis of a phase 3 trial. *Practical Radiation Oncology, 8,* e7–e15.

[26] Pinkawa, M. et al. (2017). Quality of Life after Radiation Therapy for Prostate Cancer With a Hydrogel Spacer: Five Year Results. *Int J Radiat Oncol Biol Phys., Vol. 99, No. 2,* pp. 374e377.

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 SpaceOAR® System would be reported with CPT code 0438T (which was deleted and replaced with CPT code 55874, effective January 1, 2018). CPT code 0438T was assigned to APC 5374 (Level 4 Urology and Related Services). To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5374, which had a CY 2017 payment rate of $2,542.56 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 0438T had device offset amount of $587.07 at the time the application was received. According to the applicant, the cost of the SpaceOAR® System was $2,850.

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 $2,850 for the SpaceOAR® System exceeds 112 percent of the applicable APC payment amount for the service related to the category of devices of $2,542.56 ($2850/$2,542.56 × 100 = 112 percent). Therefore, we believe the SpaceOAR® system meets the first cost significance test.

The second cost significance test, 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 $2,850 for the SpaceOAR® System exceeds the cost of the device-related portion of the APC payment amount for the related service of $587.07 by 485 percent ($2,850/$587.07) × 100 = 485 percent). Therefore, we believe that the SpaceOAR® System meets the second cost significance test.

The third cost significance test, at § 419.66(d)(3), requires 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 $2,850 for the SpaceOAR® System and the portion of the APC payment amount for the device of $587.07 exceeds the APC payment amount for the related service of $2,542.56 by 89 percent (($2,850–$587.07)/$2,542.56 × 100 = percent). Therefore, we believe that the SpaceOAR® System meets the third cost significance test.

We are inviting public comments on whether the SpaceOAR® System meets the device pass-through payment criteria discussed in this section, including the cost criteria.

B. Proposed Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applied to device-intensive APCs and is discussed in detail in section IV.B.4. of this proposed rule. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422). 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 given 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 an 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 employed 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 below are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.B.3. and IV.B.4. of this 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 above—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 above criteria are assigned device-intensive status, regardless of their APC placement.

2. Proposed Changes to the Device-Intensive Procedure Policy for CY 2019

As part of CMS' effort to better capture costs for procedures with significant device costs, for CY 2019, we are proposing to modify our criteria for device-intensive procedures. We have heard from stakeholders that the current criteria exclude some procedures that stakeholders believe 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 nonetheless qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agree that a broader definition of device-intensive procedures is warranted, and are proposing two modifications to the current criteria. First, we are proposing to allow 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, because we no longer believe that whether a device remains in the patient's body should affect its designation as a device-intensive procedure because such devices could, nonetheless, comprise a large cost of the applicable procedure. Second, we are proposing to modify 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 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, this proposed 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 are proposing 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.

In addition, to further align the device-intensive policy with the criteria used for device pass-through status, we are proposing to specify, 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 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:

(a) 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

(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).

As part of this proposal, we also are soliciting public comment on these proposed revised criteria, including whether there are any devices that are not capital equipment that commenters believe should be deemed part of device-intensive procedures that would not meet the proposed definition of single-use devices. In addition, we are soliciting public comments on the full list of proposed CY 2019 OPPS device-intensive procedures provided in Addendum P to this proposed rule, which is available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospital OutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.* Specifically, we are inviting public comment on whether any procedures proposed to receive device-intensive status for CY 2019 should not receive device-intensive status according to the proposed criteria, or if we did not assign device-intensive status for CY 2019 to any procedures commenters believed should receive device-intensive status based on the proposed criteria.

In addition, for new HCPCS codes describing procedures requiring the implantation of medical 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 medical 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. This default device offset amount of 41 percent is not calculated from claims data; instead, it is applied as a default until claims data are 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 medical devices is to ensure ASC access for new procedures until claims data become available.

In accordance with our proposal above 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 are proposing to modify this

policy and apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a medical 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 proposal to lower the default device offset from 41 percent to 31 percent, we are proposing to continue 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 of a medical device, device-intensive status will be 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, we are clarifying that since the adoption of our current policy, 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 are proposing to use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code. Clinically related and similar procedures for purposes of this policy are procedures that have little to 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 proposal, claims data from clinically related and similar codes will be 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 are proposing to 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 believe that claims data for HCPCS codes describing procedures that have very minor differences from the procedures described by new HCPCS codes would provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and would be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. For instance, for CY 2019, we are proposing to use the claims data from existing CPT code 36568 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump; younger than 5 years of age), for which the description as of January 1, 2019 is changing to ''(Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; younger than 5 years of age)'', to determine the appropriate device offset percentage for new CPT code 36X72 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; younger than 5 years of age). We believe that although CPT code 36568 is not identified as a predecessor code by CPT, the procedure described by new CPT code 36X72 was previously described by CPT code 36568 and, therefore, CPT code 36X72 is clinically related and similar to CPT code 36568, and the device offset percentage for CPT code 36568 can be accurately applied to both codes. 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 will be 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 will be used to determine whether the new HCPCS code qualifies for device-intensive status.

Additional information for our consideration of an offset percentage higher than the proposed default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a medical 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 and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically at *outpatientpps@cms.hhs.gov.* Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

The full listing of proposed CY 2019 device-intensive procedures is included in Addendum P to this proposed rule (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.

We are not proposing any changes to this policy for CY 2019.

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 Medical 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 existing 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. Proposed 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 our 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.

For CY 2019 and subsequent years, we are proposing to apply our no cost/full credit and partial credit device policies to all procedures that qualify as device-intensive under our proposed modified criteria discussed in section IV.B.2. of this proposed rule.

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 note 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), and 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 above 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 approximately $21,302, and the median cost was approximately $19,521. The final CY 2018 payment rate (calculated using the median cost) was approximately $17,560.

For CY 2019, we are proposing to continue with 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 based on calculations using the median cost instead of the geometric mean cost. For CY 2019, there are no procedures to which this policy would apply. Due to the proposed change in APC assignment for CPT code 0308T to APC 5493 (Level 3 Intraocular Procedures) from APC 5495 (Level 5 Intraocular Procedures), our payment policy for low-volume device-intensive procedures would not apply to CPT code 0308T for CY 2019 because there are now more than 100 total claims for the APC to which CPT code 0308T is assigned. For more information on the proposed APC assignment change for CPT code 0308T, we refer readers to section III.D.4. of this proposed rule.

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

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

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout this proposed rule, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. A ''biological'' as used in this proposed rule includes (but is not necessarily limited to) a ''biological product'' or a ''biologic'' as defined in 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, 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 2019 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available 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 this proposed rule, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS 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 the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.*

2. Three-Year Transitional Pass-Through Payment Period for All 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.

3. Proposed Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2018

We are proposing that the pass-through payment status of 23 drugs and biologicals would expire on December 31, 2018, as listed in Table 19 below. All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2018. These drugs and biologicals were approved for pass-through payment status on or before January 1, 2017. In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals newly approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed to be $125 for CY 2019), as discussed further in section V.B.2. of this proposed rule. We are proposing 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 are proposing to provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for CY 2019, as discussed further in section V.B.3. of this proposed rule).

TABLE 19—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS–THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2018

CY 2018 HCPCS code	CY 2018 long descriptor	CY 2018 status indicator	CY 2018 APC	Pass-through payment effective date
A9515	Choline C 11, diagnostic, per study dose	G	9461	04/01/2016
C9460	Injection, cangrelor, 1 mg	G	9460	01/01/2016
C9482	Injection, sotalol hydrochloride, 1 mg	G	9482	10/01/2016
J1942	Injection, aripiprazole lauroxil, 1 mg	G	9470	04/01/2016
J2182	Injection, mepolizumab, 1 mg	G	9473	04/01/2016
J2786	Injection, reslizumab, 1 mg	G	9481	10/01/2016
J2840	Injection, sebelipase alfa, 1 mg	G	9478	07/01/2016
J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.	G	9171	10/01/2016
J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	G	1844	04/01/2016
J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u.	G	1846	04/01/2016
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471	04/01/2016
J7342	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479	07/01/2016
J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg	G	1845	04/01/2016
J9022	Injection, atezolizumab, 10 mg	G	9483	10/01/2016
J9145	Injection, daratumumab, 10 mg	G	9476	07/01/2016
J9176	Injection, elotuzumab, 1 mg	G	9477	07/01/2016
J9205	Injection, irinotecan liposome, 1 mg	G	9474	04/01/2016
J9295	Injection, necitumumab, 1 mg	G	9475	04/01/2016
J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	9472	04/01/2016
J9352	Injection, trabectedin, 0.1 mg	G	9480	07/01/2016
Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram	G	1822	07/01/2015
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459	01/01/2016
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458	01/01/2016

The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to this proposed rule (which is available via the internet on the CMS website).

4. Proposed Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Payment Status in CY 2019

We are proposing to continue pass-through payment status in CY 2019 for 45 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status between January 1, 2017, and July 1, 2018, are listed in Table 20 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status through December 31, 2018 are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available via the internet on the CMS website). In addition, there are four drugs and biologicals that have already had 3 years of pass-through payment status but for which pass-through payment status is required to be extended for an additional 2 years 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). Because of this requirement, these drugs and biologicals are also included in Table 20, which brings the total number of drugs and biologicals with proposed pass-through payment status in CY 2019 to 49. The requirements of section 1301 of Pub. L. 115–141 are described in further detail in section V.A.5. of this proposed rule.

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 2019, we are proposing 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 2019. We are proposing that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2019 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we are proposing that their pass-through payment amount would be equal to ASP+6 percent for CY 2019 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6. of this proposed rule. We are making this proposal 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 are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2019 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 2019, consistent with our CY 2018 policy for diagnostic and therapeutic radiopharmaceuticals, we are proposing 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 2019, we are proposing to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we are proposing to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of this proposed rule), the equivalent payment provided to pass-through payment drugs and biologicals without ASP information. If WAC information also is not available, we are proposing to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The 49 drugs and biologicals that we are proposing to continue to have pass-through payment status for CY 2019 or have been granted pass-through payment status as of July 2018 are shown in Table 20 below.

TABLE 20—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2019

CY 2018 HCPCS code	CY 2019 HCPCS code	CY 2019 long descriptor	Proposed CY 2019 status indicator	Proposed CY 2019 APC	Pass-through payment effective date
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries.	G	9084	10/01/2018
A9587	A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie	G	9056	01/01/2017
A9588	A9588	Fluciclovine f-18, diagnostic, 1 millicurie	G	9052	01/01/2017
C9014	C9014	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018
C9015	C9015	Injection, c-1 esterase inhibitor (human), Haegarda, 10 units.	G	9015	01/01/2018
C9016	C9016	Injection, triptorelin extended release, 3.75 mg	G	9016	01/01/2018
C9024	C9024	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine.	G	9302	01/01/2018
C9028	C9028	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018
C9029	C9029	Injection, guselkumab, 1 mg	G	9029	01/01/2018
C9030	C9030	Injection, copanlisib, 1 mg	G	9030	07/01/2018
C9031	C9031	Lutetium Lu 177, dotatate, therapeutic, 1 mCi	G	9067	07/01/2018
C9032	C9032	Injection, voretigene neparvovec-rzyl, 1 billion vector genome.	G	9070	07/01/2018
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/01/2018
C9462	C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018
C9463	C9463	Injection, aprepitant, 1 mg	G	9463	04/01/2018
C9465	C9465	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose.	G	9465	04/01/2018
C9466	C9466	Injection, benralizumab, 1 mg	G	9466	04/01/2018
C9467	C9467	Injection, rituximab and hyaluronidase, 10 mg	G	9467	04/01/2018
C9468	C9468	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u..	G	9468	04/01/2018
C9469	C9469	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg.	G	9469	04/01/2018
C9488	C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017
C9492	C9492	Injection, durvalumab, 10 mg	G	9492	10/01/2017
C9493	C9493	Injection, edaravone, 1 mg	G	9493	10/01/2017
J0565	J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017
J0570	J0570	Buprenorphine implant, 74.2 mg	G	9058	01/01/2017

TABLE 20—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2019—Continued

CY 2018 HCPCS code	CY 2019 HCPCS code	CY 2019 long descriptor	Proposed CY 2019 status indicator	Proposed CY 2019 APC	Pass-through payment effective date
J0606	J0606	Injection, etelcalcetide, 0.1 mg	G	9031	01/01/2018
J1428	J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017
J1627	J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017
J2326	J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017
J2350	J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017
J3358	J3358	Ustekinumab, for Intravenous Injection, 1 mg	G	9487	04/01/2017
J7179	J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco.	G	9059	01/01/2017
J7210	J7210	Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.	G	9043	01/01/2017
J7328	J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg.	G	1862	01/01/2016
J7345	J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg.	G	9301	01/01/2018
J9023	J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017
J9034	J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017
J9203	J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018
J9285	J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017
Q2040	Q2040	Tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion.	G	9081	01/01/2018
Q2041	Q2041	Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion.	G	9035	04/01/2018
Q4172	Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter.	G	9082	10/01/2018
Q5103	Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2018
Q5104	Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018
Q9991	Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg.	G	9073	07/01/2018
Q9992	Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg.	G	9239	07/01/2018
Q9993	Q9993	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018
Q9995	Q9995	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018

5. Proposed Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Status as a Result of Section 1301 of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141)

As mentioned earlier, section 1301(a)(1) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141) amended section 1833(t)(6) of the Act and added a new section 1833(t)(6)(G), which provides that for drugs or biologicals whose period of pass-through payment status ended on December 31, 2017 and for which payment was packaged into a covered hospital outpatient service furnished beginning January 1, 2018, such pass-through payment status shall be extended for a 2-year period beginning on October 1, 2018 through September 30, 2020. There are four products whose period of drugs and biologicals pass-through payment status ended on December 31, 2017. These products are listed in Table 21 below. For CY 2019, we are proposing to continue pass-through payment status for the drugs and biologicals listed in Table 21 (we note that these drugs and biologicals are also listed in Table 20 above). The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

In addition, new section 1833(t)(6)(H) of the Act specifies that the payment amount for such drug or biological under this subsection that is furnished during the period beginning on October 1, 2018, and ending on March 31, 2019, shall be the greater of: (i) The payment amount that would otherwise apply under section 1833(t)(6)(D)(i) of the Act for such drug or biological during such period; or (ii) the payment amount that applied under section 1833(t)(6)(D)(i) of the Act for such drug or biological on December 31, 2017. We intend to address pass-through payment for these drugs and biologicals for the last quarter of CY 2018 through program instruction. For January 1, 2019 through March 31, 2019, we are proposing that pass-through payment for these four drugs and biologicals would be the greater of: (1) ASP+6 percent based on current ASP data; or (2) the payment rate for the drug or biological on December 31, 2017. We also are proposing for the period of April 1, 2019 through December 31, 2019 that the pass-through payment amount for these drugs and biologicals would be the amount that applies under section 1833(t)(6)(D)(i) of the Act.

We are proposing to continue to update pass-through payment rates for these four drugs and biologicals on a quarterly basis on the CMS website during CY 2019 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 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).

The four drugs and biologicals that we are proposing would have pass-through payment status for CY 2019 under section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018, are shown in Table 21 below. Included as one of the four drugs and biologicals with pass-through payment status for CY 2019 is HCPCS code Q4172 (PuraPly, and PuraPly Antimicrobial, any type, per square centimeter). PuraPly is a skin substitute product that was approved for pass-through payment status on January 1, 2015, through the drug and biological pass-through payment process. Beginning on April 1, 2015, skin substitute products are evaluated for pass-through payment status through the device pass-through payment process. However, we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66887) that skin substitutes that are approved for pass-through payment status as biologicals effective on or before January 1, 2015 would continue to be paid as pass-through biologicals for the duration of their pass-through payment period. Because PuraPly was approved for pass-through payment status through the drug and biological pass-through payment pathway, we are proposing to consider PuraPly to be a drug or biological as described by section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018, and to be eligible for extended pass-through payment under our proposal for CY 2019.

TABLE 21—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2019 IN ACCORDANCE WITH PUBLIC LAW 115–141

CY 2018 HCPCS code	CY 2019 HCPCS code	CY 2019 long descriptor	Proposed CY 2019 status indicator	Proposed CY 2019 APC	Pass-through payment effective date
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries.	G	9084	10/01/2018
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/01/2018
Q4172	Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter.	G	9082	10/01/2018
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018

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

Under the 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 2019, as we did in CY 2018, we are proposing 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 22 below.

TABLE 22—PROPOSED APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2019

Proposed CY 2019 APC	Proposed CY 2019 APC title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services.
5592	Level 2 Nuclear Medicine and Related Services.
5593	Level 3 Nuclear Medicine and Related Services.
5594	Level 4 Nuclear Medicine and Related Services.
Contrast Agent	
5571	Level 1 Imaging with Contrast.
5572	Level 2 Imaging with Contrast.
5573	Level 3 Imaging with Contrast.
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services.
5593	Level 3 Nuclear Medicine and Related Services.
Skin Substitute	
5054	Level 4 Skin Procedures.
5055	Level 5 Skin Procedures.

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

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Proposed Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $120 for CY 2018 (82 FR 59343).

Following the CY 2007 methodology, for this CY 2019 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 2019 and rounded the resulting dollar amount ($126.03) to the nearest $5 increment, which yielded a figure of $125. 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. Based on these calculations, we are proposing a packaging threshold for CY 2019 of $125.

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

To determine the proposed CY 2019 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 2017 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2017 claims processed before January 1, 2018 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of this proposed rule, or for the following policy-packaged items that we are proposing to continue to package in CY 2019: 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 2019, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we are proposing for separately payable drugs and biologicals for CY 2019, as discussed in more detail in section V.B.2.b. of this proposed rule) to calculate the CY 2019 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2017 (data that were used for payment purposes in the physician's office setting, effective April 1, 2018) to determine the proposed rule per day cost. As is our standard methodology, for CY 2019, we are proposing to use payment rates based on the ASP data from the first quarter of CY 2018 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are available via the internet on the CMS website) because these are the most recent data available for use at the time of development of this proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2018. 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 2017 hospital claims data to determine their per day cost.

We are proposing to package items with a per day cost less than or equal to $125, and identify items with a per day cost greater than $125 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2017 HCPCS codes that were reported to the CY 2018 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the internet on the CMS website) for proposed payment in CY 2019.

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 2019 OPPS/ASC proposed rule, we are proposing to use ASP data from the fourth quarter of CY 2017, 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, 2018, along with updated hospital claims data from CY 2017. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for this CY 2019 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for the final rule with comment period will be based on ASP data from the third quarter of CY 2018. 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, 2018. These payment rates would then be updated in the January 2019 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2019. For items that do not currently have an ASP-based payment rate, we are proposing to recalculate their mean unit cost from all of the CY 2017 claims data and updated cost report information available for the CY 2019 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 this 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. Under such circumstances, we are proposing 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 cost fluctuates relative to the proposed CY 2019 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2018. 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 2019, consistent with our historical practice, we are proposing 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 2018 and that were proposed for separate payment in CY 2019, and that then have per day costs equal to or less than the CY 2019 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2019 final rule, would continue to receive separate payment in CY 2019.
- HCPCS codes for drugs and biologicals that were packaged in CY 2018 and that were proposed for separate payment in CY 2019, and that then have per day costs equal to or less than the CY 2019 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2019 final rule, would remain packaged in CY 2019.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2019 but then have per day costs greater than the CY 2019 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2019 final rule, would receive separate payment in CY 2019.

c. Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, in the OPPS, we package several categories of drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than that at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: ''We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy'' (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

d. Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes

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 finalize the packaging of 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 above 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 2018, the payment rate for APC 5053 (Level 3 Skin Procedures) was $488.20, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,568.43, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $2,710.48. This information also is available in Addenda A and B of the CY 2018 OPPS/ASC final rule with comment period (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 are proposing to continue it for CY 2019. 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). For CY 2019, as with our policy since CY 2016, we are proposing 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. For CY 2019, as for CY 2018, we are proposing to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, as described in more detail later in this section, for CY 2019, as for CY 2018, we are proposing 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 2019, we are proposing that any skin substitute product that was assigned to the high cost group in CY 2018 would be assigned to the high cost group for CY 2019, regardless of whether it exceeds or falls below the CY 2019 MUC or PDC threshold.

For this CY 2019 OPPS/ASC proposed rule, consistent with the methodology as established in the CY 2014 through CY 2017 final rules with comment period, we analyzed CY 2017 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2019 MUC threshold is $49 per cm^2 (rounded to the nearest $1) and the proposed CY 2019 PDC threshold is $895 (rounded to the nearest $1).

For CY 2019, we are proposing to continue to assign skin substitutes with pass-through payment status to the high cost category. We are proposing 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 are proposing 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 would use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. We are proposing to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b. of this proposed rule to establish a payment rate of WAC+3 percent for separately payable drugs and biologicals that do not have ASP data available. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2019 MUC threshold. 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).

Some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year. 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), for CY 2018, 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 refinement to the existing policies is 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 requests 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. We have identified four potential methodologies that have been raised to us that we encourage the public to review and provide comments on. We are 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. We also are interested in any new ideas that are not represented below along with an analysis of how different skin

substitute products would fare under such ideas. We intend to explore the full array of public comments on these ideas for the CY 2020 rulemaking, and we will consider the feedback received in response to this proposed rule in developing proposals for CY 2020.

• *Establish a lump-sum ''episode-based'' payment for a wound care episode.* Under this option, a hospital would receive a lump sum payment for all wound care services involving procedures using skin substitutes. The payment would be made for a wound care ''episode'' (such as 12 weeks) for one wound. The lump sum payment could be the same for all skin substitutes or could vary based on the estimated number of applications for a given skin substitute during the wound care episode. Under this option, payment to the provider could be made at the start of treatment, or at a different time, and could be made once or split into multiple payments. Quality metrics, such as using the recommended number of treatments for a given skin substitute during a treatment episode, and establishing a plan of care for patients who do not experience 30-percent wound healing after 4 weeks, could be established to ensure the beneficiary receives appropriate care while limiting excessive additional applications of skin substitute products.

• *Eliminate the high cost/low cost categories for skin substitutes and only have one payment category and set of procedure codes for all skin substitute products.* This option would reduce the financial incentives to use expensive skin substitutes and would provide incentives to use less costly skin substitute products that have been shown to have similar efficacy treating wounds as more expensive skin substitute products. A single payment category would likely have a payment rate that is between the current rates paid for high cost and low cost skin substitute procedures. Initially, a single payment category may lead to substantially higher payment for skin graft procedures performed with cheaper skin substitutes as compared to their costs. However, over time, payment for skin graft procedures using skin substitutes might reflect the lower cost of the procedures.

• *Allow for the payment of current add-on codes or create additional procedure codes to pay for skin graft services between 26 cm² and 99 cm² and substantially over 100 cm².* Under this option, payment for skin substitutes would be made more granularly based on the size of the skin substitute product being applied. This option also would reduce the risk that hospitals may not use enough of a skin substitute to save money when performing a procedure. However, such granularity in the use of skin substitutes could conflict with the goals of a prospective payment system, which is based on a system of averages. Specifically, it is expected that some skin graft procedures will be less than 25 cm² or around 100 cm² and will receive higher payments compared to the cost of the services. Conversely, services between 26 cm² and 99 cm² or those that are substantially larger than 100 cm² will receive lower payments compared to the cost of the services, but the payments will average over many skin graft procedures to an appropriate payment rate for the provider.

• *Keep the high cost/low cost skin substitute categories, but change the threshold used to assign skin substitutes in the high-cost or low-cost group.* Consider using other benchmarks that would establish more stable thresholds for the high cost and low cost groups. Ideas include, but are not limited to, fixing the MUC or PDC threshold at amount from a prior year, or setting global payment targets for high cost and low cost skin substitutes and establishing a threshold that meets the payment targets. Establishing different thresholds for the high cost and low cost groups could allow for the use of a mix of lower cost and higher cost skin substitute products that acknowledges that a large share of skin substitutes products used by Medicare providers are higher cost products but still providing substantial cost savings for skin graft procedures. Different thresholds may also reduce the number of skin substitute products that switch between the high cost and low cost groups in a given year to give more payment stability for skin substitute products.

To allow stakeholders time to analyze and comment on the potential ideas raised above, for CY 2019, we are proposing to continue our policy established in CY 2018 to assign skin substitutes to the low cost or high cost group. However, for CY 2020, we may revise our policy to reflect one of the potential new methodologies discussed above or a new methodology included in public comments in response to this proposed rule. Specifically, for CY 2019, we are proposing 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 2018, in which case we will assign the product to the high cost group for CY 2019, regardless of whether it exceeds the CY 2019 MUC or PDC threshold. We also are proposing to assign to the high cost group any skin substitute product that exceeds the CY 2019 MUC or PDC threshold and assign to the low cost group any skin substitute product that does not exceed the CY 2019 MUC or PDC thresholds and were not assigned to the high cost group in CY 2018. We are proposing 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 2019 MUC. In addition, we are proposing to use WAC+3 percent instead of WAC+6 percent for skin substitute products that do not have ASP pricing information or have claims data to determine if those products' costs exceed the CY 2019 MUC. We also are proposing to retain our established policy to assign new skin substitute products with pricing information to the low cost group.

Table 23 below displays the proposed CY 2019 high cost or low cost category assignment for each skin substitute product.

TABLE 23—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2019

CY 2019 HCPCS code	CY 2019 short descriptor	CY 2018 high/low assignment	Proposed CY 2019 high/low assignment
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.

TABLE 23—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2019—Continued

CY 2019 HCPCS code	CY 2019 short descriptor	CY 2018 high/low assignment	Proposed CY 2019 high/low assignment
Q4105	Integra DRT	High	High.*
Q4106	Dermagraft	High	High.
Q4107	GraftJacket	High	High.
Q4108	Integra Matrix	High	High.
Q4110	Primatrix	High	High.*
Q4111	Gammagraft	Low	Low.
Q4115	Alloskin	Low	Low.
Q4116	Alloderm	High	High.
Q4117	Hyalomatrix	Low	Low.
Q4121	Theraskin	High	High.*
Q4122	Dermacell	High	High.
Q4123	Alloskin	High	High.
Q4124	Oasis Tri-layer Wound Matrix	Low	Low.
Q4126	Memoderm/derma/tranz/integup	High	High.*
Q4127	Talymed	High	High.
Q4128	Flexhd/Allopatchhd/Matrixhd	High	High.
Q4131	Epifix	High	High.
Q4132	Grafix core and grafixpl core, per square centimeter	High	High.
Q4133	Grafix prime and grafixpl prime, per square centimeter	High	High.
Q4134	hMatrix	Low	Low.
Q4135	Mediskin	Low	Low.
Q4136	Ezderm	Low	Low.
Q4137	Amnioexcel or Biodexcel, 1cm	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, 1cm	High	High.*
Q4148	Neox cord 1k, neox cord rt, or clarix cord 1k, per square centimeter	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 1 square cm	High	High.
Q4154	Biovance 1 square cm	High	High.
Q4156	Neox 100 or clarix 100, per square centimeter	High	High.
Q4157	Revitalon 1 square cm	High	High.*
Q4158	Kerecis omega3, per square centimeter	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 square centimeter	High	High.
Q4164	Helicoll, per square cm	High	High.*
Q4165	Keramatrix, per square cm	Low	Low.
Q4166	Cytal, per square cm	Low	Low.
Q4167	Truskin, per square cm	Low	Low.
Q4169	Artacent wound, per square cm	High	High.*
Q4170	Cygnus, per square cm	Low	Low.
Q4172+	PuraPly, PuraPly antimic	High	High.
Q4173	Palingen or palingen xplus, per sq cm	High	High.
Q4175	Miroderm, per square cm	High	High.
Q4176	Neopatch, per square centimeter	Low	Low.
Q4178	Floweramniopatch, per square centimeter	High	High.
Q4179	Flowerderm, per square centimeter	Low	Low.
Q4180	Revita, per square centimeter	High	High.
Q4181	Amnio wound, per square centimeter	Low	Low.
Q4182	Transcyte, per square centimeter	Low	Low.

*These products do not exceed either the MUC or PDC threshold for CY 2019, but are assigned to the high cost group because they were assigned to the high cost group in CY 2018.

+Pass-through payment status in CY 2019.

e. Proposed 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 believed 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 are proposing 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 2019.

For CY 2019, 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 2017 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 2019 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 2017 claims data to make the proposed packaging determinations for these drugs: 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 2019 drug packaging threshold of $125 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2019 drug packaging threshold of $125 (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 2019 is displayed in Table 24 below.

TABLE 24—PROPOSED HCPCS CODES TO WHICH THE CY 2019 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

CY 2019 HCPCS code	CY 2019 long descriptor	Proposed CY 2019 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
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

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

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged 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.[27]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In this CY 2019 OPPS/ASC proposed rule, we are proposing 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 continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2018.

b. Proposed CY 2019 Payment Policy

For CY 2019, we are proposing to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We are proposing to continue to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent. We refer readers to section V.A.7. of this proposed rule for more information about how the payment rate for drugs acquired with a 340B discount was established.

In the case of a drug or biological during an initial sales period in which data on the prices for sales for 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), 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 proposed rule, under section 1847A(c)(4), although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that certain payments 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 partial quarter WAC-based pricing. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS proposed rule, we are proposing that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act would utilize a 3-percent add-on in place of the 6-percent add-on that is currently being used. For the OPPS, we also are proposing 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 apply this provision to non-SCOD separately payable drugs. Because we are proposing 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 are proposing 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. For drugs and biologicals that would otherwise be subject to a payment

[27] 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.*

reduction because they were acquired under the 340B Program, the 340B Program rate (in this case, WAC minus 22.5 percent) would continue to apply. We refer readers to the CY 2019 PFS proposed rule for additional background on this anticipated proposal.

We are proposing that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also are proposing that the budget neutral weight scalar is not applied in determining payments for these separately paid drugs and biologicals. We note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule (available via the internet on the CMS website), which illustrate the proposed CY 2019 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, 2018, or WAC, AWP, or mean unit cost from CY 2017 claims data and updated cost report information available for this proposed rule. In general, these published payment rates are not the same as the actual January 2019 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2019 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2018 (July 1, 2018 through September 30, 2018) will be used to set the payment rates that are released for the quarter beginning in January 2019 near the end of December 2018. In addition, payment rates for drugs and biologicals in Addenda A and B to this proposed rule for which there was no ASP information available for April 2018 are based on mean unit cost in the available CY 2017 claims data. If ASP information becomes available for payment for the quarter beginning in January 2019, 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 this proposed rule (reflecting April 2018 ASP data) that do not have ASP information available for the quarter beginning in January 2019. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2017 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2019 payment purposes and are only illustrative of the proposed CY 2019 OPPS payment methodology using the most recently available information at the time of issuance of this proposed rule.

c. Biosimilar Biological Products

For CY 2016 and CY 2017, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPS/ASC proposed rule (82 FR 33630), for CY 2018, we proposed to continue this same payment policy for biosimilar biological products.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), we noted that, with respect to comments we received regarding OPPS payment for biosimilar biological products, in the CY 2018 PFS final rule, CMS finalized a policy to implement separate HCPCS codes for biosimilar biological products. Therefore, consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, HCPCS coding for biosimilar biological products will be based on 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 will be eligible for pass-through payment and not just the first biosimilar biological product for a reference product. For CY 2019, we are proposing 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 ASP (of the biosimilar) minus 22.5 percent of the reference product (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's product ASP. Biosimilars that do not have pass-through payment status and are not acquired under the 340B Program also are paid their own ASP+6 percent of the reference product's ASP.

Several stakeholders raised concerns to us that the current 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 agree 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 believe that these changes would better reflect the resources and production costs that biosimilar manufacturers incur, and we also 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 believe 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, for CY 2019, we are proposing 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 are proposing 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.

3. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2019, we are proposing 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 2019. Therefore, we are proposing for CY 2019 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 are proposing to rely on CY 2017 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 2019 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

4. Proposed Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, 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).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation is that this additional payment will be needed for the duration of the industry's conversion to alternative methods to producing Tc-99m without HEU. We also stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68316). A 2016 report from the National Academies of Sciences, Engineering, and Medicine anticipates the conversion of Tc-99m production from non-HEU sources will not be complete until the end of 2019.[28] In addition, one of the manufacturers of Tc-99m generators supports continuing the payment adjustment at the current level because approximately 30 percent of Tc-99m continues to be produced from non-HEU sources. We also received comments from a trade group of nuclear pharmacies and cyclotron operators supporting an increase in the payment adjustment by the rate of inflation to cover more of the cost of Tc-99m from non-HEU sources.

We appreciate the feedback from stakeholders. However, we continue to believe that the current adjustment is sufficient for the reasons we have outlined in this and prior rulemakings. The information from stakeholders and the National Academies of Sciences, Engineering, and Medicine indicates that the conversion of the production of Tc-99m from non-HEU sources may take more than 1 year after CY 2018. Therefore, for CY 2019 and subsequent years, we are proposing to continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources. We intend to reassess this payment policy once conversion to non-HEU sources is closer to completion or has been completed.

5. Proposed Payment for Blood Clotting Factors

For CY 2018, 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 (82 FR 59353). That is, for CY 2018, 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 2018 updated furnishing fee was $0.215 per unit.

For CY 2019, we are proposing 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 are proposing to announce the actual figure for the percent change in the

[28] National Academies of Sciences, Engineering, and Medicine. 2016. Molybdenum-99 for Medical Imaging. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23563.*

applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

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

For CY 2019, we are proposing to continue to use the same payment policy as in CY 2018 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 2019 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this proposed rule, which is available via the internet on the CMS website.

7. CY 2019 Proposed OPPS Payment Methodology for 340B Purchased Drugs

In the CY 2018 OPPS/ASC proposed rule (82 FR 33558 through 33724), we proposed changes to the Medicare Part B drug payment methodology for 340B hospitals. We proposed these changes to better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. We believed that such changes would allow Medicare beneficiaries (and the Medicare program) to pay less 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 on 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. Our goal is 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 (CAHs) are not included in this 340B policy change because they are paid under section 1834(g) of the Act. We also excepted rural sole community hospitals (SCHs), 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 on pass-through payment status, which are required to be paid based on the ASP methodology or vaccines, which are excluded from the 340B Program.

Another topic that has been brought to our attention since we finalized the payment adjustment for 340B-acquired drugs in the CY 2018 OPPS/ASC final rule with comment period is whether drugs that do not have ASP pricing but instead receive WAC or AWP pricing are subject to the 340B payment adjustment. We did not receive public comments on this topic in response to the CY 2018 OPPS/ASC proposed rule. However, we have since heard from stakeholders that there has been some confusion about this issue. We want to clarify that the 340B payment adjustment does apply 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. The 340B payment adjustment for WAC-priced drugs is WAC minus 22.5 percent and AWP-priced drugs have a payment rate of 69.46 percent of AWP when the 340B payment adjustment is applied. 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. The number of separately payable drugs receiving WAC or AWP pricing that are affected by the 340B payment adjustment is small—consisting of less than 10 percent of all separately payable Medicare Part B drugs in April 2018.

Data limitations inhibit our ability to identify which drugs were acquired under the 340B Program in the Medicare OPPS claims data. This lack of information within the claims data has limited researchers' and our ability to precisely analyze differences in acquisition cost of 340B and non-340B acquired drugs with Medicare claims data. Accordingly, in the CY 2018 OPPS/ASC proposed rule (82 FR 33633), we stated our intent to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B Program. Because a significant portion of hospitals paid under the OPPS participate in the 340B Program, we stated our belief that it is appropriate to presume that a separately payable drug reported on an OPPS claim was purchased under the 340B Program, unless the hospital identifies that the drug was not purchased under the 340B Program. We stated in the proposed rule that we intended to provide further details about this modifier in the CY 2018 OPPS/ASC final rule with comment period and/or through subregulatory guidance, including guidance related to billing for dually eligible beneficiaries (that is, beneficiaries covered under Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B Program. 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, CMS implemented modifier ''JG'', effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as CAHs or those hospitals paid under the Maryland waiver), or excepted from the 340B drug payment policy for CY 2018, are 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 SCHs, children's hospitals and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment. These hospitals are 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 modifier ''JG''.

For CY 2019, we are proposing to continue the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars. We are proposing, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, to pay for separately payable Medicare Part B drugs (assigned status indicator ''K''), other than vaccines and drugs on pass-through payment status, that meet

the definition of ''covered outpatient drug'' as defined in the section 1927(k) of the Act, that are acquired through the 340B Program at ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. Medicare Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator ''L'' or ''M'') and drugs with OPPS transitional pass-through payment status (assigned status indicator ''G''). As discussed in section V.A.2.c. of this proposed rule, we are proposing to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP. We also are proposing that Medicare would continue to pay for drugs or biologicals that were not purchased with a 340B discount at ASP+6 percent.

As stated earlier, to effectuate the payment adjustment for 340B-acquired drugs, CMS implemented modifier ''JG'', effective January 1, 2018. For CY 2019, we are proposing that hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS, or excepted from the 340B drug payment policy for CY 2018, continue to be required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. We also are proposing for CY 2019 that rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from the 340B payment adjustment. We are proposing that these hospitals be required to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent.

VI. Proposed 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 prorata 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 2019 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 2019. 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 2018 or beginning in CY 2019. The sum of the proposed CY 2019 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2019 pass-through spending estimate for device categories with pass-through payment status. We base 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 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 this proposed rule, we are proposing 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 2019, we also are proposing 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 2019 for this group of items is $0, as discussed below, because we are proposing to pay for most nonpass-through separately payable drugs and biologicals under the CY 2019 OPPS at ASP+6 percent (with the exception of 340B-acquired separately payable drugs, for which we do not yet have sufficient data to estimate a share of total drug payments), and because we are proposing to pay for CY 2019 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A. of this 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 nonpass-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 II.A.3. of this proposed rule. We are proposing 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 2019. Therefore, our proposed estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2019 is not $0, as discussed below. In section V.A.5. of this 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 are proposing 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 are proposing 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 2019. 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 2018 or beginning in CY 2019. The sum of the CY 2019 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2019 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending

We are proposing to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2019, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2018 (82 FR 59371 through 59373).

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 2019, there are no active categories for CY 2019. Because there are no active device categories for CY 2019, we are proposing an estimate for the first group of devices of $0. In estimating our proposed CY 2019 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 2019; additional device categories that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2019; and contingent projections for new device categories established in the second through fourth quarters of CY 2019. We are proposing to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, the proposed estimate of CY 2019 pass-through spending for this second group of device categories is $10 million.

To estimate proposed CY 2019 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 CY 2019, we are proposing 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 2019 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 2019, we estimated the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately paid at ASP+6 percent, which is zero 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 are proposing to include in the CY 2019 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. For this proposed rule, using the proposed methodology described above, we calculated a CY 2019 proposed spending estimate for this first group of drugs and biologicals of approximately $61.5 million.

To estimate proposed CY 2019 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of this proposed rule were newly eligible for pass-through payment in CY 2019, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2018, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2019), we are proposing 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 2019 pass-through payment estimate. We also are proposing to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2019 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $55.2 million.

In summary, in accordance with the methodology described earlier in this section, for this proposed rule, 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 2019 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2019 is approximately $126.7 million (approximately $10 million for device categories and approximately $116.7 million for drugs and biologicals) which represents 0.18 percent of total projected OPPS payments for CY 2019 (approximately $70 billion). Therefore, we estimate that pass-through spending in CY 2019 would not amount to 2.0 percent of total projected OPPS CY 2019 program spending.

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

As we did in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59373), for CY 2019, we are proposing 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 are proposing to continue our payment policy for critical care services for CY 2019. For a description of the current payment policy for critical care services, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). In this proposed rule, we are seeking public comments on any changes to these codes that we should consider for future rulemaking cycles. We continue to encourage those commenters to provide the data and analysis necessary to justify any suggested changes.

In section X.V. of this proposed rule, we are proposing 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 (MPFS)-equivalent payment rate for the hospital outpatient clinic visit (HCPCS code G0463) when it is furnished by excepted off-campus provider-based departments. For a full discussion of this proposal as well as the comment solicitation on potential methods to control for unnecessary increases in the volume of covered outpatient department services, we refer readers to section X.B. of this proposed rule.

VIII. Proposed 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.

Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the outpatient department (OPD) services to be covered under the OPPS. The Medicare regulations that implement this provision specify, at 42 CFR 419.21, that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs as well as Medicare Part B services furnished to hospital outpatients designated by the Secretary, which include partial hospitalization services (65 FR 18444 through 18445).

Section 1833(t)(2)(C) of the Act requires the Secretary, in part, to establish relative payment weights for covered OPD services (and any groups of such services described in section 1833(t)(2)(B) of the Act) based on median (or, at the election of the Secretary, mean) hospital costs using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, 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 accordance with these provisions, we have developed the PHP APCs. Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we established a per diem payment methodology for the PHP APCs, effective for services furnished on or after July 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs were used to calculate the relative payment weights for the PHP APCs. Section 1833(t)(9)(A) of the Act requires the Secretary 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 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.

We began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In that final rule with comment period, we made two refinements to the methodology for computing the PHP median: The first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill.

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tier payment approach for partial hospitalization services under which we paid one amount for days with 3 services under PHP APC 0172 (Level 1 Partial Hospitalization) and a higher amount for days with 4 or more services under PHP APC 0173 (Level 2 Partial Hospitalization) (73 FR 68688 through 68693). We also finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694). Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements under 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). We also revised the partial hospitalization benefit to include several coding updates (73 FR 68695 through 68697).

For 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. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and

payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 (for Level 1 services) and APC 0173 (for Level 2 services)) and two for hospital-based PHPs (APC 0175 (for Level 1 services) and 0176 (for Level 2 services)), based on each provider type's own unique data. For CY 2011, we also instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates based solely on CMHC data. Under the transition methodology, CMHC APCs Level 1 and Level 2 per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based PHP median costs and the CY 2011 final CMHC median costs and then adding that number to the CY 2011 final CMHC median costs. A 2-year transition under this methodology moved us in the direction of our goal, which is to pay appropriately for partial hospitalization services based on each provider type's data, while at the same time allowing providers time to adjust their business operations and protect access to care for Medicare beneficiaries. We also stated that we would review and analyze the data during the CY 2012 rulemaking cycle and, based on these analyses, we might further refine the payment mechanism. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion.

In addition, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. In accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth under section 1861(ff)(3)(B) of the Act (75 FR 71990).

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), 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.

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. We established these four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims and cost data for each provider type. 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), we solicited comments on possible future initiatives that may help to ensure the long-term stability of PHPs and further improve the accuracy of payment for PHP services, but proposed no changes. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75050 through 75053), we summarized the comments received on those possible future initiatives. We also 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 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 PHP APC geometric mean per diem costs, using the most recent claims and cost data for each provider type.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70465), we described our extensive analysis of the claims and cost data and ratesetting methodology. We found aberrant data from some hospital-based PHP providers that were not captured using the existing OPPS ±3 standard deviation trims for extreme cost-to-charge ratios (CCRs) and excessive CMHC charges resulting in CMHC geometric mean costs per day that were approximately the same as or more than the daily payment for inpatient psychiatric facility services. Consequently, we implemented a trim to remove hospital-based PHP service days that use a CCR that was greater than 5 to calculate costs for at least one of their component services, and a trim on CMHCs with a geometric mean cost per day that is above or below 2 (±2) standard deviations from the mean. We stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70456) that, without using a trimming process, the data from these providers would inappropriately skew the geometric mean per diem cost for Level 2 CMHC services.

In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70459 through 70460), we corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers. We corrected the cost inversion with an equitable adjustment to the actual geometric mean per diem costs by increasing the Level 2 hospital-based PHP APC geometric mean per diem costs and decreasing the Level 1 hospital-based PHP APC geometric mean per diem costs by the same factor, to result in a percentage difference equal to the average percent difference between the hospital-based Level 1 PHP APC and the Level 2 PHP APC for partial hospitalization services from CY 2013 through CY 2015.

Finally, we renumbered the PHP APCs, which were previously 0172, 0173, 0175, and 0176, to 5851, 5852, 5861, and 5862, respectively. For a detailed discussion of the PHP ratesetting process, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70467).

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. However, we finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and to combine the Level 1 and Level 2 APCs for hospital-based PHPs because we believed this would best reflect actual geometric mean per diem costs going forward, provide more predictable per diem costs, particularly given the small number of CMHCs, and generate more appropriate payments for these services, for example by avoiding the cost inversions for hospital-based PHPs addressed in the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70459 and 81 FR 79682). We implemented an 8-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities by limiting the impact of inflated CMHC charges on outlier payments. We will continue to monitor the trends in outlier payments

and consider policy adjustments as necessary.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59373 through 59381), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. 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.

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).

B. Proposed PHP APC Update for CY 2019

1. Proposed PHP APC Geometric Mean per Diem Costs

For CY 2019, in this CY 2019 OPPS/ASC proposed rule, we are proposing to continue to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. Specifically, we are proposing to continue to use CMHC APC 5853 (Partial Hospitalization (3 or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (3 or More Services Per Day)). We are proposing to continue to calculate the geometric mean per diem costs for CY 2019 for APC 5853 for CMHCs using only CY 2017 CMHC claims data and the most recent CMHC cost data, and the CY 2019 geometric mean per diem costs for APC 5863 for hospital-based PHPs using only CY 2017 hospital-based PHP claims data and the most recent hospital cost data.

2. Development of the Proposed PHP APC Geometric Mean per Diem Costs

In this CY 2019 OPPS/ASC proposed rule, we are proposing that for CY 2019 and subsequent years, to follow 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 determine the PHP APCs' proposed geometric mean per diem costs and to calculate the proposed payment rates for APCs 5853 and 5863, incorporating the modifications made in our 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 proposed geometric mean per diem cost for hospital-based PHP APC 5863 would be based upon actual hospital-based PHP claims and costs for PHP service days providing 3 or more services. Similarly, the proposed geometric mean per diem cost for CMHC APC 5853 would be based upon actual CMHC claims and costs for CMHC service days providing 3 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 per diem costs, after applying the OPPS budget neutrality adjustments described in section II.A.4. of this proposed rule.

We are proposing to apply our established methodologies in developing the CY 2019 proposed geometric mean per diem costs and payment rates, including the application of a ±2 standard deviation trim on costs per day for CMHCs and a CCR greater than 5 hospital service day trim for hospital-based PHP providers. These two trims were finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70462) for CY 2016 and subsequent years.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this CY 2019 proposed 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 is not skewed by providers with extreme data. Before any trims or exclusions were applied, there were 44 CMHCs in the PHP claims data file. Under the ±2 standard deviation trim policy, we exclude any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day is more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. By applying this trim for CY 2019 ratesetting, in this proposed rule, we excluded 4 CMHCs with geometric mean costs per day below the trim's lower limit of $53.33 and 4 CMHCs with geometric mean costs per day above the trim's upper limit of $274.43 from the proposed ratesetting for CY 2019. This standard deviation trim removed 8 providers from the ratesetting whose data would have skewed the calculation of the proposed geometric mean per diem costs for CMHCs.

In accordance with our PHP ratesetting methodology, we also remove service days with no wage index values because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). For this CY 2019 proposed rule ratesetting, no CMHCs were missing wage index data for all of their service days. Therefore, we did not exclude any CMHCs due to the lack of wage index data.

In addition to our trims and data exclusions, before determining the proposed 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 1 to the statewide hospital ancillary CCR (80 FR 70457). For this CY 2019 proposed rule ratesetting, we identified 3 CMHCs that had CCRs greater than 1. These CMHCs' CCRs were 1.053, 1.009, and 1.025, and each was defaulted to its appropriate statewide hospital ancillary CCR for CY 2019 ratesetting purposes.

In summary, these data preparation steps adjusted the CCR for 3 CMHCs by defaulting to the appropriate statewide hospital ancillary CCR and excluded 8 CMHCs, resulting in the inclusion of a total of 36 CMHCs (44 total—8 excluded) in our CY 2019 proposed rule ratesetting modeling. The trims removed 645 CMHC claims out of a total of 13,152 CMHC claims, resulting in 12,507 CMHC claims used for ratesetting purposes. We believe that excluding providers with extremely low or high geometric mean costs per day or extremely low or high CCRs protects CMHCs from having that data inappropriately skew the calculation of the proposed CMHC APC geometric mean per diem cost. Moreover, we believe that these trims, exclusions, and adjustments help prevent inappropriate fluctuations in the proposed PHP APC geometric mean per diem payment rates.

After applying all of the above 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 the proposed PHP APC geometric mean per diem cost.[29]

[29] Each revenue code on the CMHC claim must have a HCPCS code and charge associated with it.

The proposed CY 2019 geometric mean per diem cost for all CMHCs for providing 3 or more services per day (CMHC PHP APC 5853) is $119.51.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this CY 2019 proposed rule, we followed a data preparation process for hospital-based PHP providers that is similar to that used for CMHCs by applying trims and data exclusions as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) so that our ratesetting is not skewed by providers with extreme data. Before any trimming or exclusions were applied, there were 394 hospital-based PHP providers in the CY 2017 PHP claims data used in this CY 2019 OPPS/ASC proposed rule.

For hospital-based PHP providers, we applied a trim on hospital service days when the CCR was greater than 5 at the cost center level. This trim removed hospital-based PHP service days that use a CCR greater than 5 to calculate costs for at least one of their component services. Unlike the ±2 standard deviation trim, which excluded CMHC providers that failed the trim, the CCR greater than 5 trim excluded any hospital-based PHP service day where any of the services provided on that day were associated with a CCR greater than 5 (in other words, 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 from our proposed rule ratesetting affected service days from 4 hospital-based PHP providers with CCRs ranging from 5.2024 to 13.1952. However, 100 percent of the service days for 3 of these affected hospital-based PHP providers had at least 1 service associated with a CCR greater than 5, so the trim removed these 3 providers entirely from our proposed rule ratesetting. The fourth provider remained in the ratesetting data, but with affected service days trimmed out. In addition, 16 hospital-based PHPs reported zero daily costs and, therefore, were removed for having no days with PHP payment; no hospital-based PHPs were removed for missing wage index data; and 1 hospital-based PHP was removed by the OPPS ±3 standard deviation trim on costs per day.

Therefore, we excluded 20 hospital-based PHP providers [(3 with CCRs greater than 5) + (16 with zero daily costs) + (1 after applying the ±3 standard deviation trim)], resulting in 374 (394 total—20 excluded) hospital-based PHP providers in the data used for proposed rule ratesetting. In addition, 5 hospital-based PHP providers were defaulted to using their overall hospital ancillary CCRs due to outlier cost center CCR values, which ranged from 0.0331 to 72.7320. After completing these data preparation steps, we calculated the proposed CY 2019 geometric mean per diem cost for hospital-based PHP APC 5863 for hospital-based PHP 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) to calculate the geometric mean per diem cost.[30] The proposed CY 2019 geometric mean per diem cost for hospital-based PHP providers that provide 3 or more services per service day (hospital-based PHP APC 5863) is $220.52.

The proposed CY 2019 PHP APC geometric mean per diem costs for CMHC PHP APC 5853 are $119.51 and for hospital-based PHP APC 5863 are $220.52, as stated above and shown in Table 25. The proposed PHP APCs payment rates, which are derived from these proposed PHP APCs geometric mean per diem costs, are included in Addendum A to this proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*).[31]

TABLE 25—CY 2019 PROPOSED PHP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2019 APC	Group title	Proposed PHP APC geometric mean per diem costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$119.51
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	220.52

We multiply each claim service line's charges by the CMHC's overall CCR (or statewide ancillary 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 3 or more services provided to be assigned to CMHC APC 5853. The 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 3 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 geometric mean per diem cost for each PHP APC by taking the *n*th root of the product of *n* numbers for days where 3 or more services were provided.

[30] 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; that CCR is determined by using the OPPS 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 3 or more services provided to be assigned to hospital-based PHP APC 5863. The 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 3 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 geometric mean per diem cost for hospital-based PHP APC 5863.

[31] As discussed in section II.A. of this CY 2019 OPPS/ASC proposed rule, OPPS APC geometric mean per diem costs (including PHP APC geometric mean per diem costs) are divided by the geometric mean per diem costs for APC 5012 (Clinic Visits and Related Services) to calculate each PHP APC's unscaled relative payment weight. An unscaled relative payment weight is one that is not yet adjusted for budget neutrality. Budget neutrality is required under section 1833(t)(9)(B) of the Act, and ensures that the estimated aggregate weight under the OPPS for a calendar year is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To adjust for budget neutrality (that is, to scale the weights), we compare the estimated aggregated weight using the scaled relative payment weights from the previous calendar year at issue. We refer readers to the ratesetting procedures described in Part 2 of the OPPS Claims Accounting narrative and in section II. of this proposed rule for more information on scaling the weights, and for details on the final steps of the process that lead to PHP APC per diem payment rates. The OPPS Claims Accounting narrative is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

3. Proposed Changes to the Revenue-Code-to-Cost Center Crosswalk

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79691), we received public comments identifying an issue that may have contributed to a decreased PHP median [sic] cost for hospital-based PHPs. The commenters noted that the lack of a required standardized PHP cost center on the Medicare cost report may be creating some cost-finding nuances in the cost report itself—that hospital-based PHP costs are combined with the costs of less expensive non-PHP outpatient mental health services during CCR calculation, thus ''diluting'' the CCR values. We agreed with the commenters that, if PHP costs are combined with other less intensive outpatient mental health treatment costs in the same cost center, the CCR values could be diluted, leading to lower geometric mean per diem costs being calculated. We stated in response that we would consider adding a cost center to the hospital cost report for PHP costs only.

On November 17, 2017, in Transmittal No. 12, we added a new cost center, ''Partial Hospitalization Program,'' on Line 93.99 of Worksheet A (Line 93.99 is also displayed on Worksheets B, Parts I and II, B–1; and C, Parts I and II) for hospital-based PHPs, for cost reporting periods ending on or after August 31, 2017 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R12P240.pdf*). On January 30, 2018, in Transmittal No. 13, we changed the implementation date from cost reporting periods ending on or after August 31, 2017, to cost reporting periods ending on or after September 30, 2017 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R12P240.pdf*). The instructions for this new PHP cost center (Line 93.99) indicate that effective for cost reporting periods ending on or after September 30, 2017, the provider is to enter the costs of providing hospital-based partial hospitalization program (PHP) services as defined in section 1861(ff) of the Act. Therefore, this cost center is to include all costs associated with providing PHP services, as defined in the statute (for example, occupational therapy, individual and group therapy, among others). It should not include costs for non-PHP outpatient mental health services, such as costs from what providers refer to as ''Intensive Outpatient Programs.''

During current hospital-based-PHP ratesetting, costs are estimated by multiplying revenue code charges on the claim by the appropriate cost center-level CCR from the hospital cost report (80 FR 70465). Each PHP revenue code is associated with particular cost centers on the cost report (80 FR 70464). The appropriate cost center-level CCR is identified by using the OPPS Revenue-Code-to-Cost-Center crosswalk; the current crosswalk is discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228) and is available on the CMS website at: *https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS–1678-FC-2018-OPPS-FR-Revenue-Code-to-Cost-Center-Crosswalk.zip.* The Revenue-Code-to-Cost-Center crosswalk identifies the primary, secondary (if any), and tertiary (if any) cost centers that are associated with each PHP revenue code, and which are the source for the CCRs used in PHP ratesetting. As discussed in the CY 2002 OPPS interim final rule (66 FR 59885), hospital-based PHP CCRs are assessed by applying the existing OPPS ±3 standard deviation trim to hospital-based PHP CCRs within each cost center and to the overall hospital ancillary CCR. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464), we stated that, if the primary cost center has no CCR or if it fails the ±3 standard deviation trim, the ratesetting system will look for a CCR in the secondary cost center. If the secondary cost center has no CCR or if it fails the ±3 standard deviation trim, the system will move to the tertiary cost center to look for a CCR. If the tertiary cost center has no CCR or if it fails the ±3 standard deviation trim, the ratesetting system will default to using the hospital's overall ancillary CCR. If the hospital's overall ancillary CCR fails the ±3 standard deviation trim, we exclude the hospital from ratesetting. While the hierarchy requires a primary cost center to be associated with a given revenue code, it is optional for there to be secondary or tertiary cost centers.

With the new PHP cost center, the crosswalk must be updated for hospital-based PHP cost estimation to correctly match hospital-based PHP revenue code charges with the PHP cost center CCR for future ratesetting. However, because the PHP-allowable revenue codes are also used for reporting non-PHP mental health services, we could not designate the PHP cost center as the primary cost center in the existing OPPS Revenue-Code-to-Cost-Center crosswalk. Therefore, we are proposing to create a separate PHP-only Revenue-Code-to-Cost-Center crosswalk for use in CY 2019 and subsequent years, which would provide a more accurate and operationally simpler method of matching hospital-based PHP charges to the correct hospital-based PHP cost center CCR without affecting non-PHP ratesetting. We note that, because CMHCs have their own cost reports, we use each CMHC's overall CCR in estimating costs for PHP ratesetting (80 FR 70463 and 70464). As such, CMHCs do not have a crosswalk and, therefore, this proposal to create a PHP-only crosswalk does not apply to CMHCs. Therefore, we are proposing that, for CY 2019 and subsequent years, hospital-based PHPs would follow a new Revenue-Code-to-Cost-Center crosswalk that only applies to hospital-based PHPs. We are proposing that this new PHP-only Revenue-Code-to-Cost-Center crosswalk would be comprised of the existing PHP allowable revenue codes and would map each of those PHP-allowable revenue codes to the new PHP cost center Line 93.99 as the primary cost center source for the CCR. We also are proposing to designate as the new secondary cost center the cost center that is currently listed as the existing primary cost center, and to designate as the new tertiary cost center the cost center that is listed as the existing secondary cost center.

In addition, we are proposing one exception to this policy for the mapping for revenue code 0904, which is the only PHP-allowable revenue code in the existing crosswalk with a tertiary cost center source for the CCR. We are proposing that for revenue code 0904, the secondary cost center for CY 2019 and subsequent years would be the existing secondary cost center 3550 (''Psychiatric/Psychological Services''). Similarly, we are proposing that for revenue code 0904, the tertiary cost center for CY 2019 and subsequent years would be existing tertiary cost center 9000 (''Clinic''). We considered expanding the Revenue-Code-to-Cost-Center crosswalk hierarchy to add a 4th or quaternary level to the hierarchy, before the system would default to the overall hospital ancillary CCR. However, we evaluated the usage of the current hierarchy for revenue code 0904 for the CY 2017, CY 2018, and CY 2019 PHP ratesetting modelling, and found that expanding the hierarchy would not be necessary. Our analysis showed that the existing primary cost center 3580 (''Recreational Therapy'') for revenue code 0904 had not been used during any of the past 3 years.

Our current and proposed PHP-only Revenue-Code-to-Cost-Center Crosswalks are shown in Table 26 below.

TABLE 26—CURRENT AND PROPOSED PHP-ONLY REVENUE—CODE-TO-COST-CENTER CROSSWALKS

PHP allowable revenue code	Current hierarchy (applicable in CY 2018)			Proposed new PHP-only hierarchy (applicable in CY 2019 and beyond)		
	Primary cost center source for CCR	Secondary cost center source for CCR	Tertiary cost center source for CCR	Primary cost center source for CCR	Secondary cost center source for CCR	Tertiary cost center source for CCR
0430	6700 Occupational Therapy.			9399 (PHP)	6700 Occupational Therapy.	
0431	6700 Occupational Therapy.			9399 (PHP)	6700 Occupational Therapy.	
0432	6700 Occupational Therapy.			9399 (PHP)	6700 Occupational Therapy.	
0433	6700 Occupational Therapy.			9399 (PHP)	6700 Occupational Therapy.	
0434	6700 Occupational Therapy.			9399 (PHP)	6700 Occupational Therapy.	
0435	RESERVED.					
0436	RESERVED.					
0437	RESERVED.					
0438	RESERVED.					
0439	6700 Occupational Therapy.			9399 (PHP)	6700 Occupational Therapy.	
0900	3550 (Psychiatric/Psychological Services.	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/Psychological Services).	9000 (Clinic).
0904	3580 (Recreational Therapy).	3550 (Psychiatric/Psychological Services.	9000 (Clinic)	9399 (PHP)	3550 (Psychiatric/Psychological Services).	9000 (Clinic).
0914	3550 (Psychiatric/Psychological Services.	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/Psychological Services).	9000 (Clinic).
0915	3550 (Psychiatric/Psychological Services.	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/Psychological Services).	9000 (Clinic).
0916	3550 (Psychiatric/Psychological Services.	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/Psychological Services).	9000 (Clinic).
0918	3550 (Psychiatric/Psychological Services.	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/Psychological Services).	9000 (Clinic).
0942	9000 (Clinic)			9399 (PHP)	9000 (Clinic)	

4. PHP Service Utilization Updates

While we are not proposing any changes to this policy, we will continue to monitor the provision of days with only 3 services. 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 2017 claims data used for this CY 2019 proposed rule revealed some changes in the provision of individual therapy compared to CY 2016 and CY 2015 claims data as shown in the table below.

TABLE 27—PROVISION OF INDIVIDUAL THERAPY, BY PROVIDER TYPE AND CLAIMS YEAR

	Percent of days with 3 services only	Percent of days with 4 or more services
CMHCs:		
CY 2015 Claims	7.9	4.4
CY 2016 Claims	8.5	5.0
CY 2017 Claims	4.8	4.2
Hospital-based PHPs:		
CY 2015 Claims	4.0	6.2
CY 2016 Claims	4.7	5.8
CY 2017 Claims	4.1	12.2

As shown in Table 27, CMHCs have decreased the provision of individual therapy, based on the CY 2017 claims used for this proposed rule. In contrast, the CY 2017 claims data show that hospital-based PHPs have greatly increased the provision of individual therapy.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33640 and 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 4 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 APC 5853 and APC 5863 for providing 3 or more PHP services per day, we are continuing to monitor utilization of days with only 3 PHP services. Table 28 below shows the utilization findings based on the most recent claims data.

TABLE 28—PERCENTAGE OF PHP DAYS BY SERVICE UNIT FREQUENCY

	CY 2015 (%)	CY 2016 * (%)	CY 2017 * (%)	% Change ** (%)
CMHCs:				
Percent of Days with 3 services	4.7	4.8	4.8	0.0
Percent of Days with 4 services	62.9	70.3	76.3	8.5
Percent of Days with 5 or more services	32.4	24.9	18.9	−24.1
Hospital-based PHPs:				
Percent of Days with 3 services	12.4	10.95	9.3	−14.7
Percent of Days with 4 services	69.8	64.9	56.1	−13.6
Percent of Days with 5 or more services	17.8	24.1	34.6	43.6

* May not sum to 100 percent by provider type due to rounding.
** (CY 2017–CY 2016)/CY 2016.

As shown in Table 28, the CY 2017 claims data used for this proposed rule showed that PHPs maintained an appropriately low utilization of 3 service days compared to CY 2016 and CY 2015. Compared to CY 2016, hospital-based PHPs have provided fewer days with 3 services only, fewer days with 4 services only, and more days with 5 or more services. Compared to CY 2016, CMHCs have remained steady in providing an appropriately low level of 3 service days, increased their provision of days with 4 services, but have decreased their provision of days with 5 or more services.

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 3 services, particularly now that the single-tier PHP APCs 5853 and 5863 are in place for providing 3 or more services per day to CMHCs and hospital-based PHPs, respectively. The CY 2017 data are the first year of claims data to reflect the change to the single-tier PHP APCs, and the level of utilization of days with 3 services only indicates providers are not reducing care for this patient population by providing more days with only 3 services.

It is important to reiterate our expectation that days with only 3 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 3 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 3 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 3 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).

C. Outlier Policy for CMHCs

In this proposed rule, for CY 2019, we are proposing 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 below. We refer readers to section II.G. of this proposed rule for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 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). For CMHCs, we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). 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 below. As previously stated, we are proposing to continue to calculate the CMHC outlier percentage according to previously established policies, and we are not proposing any changes to our current methodology for calculating the CMHC outlier percentage for CY 2019. To calculate the CMHC outlier percentage, we follow three steps:

- *Step 1:* We multiply the OPPS outlier threshold, which is 1.0 percent, by the total estimated OPPS Medicare payments (before outliers) for the prospective year to calculate the estimated total OPPS outlier payments: (0.01 × Estimated Total OPPS Payments) = Estimated Total OPPS Outlier Payments.
- *Step 2:* We estimate CMHC outlier payments by taking each provider's estimated costs (based on their allowable charges multiplied by the provider's CCR) minus each provider's estimated CMHC outlier multiplier threshold (we refer readers to section VIII.C.3. of this proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the CMHC PHP APC payment rate. If the provider's costs exceed the threshold, we multiply that excess by 50 percent, as described in section VIII.C.3. of this proposed rule, to determine the estimated outlier payments for that provider. CMHC outlier payments are capped at 8 percent of the provider's estimated total per diem payments (including the beneficiary's copayment), as described in section VIII.C.5. of this proposed rule, so any provider's costs that exceed the CMHC outlier cap would have its payments adjusted downward. After accounting for the CMHC outlier cap, we sum all of the estimated outlier payments to determine the estimated total CMHC outlier payments.

(Each Provider's Estimated Costs − Each Provider's Estimated Multiplier Threshold) = A. If A > 0, then (A × 0.50) = Estimated CMHC Outlier Payment (before cap) = B. If B > (0.08 × Provider's Total Estimated Per Diem Payments), then cap-adjusted B = (0.08 × Provider's Total Estimated Per Diem Payments); otherwise, B = B. Sum (B or cap-adjusted B) for Each Provider = Total CMHC Outlier Payments.

- Step 3: We determine the percentage of all OPPS outlier payments that CMHCs represent by dividing the estimated CMHC outlier payments from Step 2 by the total OPPS outlier payments from Step 1: (Estimated CMHC Outlier Payments/Total OPPS Outlier Payments).

In CY 2018, we designated approximately 0.03 percent of that estimated 1.0 percent hospital outpatient outlier threshold for CMHCs (82 FR 59381), based on this methodology. In this proposed rule, we are proposing to continue to use the same methodology for CY 2019. Therefore, based on our CY 2019 payment estimates, CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2019, excluding outlier payments. We are proposing 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 above.

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). This cutoff point is sometimes called a multiplier threshold (70 FR 68550). For CY 2018, the highest CMHC PHP APC payment rate is the payment rate for CMHC PHP APC 5853. In addition, in 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))].

In this proposed rule, for CY 2019, in accordance with our existing policy, we are proposing 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 2019, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the proposed payment rate for CMHC APC 5853, the outlier payment would be calculated as [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))].

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that lead to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. The main vulnerability in the OPPS outlier payment system is the time lag between the update of the CCRs that are based on the latest settled cost report and the current charges that creates the potential for hospitals and CMHCs to set their own charges to exploit the delay in calculating new CCRs. CMS 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.

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*).

In this proposed rule, we are proposing to continue these policies for CY 2019.

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, 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. For CY 2018, we continued this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381).

In this proposed rule, we are proposing to continue this policy for CY 2019, such that the CMHC outlier payment cap would be 8 percent of the CMHC's total per diem payments.

6. Fixed-Dollar Threshold

Finally, 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).

In this proposed rule, we are proposing to continue this policy for CY 2019.

IX. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full historical discussion of our longstanding policies on how we identify procedures that are typically provided only in an inpatient setting (referred to as the inpatient only (IPO) list) and, therefore, will not be paid by Medicare under the OPPS, and on the criteria that we use to review the IPO list each year to determine whether or not any procedures should be removed from the list. The complete list of codes that describe procedures that would be paid by Medicare in CY 2019 as inpatient only procedures is included as Addendum E to this proposed rule (which is available via the internet on the CMS website).

B. Proposed Changes to the Inpatient Only (IPO) List

1. Methodology for Identifying Appropriate Changes to IPO List

In this proposed rule, for CY 2019, we are proposing to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65834)) of reviewing the current list of procedures on the IPO list to identify any procedures that may be removed from the list. We have established five criteria that are part of this methodology. As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we utilize these criteria when reviewing procedures to determine whether 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:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that we have already removed from the IPO list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

Using the above-listed criteria, for the CY 2019 OPPS, we have identified two procedures described by the following codes that we are proposing to remove from the IPO list for CY 2019: CPT code 31241 (Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery) and CPT code 01402 (Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty). We also are proposing to add to the IPO list for CY 2019 the procedure described by HCPCS code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel). The procedures that we are proposing to remove from the IPO list for CY 2019 and subsequent years, including the HCPCS codes, long descriptors, and the proposed CY 2019 payment indicators, are displayed in Table 29 of this proposed rule.

As noted earlier, we are proposing to remove the procedure described by CPT code 31241 from the IPO list for CY 2019. After reviewing the clinical characteristics of the procedure described by CPT code 31241 and consulting with stakeholders and our clinical advisors regarding this procedure, we believe that this procedure meets criterion 3—the procedure is related to codes that we have already removed from the IPO list. We are proposing that the procedure described by CPT code 31241 be assigned to C–APC 5153 (Level 3 Airway Endoscopy) with a status indicator of ''J1''. We are seeking comment on whether the public believes that the procedure described by CPT code 31241 meets criterion 3 and whether the procedure meets any of the other five criteria for removal from the IPO list.

We also are proposing to remove the procedure described by CPT code 01402 from the IPO list. After reviewing the clinical characteristics of the procedure described by CPT code 01402, we believe that this procedure meets criteria 3 and 4. This procedure is typically billed with the procedure described by CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)), which was removed from the IPO list for CY 2018 (82 FR 52526). We are seeking public comment on whether the procedure described by CPT code 01402 meets criteria 3 and 4 and whether the procedure meets any of the other five criteria for removal from the IPO list.

In addition, we are proposing to add the procedure described by HCPCS code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when

performed, single vessel) to the IPO list for CY 2019. The IPO list specifies those procedures and services for which the hospital will be paid only when the procedures are provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (76 FR 74353). After evaluating the procedure described by HCPCS code C9606 against the criteria described above, we believe that the procedure should be added to the IPO list because this procedure is performed during acute myocardial infarction and it is similar to the procedure described by CPT code 92941 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, artherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel), which was added to the IPO list for CY 2018 (82 FR 52526). We are seeking public comment on whether the procedure described by HCPCS code C9606 should be added to the IPO list for CY 2019.

2. Solicitation of Public Comments on the Potential Removal of Procedure Described by CPT Code 0266T From the IPO List

CPT code 0266T describes the 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). The procedure described by CPT code 0266T has been included on the IPO list since the procedure code became effective in CY 2011.

There are several codes that describe procedures that are similar to the procedure described by CPT code 0266T that are not on the IPO list, including: CPT code 0267T (Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)) and CPT code 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)). The device that is billed with these two procedures has been granted a Category B Investigational Device Exemption (IDE) from FDA.[32] Currently, there is limited information available to determine the typical site of service and the ability for the procedure to be safely performed in the outpatient setting. At this time, we do not believe that we have adequate information to determine whether the procedure described by CPT code 0266T should be removed from the IPO list. Therefore, we are seeking public comments on the removal of the procedure described by CPT code 0266T from the IPO list. Specifically, we are seeking public comments on whether the procedure described by CPT code 0266T meets any of the criteria to be removed from the IPO list and the APC assignment and status indicator for this code.

TABLE 29—PROPOSED CHANGES TO THE INPATIENT ONLY LIST FOR CY 2019

CY 2019 CPT code	CY 2019 long descriptor	Proposed action	Proposed CY 2019 OPPS APC assignment	Proposed CY 2019 OPPS status indicator
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	Remove from IPO list.	5153	J1
01402	Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty.	Remove from IPO list.	N/A	N
C9606	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel.	Add to IPO list	N/A	C

The complete list of codes (the IPO list) that are proposed to be placed on the IPO list for CY 2019 are included as Addendum E to this proposed rule (which is available via the internet on the CMS website).

X. Proposed Nonrecurring Policy Changes

A. Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments

The June 2017 Report to Congress[33] by the Medicare Payment Advisory Commission (MedPAC) states that, in recent years, there has been significant growth in the number of health care facilities located apart from hospitals that are devoted primarily to emergency department services. This includes both off-campus provider-based emergency departments that are eligible for payment under the OPPS and independent freestanding emergency departments not affiliated with a hospital that are not eligible for payment under the OPPS. Since 2010, we have observed a noticeable increase in the number of hospital outpatient emergency department visits furnished under the OPPS. MedPAC and other entities have expressed concern that services may be shifting to the higher acuity and higher cost emergency department setting due to: (1) Higher payment rates for services performed in off-campus provider-based emergency departments compared to similar services provided in other settings (that is, physician offices or urgent care clinics); and (2) the exemption for services provided in an emergency department included under section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–25), whereby all items and services (emergency and nonemergency) furnished in an emergency department are excepted from the payment implications of section 603, as long as the department maintains its status as an emergency department under the regulation at 42 CFR 489.24(b).

MedPAC and other entities are concerned that these payment

[32] Available at: *https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html.*

[33] Available at: *http://www/medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.*

incentives may be a key contributing factor to the growth in the number of emergency departments located off-campus from a hospital. MedPAC recommended in its March 2017 [34] and June 2017 Reports to Congress that CMS require hospitals to append a modifier to claims for all services furnished in off-campus provider-based emergency departments, so that CMS can track the growth of OPPS services provided in this setting.

In order to participate in Medicare as a hospital, the facility must meet the statutory definition of a hospital at section 1861(e) of the Act, which requires a facility to be primarily engaged in providing care and services to inpatients. In addition, 42 CFR 482.55 requires hospital emergency department services (to include off-campus provider-based emergency departments) to be fully integrated with departments and services of the hospital. The integration must be such that the hospital can immediately make available the full extent of its patient care resources to assess and furnish appropriate care for an emergency patient. Such services would include, but are not limited to, surgical services, laboratory services, and radiology services, among others. The emergency department must also be integrated with inpatient services, which means the hospital must have a sufficient number of inpatient beds and nursing units to support the volume of emergency department patients that could require inpatient services. The provision of services, equipment, personnel and resources of other hospital departments and services to emergency department patients must be within timeframes that protect the health and safety of patients and is within acceptable standards of practice.

We agree with MedPAC's recommendation and believe we need to develop data to assess the extent to which OPPS services are shifting to off-campus provider-based emergency departments. Therefore, we are announcing in this proposed rule that we are implementing through the subregulatory HCPCS modifier process a new modifier for this purpose effective beginning January 1, 2019.

We will create a HCPCS modifier (ER—Items and services furnished by a provider-based off-campus emergency department) that is to be reported with every claim line for outpatient hospital services furnished in an off-campus provider-based emergency department. The modifier would be reported on the UB–04 form (CMS Form 1450) for hospital outpatient services. Critical access hospitals (CAHs) would not be required to report this modifier.

B. Proposal and Comment Solicitation on Method To Control for Unnecessary Increases in the Volume of Outpatient Services

When the Medicare program was first implemented, payment for hospital services (inpatient and outpatient) was based on hospital-specific reasonable costs attributable to furnishing services to Medicare beneficiaries. Although payment for most Medicare hospital inpatient services became subject to a prospective payment system (PPS) under section 1886(d) of the Act in 1983, Medicare hospital outpatient services continued to be paid based on hospital-specific costs. This methodology for payment provided little incentive for hospitals to furnish such outpatient services efficiently and in a cost effective manner. At the same time, advances in medical technology and changes in practice patterns were bringing about a shift in the site of medical care from the hospital inpatient setting to the hospital outpatient setting.

In the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986) (Pub. L. 99–509), the Congress paved the way for development of a PPS for hospital outpatient services. Section 9343(g) of OBRA 1986 mandated that fiscal intermediaries require hospitals to report claims for services under the Healthcare Common Procedure Coding System (HCPCS). Section 9343(c) of OBRA 1986 extended the prohibition against unbundling of hospital services under section 1862(a)(14) of the Act to include outpatient services as well as inpatient services. The codes under the HCPCS enabled us to determine which specific procedures and services were billed, while the extension of the prohibition against unbundling ensured that all nonphysician services provided to hospital outpatients were reported on hospital bills and captured in the hospital outpatient data that were used to develop an outpatient PPS.

The brisk increase in hospital outpatient services further led to an interest in creating payment incentives to promote more efficient delivery of hospital outpatient services through a Medicare outpatient PPS. Section 9343(f) of OBRA 1986 and section 4151(b)(2) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101–508) required that we develop a proposal to replace the existing hospital outpatient payment system with a PPS and submit a report to the Congress on a new proposed system. The statutory framework for the Outpatient Prospective Payment System (OPPS) was established by section 4523 of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33), which amended section 1833 of the Act by adding subsection (t), which establishes a PPS for hospital outpatient department services, and by section 201 of the Balanced Budget Reconciliation Act (BBRA) of 1999 (Pub. L. 106–113), which amended section 1833(t) of the Act to require outlier and transitional pass-through payments. At the onset of the OPPS, there was significant concern over observed increases in the volume of outpatient services and corresponding rapidly growing beneficiary coinsurance. Accordingly, most of the focus was on finding ways to address those issues.

When section 4523 of the BBA of 1997 established the OPPS, it included specific authority under section 1833(t)(2)(F) of the Act that requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered outpatient department (OPD) services.[35] In the initial rule that proposed to implement the OPPS (63 FR 47585 through 47587), we discussed several possible approaches for controlling the volume of covered outpatient department services furnished in subsequent years, solicited comments on those options, and stated that the agency would propose an appropriate ''volume control'' mechanism for services furnished in CY 2001 and beyond after completing further analysis. For the CY 2000 OPPS, we proposed to implement a method that was similar to the one used under the Medicare Physician Fee Schedule (PFS) (known as the sustainable growth rate or ''SGR''), which would be triggered when expenditure targets, based on such factors as volume, intensity, and beneficiary enrollment, were exceeded (63 FR 47586 through 47587). However, as we discussed in the CY 2001 OPPS final rule (65 FR 18503) and the CY 2002 OPPS final rule (66 FR 59908), we delayed the implementation of the proposed volume control method as suggested by the ''President's Plan to Modernize and Strengthen Medicare for the 21st Century'' to give hospitals time to adjust to the OPPS and CMS time to continue to examine methods to control unnecessary increases in the volume of covered OPD services.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66612), we noted that we had

[34] Available at: *http://medpac.gov/docs/default-souce/reports/mar17_entirereport.pdf.*

[35] Available at: *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

significant concerns about the growth in program expenditures for hospital outpatient services, and that while the OPPS was developed in order to address some of those concerns, its implementation had not generally slowed that growth in expenditures. To address some of those concerns, we established a set of packaging policies beginning in the CY 2008 that would explicitly encourage efficiency in the provision of services in the hospital outpatient setting and potentially control future growth in the volume of OPPS services (72 FR 66612). Specifically, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), we adopted a policy to package seven categories of items and services into the payment for the primary diagnostic or therapeutic modality to which we believe these items are typically ancillary or supportive.

Similarly, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925 through 74948), we expanded our packaging policies to include more categories of packaged items and services as part of a broader initiative to make the OPPS more like a prospective payment system and less like a per service fee schedule. Packaging can encourage hospitals to furnish services efficiently while also enabling hospitals to manage their resources with the maximum flexibility, thereby encouraging long-term cost containment, which is an essential component of a prospective payment system. While most of the packaging policies established in the CY 2014 OPPS focused on ancillary services that were part of a primary procedure, we also introduced the concept of comprehensive APCs (C–APCs) (78 FR 74861 through 74910), which were implemented beginning in the CY 2015 OPPS (79 FR 66798 through 66810). Comprehensive APCs package payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level.

While we have developed many payment policies with these goals in mind, growth in program expenditures for hospital outpatient services paid under the OPPS continues. As illustrated in Table 30 below, total spending has been growing at a rate of roughly 8 percent per year under the OPPS, and total spending under the OPPS is projected to further increase by more than $5 billion from approximately $70 billion in CY 2018 through CY 2019 to nearly $75 billion. This is approximately twice the total estimated spending in CY 2008, a decade ago. We continue to be concerned with this rate of increase in program expenditures under the OPPS for several reasons. The OPPS was originally designed to manage Medicare spending growth. What was once a cost-based system was mandated by law to become a prospective payment system, which arguably should have slowed the increases in program spending. To the contrary, the OPPS has been the fastest growing sector of Medicare payments out of all payment systems under Medicare Parts A and B. Furthermore, we are concerned that the rate of growth suggests that payment incentives, rather than patient acuity or medical necessity, may be affecting site-of-service decision-making. This site-of-service selection has an impact on not only the Medicare program, but also on Medicare beneficiary out-of-pocket spending. Therefore, to the extent that there are lower-cost sites-of-service available, we believe that beneficiaries and the physicians treating them should have that choice and not be encouraged to receive or provide care in higher paid settings solely for financial reasons. For example, to provide for easier comparisons between hospital outpatient departments and ASCs, as previously discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59389), we also will make available a website that provides comparison information between the OPPS and ASC payment and copayment rates, as required under section 4011 of the 21st Century Cures Act (Pub. L. 114–255). Making this information available can help beneficiaries and their physicians determine the cost and appropriateness of receiving care at different sites of service. Although resources such as this website will help beneficiaries and physicians select a site of service, we do not believe this information alone is enough to control unnecessary volume increases. The growth in OPPS expenditures and the increase in the volume and intensity of hospital outpatient services are illustrated in Tables 30 and 31 below, respectively.

TABLE 30—GROWTH IN EXPENDITURES UNDER OPPS FROM CY 2010 THROUGH CY 2019 *

[In millions]

Calendar year (CY)	Incurred cost	Percent increase
CY 2010	$36,774	
CY 2011	39,781	8.2
CY 2012	43,154	8.5
CY 2013	46,462	7.7
CY 2014	52,425	12.8
CY 2015	56,274	7.3
CY 2016	59,896	6.4
CY 2017	64,770	8.1
CY 2018	69,642	7.5
CY 2019 (Estimated)	75,315	8.1

* Includes Medicare Part B Drug Expenditures.

TABLE 31—PERCENTAGE INCREASE IN VOLUME AND INTENSITY OF HOSPITAL OUTPATIENT SERVICES *

Calendar year (CY)	Percentage increase
CY 2011	3.7
CY 2012	5.1
CY 2013	5.5
CY 2014	8.0
CY 2015	3.5

TABLE 31—PERCENTAGE INCREASE IN VOLUME AND INTENSITY OF HOSPITAL OUTPATIENT SERVICES *—Continued

Calendar year (CY)	Percentage increase
CY 2016	6.5
CY 2017	5.8
CY 2018	5.4
CY 2019 (Estimated)	5.3

* Includes Medicare Part B Drug Expenditures.

As noted in its March 2018 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) found that, from 2011 through 2016, combined program spending and beneficiary cost-sharing on services covered under the OPPS increased by 51 percent, from $39.8 billion to $60.0 billion, an average of 8.6 percent per year.[36] In its 2018 report, MedPAC also noted that ''A large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the unnecessary shift of services from (lower cost) physician offices to (higher cost) HOPDs''.[37] We would consider these shifts in the sites of service unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting.

As noted in MedPAC's March 2017 Report to Congress, ''from 2014 to 2015, the use of outpatient services increased by 2.2 percent per Medicare FFS beneficiary. Over the decade ending in 2015, volume per beneficiary grew by 47 percent. One-third of the growth in outpatient volume from 2014 to 2015 was due to an increase in the number of evaluation and management (E&M) visits billed as outpatient services. This growth in part reflects hospitals purchasing freestanding physician practices and converting the billing from the Physician Fee Schedule to higher paying hospital outpatient department (HOPD) visits. The conversions shift market share from freestanding physician offices to HOPDs. From 2012 to 2015, hospital-based E&M visits per beneficiary grew by 22 percent, compared with a 1-percent decline in physician office-based visits.'' [38]

MedPAC has documented how the billing for these services has shifted from physician offices to higher-cost outpatient sites of care for several years. At the same time, MedPAC has repeated its recommendation that the difference in payment rates between hospital outpatient departments and physician offices should be reduced or eliminated. It specifically recommended in its 2012 Report to Congress that the payment rates for E&M visits provided in hospital outpatient departments be reduced so that total payment rates for these visits are the same, whether the service is provided in a hospital outpatient department or a physician office. In its 2014 Report to Congress, MedPAC recommended that Congress direct the Secretary to reduce or eliminate differences in payment rates between hospital outpatient departments and physician offices for selected APCs. Both of these recommendations were reiterated in MedPAC's March 2017 Report to Congress.

As previously noted, in addition to the concern that the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, we also are 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 freestanding physician offices. For example, MedPAC estimates that ''the Medicare program spent $1.0 billion more in 2009, $1.3 billion more in 2014, and $1.6 billion more in 2015 than it would have if payment rates for E&M office visits in HOPDs were the same as freestanding office rates. Relatedly, beneficiaries' cost-sharing was $260 million higher in 2009, $325 million higher in 2014, and $400 million higher in 2015 than it would have been because of the higher rates paid in HOPD settings.'' [39] We believe that this volume growth and the resulting increase in beneficiary cost-sharing is unnecessary because it appears to have been incentivized by the difference in payment for each setting rather than patient acuity. If there was not a difference in payment rates, we believe that we would not have seen the increase in beneficiaries' cost-sharing and the shift in site-of-service.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41013), we stated that we continued to seek a better understanding of how the growing trend toward hospital acquisition of physicians' offices and subsequent treatment of those locations as off-campus provider-based departments (PBDs) of hospitals affects payments under the PFS and the OPPS, as well as beneficiary cost-sharing obligations. We noted that MedPAC continued to question the appropriateness of increased Medicare payment and beneficiary cost-sharing when physicians' offices become hospital outpatient departments and that MedPAC recommended that Medicare pay selected hospital outpatient services at PFS rates (MedPAC March 2012 and June 2013 Reports to Congress).

To understand how this trend was affecting Medicare, we explained that we needed information on the extent to which this shift was occurring. To that end, during the CY 2014 OPPS/ASC rulemaking cycle, we sought public comment regarding the best method for collecting information and data that would allow us to analyze the frequency, type, and payment for physicians' services and hospital outpatient services furnished in off-campus PBDs of hospitals (78 FR 75061 through 75062 and 78 FR 74427 through 74428). Based on our analysis of the public comments we received, we believed that the most efficient and equitable means of gathering this important information across two different payment systems would be to create a HCPCS modifier to be reported with every code for physicians' services and hospital outpatient services furnished in an off-campus PBD of a hospital on both the CMS–1500 claim form for physicians' services and the UB–04 form (CMS Form 1450 and OMB Control Number 0938–0997) for hospital outpatient services. We noted that a main provider may treat an off-campus facility as provider-based if certain requirements at 42 CFR 413.65 are satisfied, and we define a ''campus'' at 42 CFR 413.65(a)(2) to be the physical

[36] Available at: *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0.*

[37] *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0.*

[38] Available at: *http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch3.pdf?sfvrsn=0.*

[39] Ibid.

area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

In 2015, the Congress took steps to address the higher Medicare payments for services furnished by certain off-campus provider-based departments (PBDs) that may be associated with hospital acquisition of physicians' offices through section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015. In the CY 2017 OPPS/ASC proposed rule, we discussed the provision of section 603 of the Bipartisan Budget Act of 2015, which amended section 1833(t) of the Act. For the full discussion of our initial implementation of this provision, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (79720 through 79729).

Section 603 of the Bipartisan Budget Act of 2015 (Section 603) amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met. We note that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65.

Section 603 amended section 1833(t)(1)(B) of the Act by adding a new clause (v), which excludes from the definition of ''covered OPD services'' applicable items and services (defined in paragraph (21)(A) of the section) that are furnished on or after January 1, 2017, by an off-campus PBD, as defined in paragraph (21)(B) of the section. Section 603 also added a new paragraph (21) to section 1833(t) of the Act, which defines the terms ''applicable items and services'' and ''off-campus outpatient department of a provider,'' requires the Secretary to make payments for such applicable items and services furnished by an off-campus PBD under an applicable payment system (other than the OPPS), provides that hospitals shall report on information as needed for implementation of the provision, and establishes a limitation on administrative and judicial review of the Secretary's determinations of applicable items and services, applicable payment system, whether a department meets the definition of an off-campus outpatient department of a provider, and information hospitals are required to report. In defining the term ''off-campus outpatient department of a provider,'' section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider (as defined at 42 CFR 413.65(a)(2) as that regulation was in effect on November 2, 2015, the date of enactment of Pub. L. 114–74) that is not located on the campus of such provider, or within the distance from a remote location of a hospital facility. Section 1833(t)(21)(B)(ii) of the Act excepts from the definition of ''off-campus outpatient department of a provider,'' for purposes of paragraphs (1)(B)(v) and (21)(B) of the section, an off-campus PBD that was billing under section 1833(t) of the Act with respect to covered OPD services furnished prior to the date of enactment of the Bipartisan Budget Act of 2015, that is, November 2, 2015. We note that the definition of ''applicable items and services'' specifically excludes items and services furnished by a dedicated emergency department as defined at 42 CFR 489.24(b) and the definition of ''off-campus outpatient department of a provider'' does not include PBDs located on the campus of a hospital or within the distance (described in the definition of campus at § 413.65(a)(2)) from a remote location of a hospital facility; the items and services furnished by these excepted off-campus PBDs on or after January 1, 2017 continued to be paid under the OPPS.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79720), we established a number of policies to implement section 603 of the Bipartisan Budget Act of 2015. Broadly, we: (1) Defined applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and services will instead be made under the applicable payment system designated under section 1833(t)(21)(C) of the Act; (2) defined off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) established policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. To do so, we finalized policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the OPPS; established the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBDs and for the items and services furnished by such excepted off-campus PBDs); and described the applicable payment system for nonexcepted items and services (generally, the PFS).

As part of developing policies to implement the section 603 amendments to section 1833(t) of the Act, we solicited public comments on information collection requirements for implementing this provision in accordance with section 1833(t)(21)(D) of the Act (81 FR 45686; 81 FR 79709 through 79710). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79719 and 79725), we created modifier ''PN'' to collect data for purposes of implementing section 603 but also to trigger payment under the newly adopted PFS rates for nonexcepted items and services.

While the changes required by the section 603 amendments to section 1833(t) of the Act address some of the concerns related to shifts in settings of care and overutilization in the hospital outpatient setting, the majority of hospital off-campus departments continue to receive full OPPS payment (including off-campus emergency departments and excepted off-campus departments of a hospital), which is often higher than the payment that would have been made if a similar service had been furnished in the physician office setting. Therefore, the current site-based payment creates an incentive for the misallocation of capital toward higher cost sites of care that could result in higher costs for providers, taxpayers, beneficiaries, and the Medicare program. Likewise, the differences in payment rates have unnecessarily shifted services away from the physician's office to the higher paying hospital outpatient department. We believe that the higher payment that is made under the OPPS, as compared to payment under the PFS, is likely to be incentivizing providers to furnish care in the hospital outpatient setting rather than the physician office setting. In 2012, Medicare was paying approximately 80 percent more for a 15-minute office visit in a hospital outpatient department than in a

freestanding physician office.[40] Under current policy, Medicare still pays more using the G-code for a clinic visit than it would under the PFS. In the CY 2017 OPPS/ASC interim final rule, we noted that the most frequently billed service with the ''PO'' modifier was described by HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), which is paid under APC 5012 (Clinic Visits and Related Services); the total number of CY 2017 claim lines for this service was approximately 10.7 million as of May 2017. When services are furnished in the hospital outpatient setting, an additional payment for the professional services is generally made under the PFS using the ''facility'' rate. For example, in CY 2017, the OPPS payment rate for APC 5012, which is the APC to which the outpatient clinic visit code was assigned, was $106.56. The CY 2017 PFS ''facility'' payment rate for a Level 3 visit, a service that commonly corresponds to the OPPS clinic visit, was $77.88 for a new patient and $51.68 for an established patient.

However, when services are furnished in the physician office setting, only one payment is made—typically, the ''nonfacility'' rate under the PFS. The CY 2017 PFS nonfacility payment rates for a Level 3 visit, a commonly billed service under the PFS, was $109.46 for a new patient and $73.93 for an established patient. Therefore, the total Medicare Part B payment rate (for the hospital and professional service) for a new patient when the service was furnished in the hospital outpatient setting was $184.44 ($106.56 + $77.88) compared to $109.46 in the physician office setting, or for an established patient, $158.24 ($106.56 + $51.68) in the hospital outpatient setting compared to $73.93 in the physician office setting. Under these examples, the payment rate was approximately $75 to $85 more for the same service when furnished in the hospital outpatient setting instead of the physician office setting, 20 percent of which was the responsibility of the beneficiary.

We have heard that many off-campus departments converted from physicians' offices to hospital outpatient departments, without a change in either the physical location or a change in the acuity of the patients seen. To the extent that similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another. We believe the difference in payment for these services is a significant factor in the shift in services from the physician's office to the hospital outpatient department, thus unnecessarily increasing hospital outpatient department volume and Medicare program and beneficiary expenditures.

We consider the shift of services from the physician office to the hospital outpatient department unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting due to payment incentives. We believe the increase in the volume of clinic visits is due to the payment incentive that exists to provide this service in the higher cost setting. Because these services could likely be safely provided in a lower cost setting, we believe that the growth in clinic visits paid under the OPPS is unnecessary. Further, we believe that capping the OPPS payment at the PFS-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed. In particular, we believe this method of capping payment will control unnecessary volume increases as manifested both in terms of numbers of covered outpatient department services furnished and costs of those services.

Therefore, given the unnecessary increases in the volume of clinic visits in hospital outpatient departments, for the CY 2019 OPPS, we are proposing to use our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines). Off-campus PBDs that are not excepted from section 603 (departments that bill the modifier ''PN'') already receive a PFS-equivalent payment rate for the clinic visit. In CY 2019, for an individual Medicare beneficiary, the standard unadjusted Medicare OPPS proposed payment for the clinic visit is approximately $116, with approximately $23 being the average copayment. The proposed PFS equivalent rate for Medicare payment for a clinic visit would be approximately $46 and the copayment would be approximately $9. This would save beneficiaries an average of $14 per visit. Under this proposal, an excepted off-campus PBD would continue to bill HCPCS code G0463 with the ''PO'' modifier in CY 2019, but the payment rate for services described by HCPCS code G0463 when billed with modifier ''PO'' would now be equivalent to the payment rate for services described by HCPCS code G0463 when billed with modifier ''PN''. For a discussion of the PFS relativity adjuster that will now also be used to pay for all outpatient clinic visits provided at all off-campus PBDs, we refer readers to the CY 2018 PFS final rule (82 FR 53023 through 53024), as well as the CY 2019 PFS proposed rule.

In addition, we are proposing to implement this proposed method in a non-budget neutral manner. Specifically, while section 1833(t)(9)(B) of the Act generally requires that changes made under the OPPS be made in a budget neutral manner, we note that this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act. In particular, section 1833(t)(9)(A) of the Act, titled ''Periodic review,'' provides, in part, that the Secretary must annually review and revise the groups, the relative payment weights, and *the wage and other adjustments* described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors (emphasis added).'' Section 1833(t)(9)(B) of the Act, titled ''Budget neutrality adjustment'' provides that if ''the Secretary makes *adjustments* under subparagraph (A), then the *adjustments* for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made (emphasis added).'' However, section 1833(t)(2)(F) of the Act is not an ''adjustment'' under paragraph (2). Unlike the wage adjustment under section 1833(t)(2)(D) of the Act and the outlier, transitional pass-through, and equitable adjustments under section 1833(t)(2)(E) of the Act, section 1833(t)(2)(F) of the Act refers to a ''method'' for controlling unnecessary increases in the volume of covered OPD services, not an adjustment. Likewise, sections 1833(t)(2)(D) and (E) of the Act also explicitly require the adjustments authorized by those paragraphs to be budget neutral, while the volume control method authority at section 1833(t)(2)(F) of the Act does not. Therefore, the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments

[40] Available at: *http://www.medpac.gov/docs/default-source/reports/march-2012-report-to-the-congress-medicare-payment-policy.pdf.*

under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act. Moreover, section 1833(t)(9)(C) of the Act specifies that if the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year. We interpret this provision to mean that the Secretary will have implemented a volume control method under section 1833(t)(2)(F) of the Act in a nonbudget neutral manner in the year in which the method is implemented, and that the Secretary may then make further adjustments to the conversion factor in a subsequent year to account for volume increases that are beyond the amounts estimated by the Secretary under the volume control method.

We believe implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the movement of the volume within the OPPS system in the aggregate, a concern similar to the one we discussed in the CY 2008 OPPS final rule with comment period (72 FR 66613). This estimated payment impact is displayed in Column 5 of Table 42—Estimated Impact of the Proposed Changes for the Hospital Outpatient Prospective Payment System in this proposed rule. An estimate that includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2019 President's budget approximates the estimated savings at $760 million, with $610 million of the savings accruing to Medicare, and $150 million saved by Medicare beneficiaries in the form of reduced copayments. In order to effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply reallocate expenditures that are unnecessary within the OPPS, we believe that this method must be adopted in a non-budget neutral manner. The impact associated with this proposal is further described in section XXI. of this proposed rule.

While we are developing a method to systematically control for unnecessary increases in the volume of other hospital outpatient department services, we continue to recognize the importance of not impeding development or beneficiary access to new innovations. We are soliciting public comments on how to maintain access to new innovations while controlling for unnecessary increases in the volume of covered hospital OPD services.

In addition, we are soliciting public comments on how to expand the application of the Secretary's statutory authority under section 1833(t)(2)(F) of the Act to additional items and services paid under the OPPS that may represent unnecessary increases in OPD utilization. Therefore, we are seeking public comment on the following:

- How might Medicare define the terms ''unnecessary'' and ''increase'' for services (other than the clinic visit) that can be performed in multiple settings of care? Should the method to control for unnecessary increases in the volume of covered OPD services include consideration of factors such as enrollment, severity of illness, and patient demographics?
- While we are proposing to pay the PFS payment rate for clinic visits beginning in CY 2019, we also are interested in other methods to control for unnecessary increases in the volume of outpatient services. Prior authorization is a requirement that a health care provider obtain approval from the insurer prior to providing a given service in order for the insurer to cover the service. Private health insurance plans often require prior authorization for certain services. Should prior authorization be considered as a method for controlling overutilization of services?
- For what reasons might it ever be appropriate to pay a higher OPPS rate for services that can be performed in lower cost settings?
- Several private health plans use utilization management as a cost-containment strategy. How might Medicare use the authority at section 1833(t)(2)(F) of the Act to implement an evidence-based, clinical support process to assist physicians in evaluating the use of medical services based on medical necessity, appropriateness, and efficiency?

Could utilization management help reduce the overuse of inappropriate or unnecessary services?

- How should we account for providers that serve Medicare beneficiaries in provider shortage areas, which may include certain rural areas? With respect to rural providers, should there be exceptions from this policy, such as for providers who are at risk of hospital closure or that are sole community hospitals?
- What impact on beneficiaries and the health care market would such a method to control for unnecessary increases in the volume of covered OPD services have?
- What exceptions, if any, should be made if additional proposals to control for unnecessary increases in the volume of outpatient services are made?

C. Proposal To Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

1. Historical Perspective

a. Section 603 of the Bipartisan Budget Act of 2015

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699), we discussed implementation of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and will instead be paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met. We indicated that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. Accordingly, we refer to an ''off-campus outpatient department of a provider,'' which is the term used in section 603 of the Bipartisan Budget Act of 2015, as an ''off-campus outpatient provider-based department'' or an ''off-campus PBD.'' For a detailed discussion of the legislative history and statutory authority related to payments under section 603 of the Bipartisan Budget Act of 2015, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (81 FR 79720 through 79729).

b. Applicable Payment System

To implement the amendments made by section 603 of Public Law 114–74, we issued an interim final rule with comment period (81 FR 79720) which accompanied the CY 2017 OPPS/ASC final rule with comment period to establish the PFS as the ''applicable payment system'' that applies in most

cases, and we established payment rates under the PFS for those nonexcepted items and services furnished by nonexcepted off-campus PBDs. As we discussed in the CY 2017 OPPS/ASC interim final rule with comment period (81 FR 79718) and reiterated in the CY 2018 PFS final rule with comment period (82 FR 53028), payment for Medicare Part B drugs that would be separately payable under the OPPS (assigned a status indicator of ''K'') but are not payable under the OPPS because they are furnished by nonexcepted off-campus PBDs is made in accordance with section 1847A of the Act (generally, at a rate of ASP plus 6 percent), consistent with Part B drug payment policy for items or services furnished in the physician office (nonfacility) setting. We did not propose or make an adjustment to payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018, but indicated we may consider doing so through future notice-and-comment rulemaking.

In the interim final rule with comment period that accompanied the CY 2017 OPPS/ASC final rule with comment period, we established payment policies under the PFS for nonexcepted items and services furnished by a nonexcepted off-campus PBD on or after January 1, 2017. In accordance with sections 1848(b) and (c) of the Act, PFS payment is based on the relative value of the resources involved in furnishing particular services (81 FR 79790). Resource-based relative values are established for each item and service (described by a HCPCS code) based on the work (time and intensity), practice expense (such as clinical staff, supplies and equipment, office rent, and overhead), and malpractice expense required to furnish the typical case of the service. Because Medicare makes separate payment under institutional payment systems (such as the OPPS) for the facility costs associated with many of the same services that are valued under the PFS, we establish two different PFS payment rates for many of these services—one that applies when the service is furnished in a location where a facility bills and is paid for the service under a Medicare payment system other than the PFS (the facility rate), and another that applies when the billing practitioner or supplier furnishes and bills for the entire service (the nonfacility rate). Consistent with the long-established policy under the PFS to make payment to the billing practitioner at the facility rate when Medicare makes a corresponding payment to the facility (under the OPPS, for instance) for the same service, physicians and nonphysician practitioners furnishing services in nonexcepted PBDs continue to report their services on a professional claim form and are paid for their services at the PFS facility rate.

Similarly, there are many (mostly diagnostic) services paid under the PFS that have two distinct portions of the service: A technical component (TC) and a professional component (PC). These components can be furnished independently in time or by different suppliers, or they may be furnished and billed together as a ''global'' service (82 FR 52981). Payment for these services can also be made under a combination of payment systems; for example, under the PFS for the professional component and the OPPS for the facility portion. For instance, for a diagnostic CT scan, the technical component relates to the portion of the service during which the image is captured and might be furnished in an office or HOPD setting, and the professional component relates to the interpretation and report by a radiologist.

In the CY 2017 interim final rule with comment period, we stated that we continue to believe that it is operationally infeasible for nonexcepted off-campus PBDs to bill directly under the PFS for the subset of PFS services for which there is a separately valued technical component (81 FR 79721). In addition, we explained that we believe hospitals that furnish nonexcepted items and services are likely to furnish a broader range of services than other provider or supplier types for which there is a separately valued technical component under the PFS. We stated that we therefore believe it is necessary to establish a new set of payment rates under the PFS that reflect the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS that is specific to one site of service (the off-campus PBD of a hospital) with the packaging (bundling) rules that are significantly different from current PFS rules (81 FR 79721).

In continuing to implement the requirements of sections 1833(t)(1)(B) and (t)(21) of the Act, we recognize that there is no established mechanism for allowing hospitals to report and bill under the PFS for the portion of resources incurred in furnishing the full range of nonexcepted items and services. This is because hospitals with nonexcepted off-campus PBDs that furnish nonexcepted items and services generally furnish a broader range of services than other provider or supplier types for which there is a separately valued technical component under the PFS. As such, we established a new set of payment rates under the PFS that reflected the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS specific to the nonexcepted off-campus PBDs of a hospital. Specifically, we established a PFS relativity adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD in order to calculate payment rates under the PFS. The PFS relativity adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the nonexcepted items and services furnished in nonexcepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. The current PFS relativity adjuster is set at 40 percent of the amount that would have been paid under the OPPS (82 FR 53028). These PFS rates incorporate the same packaging rules that are unique to the hospital outpatient setting under the OPPS, including the packaging of drugs that are unconditionally packaged under the OPPS. This includes packaging certain drugs and biologicals that would ordinarily be separately payable under the PFS when furnished in the physician office setting.

Nonexcepted off-campus PBDs continue to bill for nonexcepted items and services on the institutional claim utilizing a new claim line (modifier ''PN'') to indicate that an item or service is a nonexcepted item or service. For a detailed discussion of the current PFS relativity adjuster related to payments under section 603 of Public Law 114–74, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 52356 through 52637), the CY 2018 PFS final rule with comment period (82 FR 53019 through 53025), and the CY 2019 PFS proposed rule.

c. Section 340B of the Public Health Service Act

The 340B Program, which was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992, is administered by the Health Resources and Services Administration (HRSA) within HHS. The 340B Program allows participating hospitals and other health care providers to purchase certain ''covered outpatient drugs'' (as defined under section 1927(k) of the Act and interpreted by HRSA through various

guidance documents) at discounted prices from drug manufacturers.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33632 through 33635), we proposed changes to the payment methodology under the OPPS for separately payable drugs and biologicals acquired under the 340B Program. We stated that these changes would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. Such changes would allow Medicare beneficiaries (and the Medicare program) to pay less when hospitals participating in the 340B Program furnish drugs that are purchased under the 340B Program to Medicare beneficiaries. Subsequently, in the CY 2018 OPPS/ASC final rule with comment period, we finalized our proposal that separately payable, covered outpatient drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program will be paid ASP minus 22.5 percent, rather than ASP plus 6 percent, when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. CAHs are not subject to this 340B policy change because they are paid under section 1834(g) of the Act. Rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals are excepted from the alternative payment methodology for 340B-acquired drugs and biologicals. 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 to vaccines, which are excluded from the 340B Program.

2. Proposal To Pay an Adjusted Amount for 340B-Acquired Drugs and Biologicals Furnished in Nonexcepted Off-Campus PBDs in CY 2019 and Subsequent Years

As noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79716), prior to the implementation of the payment adjustment under the OPPS for drugs and biologicals acquired under the 340B program, separately payable drugs and biologicals were paid the same rate at both excepted and nonexcepted off-campus departments of a hospital. The policy we finalized in the CY 2018 OPPS/ASC final rule with comment period, in which we adjust the payment rate for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from ASP plus 6 percent to ASP minus 22.5 percent, applies to separately payable drugs and biologicals paid under the OPPS (81 FR 59353 through 59369). Under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, however, nonexcepted items and services furnished by nonexcepted off-campus PBDs are no longer covered outpatient department services and, therefore, are not payable under the OPPS. This means that nonexcepted off-campus PBDs are not subject to the payment changes finalized in the CY 2018 OPPS/ASC final rule with comment period that apply to hospitals and PBDs paid under the OPPS. Because the separately payable drugs and biologicals acquired under the 340B Program and furnished in nonexcepted off campus PBDs are no longer covered outpatient department services, these drugs and biologicals are currently paid in the same way Medicare Part B drugs are paid in the physician office and other nonhospital settings—typically at ASP plus 6 percent—regardless of whether they are acquired under the 340B Program.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59367 through 59368), we discussed public comments that we received that noted that the alternative payment methodology for 340B-acquired drugs and biologicals did not apply to nonexcepted off-campus PBDs of a hospital and could result in behavioral changes that may undermine CMS' policy goals of reducing beneficiary cost-sharing liability and undercut the goals of section 603 of the Public Law 114–74. Commenters recommended that, if CMS adopted a final policy to establish an alternative payment methodology for 340B drugs in CY 2018, CMS should also apply the same adjustment to payment rates for drugs furnished in nonexcepted off-campus PBDs of a hospital if such drugs were acquired under the 340B Program (82 FR 59367). While we did not propose to adjust payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018, we indicated that we would consider adopting such a policy in future rulemaking.

The current PFS payment policies for nonexcepted items and services incorporate a significant number of payment policies and adjustments made under the OPPS (81 FR 79726; 82 FR 53024 through 53025). In establishing these policies in prior rulemaking, we pointed out that the adoption of these policies was necessary in order to maintain the integrity of the PFS relativity adjuster because it adjusts payment rates developed under the OPPS (81 FR 79726). For example, it is necessary to incorporate OPPS packaging rules into the site-specific PFS rate because the PFS relativity adjuster is applied to OPPS rates that were developed based on those packaging rules. In addition, many of the OPPS policies and adjustments are replicated under the nonexcepted off-campus PBD site-specific PFS rates because they are specifically applicable to hospitals as a setting of care. For example, we adopted the geographic adjustments used for hospitals instead of the adjustments developed for the PFS localities, which reflect cost differences calculated for professionals and suppliers rather than hospitals (81 FR 79726).

We agree with commenters that the difference in the payment amounts for 340B-acquired drugs furnished by hospital outpatient departments—excepted off-campus PBDs versus nonexcepted off-campus PBDs—creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to nonexcepted off-campus PBDs to receive a higher payment amount for these drugs, thereby undermining our goals of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality through the section 603 amendments to section 1833(t) of the Act. Therefore, for CY 2019, we are proposing changes to the Medicare Part B drug payment methodology for drugs and biologicals furnished and billed by nonexcepted off-campus departments of a hospital that were acquired under the 340B Program. Specifically, for CY 2019 and subsequent years, we are proposing to pay under the PFS the adjusted payment amount of ASP minus 22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program when they are furnished by nonexcepted off-campus PBDs of a hospital. Furthermore, in this CY 2019 OPPS/ASC proposed rule, we are proposing to except rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from this payment adjustment. We believe that our proposed payment policy would better reflect the resources and acquisition costs that nonexcepted off-campus PBDs incur for these drugs and biologicals.

We note that, ordinarily, Medicare pays for drugs and biologicals furnished in the physician's office setting at ASP plus 6 percent. This is because section 1842(o)(1)(A) of the Act provides that if a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be

made under Medicare Part B and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount for the drug or biological is equal to the following: The amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13) of the Act, as the case may be for the drug or biological.

Generally, in the hospital outpatient department setting, low-cost drugs and biologicals are packaged into the payment for other services billed under the OPPS. Separately payable drugs (1) have pass-through payment status, (2) have a cost per day exceeding a threshold, or (3) are not policy-packaged or packaged in a C–APC. As described in section V.A.1. of this proposed rule, section 1847A of the Act establishes the 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 WAC, and the AWP (82 FR 59337). As noted in section V.B.2.b. of this proposed rule, since CY 2013, our policy has been to pay for separately payable drugs and biologicals at ASP plus 6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default) (82 FR 59350). Consequently, in the case of services furnished in a hospital outpatient department, Medicare pays ASP plus 6 percent for separately payable Part B drugs and biologicals unless those drugs or biologicals are acquired under the 340B Program, in which case they are paid at ASP minus 22.5 percent. For a detailed discussion of our current OPPS drug payment policies, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59343 through 59371).

As a general matter, in the nonexcepted off-campus PBD setting, we pay hospitals under the PFS for all drugs and biologicals that are packaged under the OPPS based on a percentage of the OPPS payment rate, which is determined using the PFS relativity adjuster. Because OPPS packaging rules apply to the PFS payments to nonexcepted off-campus PBDs, the PFS payment for some nonexcepted items and services that are packaged includes payment for some drugs and biologicals that would be separately billable under the PFS if a similar service had been furnished in the office-based setting. As we noted in the CY 2017 final rule with comment period, in analyzing the term ''applicable payment system,'' we considered whether and how the requirements for payment could be met under alternative payment systems in order to pay for nonexcepted items and services, and considered several payment systems under which payment is made for similar items and services (81 FR 79712). Because the PFS relativity adjuster that is applied to calculate payment to hospitals for nonexcepted items and services furnished in nonexcepted off-campus PBDs is based on a percentage (40 percent) of the amount determined under the OPPS for a particular item or service, and the OPPS is a prospective payment system, we believe that items and services furnished by nonexcepted off-campus PBDs paid under the PFS are payable on a prospective payment basis. Therefore, we believe we have flexibility to pay for separately-payable drugs and biologicals furnished in nonexcepted off-campus PBDs at an amount other than the amount dictated by sections 1842(o)(1)(C) and 1847A of the Act.

As we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59354), several recent studies and reports on Medicare Part B payments for 340B-acquired drugs highlight a difference in Medicare Part B drug spending between 340B hospitals and non-340B hospitals as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost. When we initially developed the policy for nonexcepted off-campus PBDs, most separately payable drugs and biologicals were paid, both in the OPPS and in other Part B settings, such as physician offices, through similar methodologies under section 1847A/1842(o) of the Act. For drugs and biologicals that are packaged in the OPPS, we adopted similar packaging payment policies for purposes of making the site-specific payment under the PFS for nonexcepted off-campus PBDs. Because hospitals can, in some cases, acquire drugs and biologicals under the 340B Program for use in nonexcepted off-campus PBDs, we believe that not adjusting payment exclusively for these departments would present a significant incongruity between the payment amounts for these drugs depending upon where (for example, excepted or nonexcepted PBD) they are furnished. This incongruity would distort the relative accuracy of the resource-based payment amounts under the site-specific PFS rates and could result in significant perverse incentives for hospitals to acquire drugs and biologicals under the 340B Program and avoid Medicare payment adjustments that account for the discount by providing these drugs to patients predominantly in nonexcepted off-campus PBDs. In light of the significant drug payment differences between excepted and nonexcepted off-campus PBDs, in combination with the potential eligibility for discounts, which result in reduced costs under the 340B Program for both kinds of departments, our current payment policy could undermine the validity of the use of the OPPS payment structure in nonexcepted off campus PBDs. In order to avoid such perverse incentives and the resulting distortions, we are proposing, pursuant to our authority at section 1833(t)(21)(C) of the Act to identify the PFS as the ''applicable payment system'' for 340B-acquired drugs and biologicals and, accordingly, to pay under the PFS instead of under section 1847A/1842(o) of the Act an amount equal to ASP minus 22.5 percent for drugs and biologicals acquired under the 340B Program that are furnished by nonexcepted off-campus PBDs. We believe this proposed change in policy would eliminate the significant incongruity between the payment amounts for these drugs, depending upon whether they are furnished by excepted off-campus PBDs or nonexcepted off-campus PBDs, which we believe is an unnecessary difference in payment where the 340B Program does not differentiate between PBDs paid under the OPPS and PBDs paid under the PFS using the PFS relativity adjuster.

D. Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider

1. Background

a. Section 603 of the Bipartisan Budget Act of 2015

We refer readers to section X.C.1.a. of this proposed rule for a discussion of the provisions of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), as implemented in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719). As discussed in the CY 2017 OPPS/ASC final rule with comment period, we adopted the PFS as the applicable payment system for nonexcepted items and services furnished and billed by off-campus PBDs. In addition, we indicated that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. For a detailed discussion of the history and statutory authority related to payments under section 603 of Public Law 114–74, we refer readers to the CY 2017 OPPS/ASC final rule with

comment period (81 FR 79699 through 79719) and the interim final rule with comment period (81 FR 79720 through 79729).

b. Expansion of Services at an Off-Campus PBD Excepted Under Section 1833(t)(21)(B)(ii) of the Act

In the CY 2017 OPPS/ASC proposed rule (81 FR 45685), we noted that we had received questions from some hospitals regarding whether an excepted off-campus PBD could expand the number or type of services the department furnishes and maintain excepted status for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act. We indicated that we were concerned that if excepted off-campus PBDs could expand the types of services provided at the excepted off-campus PBDs and also be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and expand services furnished by existing excepted off-campus PBDs as a result (81 FR 45685). This could result in newly purchased physician practices furnishing services that are paid at OPPS rates, which we believed these amendments to section 1833(t) of the Act were intended to address (81 FR 45685). We believed section 1833(t)(21)(B)(ii) of the Act excepted off-campus PBDs and the items and services that are furnished by such excepted off-campus PBDs for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act as they were being furnished on the date of enactment of section 603 of the Bipartisan Budget Act of 2015, as guided by our regulatory definition at § 413.65(a)(2) of a department of a provider (81 FR 45685). Thus, in the CY 2017 OPPS/ASC proposed rule, we proposed that if an excepted off-campus PBD furnished items and services from a clinical family of services (clinical families of services were identified in Table 21 of the CY 2017 proposed rule (81 FR 45685 through 45686)) that it did not furnish prior to November 2, 2015, and thus did not also bill for, services from these new expanded clinical families of services would not be covered OPD services, and instead would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act as described in section X.A.1.c. of the proposed rule. In addition, in that rule, we proposed not to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish (81 FR 45685).

The majority of commenters, including several hospital associations, regional health systems, and medical equipment manufacturers opposed the proposals primarily because they believed: (1) CMS exceeded its statutory authority, as the statutory language included in section 603 does not address changes in service mix by excepted off-campus PBDs; (2) CMS' proposal does not account for evolving technologies and would hinder beneficiary access to those innovative technologies; (3) the term ''clinical families of service'' appeared to be a new term created by CMS for the purpose of implementing section 603 and it would be difficult for CMS and hospitals to manage changes in the composition of APCs and HCPCS code changes contained in those APCs; and (4) the proposal created significant operational challenges and administrative burden for both CMS and hospitals because commenters believed it was unnecessarily complex (81 FR 79706 through 79707).

In addition, MedPAC explained in its comment letter that the proposal was unnecessarily complex and instead suggested that CMS adopt a different approach by determining how much the Medicare program had paid an excepted off-campus PBD for services billed under the OPPS during a 12-month baseline period that preceded November 2, 2015 and to cap the OPPS payment made to the off-campus PBD at the amount paid during the baseline period.[41] Some commenters, including physician group stakeholders, supported CMS' intent to monitor service line expansion and changes in billing patterns by excepted off-campus PBDs. These commenters urged CMS to work to operationalize a method that would preclude an excepted off-campus PBD from expanding the excepted services for which it is paid under the OPPS into wholly new clinical areas, as they believed an excepted, off-campus PBD should only be able to bill under the OPPS for those items and services for which it submitted claims prior to November 2, 2015 (82 FR 33647).

In response to public comments, we did not finalize our proposal to limit the expansion of excepted services at excepted off-campus PBDs. However, we stated our intent to monitor this issue and expressed interest in additional feedback to help us consider whether excepted off-campus PBDs that expand the types of services offered after November 2, 2015 should be paid for furnishing those items and services under the applicable payment system (that is, the PFS) instead of the OPPS. Specifically, we requested comments on how either a limitation on volume or a limitation on lines of service would work in practice (81 FR 79707).

In addition, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79707), we sought public comments on how either a limitation on volume of services, or a limitation on lines of service, as we laid out in the CY 2017 OPPS/ASC proposed rule, could be implemented. Specifically, we stated that we were interested in what data were available or could be collected that would have allowed us to implement a limitation on the expansion of excepted services.

We provided a summary of and responses to comments received in response to the CY 2017 OPPS/ASC final rule with comment period in the CY 2018 OPPS/ASC proposed rule. As stated in that rule, several of the public comments received in response to the comment solicitation included in the CY 2017 OPPS/ASC final rule with comment period were repeated from the same stakeholders in response to the CY 2017 OPPS/ASC proposed rule. These commenters again expressed concern regarding CMS' authority to address changes in service-mix; that a limitation on service expansion or volume would stifle innovative care delivery and use of new technologies; and that limiting service line expansion using clinical families of service was not workable. Because these commenters did not provide new information, we referred readers to the CY 2017 OPPS/ASC final rule with comment period for our responses to comments on statutory authority and concerns about hindering access to innovative technologies (81 FR 79707 and 82 FR 59388). A summary of and our responses to the other comments received in response to the comment solicitation included in the CY 2017 OPPS/ASC final rule with comment period were included in the CY 2018 OPPS/ASC proposed rule (82 FR 33645 through 33648).

In the CY 2018 OPPS/ASC proposed rule, we did not propose any policies related to clinical service line expansion or volume increases at excepted off-campus PBDs. However, we stated that we would continue to monitor claims data for changes in billing patterns and utilization, and we again invited public comments on the issue of service line expansion. In response to the CY 2018 comment solicitation, MedPAC largely reiterated the comments it submitted in response to the CY 2017 OPPS/ASC rulemaking and acknowledged the challenges of implementing its recommended approach as such

[41] Available at: *http://medpac.gov/docs/default-source/comment-letters/08172016_opps_asc_comment_2017_medpac_sec.pdf?sfvrsn=0.*

approach would necessitate CMS requiring hospitals to report the amount of OPPS payments received by each excepted off-campus PBD during the baseline period (such as November 2014 through November 2015) because CMS was not collecting data on payments made to each individual PBD during that period. In its comments, MedPAC recommended that, to help ensure the accuracy of these data, CMS could selectively audit hospitals.[42] Another commenter expressed support for CMS' efforts to continue to implement and expand site-neutral payment policies for services where payment differentials are not warranted, such as between HOPDs and ASCs or physician offices.

2. CY 2019 Proposal

As previously expressed in CYs 2017 and 2018 OPPS/ASC rulemaking, we continue to be concerned that if excepted off-campus PBDs are allowed to furnish new types of services that were not provided at the excepted off-campus PBDs prior to the date of enactment of the Bipartisan Budget Act of 2015 and can be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off-campus PBDs. This could result in newly purchased physician practices furnishing services that are paid at OPPS rates, which we believe the section 603 amendments to section 1833(t) of the Act are intended to prevent. Of note, these statutory amendments ''came after years of nonpartisan economists, health policy experts, and providers expressing concern over the Medicare program's [OPPS] paying more for the same services provided at HOPDs than in other settings—such as an ambulatory surgery center, physician office, or community outpatient facility.''[43] Experts raised concerns that this payment inequity drove the acquisition of ''standalone or independent practices and facilities by hospitals, resulted in higher costs for the Medicare system and taxpayers, and also resulted in beneficiaries needlessly facing higher cost-sharing in some settings than in others.''[44] In addition, some experts argued that, ''to the extent this payment differential accelerated consolidation of providers, this would result in reduced competition among both hospitals and nonaffiliated outpatient service providers. This, in turn, could reduce large hospital systems' incentives to reduce costs, increase efficiency, or focus on patient outcomes.''[45]

The Government Accountability Office (GAO) stated in its December 2015 Report to Congress that ''from 2007 through 2013, the number of vertically consolidated physicians nearly doubled, with faster growth in more recent years.'' GAO concluded that, ''regardless of what has driven hospitals and physicians to vertically consolidate, paying substantially more for the same service when performed in an HOPD rather than a physician office provides an incentive to shift services that were once performed in physician offices to HOPDs after consolidations have occurred.''[46]

While there is no congressional record available for section 603 of the Bipartisan Budget Act of 2015, we do not believe that Congress intended to allow for new service lines to be paid OPPS rates because providing for such payment would allow for excepted off-campus PBDs to be paid higher rates for types of services they were not performing prior to enactment of the Bipartisan Budget Act of 2015 that would be paid at lower rates if performed in a nonexcepted PBD. Similarly, we are concerned that a potential shift of services from nonexcepted PBDs to excepted PBDs, or to excepted PBDs generally, may be occurring, given the higher payment rate in this setting. We believe that the growth of service lines in currently excepted off-campus PBDs may be an unintended consequence of our current policy, which allows continued full OPPS payment for any services furnished by excepted off-campus PBDs, including services in new service lines.

In prior rulemaking, and as discussed in section X.A. of this proposed rule, we noted our concerns and discussed our efforts to begin collecting data and monitoring billing patterns for off-campus PBDs. Specifically, as described in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66910 through 66914), we created HCPCS modifier ''PO'' (Services, procedures, and/or surgeries furnished at off-campus provider-based outpatient departments) for hospital claims to be reported with every code for outpatient hospital items and services furnished in an off-campus PBD of a hospital. Reporting of this new modifier was voluntary for CY 2015, with reporting required beginning on January 1, 2016. In addition, we established modifier ''PN'' (Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital) to identify and pay nonexcepted items and services billed on an institutional claim. Effective January 1, 2017, nonexcepted off-campus PBDs of a hospital were required to report this modifier on each claim line for nonexcepted items and services to trigger payment under the PFS instead of the OPPS. As a conforming revision, effective January 1, 2017, the modifier ''PO'' descriptor was revised to ''excepted service provided at an off-campus, outpatient, provider-based department of a hospital'' and this modifier continued to be used to identify items and services furnished by an excepted off-campus PBD of a hospital.

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33647), a few commenters supported CMS' intent to monitor service line expansion and changes in billing patterns by excepted off-campus PBDs. These commenters urged CMS to work to operationalize a method that would preclude an excepted off-campus PBD from increasing its payment advantage under the OPPS by expanding into wholly new clinical areas (82 FR 33647). Moreover, a few commenters urged CMS to pursue a limitation on service line expansion to ensure designation as an excepted off-campus PBD is not ''abused'' (82 FR 33647). One commenter suggested that CMS evaluate outpatient claims with the ''PO'' modifier to develop a list of ''grandfathered'' items and services for which the excepted off-campus PBD may continue to be paid under the OPPS (82 FR 33647). In response to these comments, we stated that we were concerned with the practicality of developing a list of excepted items and services for each excepted off-campus PBD, given the magnitude of such a list (82 FR 33647). We noted in the CY 2018 OPPS/ASC final rule with comment period, however, that we continued to monitor claims data for changes in billing patterns and utilization, and invited comments on this issue (82 FR 59388).

In light of our prior stated concerns about the expansion of services in excepted off-campus PBDs, for CY 2019 and subsequent years, we are proposing that if an excepted off-campus PBD furnishes services from any clinical family of services (as clinical families of services are defined in Table 32 of this proposed rule) from which it did not

[42] Available at: *http://medpac.gov/docs/default-source/comment-letters/09082017_opps_asc_2018_medpac_comment_sec.pdf?sfvrsn=0.*

[43] Available at: *https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Letters/20160205SiteNeutralLetter%5b1%5d.pdf.*

[44] Ibid.

[45] Ibid.

[46] GA0–16–189, ''Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform.'' Available at: *https://www.gao.gov/assets/680/674347.pdf.*

furnish an item or service during a baseline period from November 1, 2014 through November 1, 2015 (and subsequently bill under the OPPS for that item or service), items and services from these new clinical families of services would not be excepted items and services and, thus, would not be covered OPD services, and instead would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act and paid under the PFS. Furthermore, in this CY 2019 OPPS/ASC proposed rule, we are proposing to revise 42 CFR 419.48 to limit the definition of ''excepted items and services'' in accordance with this proposal. Generally, excepted items and services are items or services that are furnished on or after January 1, 2017 by an excepted off-campus PBD (as defined in § 419.48) that has not impermissibly relocated or changed ownership. Beginning on January 1, 2019, excepted items and services would be items or services that are furnished and billed by an excepted off-campus PBD (defined in § 419.48) only from the clinical families of services (described later in this section) for which the excepted off-campus PBD furnished (and subsequently billed under the OPPS) for at least one item or service from November 1, 2014 through November 1, 2015. Further, for purposes of this section, ''new clinical families of services'' would be items or services: (1) That are furnished and billed by an excepted off-campus PBD; (2) that are otherwise paid under the OPPS through one of the APCs included in Table 32 of this proposed rule; and (3) that belong to a clinical family listed in Table 32 from which the excepted off-campus PBD did not furnish an item or service during the baseline period from November 1, 2014 through November 1, 2015 (and subsequently bill for that service under the OPPS). In addition, for CY 2019, we are proposing that if an excepted off-campus PBD furnishes a new item or service from a clinical family of services listed in Table 32 from which the off-campus PBD furnished a service from November 1, 2014 through November 1, 2015, such service would continue to be paid under the OPPS because items and services from within a clinical family of services for which the nonexcepted off-campus PBD furnished an item or service during the baseline period would not be considered a ''service expansion.''

In order to determine the types of services provided at an excepted off-campus PBD, for purposes of OPPS payment eligibility, excepted off-campus PBDs will be required to ascertain the clinical families from which they furnished services from November 1, 2014 through November 1, 2015 (that were subsequently billed under the OPPS). In addition, items and services furnished by an excepted off campus PBD that are not identified below in Table 32 of this proposed rule must be reported with modifier ''PN''. We selected the year prior to the date of enactment of the Bipartisan Budget Act of 2015 as the baseline period because it is the most recent year preceding the date of enactment of section 603 and we believe that a full year of claims data would adequately reflect the types of service lines furnished and billed by an excepted off-campus PBD. We considered expanding the baseline period to include a timeframe prior to November 2014, but are not proposing this alternative due to the possibility that hospital claims data for an earlier time period may not be readily available and reviewing claims from a longer timeframe may impose undue burden. If an excepted off-campus PBD did not furnish services under the OPPS until after November 1, 2014, we are proposing that the 1-year baseline period begins on the first date the off-campus PBD furnished covered OPD services prior to November 2, 2015. For providers that met the mid-build requirement (as defined at section 1833(t)(21)(B)(v) of the Act), we are proposing to establish a 1-year baseline period that begins on the first date the off-campus PBDs furnished a service billed under the OPPS. We are proposing changes to our regulation at 42 CFR 419.48 to include these alternative baseline periods. For guidance on the implementation of sections 16001 and 16002 of the 21st Century Cures Act, we refer readers to the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Sections-16001-16002.pdf.* We are concerned that a 1-year baseline may be unnecessarily long to the extent that such baseline would be, at least in part, a prospective period during which such departments would have time and an incentive to bill services from as many service lines as possible, thereby limiting the effect of this policy. We welcome public comment on whether a different baseline period, such as 3 or 6 months, should be used for off-campus PBDs that began furnishing services and billing after November 1, 2014, or that met the mid-build requirement.

We are aware of past stakeholder concern regarding limiting service line expansion for excepted off-campus PBDs using the 19 clinical families identified below in Table 32 of this proposed rule. However, we believe that the proposed clinical families recognize all clinically distinct service lines for which a PBD might bill under the OPPS, while at the same time allow for new services within a clinical family of services to be considered for designation as ''excepted items and services'', as defined in the regulations at 42 CFR 419.48 where the types of services within a clinical family expand due to new technology or innovation. We believe that requiring excepted off-campus PBDs to limit their services to the exact same services they furnished during the proposed baseline period would be too restrictive and administratively burdensome. We are requesting public comments on the proposed clinical families. We also are soliciting public comments on whether any specific groups of hospitals should be excluded from our proposal to limit the expansion of excepted services, such as certain rural hospitals (for example, rural sole community hospitals), in light of recent reports of hospital closures in rural areas.

In addition, we are soliciting public comments on alternate methodologies to limit the expansion of excepted services in excepted off-campus PBDs for CY 2019. Specifically, we are inviting public comments on the adoption and implementation of other methodologies, such as the approach recommended by MedPAC (discussed earlier in this section) in response to the CY 2017 and CY 2018 proposals whereby CMS would establish a baseline service volume for each applicable off-campus PBD, cap excepted services (regardless of clinical family) at that limit, and when the hospital reaches the annual cap for that location, additional services furnished by that off-campus PBD would no longer be considered covered OPD services and would instead be paid under the PFS (the annual cap could be updated based on the annual updates to the OPPS payment rates). Under such alternate approach, hospitals would need to report service volume for each off-campus PBD for the applicable period (such as November 1, 2014–November 1, 2015) and such applicable periods would be subject to audit.

TABLE 32—PROPOSED CLINICAL FAMILIES OF SERVICES FOR PURPOSES OF SECTION 603 IMPLEMENTATION

Clinical families	APCs
Airway Endoscopy	5151–5155.
Blood Product Exchange	5241–5244.
Cardiac/Pulmonary Rehabilitation	5771; 5791.
Diagnostic/Screening Test and Related Procedures	5721–5724; 5731–5735; 5741–5743.
Drug Administration and Clinical Oncology	5691–5694.
Ear, Nose, Throat (ENT)	5161–5166.
General Surgery and Related Procedures	5051–5055; 5061; 5071–5073; 5091–5094; 5361–5362.
Gastrointestinal (GI)	5301–5303; 5311–5313; 5331; 5341.
Gynecology	5411–5416.
Major Imaging	5523–5525; 5571–5573; 5593–5594.
Minor Imaging	5521–5522; 5591–5592.
Musculoskeletal Surgery	5111–5116; 5101–5102.
Nervous System Procedures	5431–5432; 5441–5443; 5461–5464; 5471.
Ophthalmology	5481, 5491–5495; 5501–5504.
Pathology	5671–5674.
Radiation Oncology	5611–5613; 5621–5627; 5661.
Urology	5371–5377.
Vascular/Endovascular/Cardiovascular	5181–5184; 5191–5194; 5200; 5211–5213; 5221–5224; 5231–5232.
Visits and Related Services	5012; 5021–5025; 5031–5035; 5041; 5045; 5821–5823.

XI. Proposed CY 2019 OPPS Payment Status and Comment Indicators

A. Proposed CY 2019 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 2019, we are not proposing to make any changes to the definitions of status indicators that were listed in Addendum D1 to the CY 2018 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-Items/CMS-1656-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.*

The complete list of the payment status indicators and their definitions that would apply for CY 2019 is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

The proposed CY 2019 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

B. Proposed CY 2019 Comment Indicator Definitions

In this proposed rule, we are proposing to use four comment indicators for the CY 2019 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2018 and we are proposing to continue their use in CY 2019. The proposed CY 2019 OPPS comment indicators are as follows:

- ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NC''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will *not* be accepted on the final APC assignment for the new code.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPPS comment indicators for CY 2019 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

XII. Proposed 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 and 2018 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; and 82 FR 59401 through 59424, 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 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. We define 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 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 § 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 (§ 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 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, which we finalized in the CY 2012 OPPS/ASC final rule with comment period, is used to update HCPCS and CPT codes (76 FR 42291; 76 FR 74380 through 74381).

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 (including all procedures newly proposed for removal from the OPPS inpatient list), 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 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 American Medical Association (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 are separately paid under the OPPS (72 FR 42478).

As we noted in the CY 2008 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 (72 FR 42477).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59402 through 59403), we noted that some stakeholders have suggested that certain procedures that are outside the CPT surgical range but that are similar to surgical procedures currently covered in an ASC setting should be ASC covered surgical procedures. For example, some stakeholders have recommended adding certain cardiovascular procedures to the ASC Covered Procedures List (CPL) due to their similarity to currently-covered peripheral endovascular procedures in the surgical code range for surgery and cardiovascular system. Further, stakeholders also noted that the AMA's CPT code manual states that the listing of a procedure in a specific section of the book may reflect historical or other considerations and should not be interpreted as strictly classifying the

procedure as ''surgery'' or ''not surgery'' for insurance purposes. As the CPT codebook states: ''It is equally important to recognize that as techniques in medicine and surgery have evolved, new types of services, including minimally invasive surgery, as well as endovascular, percutaneous, and endoscopic interventions have challenged the traditional distinction of Surgery vs Medicine. *Thus, the listing of a service or procedure in a specific section of this book should not be interpreted as strictly classifying the service or procedure as 'surgery' or 'not surgery' for insurance or other purposes.* The placement of a given service in a specific section of the book may reflect historical or other considerations (e.g., placement of the percutaneous peripheral vascular endovascular interventions in the Surgery/Cardiovascular System section, while the percutaneous coronary interventions appear in the Medicine/Cardiovascular section)'' (emphasis added) (CPT® 2018 Professional Edition, ''Instructions for Use of the CPT Code Book,'' page xii.). While we continue to believe that using the CPT code range to define surgery represents a logical, appropriate, and straightforward approach to defining a surgical procedure, we also believe it may be appropriate for us to use the CPT surgical range as a guide rather than a strict determinant as to whether a procedure is surgical, which would give us more flexibility to include ''surgery-like'' procedures on the ASC CPL.

We also are cognizant of the dynamic nature of ambulatory surgery and the continued shift of services from the inpatient setting to the outpatient setting over the past decade. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59402 through 59403), we responded to public comments that we had solicited regarding services that are described by Category I CPT codes outside of the surgical range, or Level II HCPCS codes or Category III CPT codes that do not directly crosswalk and are not clinically similar to procedures in the CPT surgical range, but that nonetheless may be appropriate to include as covered surgical procedures that are payable when furnished in the ASC setting. Commenters offered mixed views for changing the current definition of surgery; however, most commenters were supportive of changing the definition. Some commenters recommended broadening the definition of surgery to include procedures not described by the CPT surgical range. Another commenter recommended making all surgical codes payable in a hospital outpatient department payable in an ASC and further suggested that CMS at least redefine surgical procedures to include invasive procedures such as percutaneous transluminal angioplasty and cardiac catheterization.

One commenter recommended using a definition of surgery developed by the AMA Specialty Society Relative Value Scale Update Society for use in the agency's Physician Fee Schedule (PFS) professional liability insurance relative values. In calculating the professional liability insurance relative values, certain cardiology codes outside the CPT surgical range are considered surgical codes for both the calculation and assignment of the surgery-specific malpractice risk factors. However, we note that the distinction between ''surgical'' and ''non-surgical'' codes developed by the AMA Specialty Society Relative Value Scale Update Society is used by CMS to calculate professional liability risk factors and not necessarily to define surgery. The codes considered surgeries by the AMA Society Relative Value Scale Update Society were most recently displayed on the CMS website for the CY 2018 MPFS final rule under the file ''Invasive Cardiology Services Outside of Surgical HCPCS Code Range Considered Surgery.'' We refer readers to that file, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2018-PFS-FR-Invasive-Cardiology.zip.*

After further consideration of comments we received in response to the CY 2018 OPPS/ASC final rule with comment period, we are proposing to revise our definition of ''surgery'' for CY 2019 to account for ''surgery-like'' procedures that are assigned codes outside the CPT surgical range (10000–69999). We believe it is appropriate to expand our definition of covered surgical procedures to include Category I CPT codes that are not in the Category I CPT surgical range but that directly crosswalk or are clinically similar to procedures in the Category I CPT code surgical range because, as commenters have noted, the CPT Codebook's classification of certain procedures as ''surgical'' should not be considered dispositive of whether a procedure is or is not surgery. We also believe that considering these codes for potential inclusion on the covered surgical procedures list is consistent with our policy for Level II HCPCS codes and Category III CPT codes.

For CY 2019, we are proposing that these newly-eligible ''surgery-like'' procedures are procedures that are described by Category I CPT codes that are not in the surgical range but, like procedures described by Level II HCPCS codes or by Category III CPT codes under our current policy, directly crosswalk or are clinically similar to procedures in the Category I CPT surgical range. These Category I CPT codes would be limited to those 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 are inviting comments on our proposal to revise the definition of surgery for the ASC prospective payment system. We also are soliciting comments on whether we should expand our definition of ''surgery'' to include procedures that fall outside the CPT surgical range, but fall within the definition of ''surgery'' developed by the AMA Specialty Society Relative Value Scale Update Society for use in the agency's Physician Fee Schedule (PFS) professional liability insurance relative values, that we determine 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.

B. Proposed Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised Category I and Category III CPT Codes and Level II HCPCS Codes

Category I CPT, Category III CPT, and Level 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 and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify items, 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 2018 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we are proposing to solicit public comments in this proposed rule (and respond to those comments in the CY 2019 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2019 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2020 OPPS/ASC final rule with comment period).

We note that we sought public comments in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59405 through 59406) on the new and revised Level II HCPCS codes effective October 1, 2017, or January 1, 2018. These new and revised codes, with an effective date of October 1, 2017, or January 1, 2018, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2018 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 2018 OPPS/ASC final rule with comment period. We will respond to public comments and finalize the treatment of these codes under the ASC payment system in the CY 2019 OPPS/ASC final rule with comment period.

In Table 33 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 OPPS.

TABLE 33—COMMENT AND FINALIZATION TIMEFRAMES FOR NEW OR REVISED HCPCS CODES

ASC quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2018	Level II HCPCS Codes	April 1, 2018	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
July 1, 2018	Level II HCPCS Codes	July 1, 2018	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2018	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
October 1, 2018	Level II HCPCS Codes	October 1, 2018	CY 2019 OPPS/ASC final rule with comment period.	CY 2020 OPPS/ASC final rule with comment period.
January 1, 2019	Category I and III CPT Codes	January 1, 2019	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
	Level II HCPCS Codes	January 1, 2019	CY 2019 OPPS/ASC final rule with comment period.	CY 2020 OPPS/ASC final rule with comment period.

Note: 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. We refer readers to section III.A.3. of this CY 2019 OPPS/ASC proposed rule for further discussion of this issue.

2. Proposed Treatment of New and Revised Level II HCPCS Codes Implemented in April 2018 for Which We Are Soliciting Public Comments in This Proposed Rule

In the April 2018 ASC quarterly update (Transmittal 3996, CR 10530, dated March 09, 2018), we added nine new Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 34 below lists the new Level II HCPCS codes that were implemented April 1, 2018, along with their proposed payment indicators for CY 2019. The proposed payment rates, where applicable, for these April codes can be found in Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website).

TABLE 34—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2018

CY 2018 HCPCS code	CY 2019 long descriptor	Proposed CY 2019 payment indicator
C9462	Injection, delafloxacin, 1 mg	K2
C9463	Injection, aprepitant, 1 mg	K2
C9464	Injection, rolapitant, 0.5 mg	K2
C9465	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose	K2
C9466	Injection, benralizumab, 1 mg	K2
C9467	Injection, rituximab and hyaluronidase, 10 mg	K2
C9468	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u	K2
C9469*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	K2
C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)	J8

*HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), which was effective April 1, 2018, was deleted June 30, 2018 and replaced with HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) effective July 1, 2018.

We are inviting public comments on these proposed payment indicators and the proposed payment rates for the new HCPCS codes that were recognized as ASC covered surgical procedures and ancillary services in April 2018 through the quarterly update CRs, as listed in Table 34 above. We are proposing to finalize their payment indicators and their payment rates in the CY 2019 OPPS/ASC final rule with comment period.

3. Proposed Treatment of New and Revised Level II HCPCS Codes Implemented in July 2018 for Which We Are Soliciting Public Comments in This Proposed Rule

In the July 2018 ASC quarterly update (Transmittal 4076, Change Request 10788, dated June 26, 2018), we added eight new Level II HCPCS codes to the list of covered ancillary services. Table 35 below lists the new HCPCS codes that are effective July 1, 2018. The proposed payment rates, where applicable, for these July codes can be found in Addendum BB to this proposed rule (which is available via the internet on the CMS website).

TABLE 35—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2018

CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2019 payment indicator
C9030	Injection, copanlisib, 1 mg	K2
C9032	Injection, voretigene neparvovec-rzyl, 1 billion vector genome	K2
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	K2
Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units	K2
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	K2
Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	K2
Q9993*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	K2
Q9995	Injection, emicizumab-kxwh, 0.5 mg	K2

*HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), which was effective April 1, 2018, was deleted June 30, 2018 and replaced with HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) effective July 1, 2018.

Through the July 2018 quarterly update CR, we are also implementing an ASC payment for one new Category III CPT code as an ASC covered ancillary service, effective July 1, 2018. This code is listed in Table 36 below, along with its proposed payment indicator. The CY 2019 proposed payment rate for this new Category III CPT code can be found in Addendum BB to this proposed rule (which is available via the internet on the CMS website).

TABLE 36—NEW CATEGORY III CPT CODE FOR COVERED ANCILLARY SERVICE EFFECTIVE ON JULY 1, 2018

CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2019 payment indicator
0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia	Z2

We are inviting public comments on these proposed payment indicators and the proposed payment rates for the new Category III CPT code and Level II HCPCS codes that were or are expected to be newly recognized as ASC covered surgical procedures or covered ancillary services in July 2018 through the quarterly update CRs, as listed in Tables 34, 35 and 36 above. We are proposing to finalize their payment indicators and their payment rates in the CY 2019 OPPS/ASC final rule with comment period.

4. Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2018 and January 1, 2019 for Which We Will Be Soliciting Public Comments in the CY 2019 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new and revised Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the OPPS and the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS website, and also through the January OPPS quarterly update CRs. In the past, we also released new and revised Level II 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.

For CY 2019, consistent with our established policy, we are proposing that the Level II HCPCS codes that will be effective October 1, 2018, and January 1, 2019, would be flagged with comment indicator ''NI'' in Addendum B to the CY 2019 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2019. We will invite public comments in the CY 2019 OPPS/ASC final rule with comment period on the interim status indicator and APC assignments, and payment rates for these codes that will be finalized in the CY 2020 OPPS/ASC final rule with comment period.

5. Proposed Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2019 for Which We Are Soliciting Public Comments in This CY 2019 OPPS/ASC Proposed Rule

For new and revised CPT codes effective January 1, 2019, that were received in time to be included in this proposed rule, we are proposing APC and status indicator assignments. We will accept comments and finalize the APC and status indicator assignments in the OPPS/ASC final rule with comment period. For those new/revised CPT codes that are received too late for inclusion in this OPPS/ASC proposed rule, we may either make interim final assignments in the final rule with

comment period or possibly use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle.

For the CY 2019 ASC update, the new and revised CY 2019 Category I and III CPT codes will be effective on January 1, 2019, and can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website). The new and revised CY 2019 Category I and III CPT codes are assigned to comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year and that comments will be accepted on the proposed payment indicator. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code.

Therefore, we include the 5-digit placeholder codes and their long descriptors for the new and revised CY 2019 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) so that the public can comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled ''CY 2019 OPPS/ASC Proposed Rule 5-Digit Placeholder Code,'' to this proposed rule. The final CPT code numbers will be included in the CY 2019 OPPS/ASC final rule with comment period. We note that not every code listed in Addendum O is subject to comment. For the new/revised Category I and III CPT codes, we are requesting comments on only those codes that are assigned to comment indicator ''NP''.

In summary, we are soliciting public comments on the proposed CY 2019 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2019. The CPT codes are listed in Addendum AA and Addendum BB to this proposed rule with short descriptors only. We list them again in Addendum O to this proposed rule with long descriptors. We also are proposing to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2019 OPPS/ASC final rule with comment period. The proposed payment indicator for these codes can be found in Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website).

C. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are performed 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 list of covered surgical procedures 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 list of covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2019 to Covered Surgical Procedures Designated as Office-Based

In developing this proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2017 volume and utilization data and the clinical characteristics for all covered surgical procedures that are assigned payment indicator ''G2'' (nonoffice-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2017, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2'', ''P3'', or ''R2'' in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59406 through 59408).

Our review of the CY 2017 volume and utilization data resulted in our identification of 4 covered surgical procedures that we believe meet the criteria for designation as office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and we believe that the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT codes that we are proposing to permanently designate as office-based for CY 2019 are listed in Table 37 below.

TABLE 37—ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2019

CY 2019 CPT code	CY 2019 long descriptor	CY 2018 ASC payment indicator	Proposed CY 2019 ASC payment indicator *
31573	Laryngoscopy, flexible; with therapeutic injection(s) (*e.g.,* chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral.	G2	P3
36513	Therapeutic apheresis; for platelets	G2	R2
36902	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty.	G2	P3
36905	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty.	G2	P3

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.25 percent update to the MPFS payment rates for CY 2019. For a discussion of the MPFS rates, we refer readers to the CY 2019 MPFS proposed rule.

We also reviewed CY 2017 volume and utilization data and other information for 10 procedures designated as temporary office-based in Tables 84 and 85 in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59408). Of these 10 procedures, there were very few claims in our data and no claims data for 4 procedures described by CPT codes 38222, 65785, 67229, and 0402T. Consequently, we are proposing to maintain the temporary office-based designations for these 4 codes for CY 2019. We list all of these codes for which we are proposing to maintain the temporary office-based designations for CY 2019 in Table 38 below. The procedures for which the proposed office-based designations for CY 2019 are temporary also were indicated by asterisks in Addendum AA to this proposed rule (which is available via the internet on the CMS website).

The volume and utilization data for the remaining six procedures that have a temporary office-based designation for CY 2018, described by CPT codes 10030, 36473, 36901, 64461, and 64463, and HCPCS code G0429, are sufficient to indicate that these procedures are performed predominantly in physicians' offices and, therefore, should be assigned an office-based payment indicator in CY 2018. Consequently, we are proposing to assign payment indicator ''P2'', ''P3'', or ''G2'' to these covered surgical procedure codes in CY 2019.

TABLE 38—PROPOSED CY 2019 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED IN THE CY 2018 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2019 CPT/ HCPCS code	CY 2019 long descriptor	CY 2018 ASC payment indicator *	CY 2019 ASC proposed payment indicator **
38222	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	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 (*e.g.,* 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).	R2 *	R2 ***
10030	Image-guided fluid collection drainage by catheter (*e.g.,* abscess, hematoma, seroma, lymphocele, cyst), soft tissue (*e.g.,* extremity, abdominal wall, neck), percutaneous.	P2 *	G2
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated.	P2 *	P3 **
36901	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report.	P2 *	P3 **
64461	Paravertebral block (pvb) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	P3 *	G2
64463	Paravertebral block (pvb) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed).	P3 *	G2
G0429	Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (lds) (*e.g.,* as a result of highly active antiretroviral therapy).	P3 *	P3 **

* If designation is temporary.
** Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.25 percent update to the MPFS payment rates for CY 2019. For a discussion of the MPFS rates, we refer readers to the CY 2019 MPFS proposed rule.

For CY 2019, we are proposing to designate 8 new CY 2019 CPT codes for ASC covered surgical procedures as temporary office-based, as displayed in Table 39 below. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedures described by the new CPT codes would be predominantly performed in physicians' offices. However, because we had no utilization data for the procedures specifically described by these new CPT codes, we are proposing to make the office-based designation temporary rather than permanent, and we will reevaluate the procedures when data become available. The procedures for which the proposed office-based designation for CY 2019 is temporary are indicated by asterisks in Addendum AA to this proposed rule (which is available via the internet on the CMS website).

TABLE 39—PROPOSED CY 2019 PAYMENT INDICATORS FOR NEW CY 2019 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED

CY 2019 OPPS/ ASC proposed rule 5-digit CMS placeholder code	CY 2019 long descriptor	Proposed CY 2019 ASC payment indicator **
06X1T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2 *
10X12	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	P3 *
10X14	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3 *
10X16	Fine needle aspiration biopsy, including CT guidance; first lesion	P2 *
10X18	Fine needle aspiration biopsy, including MR guidance; first lesion	R2 *
11X02	Tangential biopsy of skin (*e.g.,* shave, scoop, saucerize, curette); single lesion	P3 *
11X04	Punch biopsy of skin (including simple closure, when performed); single lesion	P3 *
11X06	Incisional biopsy of skin (*e.g.,* wedge) (including simple closure, when performed); single lesion	P3 *

* If designation is temporary.
** Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.25 percent update to the MPFS payment rates for CY 2019. For a discussion of the MPFS rates, we refer readers to the CY 2019 MPFS proposed rule.

b. Proposed ASC Covered Surgical Procedures To Be Designated as Device-Intensive

(1) Background

As discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79739 through 79740), we implemented a payment methodology for calculating the ASC payment rates for covered surgical procedures that are designated as device-intensive.

According to this ASC payment methodology, we apply the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment 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 revised ASC payment system.

We also finalized in the CY 2017 OPPS/ASC final rule that device-intensive procedures will be subject to all of the payment policies applicable to procedures designated as an ASC device-intensive procedure under our established methodology, including our policies on no cost/full credit and partial credit devices and discontinued procedures. In addition, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79739 through 79740), we adopted a policy for new HCPCS codes describing procedures involving the implantation of medical devices that do not yet have associated claims data, to designate these procedures as device-intensive with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent is not calculated from claims data; instead, it is applied as a default until claims data are 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 involve the implantation of medical devices would be to ensure ASC access for new procedures until claims data become available. However, in certain rare instances, for example, in the case of a very expensive implantable device, we indicated we might temporarily assign a higher offset percentage if warranted by additional information, such as pricing data from a device manufacturer. Once claims data are available for a new procedure involving the implantation of a medical device, the device-intensive designation is applied to the code if the HCPCS code device offset is greater than 40 percent, according to our policy of determining device-intensive status, by calculating the HCPCS code-level device offset.

(2) Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2019

As discussed in section IV.B.2. of this proposed rule, for CY 2019 we are proposing to modify our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We are proposing to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we are proposing to modify our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. Specifically, for CY 2019 and subsequent years, we are proposing 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 are proposing that the default device offset for new codes that describe procedures that involve the implantation of medical devices would be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC involving the implantation of a medical device, we are proposing that the default device offset would be applied in the same manner as proposed in section IV.B.2 of this proposed rule.

In addition, as also proposed in section IV.B.2 of this proposed rule, to further align the device-intensive policy with the criteria used for device pass-through status, we are proposing to specify, 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 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:

(a) 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

(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).

In conjunction with our proposed modifications to the device-intensive criteria, we are proposing to amend § 416.171(b)(2) of the regulations to reflect the proposed new device criteria.

Based on our proposed modifications to our device-intensive criteria, for CY 2019, we are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to our proposed device-intensive procedure payment methodology, reflecting the proposed individual HCPCS code device-offset percentages based on CY 2017 OPPS claims and cost report data available for this proposed rule.

The ASC covered surgical procedures that we are proposing to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2019, are assigned payment indicator ''J8'' and are included in Addendum AA to this proposed rule (which is available on the CMS website). The CPT code, the CPT code short descriptor, and the proposed CY 2019 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 also are included in Addendum AA to this proposed rule. In addition, for CY 2019, we are proposing to only apply our proposed device-intensive procedure payment

methodology to device-intensive procedures under the ASC payment system when the device-intensive procedure is furnished with a surgically inserted or implanted device (including single use medical devices). Under this proposal, the payment rate under the ASC payment system for device-intensive procedures furnished without an implantable or inserted medical device would be calculated by applying the uniform ASC conversion factor to both the device portion and service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure and summing both portions (device and service) to establish the ASC payment rate.

c. Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted in ASCs at no cost/full credit or partial credit, as set forth in § 416.179 of our regulations, is consistent with the OPPS policy that was in effect until CY 2014. Specifically, the OPPS policy that was in effect through CY 2013 provided a reduction in 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 (77 FR 68356 through 68358). The established ASC policy reduces payment to ASCs when a specified device is furnished without cost or with full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68742 through 68744) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices.

As discussed in section IV.B. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPPS, our policy was to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnished a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital received partial credit in the amount of 50 percent or more (but less than 100 percent) of the cost for the specified device. For CY 2014, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a replaced 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 that 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.

All ASC covered device-intensive 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 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 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.

For partial credit, we are proposing 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 would 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 would have the option of either: (1) Submitting the claim for the device replacement 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 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 replacement 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 policy to all device-intensive procedures.

d. Proposed Additions to the List of ASC Covered Surgical Procedures

As discussed in section XII.A.3. of this proposed rule, we are proposing to revise our definition of surgery for CY 2019 to include certain ''surgery-like'' procedures that are assigned codes outside the CPT surgical range. For CY 2019, we are proposing to include procedures that are described by Category I CPT codes that are not in the surgical range but directly crosswalk or are clinically similar to procedures in the Category I CPT code surgical range 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 also are continuing to include in our definition of surgical procedures 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.

We conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, and that meet our proposed 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, we are proposing to update the list of ASC covered surgical procedures by adding 12 cardiac catheterization procedures to the list for CY 2019, as shown in Table 40 below. After reviewing the clinical characteristics of these procedures and consulting with stakeholders and our clinical advisors, we determined that these 12 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. Our regulation at 42 CFR 416.166(c) lists general exclusions from the list of ASC covered surgical procedures based on factors relating to safety, including procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, or directly involve major blood vessels. We have assessed each of the proposed added procedures against the regulatory safety criteria and believe that these procedures meet each of the criteria. Although the proposed cardiac catheterization procedures may involve blood vessels that could be considered major, based on our review of the clinical characteristics of the procedures and their similarity to other procedures that are currently included on the ASC list of covered surgical procedures, we believe these procedures may be appropriately performed in an ASC. Therefore, we are proposing to include these 12 procedures on the list of ASC covered surgical procedures for CY 2019.

As stated in the August 2, 2007 ASC final rule (72 FR 42481), we believe the involvement of major blood vessels is best considered in the context of the clinical characteristics of individual procedures, and we do not believe that it is logically or clinically consistent to exclude certain cardiac procedures from the list of ASC covered surgical procedures on the basis of the involvement of major blood vessels, yet continue to provide ASC payment for similar procedures involving major blood vessels that have a history of safe performance in ASCs, such as CPT code 36473 (Mechanicochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance) and CPT code 37223 (Insertion of stents into groin artery, endovascular, accessed through the skin or open procedure). However, we are interested in hearing any specific safety concerns from stakeholders regarding these 12 cardiac catheterization procedures and are requesting comments on whether these procedures may be safely performed in an ASC in light of the regulatory criteria governing which procedures may be added to the ASC covered procedures list.

The procedures that we are proposing to add to the ASC list of covered surgical procedures, including the HCPCS code long descriptors and the proposed CY 2019 payment indicators, are displayed in Table 40 below.

TABLE 40—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2019

CY 2019 CPT code	CY 2019 long descriptor	Proposed CY 2019 ASC payment indicator
93451	Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed.	G2
93452	Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed.	G2
93453	Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed.	G2
93454	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation.	G2
93455	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography.	G2
93456	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right heart catheterization.	G2
93457	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization.	G2
93458	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed.	G2
93459	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography.	G2
93460	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed.	G2
93461	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography.	G2
93462	Left heart catheterization by transseptal puncture through intact septum or by transapical puncture (list separately in addition to code for primary procedure).	N1

e. Proposal To Review Recently-Added Procedures to the ASC Covered Procedures List

Section 1833(i)(1) of the Act requires us 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. As noted in section XII.C.1. of this proposed rule, we evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders. Often, when a procedure is added to the ASC CPL, the provider community has limited experience in performing the procedure on the Medicare population, even if providers have greater experience with other patient populations. Because ASCs generally provide a subset of items and services that are offered by hospitals and because Medicare beneficiaries tend to be frailer and exhibit a higher number of comorbidities than other populations, we believe it may be appropriate to reevaluate recently-added procedures.

Specifically, we are proposing to review all procedures that were added to the ASC CPL within the 3 calendar years prior to the year in which we are engaging in rulemaking to assess the safety, effectiveness, and beneficiary experience of these newly-added procedures when performed in the ASC setting. Our review will begin with procedures added to the ASC CPL in CYs 2015, 2016, and 2017, and assess whether newly-added procedures continue to meet our criteria, including whether they continue not to be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC and continue not to be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. This review would include taking into account recent clinical developments and available safety findings related to the recently-added procedures.

We are proposing to review all 38 procedures that were added to the ASC CPL for CYs 2015, 2016, and 2017. The 38 procedures that were added to the ASC CPL during this time are displayed in Table 41 below, along with their HCPCS code long descriptors, the CY 2018 payment indicators, and the calendar year that each procedure was added to the ASC CPL. We also are seeking comment about these recently-added procedures from members of the public, including Medicare beneficiaries, ASC facilities, and physicians performing these procedures in the ASC setting. In addition, we are seeking comment from the public on whether these procedures continue to meet the criteria to remain on the ASC CPL. We intend to evaluate each of these 38 procedures using all available data, including clinical characteristics, utilization reflected in ASC claims and pricing data, prevailing medical practice, and any public comments we receive to determine whether they continue to meet the criteria to be a covered surgical procedure.

In addition, we are soliciting comment regarding how our systematic review should be structured in the future, including the length of time procedures should be considered recently-added, how frequently reviews should be performed in light of the time required to accumulate meaningful data and whether any future reviews should examine procedures added during a period of time greater or less than the previous 3 completed calendar years.

TABLE 41—ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2015, 2016, AND 2017

CY 2019 CPT code	CY 2019 long descriptor	CY 2018 ASC payment indicator	Calendar year added to ASC CPL
0171T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level.	J8	2016
0172T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level.	N1	2016
20936	Autograft for spine surgery only (includes harvesting the graft); local (*e.g.,* ribs, spinous process, or laminar fragments) obtained from same incision (list separately in addition to code for primary procedure).	N1	2017
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (list separately in addition to code for primary procedure).	N1	2017
20938	Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision) (list separately in addition to code for primary procedure).	N1	2017
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2.	J8	2015
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2, each additional interspace (list separately in addition to code for separate procedure).	N1	2017
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below c2.	J8	2015
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed).	J8	2015
22614	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (list separately in addition to code for primary procedure).	N1	2015
22840	Posterior non-segmental instrumentation (*e.g.,* harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at c1, facet screw fixation) (list separately in addition to code for primary procedure).	N1	2017
22842	Posterior segmental instrumentation (*e.g.,* pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (list separately in addition to code for primary procedure).	N1	2017
22845	Anterior instrumentation; 2 to 3 vertebral segments (list separately in addition to code for primary procedure).	N1	2017

TABLE 41—ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2015, 2016, AND 2017—Continued

CY 2019 CPT code	CY 2019 long descriptor	CY 2018 ASC payment indicator	Calendar year added to ASC CPL
22853	Insertion of interbody biomechanical device(s) (*e.g.,* synthetic cage, mesh) with integral anterior instrumentation for device anchoring (*e.g.,* screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (list separately in addition to code for primary procedure).	N1	2017
22854	Insertion of intervertebral biomechanical device(s) (*e.g.,* synthetic cage, mesh) with integral anterior instrumentation for device anchoring (*e.g.,* screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (list separately in addition to code for primary procedure).	N1	2017
22859	Insertion of intervertebral biomechanical device(s) (*e.g.,* synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (list separately in addition to code for primary procedure).	N1	2017
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (*e.g.,* congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles).	J8	2016
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (*e.g.,* congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms).	J8	2016
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction.	J8	2016
49406	Image-guided fluid collection drainage by catheter (*e.g.,* abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, percutaneous.	G2	2016
57120	Colpocleisis (le fort type)	G2	2016
57310	Closure of urethrovaginal fistula;	G2	2016
58260	Vaginal hysterectomy, for uterus 250 g or less	G2	2016
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)	G2	2016
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g	G2	2016
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	G2	2016
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g;	G2	2016
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	G2	2016
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	G2	2016
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical.	G2	2015
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar.	G2	2015
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar.	G2	2015
63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (list separately in addition to code for primary procedure).	N1	2015
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [*e.g.,* spinal or lateral recess stenosis]), single vertebral segment; cervical.	G2	2015
63046	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [*e.g.,* spinal or lateral recess stenosis]), single vertebral segment; thoracic.	G2	2016
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [*e.g.,* spinal or lateral recess stenosis]), single vertebral segment; lumbar.	G2	2015
63055	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (*e.g.,* herniated intervertebral disc), single segment; thoracic.	G2	2016
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (*e.g.,* herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (*e.g.,* far lateral herniated intervertebral disc).	G2	2015

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, we are proposing to update the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2019 OPPS (72 FR 42497). Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary services because of changes that are being proposed under the OPPS for CY 2019. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2018, but is proposed for packaged status under the CY 2019 OPPS, to maintain consistency with the OPPS, we would also propose to package the ancillary service under the ASC payment system for CY 2019. We are proposing to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator ''CH'', which is discussed in section XII.F. of this proposed rule, is used in Addendum BB to this proposed rule (which is available via the internet on the CMS website) to indicate covered ancillary services for which we are proposing a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2019.

All ASC covered ancillary services and their proposed payment indicators for CY 2019 are included in Addendum BB to this proposed rule (which is available via the internet on the CMS website).

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully 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 that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79732 through 79753), we updated the CY 2016 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2'', ''G2'', and ''J8'' using CY 2015 data, consistent with the CY 2017 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2017 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 MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2018 MPFS proposed and final rules) or the amount calculated using the ASC standard rate setting methodology for the procedure. In the CY 2017 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 2017 rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2017 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 codes under the OPPS. Under the OPPS, a conditionally packaged code (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 address this concern, for the device removal procedures that are conditionally packaged in the OPPS (status indicator ''Q2''), we assigned the current ASC payment indicators associated with these procedures and continued to provide separate payment since CY 2014.

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2019

We are proposing to update ASC payment rates for CY 2019 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 proposed rule. Because the proposed OPPS relative payment weights are based on geometric mean costs, the ASC system would use geometric means to determine proposed relative payment weights under the ASC standard methodology. We are proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''.

We are proposing to calculate payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') and device-intensive procedures (payment indicator ''J8'') according to our established policies and, for device-intensive procedures, using our modified definition of device-intensive procedures, as discussed in section XII.C.1.b. of this proposed rule. Therefore, we are proposing to update the payment amount for the service portion of the device-intensive procedures using the ASC standard rate setting methodology and the payment amount for the device portion based on the proposed CY 2019 OPPS 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 2019

MPFS nonfacility PE RVU-based amount or the proposed CY 2018 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2018, for CY 2019, we are proposing 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 these procedures and would continue to be paid separately under the ASC payment system.

2. Proposed Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services 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 codes that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged code 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 always packaged (payment indictor ''N1'') under the ASC payment system (except for device removal codes, as discussed in section IV. of this 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. We generally pay for separately payable radiology services at the lower of the MPFS 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.

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 (42 CFR 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; 42 CFR 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 MPFS 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 MPFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include a reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2019

For CY 2019 and subsequent years, we are proposing 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 2019 OPPS and ASC

payment rates and subsequent year payment rates. We also are proposing to continue to set the CY 2019 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 2019 and subsequent year payment rates.

Covered ancillary services and their proposed payment indicators for CY 2019 are listed in Addendum BB to this proposed rule (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard rate setting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed MPFS rates effective January 1, 2019. For a discussion of the MPFS rates, we refer readers to the CY 2019 MPFS 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.*

3. Proposed CY 2019 ASC Packaging Policy for Non-Opioid Pain Management Treatments

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 expressed a variety of views on packaging under the OPPS. In the CY 2018 OPPS/ASC final rule with comment period, we summarized the comments received in response to our request (82 FR 59255). The comments ranged from requests to unpackage most items and services that are either conditionally or unconditionally packaged under the OPPS, including drugs and devices, to specific requests for separate payment for a specific drug or device. We stated in the CY 2018 OPPS/ASC final rule with comment period that CMS would continue to explore and evaluate packaging policies under the OPPS and consider these policies in future rulemaking.

In addition to stakeholder feedback regarding OPPS packaging policies, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission) recently recommended that CMS examine payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments. The Commission was established in 2017 to study ways to combat and treat drug abuse, addiction, and the opioid crisis. The Commission's report [47] included a recommendation for CMS to ''. . . review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate post-surgical pain. . . .'' [48] With respect to the packaging policy, the Commission's report states that ''. . . the current CMS payment policy for 'supplies' related to surgical procedures creates unintended incentives to prescribe opioid medications to patients for postsurgical pain instead of administering non-opioid pain medications. Under current policies, CMS provides one all-inclusive bundled payment to hospitals for all 'surgical supplies,' which includes hospital-administered drug products intended to manage patients' postsurgical pain. This policy results in the hospitals receiving the same fixed fee from Medicare whether the surgeon administers a non-opioid medication or not.'' [49] HHS also presented an Opioid Strategy in April 2017 [50] that aims, in part, to support cutting-edge research and advance the practice of pain management. On October 26, 2017, the opioid crisis was first declared a national public health emergency under Federal law [51] and this determination was renewed on April 20, 2018.[52]

In response to stakeholder comments on the CY 2018 OPPS/ASC proposed rule and in light of the recommendations regarding payment policies for certain drugs, we recently evaluated the impact of our packaging policy for drugs that function as a supply when used in a surgical procedure on the utilization of these drugs in both the HOPD and the ASC setting. Currently, as noted above, drugs that function as a supply are packaged under the OPPS and the ASC payment system, regardless of the costs of the drugs. The costs associated with packaged drugs that function as a supply are included in the ratesetting methodology for the surgical procedures with which they are billed and the payment rate for the associated procedure reflects the costs of the packaged drugs and other packaged items and services to the extent they are billed with the procedure. In our evaluation, we used currently available data to analyze the utilization patterns associated with specific drugs that function as a supply over a 5-year time period (2013 through 2017) to determine whether this packaging policy has reduced the use of these drugs. If the packaging policy discouraged the use of drugs that function as a supply or impeded access to these products, we would expect to see a significant decline in utilization of these drugs over time, although we note that a decline in utilization could also reflect other factors, such as the availability of alternative products. We did not observe significant declines in the total number of units used in the hospital outpatient department for a majority of the drugs included in our analysis.

In fact, under the OPPS, we observed the opposite effect for several drugs that function as a supply, including Exparel (HCPCS code C9290). Exparel is a liposome injection of bupivacaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. In 2011, Exparel was approved by the FDA for administration into the postsurgical site to provide postsurgical analgesia.[53] Exparel had pass-through payment status from 2012 through 2014 and was separately paid under both the OPPS and the ASC payment system during this 3-year period. Beginning in CY 2015, Exparel was packaged as a surgical supply under both the OPPS and the ASC payment system. Exparel is currently the only non-opioid pain management drug that is packaged as a drug that functions as a supply when used in a surgical procedure under the OPPS and the ASC payment system.

From 2013 through 2017, there was an overall increase in the OPPS Medicare

[47] President's Commission on Combating Drug Addiction and the Opioid Crisis, Report (2017). Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.*

[48] Ibid, at page 57, Recommendation 19.

[49] Ibid.

[50] Available at: *https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html.*

[51] Available at: *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[52] Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[53] Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022496s000lbl.pdf.*

utilization of Exparel of approximately 229 percent (from 2.3 million units to 7.7 million units) during this 5-year time period. The total number of claims reporting Exparel increased by 222 percent (from 10,609 claims to 34,183 claims) over this time period. This increase in utilization continued, even after the 3-year drug pass-through payment period ended for this product in 2014, with 18 percent overall growth in the total number of units used from 2015 through 2017 (from 6.5 million units to 7.7 million units). The number of claims reporting Exparel increased by 21 percent during this time period (from 28,166 claims to 34,183 claims).

Thus, we have not found evidence to support the notion that the OPPS packaging policy has had an unintended consequence of discouraging the use of non-opioid treatment for postsurgical pain management in the hospital outpatient department. Therefore, based on this data analysis, we do not believe that changes are necessary under the OPPS for the packaged drug policy for drugs that function as a surgical supply when used in a surgical procedure in this setting at this time.

In terms of Exparel in particular, we have received several requests to pay separately for the drug rather than packaging payment for it as a surgical supply. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66874 and 66875), in response to comments from stakeholders requesting separate payment for Exparel, we stated that we considered Exparel to be a drug that functions as a surgical supply because it is indicated for the alleviation of postoperative pain. We also stated that we consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59345), we reiterated our position with regard to payment for Exparel, stating that we believed that payment for this drug is appropriately packaged with the primary surgical procedure. In addition, we have reviewed recently available literature with respect to Exparel, including a briefing document [54] submitted for the FDA Advisory Committee Meeting held February 14–15, 2018, by the manufacturer of Exparel that notes that ''. . . Bupivacaine, the active pharmaceutical ingredient in Exparel, is a local anesthetic that has been used for infiltration/field block and peripheral nerve block for decades'' and that ''since its approval, Exparel has been used extensively, with an estimated 3.5 million patient exposures in the US.'' [55] On April 6, 2018, the FDA approved Exparel's new indication for use as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.[56] Based on our review of currently available OPPS Medicare claims data and public information from the manufacturer of the drug, we do not believe that the OPPS packaging policy has discouraged the use of Exparel for either of the drug's indications. Accordingly, we continue to believe it is appropriate to package payment for Exparel as we do with other postsurgical pain management drugs when it is furnished in a hospital outpatient department. However, as noted in section II.A.3.b. of this proposed rule, we are seeking comments on whether separate payment would nonetheless further incentivize appropriate use of Exparel in the hospital outpatient setting and peer-reviewed evidence that such increased utilization would lead to a decrease in opioid use and addiction among Medicare beneficiaries.

Although we found increases in utilization for Exparel when it is paid under the OPPS, we did notice different effects on Exparel utilization when examining the effects of our packaging policy under the ASC payment system. In particular, during the same 5-year period of 2013 through 2017, the total number of units of Exparel used in the ASC setting decreased by 25 percent (from 98,160 total units to 73,595 total units) and the total number of claims reporting Exparel decreased by 16 percent (from 527 claims to 441 claims). In the ASC setting, after the pass-through payment status ended for Exparel at the end of 2014, the total number of units of Exparel used decreased by 70 percent (from 244,757 units to 73,595 units) between 2015 and 2017. The total number of claims reporting Exparel also decreased during this time period by 62 percent (from 1,190 claims to 441 claims). However, there was an increase of 238 percent (from 98,160 total units to 331,348 total units) in the total number of units of Exparel used in the ASC setting during the time period of 2013–2014 when the drug received pass-through payments, which indicates that the payment rate of ASP+6 percent for Exparel may have impact on its usage in the ASC setting. The total number of claims reporting Exparel also increased during this time period from 527 total claims to 1,540 total claims, an increase of 192 percent.

While several variables may contribute to this difference between utilization and claims reporting in the hospital outpatient department and the ASC setting, one potential explanation is that, in comparison to hospital outpatient departments, ASCs tend to provide specialized care and a more limited range of services. Also, ASCs are paid, in aggregate, approximately 55 percent of the OPPS rate. Therefore, fluctuations in payment rates for specific services may impact these providers more acutely than hospital outpatient departments, and, therefore, ASCs may be less likely to choose to furnish non-opioid postsurgical pain management treatments, which are typically more expensive than opioids, as a result. Another possible contributing factor is that ASCs do not typically report packaged items and services and, accordingly, our analysis may be undercounting the number of Exparel units utilized in the ASC setting.

In light of the results of our evaluation of packaging policies under the OPPS and the ASC payment system, which showed decreased utilization for certain drugs that function as a supply in the ASC setting in comparison to the hospital outpatient department setting, as well as the Commission's recommendation to examine payment policies for non-opioid pain management drugs that function as a supply, we believe a change in how we pay for non-opioid pain management drugs that function as surgical supplies may be warranted. In particular, we believe it may be appropriate to pay separately for evidence-based non-opioid pain management drugs that function as a supply in a surgical procedure in the ASC setting to address the decreased utilization of these drugs and to encourage use of these types of drugs rather than prescription opioids. Therefore, we are proposing 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 for CY 2019.

We have stated previously (82 FR 59250) that our packaging policies are designed to support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient

[54] Food and Drug Administration, Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee Briefing Document (2018). Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM596314.pdf.*

[55] Ibid, page 9.

[56] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022496s009lbledt.pdf.*

manner. The packaging policies established under the OPPS also typically apply when services are provided in the ASC setting, and the policies have the same strategic goals in both settings. While this proposal is a departure from our current ASC packaging policy for drugs (specifically, non-opioid pain management drugs) that function as a supply when used in a surgical procedure, we believe that this proposed change would incentivize the use of non-opioid postsurgical pain management drugs and is an appropriate response to the Commission's recommendation to examine payment policies for non-opioid pain management drugs that function as a supply with the overall goal of combating the current opioid addiction crisis. However, we are also interested in peer-reviewed evidence that demonstrates that use of non-opioid alternatives, such as Exparel, in the outpatient setting actually do lead to a decrease in prescription opioid use and addiction and are seeking comments containing the types of evidence that demonstrate whether and how such non-opioid alternatives affect prescription opioid use during or after an outpatient visit or procedure.

As noted, for CY 2019, we are proposing to pay separately at average sales price (ASP) plus 6 percent for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in the ASC setting. As described in section V.A.1. of this proposed rule, section 1847A of the Act establishes the 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) (82 FR 59337). As noted in section V.B.2.b. of this proposed rule, since CY 2013, our policy has been to pay for separately payable drugs and biologicals at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default) (82 FR 59350).

We are not proposing a change to the packaging policy under the OPPS for CY 2019. However, we are proposing to pay separately at ASP+6 percent for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in the ASC setting for CY 2019. Because the ASC payment rate also includes packaged payment for non-opioid pain management drugs, we intend to remove the packaged costs attributable to non-opioid pain management drugs—at this time, only Exparel qualifies—from the applicable OPPS rates prior to establishing the ASC rates in order to prevent potential overpayment of these procedures when separate payment is provided in the ASC setting.

Of the drugs that are currently packaged in the ASC setting, this policy would apply to Exparel. Exparel is the only non-opioid pain management drug that functions as a supply when used in a surgical procedure that is covered under Medicare Part B. While there are other non-opioid pain management drugs available that are also administered post-surgically, such as non-steroidal anti-inflammatory drugs (''NSAIDs''), Exparel is the currently the only drug used in the ASC setting that is both covered under Medicare Part B and policy packaged as a drug that functions as a supply in a surgical procedure. To the extent that other non-opioid drugs that function as surgical supplies come onto the U.S. market, we are proposing that this policy would apply to them as well in CY 2019. This proposal is also presented in section II.A.3.b. of this proposed rule for the OPPS. We are proposing a conforming change to the ASC regulation at 42 CFR 416.164(a)(4) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure as an ASC service for which payment is packaged into the payment for a covered surgical procedure. We also are proposing a conforming change to 42 CFR 416.164 (b)(6) to include non-opioid pain management drugs that function as a supply when used in a surgical procedure as a covered ancillary service that is integral to a covered surgical procedure.

In addition, as noted in section II.A.3.b. of this proposed rule, we are seeking comment on whether the proposed policy would decrease the dose, duration and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure (especially for beneficiaries at high-risk for opioid addiction) as well as whether there are other non-opioid pain management alternatives that would have similar effects and may, therefore, warrant separate payment. For example, we are interested in identifying whether single post-surgical analgesic injections, such as Exparel, or other non-opioid drugs or devices that are used during an outpatient visit or procedure are associated with decreased opioid prescriptions and reduced cases of associated opioid addiction following such an outpatient visit or procedure. We are also requesting comments that provide evidence (such as published peer-reviewed literature), 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 separate payment under either or both the OPPS and the ASC payment system. The reduction or avoidance of prescription opioids would be the criteria we would seek to determine whether separate payment was warranted for CY 2019. Should evidence change over time, we would consider whether a reexamination of any policy adopted in the final rule would be necessary.

In addition, we also are inviting the public to submit ideas on regulatory, subregulatory, policy, practice, and procedural changes to help prevent opioid use disorder and improve access to treatment under the Medicare program. We are interested in identifying barriers that may inhibit access to non-opioid alternatives for pain treatment and management or access to opioid use disorder treatment, including those barriers related to payment methodologies or coverage. In addition, consistent with our ''Patients Over Paperwork'' Initiative, we also are interested in suggestions to improve existing requirements in order to more effectively address the opioid epidemic.

As noted above, and discussed in section II.A.3.b.of this proposed rule we are interested in comments regarding other non-opioid treatments for acute or chronic pain besides Exparel that might be affected by OPPS and ASC packaging policies including alternative, non-opioid pain treatments, such as devices or therapy services that are not currently separable payable. We are specifically interested in comments regarding whether CMS should consider separate payment for such items and services for which payment is currently packaged under the OPPS and ASC payment systems that are effective non-opioid alternatives as well as evidence that demonstrates such items and services lead to a decrease in prescription opioid use during or after an outpatient visit or procedure in order to determine whether separate payment may be warranted. We intend to examine the evidence submitted to determine whether to adopt a final policy that incentivizes use of non-opioid alternative items and services that have evidence to demonstrate an associated decrease in prescription opioid use and addiction following an outpatient visit

or procedure. Some examples of evidence that may be relevant could include an indication on the product's FDA label or studies published in peer-reviewed literature that such product aids in the management of acute or chronic pain and is an evidence-based non-opioid alternative for acute and/or chronic pain management. We would also be interested in evidence relating to products that have shown clinical improvement over other alternatives, such as a device that has been shown to provide a substantial clinical benefit over the standard of care for pain management. This could include, for example, spinal cord stimulators used to treat chronic pain such as the devices described by HCPCS codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), and C1767 (Generator, neurostimulator (implantable), nonrechargeable) which are primarily assigned to APCs 5463–5464 (Levels 3 and 4 Neurostimulator and Related Procedures) with proposed CY 2019 payment rates of $18,718 and $27,662, respectively, that have received pass-through payment status as well as other similar devices.

Currently, all devices are packaged under the OPPS and ASC payment systems unless they have pass-through status, however, in light of the Commission's recommendation to review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, we are interested in comments from stakeholders regarding whether, similar to the goals of the proposed payment policy for non-opioid pain management drugs that function as a supply when used in a surgical procedure, a policy of providing separate payment (rather than packaged payment) for these products, indefinitely or for a specified period of time would also incentivize the use of alternative non-opioid pain management treatments and improve access to care for non-opioid alternatives, particularly for innovative and low-volume items and services.

We are also interested in comments regarding whether we should provide separate payment for non-opioid pain management treatments or products using a mechanism such as an equitable payment adjustment under our 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. For example, we are considering whether an equitable payment adjustment in the form of an add-on payment for APCs that use a non-opioid pain management drug, device or service would be appropriate. To the extent that commenters provide evidence to support this approach being adopted, we would consider adopting a final policy, which could include regulatory changes that would allow for an exception to the packaging of certain non-passthrough devices which represent non-opioid alternatives for acute or chronic pain that have evidence to demonstrate that their use leads to a decrease in opioid prescriptions or addictions, in the final rule to effectuate such change.

Alternatively, we are interested in comments on whether a reorganization of the APC structure for procedures involving these products or establishing more granular APC groupings for specific procedure and device combinations to ensure that the payment rate for such services is aligned with the resources associated with procedures involving specific devices would better achieve our goal of incentivizing increased use of non-opioid alternatives, with the aim of reducing opioid use and subsequent addiction. For example, we would consider finalizing a policy to establish new APCs for procedures involving non-opioid pain management packaged items or services if such APC would better recognize the resources involved in furnishing such items and services and decrease or eliminate the need for prescription opioids. In addition, given the general desire to encourage provider efficiency through creating larger bundles of care and packaging items and services that are integral, ancillary, supportive, dependent, or adjunctive to a primary service, we are also seeking comment on how such alternative payment structures would continue to balance the goals of incentivizing provider efficiencies with encouraging the use of non-opioid alternatives to pain management.

Furthermore, since patients may receive opioid prescriptions following receipt of a non-opioid drug or implantation of a device, we are interested in identifying any cost implications for the patient and Medicare program caused by this potential change in policy. The implications of incentivizing non-opioid pain management drugs available for postsurgical acute pain relief during or after an outpatient visit or procedure are also of interest, including for non-opioid drugs. The goal is to encourage appropriate use of such non-opioid alternatives. This comment solicitation is also discussed in section II.A.3.b. of this proposed rule.

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 42 CFR 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 42 CFR 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 2019

We did not receive any requests for review to establish a new NTIOL class for CY 2019 by March 1, 2018, the due date published in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59416).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2019.

F. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC list of covered services 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 used 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 ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the interim 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, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In the CY 2017 OPPS/ASC final rule with comment period, we responded to public comments and finalized the ASC treatment of all codes that were labeled with comment indicator ''NP'' in Addenda AA and BB to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The ''CH'' comment indicator is used in Addenda AA and BB to the proposed rule (which are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example if an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79748 through 79749), for CY 2017 and subsequent years, we finalized our policy to continue using the current comment indicators of ''NP'' and ''CH''.

2. Proposed ASC Payment and Comment Indicators

For CY 2019, there are 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 2018 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2019 compared to the CY 2018 descriptors that are included in ASC Addenda AA and BB to this proposed rule are labeled with proposed comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes are open for comment as part of this proposed rule. Proposed comment indicator ''NP'' means 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 denotes that comments will be accepted on the proposed ASC payment indicator for the new code.

We will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2019 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 to this proposed rule (which are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2019 update.

G. Calculation of the Proposed ASC Payment Rates and the Proposed 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; 42 CFR 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 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.

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. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66937), we finalized a 1-year transition policy that we applied in CY 2015 for all ASCs that experienced any decrease in their actual wage index exclusively due to the implementation of the new OMB delineations. This transition does not apply in CY 2019.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, 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. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. The complete list of statistical areas incorporating these changes is provided in the attachment to OMB Bulletin No. 15–01. According to OMB, ''[t]his bulletin establishes revised delineations for the Nation's Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provides delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas.'' (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf.*)

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.

In OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

- Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB bulletin is available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.* We note that we did not have sufficient time to include this change in the computation of the proposed FY 2019 IPPS wage index. This new CBSA may affect the budget neutrality factors and wage indexes, depending on the impact of the overall payments of ASCs located in this new CBSA. We are providing below an estimate of this new area's wage index based on the average hourly wages for new CBSA 46300 and the national average hourly wages from the wage data for the proposed FY 2019 wage index (described in section III.B. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule). Currently, provider 130002 is the only hospital located in Twin Falls County, Idaho, and there are no hospitals located in Jerome County, Idaho. Thus, the proposed wage index for CBSA 46300 is calculated using the average hourly wage data for one provider (provider 130002).

	Estimated unadjusted wage index for new CBSA 46300	Estimated occupational mix adjusted wage index for new CBSA 46300
Proposed National Average Hourly Wage	42.990625267	42.948428861
Estimated CBSA Average Hourly Wage	35.833564813	38.127590025
Estimated Wage Index	0.8335	0.8878

Other than the previously described wage index, for CY 2019, the proposed CY 2019 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 No. 15–01).

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. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2019 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS 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). Consistent with our established policy, we are proposing to scale the CY 2019 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 2017, we are proposing to compare the total payment using the CY 2018 ASC relative payment weights with the total payment using the CY 2019 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2018 and CY 2019. We are proposing to use the ratio of CY 2018 to CY 2019 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2019. The proposed CY 2019 ASC weight scalar is 0.8854 and scaling would apply to the ASC relative payment weights of the covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of this proposed rule, we had available 98 percent of CY 2017 ASC claims data.

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 2017 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2017 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for this proposed rule, is posted on the CMS website at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html.*

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 2019, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2017 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2019 ASC wage indexes. Specifically, holding CY 2017 ASC utilization, service-mix, and the proposed CY 2019 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2018 ASC wage indexes (which would fully reflect the new OMB delineations) and the total adjusted payment using the

proposed CY 2019 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 2018 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2019 ASC wage indexes and applied the resulting ratio of 1.0003 (the proposed CY 2019 ASC wage index budget neutrality adjustment) to the CY 2018 ASC conversion factor to calculate the proposed CY 2019 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 42 CFR 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 2018 OPPS/ASC rulemaking (82 FR 33668 through 33670; 59422 through 59424), we solicited and discussed comments regarding our current policy, codified at 42 CFR 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 2018 OPPS/ASC final rule with comment period, we noted that in 2008 facilities paid under the ASC payment system received approximately 65 percent of the payment that hospitals paid under the OPPS received for an average service. The differential between ASC facility payment and OPPS provider payment has continued to increase since 2008, and by 2017, facilities paid under the ASC payment system received approximately 56 percent of the payment that hospitals paid under the OPPS received for an average service. At the same time, indicators of ASC payment adequacy, such as capacity and supply of providers and providers' access to capital, suggest that Medicare beneficiaries have adequate access to ASC services.[57]

The Administration recognizes the value that ASCs may bring to the Medicare Program that results in the delivery of efficient, high-quality care to beneficiaries at a lower cost. The Administration is promoting greater price transparency across all of Medicare's payment systems. Both beneficiaries and the Medicare Program benefit from reduced expenditures when a beneficiary's clinical needs allow for a procedure to be performed in lower cost settings, such as ASCs relative to hospital outpatient departments.[58]

As articulated in the FY 2019 President's Budget, the Administration supports payment reforms that base payment on patient characteristics rather than the site of care. To that end, we are exploring ways to align payments with the costs of care and to incentivize use of the most efficient and clinically appropriate sites of care including hospital outpatient departments, ASCs, and physician offices, to the extent feasible, in future rulemaking. In the near term, however, there is concern by some stakeholders that the differential between payment updates for HOPDs and ASCs is resulting in inefficient and unnecessary shifts of care to the hospital outpatient setting and away from ASCs. We are concerned about the potential unintended consequences of using the CPI–U to update payments for ASCs, such as consolidation of ASCs or fewer physician-owned ASCs, which may contribute to higher prices; stagnation in number of ASC facilities and number of multispecialty ASC facilities; and payments being misaligned with the cost of treatment for complex patients.

We recognize commenters' belief that ASCs may incur some of the same costs that hospitals incur, which may be better reflected in the hospital market basket update than the CPI–U. Nevertheless, we recognize also that ASCs are among the only health care facilities in Medicare that do not submit cost information and therefore their rates are not updated based on a related market basket. We do not believe that the ASC cost structure is identical to the hospital cost structure for a few reasons (these differences are illustrative and not exhaustive). First, the majority of ASCs are single specialty (61 percent based on 2016 data), whereas hospitals provide a wider variety of services, and also provide inpatient care and room and board. Second, the vast majority of ASCs are for-profit and located in urban areas, whereas hospital ownership is varied and hospitals are located in more geographically diverse locations. Third, compliance with certain laws, such as the Emergency Medical Treatment and Labor Act (EMTALA), apply to hospitals and do not apply to ASCs. These differences illustrate why there is reason to believe there is a measure of misalignment between the HOPD and ASC cost structure, and should be considered when assessing the suitability of using the hospital market basket as a better proxy for ASC costs than the CPI–U.

According to commenters on last year's proposed rule, only 8.5 percent of the CPI–U inputs are related to health care, and even those inputs are based on a consumer's experience purchasing health care items, rather than a provider's experience purchasing the items necessary to furnish a health care service, and do not measure whether a facility's costs increase, such as the cost of purchasing supplies and equipment or personnel labor costs.

We also acknowledge commenters' concern that the disparity in payments between the OPPS and the ASC payment system may reduce the migration of services from the HOPD setting to the less costly ASC setting. For example, one study looked at the impact of the difference in facility fees paid to ASCs versus hospital outpatient departments on ASC growth using a fixed effects model.[59] The study found results indicating that, as ASC payments increase, patients are more likely to undergo outpatient procedures in an ASC than they are in a hospital. Another study found that the opening of an ASC in a hospital service area resulted in a decline in hospital-based outpatient surgery without increasing mortality or admission.[60] In markets where facilities opened, procedure growth at ASCs was greater than the decline in outpatient surgery use at their respective hospitals.

If a migration of services from the hospital setting to ASCs occurred, it may potentially yield savings to the Medicare program and beneficiaries if the savings from the migration of services net of any increases in total volume of services does not exceed the cost of a higher rate update factor. ASC

[57] MedPAC. Report to the Congress: March 2018.

[58] *Medicare Beneficiaries Could Save Billions if CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates,* Department of Health and Human Services, Office of Inspector General, April 2014.

[59] Munnich EL, Parente ST. Returns to Specialization: Evidence from the Outpatient Surgery Market. Journal of Health Economics. Volume 57. January 2018.

[60] Hollenbeck BK, Dunn RL, et. al. Ambulatory Surgery Centers and Their Intended Effects on Outpatient Surgery. HSR: Health Services Research. 50:5. October 2015.

payment rates would still generally be significantly less than under the OPPS.

To the extent that it is clinically appropriate for a beneficiary to receive services in a lower cost setting, we believe it would be appropriate to continue to develop payment incentives and remove payment disincentives to facilitate this choice. While there are several factors that contribute to the divergence in payment between the two systems (which were identified in the comment solicitation on ASC payment reform in the CY 2018 OPPS/ASC rulemaking), such as different distribution of costs between hospitals and ASCs and different ratesetting methodologies between the OPPS and the ASC payment system, we believe that an alternative update factor could stabilize the differential between the OPPS payment and the ASC payment, to the extent that the CPI–U has been lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate (82 FR 59422 through 59424). In addition, we note that there are many services that can safely be performed in either the hospital setting or the ASC setting and a common rate update factor recognizes that the two provider types often compete for the same patients though patient acuity is likely higher in hospitals.

Therefore, we believe providing ASCs with the same rate update mechanism as hospitals could encourage the migration of services from the hospital setting to the ASC setting and increase the presence of ASCs in health care markets or geographic areas where previously there were none or few, thus promoting better beneficiary access to care. However, because physicians have a financial interest in ASCs, higher payments could also lead to greater utilization of services.[61] At the same time, we are cognizant of concerns that Medicare does not currently collect cost data from ASCs, which makes it difficult to assess payment adequacy in the same way that it is assessed for hospitals, to validate alignment between ASC and hospital cost structure, or to establish an ASC-specific market basket. Accordingly, until we have information on the ASC cost structure, we would like to balance our desire to promote migration of services away from the HOPD to ASCs where clinically appropriate with our desire to minimize increases in beneficiary out-of-pocket costs. Therefore, as described in more specific detail below, we are proposing to apply a hospital market basket update to ASCs for an interim period of 5 years but are seeking comments on ASC costs to assess whether the hospital market basket is an appropriate proxy for ASC costs. We note that the hospital market basket is collected under OMB Control No. 0938–0050 and the information collected through hospital cost reports is used, in part, to inform the calculation of the hospital market basket.

The hospital market basket update would be derived using the same hospital inpatient market basket percentage increase that we are proposing to use to derive the OPD fee increase factor as described in section II.B. of this proposed rule and is adjusted for multifactor productivity. We are proposing this payment update methodology for a 5-year period, during which we would assess whether there is a migration of procedures from the hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there are any unintended consequences (for example, an unnecessary increase in the overall volume of services or beneficiaries' out-of-pocket costs). We believe that 5 years would be an appropriate number of years to assess changes in the migration of services, as it should provide us enough time to confirm that trends in the data are consistent over time. We welcome comment on whether implementing the hospital market basket update for a different number of years might be more appropriate.

We are interested in commenter feedback on additional ways we can evaluate the impacts of this payment change over the 5-year period. For example, we welcome input on how we should delineate between changes in the volume of a particular service due to the higher update, versus changes in the volume of a service due to changes in enrollment, patient acuity, or utilization, and what would be an appropriate interval to measure such migration of services. 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. As previously mentioned, in response to the comment solicitation in the CY 2018 OPPS/ASC proposed rule, stakeholders indicated a willingness to work with CMS to collect cost information in the least burdensome manner (82 FR 59422 through 59424).

Therefore, for CY 2019 through 2023, in response to stakeholder concerns described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59420 through 59421) that ASCs may incur some of the same costs that hospitals incur and that are better reflected in the hospital market basket update than the CPI–U, and including the concern that the payment differentials between the different settings of care due to the use of the CPI–U may stagnate the migration of services from hospitals to the ASC setting, even though those services can be safely performed in ASCs, we are proposing to update ASC payment rates using the hospital market basket and to revise our regulations under 42 CFR 416.171(a)(2), which address the annual update to the ASC conversion factor, to reflect this proposal. In addition, we are requesting comments and evidence to assess whether the hospital market basket is an appropriate proxy for ASC costs. Under this proposal, for CY 2019, we would use the proposed FY 2019 hospital market basket update as published in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20381). This proposed update to ASC payment rates would be derived using the same hospital inpatient market basket percentage increase that we are proposing to use to derive the OPD fee increase factor as described in section II.B. of this proposed rule. We also are seeking comments on an alternative proposal to maintain CPI–U while collecting evidence to justify a different payent pdate, or adopting the new proposed payhment update based on the hospital market basket permanently. We are requesting comments on what type of evidence should be used to justify a different payment update and how CMS should go about collecting that information in the least burdensome way possible.

Section 1833(t)(3)(G)(v) of the Act applies an additional adjustment of 0.75 for CY 2019 to hospitals. We note that such adjustment was authorized by the Affordable Care Act and that, while the Affordable Care Act authorized a productivity adjustment for ASCs (as it did for hospitals), it expressly did not authorize the ''additional adjustment'' that was mandated for hospitals. The additional adjustment is separate and distinct from the productivity adjustment that already applies to both hospitals and ASCs and there does not appear to be a correlation between the productivity adjustment and the additional adjustment. Further, application of the additional adjustment may be contrary to the goals we have

[61] Munnich EL, Parente ST. Returns to Specialization: Evidence from the Outpatient Surgery Market. Journal of Health Economics. Volume 57. January 2018.

articulated that led us to propose to apply the hospital market basket to the ASC payment system in the first place; that is, we believe that proposing to apply the hospital market basket to ASC rates may encourage the migration of services from the hospital setting to the ASC setting. However, if we were to propose to apply the additional adjustment, the ASC rate update would be 1.25 percent, instead of the proposed 2.0 percent. The 1.25 percent is lower than applying the CPI–U rate update factor, which would have been 1.3 percent for CY 2019. This lower update would appear contrary to the goals set forth earlier in this section. However, we are seeking comment on whether applying this additional adjustment may nonetheless be appropriate.

While we expect this proposal would increase spending, by both the government and beneficiaries, relative to the current update factor over the 5-year period, as previously stated, we believe that the proposal could encourage the migration of services that are currently performed in the hospital outpatient setting to the ASC setting, which could result in savings to beneficiaries and the Medicare program. We believe that it is important to maximize patient choice to obtain services at a lower cost to the extent feasible. We believe also that without cost data from ASCs to examine their cost structure and adequacy of payment, we lack key data that may help inform the development of payment policies that are based on patients' clinical needs rather than the site of care.

If, after review of all comments and all available evidence, we choose to finalize this proposal, we will continue to monitor site-of-service shifts for the duration of this policy to determine if services move safely to lower cost settings and to explore collecting additional data that may help inform further development of the ASC payment system. We are proposing to continue to use the adjusted hospital market basket update through CY 2023 (for 5 years total). We intend to reassess whether application of the hospital market basket update to ASC rates has provided more patient choice to obtain services at a lower cost beginning with the CY 2024 rulemaking period, or sooner if appropriate. Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v), which requires that any annual update under the ASC payment system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, effective with the calendar year beginning January 1, 2011. The statute 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) (the ''MFP adjustment''). Clause (iv) of section 1833(i)(2)(D) of the Act authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) of section 1833(i)(2)(D) of the Act states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASC Quality Reporting (ASCQR) Program. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), we finalized a methodology to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for the CY 2014 payment determination and subsequent years. The application of the 2.0 percentage point reduction to the annual update factor, which we are proposing to be the hospital market basket update, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We amended §§ 416.160(a)(1) and 416.171 to reflect these policies.

In prior years, in accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determined the ''percentage increase'' in the CPI–U, which we interpreted cannot be a negative percentage. Thus, in the instance where the percentage change in the CPI–U for a year was negative, we would hold the CPI–U update factor for the ASC payment system to zero (75 FR 72062). Consistent with past practice, in the instance where the percentage change in the hospital market basket for a year is negative, we are proposing to hold the hospital market basket update factor for the ASC payment system to zero. For the CY 2014 payment determination and subsequent years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality information under the policies established by the Secretary in accordance with section 1833(i)(7) of the Act.

Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the annual update factor, after application of any quality reporting reduction, by the MFP adjustment, and states that application of the MFP adjustment to the annual update factor after application of any quality reporting reduction may result in the update being less than zero for a year. If the application of the MFP adjustment to the annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting update to the ASC payment rates would be negative and payments would decrease relative to the prior year. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064) for examples of how the MFP adjustment is applied to the ASC payment system.

For this proposed rule, as published in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20381), based on IHS Global Inc.'s (IGI's) 2017 fourth quarter forecast with historical data through the third quarter of 2017, the hospital market basket update for CY 2019 is projected to be 2.8 percent.

We finalized the methodology for calculating the MFP adjustment in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 MPFS 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). For this proposed rule, as published in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20382) based on IGI's 2017 fourth quarter forecast, the proposed MFP adjustment for CY 2019 is projected to be 0.8 percent.

We note that the update factor for CY 2019 under the current policy, which is to increase the payment amounts by the percentage increase in the CPI–U, U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved, is currently projected to be 2.1 percent (based on IGI's first quarter 2018 forecast). If we were to derive the MFP adjustment that aligns with this

payment update under current policy (ending with the midpoint of the year involved), the MFP adjustment is projected to be 0.8 percent, which would lead to a proposed update amount of 1.3 percent.

For CY 2019, we are proposing to utilize the hospital market basket update of 2.8 percent minus the MFP adjustment of 0.8 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.0 percent for ASCs meeting the quality reporting requirements. Therefore, we are proposing to apply a 2.0 percent MFP-adjusted hospital market basket update factor to the CY 2018 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2019 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 are proposing to utilize the hospital market basket update of 2.8 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.8 percentage point MFP adjustment. Therefore, we are proposing to apply a 0.0 percent MFP-adjusted hospital market basket update factor to the CY 2018 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also are proposing 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 2019 ASC update for the final rule with comment period.

For CY 2019, we are proposing to adjust the CY 2018 ASC conversion factor ($45.575) by the proposed wage index budget neutrality factor of 1.0003 in addition to the MFP-adjusted hospital market basket update factor of 2.0 percent discussed above, which results in a proposed CY 2019 ASC conversion factor of $46.500 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2018 ASC conversion factor ($45.575) by the proposed wage index budget neutrality factor of 1.0003 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.0 percent discussed above, which results in a proposed CY 2019 ASC conversion factor of $45.589.

3. Display of Proposed CY 2019 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS website) display the proposed updated ASC payment rates for CY 2019 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 proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed MPFS rates that would be effective January 1, 2019. For a discussion of the MPFS rates, we refer readers to the CY 2019 MPFS proposed rule.

The proposed payment rates included in these addenda reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the proposed CY 2019 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 2018. 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.

The values displayed in the column titled ''Proposed CY 2019 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2019. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the proposed CY 2019 payment rate displayed in the ''Proposed CY 2019 Payment Rate'' column, each ASC payment weight in the ''Proposed CY 2019 Payment Weight'' column was multiplied by the proposed CY 2019 conversion factor of $46.500. The proposed 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 (as discussed in section XII.G.2.b. of this proposed rule). In Addendum BB, there are no relative payment weights displayed in the ''Proposed CY 2019 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2019 Payment'' column displays the proposed CY 2019 national unadjusted ASC payment rates for all items and services. The proposed CY 2019 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 April 2018.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2019.

XIII. 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 (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). In addition to the Hospital IQR and Hospital OQR Programs, CMS has implemented quality reporting programs as well as value-based purchasing programs for other care settings.

We refer readers to section I.A.2. of this proposed rule where we discuss our new Meaningful Measures Initiative and our approach in evaluating quality program measures.

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 2018 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; and 81 FR 79753 through 79797; 82 FR 59424 through 59445). We have also codified certain requirements under the Hospital OQR Program at 42 CFR 419.46.

4. Meaningful Measures Initiative

In this proposed rule, we are proposing a number of new policies for the Hospital OQR Program. We developed these proposals after conducting an overall review of the program under our new Meaningful Measures Initiative, which is discussed in more detail in section I.A.2. of this proposed rule. The proposals reflect our efforts to ensure that the Hospital OQR Program measure set continues to promote improved health outcomes for our beneficiaries while minimizing costs, which can consist of several different types of costs including, but not limited to: (1) Facility information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the facility cost associated with complying with other quality programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or State regulations (if applicable). They also reflect our efforts to improve the usefulness of the data that we publicly report in the Hospital OQR Program. Our goal is to improve the usefulness and usability of CMS quality program data by streamlining how facilities are reporting and accessing data, while maintaining or improving consumer understanding of the data publicly reported on a *Compare* website. We believe this framework will allow hospitals and patients to continue to obtain meaningful information about HOPD performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in this program do not outweigh the benefits of improving beneficiary care.

B. Hospital OQR Program Quality Measures

1. Considerations in the Selection of Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We are not proposing any changes to these policies.

2. Accounting for Social Risk Factors in the Hospital OQR Program

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59425 through 59427), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[62] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[63] As we noted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59425), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59425), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[64] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[65]

[62] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities;* or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[63] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[64] National Quality Forum. Final Report-Disparities Project. September 2017. Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx.*

[65] National Quality Forum. Health Equity Program: Social Risk Initiative 2.0. 2017. Available

allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or facility that would also allow for a comparison of those differences, or disparities, across facilities. Feedback we received through our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patients' backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public. We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower beneficiaries and other consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discourage the provision of care to more medically complex patients. Commenters also noted that value-based purchasing program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to reduce health disparities among patient groups within and across health care settings by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

3. 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). Thus, quality measures adopted in a previous year's rulemaking are retained in the Hospital OQR Program for use in subsequent years unless otherwise specified. We refer readers to that final rule with comment period for more information. We are not proposing any changes to our retention policy; however, we are proposing to codify this policy at proposed 42 CFR 419.46(h)(1).

4. Removal of Quality Measures From the Hospital OQR Program Measure Set

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60315), we finalized a process 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.[66] We are not proposing any changes to this policy; however, we are proposing to codify this policy at 42 CFR 419.46(h)(3). We refer readers to section XIII.B.4.a. of this proposed rule for more details.

a. Considerations in Removing Quality Measures from the Hospital OQR Program

(1) Immediate Removal

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635), we finalized a process for immediate retirement, which we later termed ''removal,'' of Hospital OQR Program measures, based on evidence that the continued use of the measure as specified raise patient safety concerns.[67] We are not proposing any changes to our policy to immediately remove measures as a result of patient safety concerns; however, we are proposing to codify that policy at 42 CFR 419.46(h)(2).

(2) Consideration Factors for Removing Measures

In the CY 2013 OPPS/ASC final rule with comment period, we finalized a set of factors[68] for determining whether to remove measures from the Hospital OQR Program (77 FR 68472 through 68473). These factors are:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures).
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences such as patient harm.

In addition, we refer readers to the CY 2015 OPPS/ASC final rule with comment period where we finalized the criteria for determining when a measure is ''topped-out'' (79 FR 66769). In that final rule with comment period, we finalized two criteria for determining when a measure is ''topped out'' under the Hospital OQR Program: (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10 (79 FR 66942).

The benefits of removing a measure from the Hospital OQR Program are

at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357.*

[66] 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.

[67] 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.

[68] 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.

assessed on a case-by-case basis (79 FR 66941 through 66942). We note that, under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor. We note that in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967), a similar measure removal policy was finalized for the ASCQR Program. In this proposed rule, we are proposing to: (1) Update measure removal Factor 7; (2) add a new removal Factor 8; and (3) codify our measure removal policies and factors at 42 CFR 419.46(h) effective upon finalization of the CY 2019 OPPS/ASC final rule and for subsequent years. We also are providing clarification of our ''topped-out'' criteria.

(3) Proposed Update to Measure Removal Factor 7

As shown above, Factor 7 under the Hospital OQR Program states, ''collection or public reporting of a measure leads to negative unintended consequences *such as* patient harm.'' In contrast, under the ASCQR Program, Factor 7 reads as follows, ''collection or public reporting of a measure leads to negative unintended consequences *other than* patient harm'' (79 FR 66967). We believe the wording in the ASCQR Program is more appropriate because measures causing patient harm would be removed from the program immediately, outside of rulemaking, in accordance with our previously finalized policy to immediately remove measures as a result of patient safety concerns (74 FR 60634 and discussed above). Therefore, in this proposed rule, we are proposing to change measure removal Factor 7 in the Hospital OQR Program to ''collection or public reporting of a measure leads to negative unintended consequences other than patient harm'' such that it aligns with measure removal Factor 7 in the ASCQR Program.

(4) Proposed New Measure Removal Factor 8

We are proposing to adopt an additional factor to consider when evaluating measures for removal from the Hospital OQR Program measure set:

- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

As we discuss in section I.A.2. of this proposed rule with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the Hospital OQR Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Facility information collection burden and related costs and burden associated with the submission/reporting of quality measures to CMS; (2) the facility cost associated with complying with other programmatic requirements; (3) the facility cost associated with participating in multiple quality programs and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure including measure maintenance and public display; and (5) the facility cost associated with compliance with other Federal and State regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for health care providers to track confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

In weighing the costs against the benefits, we evaluate the benefits of the measure, but, we assess the benefits through the framework of our Meaningful Measures Initiative, as we discussed in section I.A.2. of this proposed rule. One key aspect of patient benefits is assessing the improved beneficiary health outcomes if a measure is retained in our measure set. We believe that these benefits are multifaceted, and are illustrated through the Meaningful Measures framework's 6 domains and 19 areas. For example, we assessed the Healthcare Worker Influenza Vaccination and patient Influenza Vaccination measures categorized in the Quality Priority ''Promote Effective Prevention and Treatment of Chronic Disease'' in the meaningful measure area of ''Preventive Care'' across multiple CMS programs, and considered: patient outcomes, such as mortality and hospitalizations associated with influenza; CMS measure performance in a program; and other available and reported influenza process measures, such as population influenza vaccination coverage.

When these costs outweigh the evidence supporting the benefits to patients with the continued use of a measure in the Hospital OQR Program, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the Hospital OQR Program is to improve beneficiary outcomes by incentivizing health care facilities to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data (including percentage payment adjustment data) is of limited use because it cannot be easily interpreted by beneficiaries, and used to inform their choice of facility. In these cases, removing the measure from the Hospital OQR Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are proposing that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care facilities to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. We are inviting public comment on our proposal to adopt an additional measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period and for subsequent years.

We refer readers to section XIII.B.4.b. of this proposed rule, where we are proposing to remove two measures based on this proposed measure removal factor. We note that we have also proposed this same removal factor for the ASCQR Program in section XIV.B.3.b. of this proposed rule, as well as for other quality reporting and value-based purchasing programs for FY 2019 including: the Hospital Value-Based Purchasing (VBP) Program (83 FR 20409), the Hospital IQR Program (83 FR 20472); the PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program (83 FR 20501 through 20502); the Long-Term Care Hospital Quality

Reporting Program (LTCH QRP) (83 FR 20512); the Hospice Quality Reporting Program (HQRP) (83 FR 20956); the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) (83 FR 21000); the Skilled Nursing Facility Quality Reporting Program (SNF QRP) (83 FR 21082); and the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program (83 FR 21118).

If our proposals to update one and add one new removal factor are finalized as proposed, the new removal factors list would be:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures).
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

(5) Proposed Codification at 42 CFR 419.46(h)(2) and (3)

We are proposing to codify our measure removal policies, including proposals made in this rule, in proposed 42 CFR 419.46(h)(2) and (3).

(6) Clarification of Removal Factor 1: ''Topped-Out'' Measures

As noted above, we refer readers to the CY 2015 OPPS/ASC final rule with comment period where we finalized the criteria for determining when a measure is ''topped-out'' (79 FR 66769). In that final rule with comment period, we finalized two criteria for determining when a measure is ''topped out'' under the Hospital OQR Program: (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10 (79 FR 66942).

In this proposed rule, we are clarifying our process for calculating the truncated coefficient of variation (TCOV), particularly for two of the measures (OP–11 and OP–14) proposed for removal from the Hospital OQR Program. In accordance with our finalized methodology (79 FR 66942), we determine the truncated coefficient of variation (TCOV) by calculating the truncated standard deviation (SD) divided by the truncated mean. As discussed above, our finalized removal criteria state that to be considered ''topped-out,'' a measure must have a truncated TCOV of less than 0.10. We utilize the TCOV because it is generally a good measure of variability and provides a relative methodology for comparing different types of measures.

Unlike the majority of the measures, for which a higher rate (indicating a higher proportion of a desired event) is the preferred outcome, some measures—in particular, OP–11 and OP–14—assess the rate of rare, undesired events for which a lower rate is preferred. For example, OP–11 assesses the use of both a contrast and non-contrast CT Thorax study at the same time, which is not recommended, as no clinical guidelines or peer-reviewed literature supports such CT Thorax ''combined studies.'' However, when determining the TCOV for a measure assessing rare, undesired events, the mean–or average rate of event occurrence–is very low, and the result is a TCOV that increases rapidly and approaches infinity as the proportion of rare events declines.[69] We note that the SD, the variability statistic, is the same in magnitude for measures assessing rare and nonrare events.

In this proposed rule, we are proposing to remove two measures that assess the rate of rare, undesired events for which a lower rate is preferred—OP–11 and OP–14—and refer readers to section XIII.B.4.b. of this proposed rule, where these proposals are discussed in detail. Because by design these measures have maintained very low rates of rare, undesired events (indicating the preferred outcomes), we utilized the mean of *non-adverse* events in our calculation of the TCOV. For example, for OP–11, to calculate the TCOV, we divide the SD by the average rate of patients *not* receiving both contrast and non-contrast abdominal CT (1.0 minus the rate of patients receiving both), rather than the rate of those receiving both types of CT. Utilizing this methodology results in a TCOV that is comparable to that calculated for other measures and allows us to assess rare-event measures by still generally using our previously finalized topped-out criteria.

b. Proposed Removal of Quality Measures from the Hospital OQR Program Measure Set

In this proposed rule, we are proposing to remove a total of 10 measures from the Hospital OQR Program measure set across the CY 2020 and CY 2021 payment determinations. Specifically, beginning with the CY 2020 payment determination, we are proposing to remove (1) OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and beginning with the CY 2021 payment determination, we are proposing to remove—(2) OP–5: Median Time to ECG (NQF #0289); (3) OP 31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536); (4) OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); (5) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); (6) OP–9: Mammography Follow-up Rates (no NQF number); (7) OP–11: Thorax Computed Tomography (CT)—Use of Contrast Material (NQF #0513); (8) OP–12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data (NQF endorsement removed); (9) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT (no NQF number); and (10) OP–17: Tracking Clinical Results between Visits (NQF endorsement removed). We are proposing to remove these measures under the following removal factors: proposed measure removal Factor 8—the costs associated with a measure outweigh the benefit of its continued use in the program; measure removal Factor 3—a measure does not align with current clinical guidelines or practice; measure removal Factor 1—measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures); and measure removal Factor 2—performance or improvement on a measure does not result in better patient outcomes. These

[69] Rose-Hulman Institute of Technology. Denominator approaching zero. Available at: *https://www.rose-hulman.edu/media/89584/lclimitsguide.pdf.*

proposed measure removals are discussed in detail below.

(1) Proposed Measure Removal for the CY 2020 Payment Determination and Subsequent Years—Proposed Removal of OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

For the CY 2020 payment determination and subsequent years, we are proposing to remove one NHSN measure under proposed measure removal Factor 8, the costs associated with this measure outweigh the benefit of its continued use in the program.

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75099), where we adopted OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), beginning with the CY 2016 payment determination and for subsequent years. This process-of-care measure, also a National Healthcare Safety Network (NHSN) measure, assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. We initially adopted this measure based on our recognition that influenza immunization is an important public health issue and vital component to preventing healthcare associated infections. We believe that the measure addresses this public health concern by assessing influenza vaccination in the HOPD among health care personnel (HCP), who can serve as vectors for influenza transmission.

In this proposed rule, we are proposing to remove OP–27, beginning with the CY 2020 payment determination under our proposed measure removal Factor 8 because we have concluded that the costs associated with this measure outweigh the benefit of its continued use in the program.

The information collection burden for the Influenza Vaccination Coverage Among Healthcare Personnel measure is less than for measures that require chart-abstraction of patient data because influenza vaccination among healthcare personnel can be calculated through review of records maintained in administrative systems and because facilities have fewer healthcare personnel than patients. As such, OP–27 does not require review of as many records. However, this measure does still pose information collection burden on facilities due to the requirement to identify personnel who have been vaccinated against influenza and for those not vaccinated, the reason why.

Furthermore, as we stated in section XIII.B.4.a. of this proposed rule, costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For example, it may be costly for health care providers to maintain general administrative knowledge to report these measures. In addition, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information.

In our analysis of the Hospital OQR Program measure set, we recognized that some facilities face challenges with respect to the administrative requirements of the NHSN in their reporting of the Influenza Vaccination Coverage Among Healthcare Personnel measure. These administrative requirements (which are unique to NHSN) include annually completing NHSN system user authentication. Enrolling in NHSN is a five-step process that the Centers for Disease Control and Prevention (CDC) estimates takes an average of 263 minutes per facility.[70]

Furthermore, submission via NHSN requires the system security administrator of participating facilities to re-consent electronically, ensure that contact information is kept current, ensure that the hospital has an active facility administrator account, keep Secure Access Management Service (SAMS) credentials active by logging in approximately every 2 months and changing their password, create a monthly reporting plan, and ensure the facility's CCN information is up-to-date. Unlike acute care hospital which participate in other quality programs, such as the Hospital IQR and HAC Reduction Programs, HOPDs are only required to participate in NHSN to submit data for this one measure. In our assessment, we also considered that the vast majority (99.7 percent) of Hospital OQR Program eligible hospitals already report this measure in the Hospital IQR Program for workers providing any services to inpatient care. The Hospital IQR Program measure includes the vast majority of all hospital personnel, since many workers in outpatient departments provide services to both inpatient and outpatient departments (adopted at 76 FR 51631 through 51633). These workers include most emergency department clinicians, specialists such as pharmacists and imaging professionals, and custodians and other support staff working across the hospital.

We continue to believe that the OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure provides the benefit of protecting patients against influenza. However, we believe that these benefits are offset by other efforts to reduce influenza infection among patients, such as numerous healthcare employer requirements for health care personnel to be vaccinated against influenza.[71] We also expect that a portion of MIPS-eligible clinicians nationwide will report on the Preventive Care and Screening: Influenza Immunization measure through the Quality Payment Program (QPP).[72] Although MIPS-eligible clinicians may voluntarily select measures from a list of options, HOPD providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure. We remain responsive to the public health concern of influenza infection within the Medicare FFS population by collecting data on rates of influenza immunization among patients.[73] Thus, the public health concern of influenza immunization is addressed via these other efforts to track influenza vaccination. The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area. In addition, as we discuss in section XIII.B.4.a of this proposed rule, where we are proposing to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

We wish to minimize the level of cost of our programs for participating facilities, as discussed under the Meaningful Measures Initiative, described in section I.A.2. of this proposed rule. In our assessment of the Hospital OQR Program measure set, we prioritized measures that align with this Initiative's framework as the most important to the Hospital OQR Program's population. Our assessment concluded that while the OP–27 measure continues to provide benefits, these benefits are diminished by other factors and are outweighed by the costs and burdens of reporting this chart-abstracted measure.

[70] CDC, National Healthcare Safety Network (NHSN). Five-Step Enrollment for Acute Care Hospitals/Facilities. Available at: *https://www.cdc.gov/nhsn/acute-care-hospital/enroll.html* (the estimates for time to complete are 2 hours 45 minutes for step 1, 10 minutes for step 2, 16 minutes for step 3a, 35 minutes for step 3b, 32 minutes for step 4, and 5 minutes for step 5; totaling 263 minutes).

[71] CDC, Influenza Vaccination Information for Health Care Workers. Available at: *https://www.cdc.gov/flu/healthcareworkers.htm.*

[72] QPP 2017 Measures Selection: Influenza. Retrieved from: *https://qpp.cms.gov/mips/quality-measures.*

[73] Ibid.

For these reasons, we are proposing to remove OP–27: NHSN Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) from the Hospital OQR Program beginning with the CY 2020 payment determination and for subsequent years. We note that if proposed measure removal Factor 8 is not finalized, removal of this measure would also not be finalized. We note that this measure is also proposed for removal from the ASCQR Program in section XIV.B.3.c. of this proposed rule and the IPFQR Program in the FY 2019 IPF PPS proposed rule (83 FR 21104).

(2) Proposed Measure Removals for the CY 2021 Payment Determination and Subsequent Years

For the CY 2021 payment determination and subsequent years, we are proposing to remove: Four measures under proposed measure removal Factor 8; one measure under measure removal Factor 3; two measures under removal Factor 1; and two measures under measure removal Factor 2.

(a) Proposed Measure Removals Under Proposed Removal Factor 8: OP–5, OP–29, OP–30, and OP–31

In this proposed rule, we are proposing to remove four measures under our proposed measure removal Factor 8 for the CY 2021 payment determination and subsequent years: OP–5, OP–29, OP–30, and OP–31. We note that if proposed measure removal Factor 8 is not finalized, removal of these measures would also not be finalized. The proposals are discussed in more detail below. We note that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination, but we decided on proposing to delay removal until the CY 2021 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for this measure begins during CY 2018 for the CY 2020 payment determination.

• Proposed Removal of OP–5: Median Time to ECG (NQF #0289)

We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66865) where we adopted OP–5: Median Time to ECG (NQF #0289) beginning with the CY 2009 payment determination.[74] This chart-abstracted measure assesses the median number of minutes before outpatients with heart attack (or chest pain that suggests a possible heart attack) received an electrocardiograph (ECG) test to help diagnose heart attack.

We are proposing to remove the OP–5 measure beginning with the CY 2021 payment determination under our proposed measure removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. As noted above, OP–5 is a chart-abstracted measure, which can be potentially more challenging for facilities to report than claims-based or structural measures. Chart-abstraction requires facilities to select a sample population, access historical records from several clinical data quarters past, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. As described in section I.A.2. of this proposed rule, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the Hospital OQR Program would reduce program complexity.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities, especially when taking into consideration that, although this measure is not topped-out, we have come to the conclusion that the benefit of this measure is limited. Based on our analysis of data submitted by 1,995 hospitals from Quarter 3 in 2016 through Quarter 2 in 2017 the variation in average measure performance between hospitals is minimal, with a difference in median time to ECG of less than 2 minutes between the 75th and 90th percentile hospitals. Furthermore, the difference between the 25th and 75th percentile, distinguishing between high and low performers, is only 5.5 minutes, further indicating that variations are not sufficiently large to inform beneficiary decision-making to justify the costs of collecting the data. These data are demonstrated in the table below.

DIFFERENCES IN PERFORMANCE FOR OP–5: MEDIAN WAIT TIME TO ECG

Period	Number of hospitals	25th Percentile	75th Percentile	90th Percentile
2016 Q3—2017 Q2	1,995	11.0 minutes	5.5 minutes	3.8 minutes.

We believe that the minimal variation in hospital performance does not help beneficiaries to make informed care decisions, since distinguishing meaningful differences in hospital performance on this measure is difficult. As such, the measure benefit is limited, and no longer meaningfully supports program objectives of informing beneficiary choice.

Thus, we believe that costs and burdens to both facilities and CMS such as program oversight, measure maintenance, and public display, associated with keeping this measure in the program outweigh the limited benefit associated with the measure's continued use. Therefore, we are proposing to remove OP–5: Median Time to ECG from the Hospital OQR Program beginning with the CY 2021 payment determination and for subsequent years.

• Proposed Removal of OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75099 through 75100) where we adopted OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0659) beginning with the CY 2016 payment determination. This chart-abstracted process measure assesses the ''[p]ercentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report'' (78 FR 75099). This measure aims to assess whether average risk patients

[74] This measure was formerly called ''ED–AMI–4—Median Time to Electrocardiogram (ECG)'' in the cited **Federal Register**.

with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is less than the recommended amount of 10 years.

In this proposed rule, we are proposing to remove OP–29: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and for subsequent years under our proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We adopted OP–29: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75099 through 75100) noting that performing colonoscopy too frequently increases patients' exposure to procedural harm. However, we now believe that the costs of this measure outweigh the benefit of its continued use in the program.

Chart-abstraction requires facilities to select a sample population, access historical records from several current and historic clinical data quarters, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. In addition to submission of manually chart-abstracted data, we take all burden and costs into account when evaluating a measure. Removing OP–29 would reduce the burden and cost to facilities associated with collection of information and reporting on their performance associated with the measure.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities especially when taking into consideration the availability of other CMS quality measures that are relevant in the clinical condition and highly correlated in performance across measures. Another colonoscopy-related measure required in the Hospital OQR Program, OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF# 2539), measures all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure (79 FR 66949). This claims-based outcomes measure does not require chart-abstraction, and similarly contributes data on quality of care related to colonoscopy procedures, although the measure does not specifically track processes such as follow-up intervals. When we adopted OP–32, we believed this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to facilities and patients all unplanned hospital visits following the procedure (79 FR 66949). Furthermore, the potential benefits of keeping OP–29 in the program are mitigated by the existence of the same measure (Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients) [75] for gastroenterologists in the Merit-Based Incentive Payment System (MIPS) for the 2019 performance period in the QPP (82 FR 30292). Thus, we believe the issue of preventing harm to patients from colonoscopy procedures that are performed too frequently is adequately addressed through MIPS in the QPP, because we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS. We note that although MIPS-eligible clinicians may voluntarily select measures from a list of options, HOPD providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure without being penalized if they determine there is value for various quality improvement efforts.[76] The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area.

Furthermore, we seek to align our quality reporting work with the Patients Over Paperwork and the Meaningful Measures Initiatives described in section I.A.2. of this proposed rule. The purpose of this effort is to hold providers accountable for only the measures that are most important to patients and clinicians and those that are focused on patient outcomes in particular, because outcome measures evaluate the actual results of care. As described in section I.A.2. of this proposed rule, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the Hospital OQR Program would reduce program complexity. In addition, as we discuss in section XIV.B.3.b. of this proposed rule, where we are proposing to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Therefore, due to the combination of factors of the costs of collecting data for this chart-abstracted measure, the preference for an outcomes measure in the Hospital OQR Program that provides valuable data for the same procedure, and the existence of the same measure in another CMS program, we believe that the burdens and costs associated with this measure outweigh the limited benefit to beneficiaries. As a result, we are proposing to remove OP–29: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and for subsequent years. We note that we are also proposing to remove a similar measure in the ASCQR Program in section XIV.B.3.c. of this proposed rule.

- Proposed Removal of OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use

We refer readers to CY 2014 OPPS/ASC final rule with comment period (78 FR 75102) where we adopted OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659) beginning with the CY 2016 payment determination. This chart-abstracted process measure assesses the percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report.

In this proposed rule, we are proposing to remove OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use beginning with the CY 2021 payment determination and for subsequent years under our proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We adopted OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use in the CY 2014 OPPS/ASC final rule

[75] QPP Measure Selection: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients. Available at: *https://qpp.cms.gov/mips/quality-measures*.

[76] CMS finalized that services furnished by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology will not be subject to the MIPS payments adjustments, but eligible clinicians payable under those methodologies may have the option to still voluntarily report on applicable measures and the data reported will not be used to determine future eligibility (82 FR 53586).

with comment period (78 FR 75102) noting that colonoscopy screening for high risk patients is recommended based on risk factors and one such factor is a history of adenomatous polyps. The frequency of colonoscopy screening varies depending on the size and amount of polyps found, with the general recommendation of a 3-year follow-up. We stated that this measure is appropriate for the measurement of quality of care furnished by hospital outpatient departments because colonoscopy screening is commonly performed in these settings (78 FR 75102). However, we now believe that the costs of this measure outweigh the benefit of its continued use in the program.

Chart-abstraction requires facilities to select a sample population, access historical records from several clinical data quarters past, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. In addition to submission of manually chart-abstracted data, we take all burden and costs into account when evaluating a measure. Removing OP–30 would reduce the burden and cost to facilities associated with collection of information and reviewing their data and performance associated with the measure.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities especially when taking into consideration the availability of other CMS quality measures. Another colonoscopy-related measure required in the Hospital OQR Program, OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF# 2539) measures all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure (79 FR 66949). This claims-based outcome measure does not require chart-abstraction, and similarly contributes data on quality of care related to colonoscopy procedures, although the measure does not specifically track processes such as follow-up intervals. When we adopted OP–32, we believed this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to facilities and patients all unplanned hospital visits following the procedure (79 FR 66949). Furthermore, the potential benefits of keeping OP–30 in the program are mitigated by the existence of the same measure for gastroenterologists in the Merit-Based Incentive Payment System (MIPS) for the 2019 performance period in the QPP (82 FR 30292). Thus, we believe the issue of preventing harm to patients from colonoscopy procedures that are performed too frequently is adequately addressed through MIPS in the QPP because we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS. Although MIPS-eligible clinicians may voluntarily select measures from a list of options, HOPD providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure without being penalized if they determine there is value for various quality improvement efforts.[77] The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area.

Furthermore, we seek to align our quality reporting work with the Patients Over Paperwork and the Meaningful Measures Initiatives described in section I.A.2. of this proposed rule. The purpose of this effort is to hold providers accountable for only the measures that are most important to patients and clinicians and those that are focused on patient outcomes in particular, because outcome measures evaluate the actual results of care. As described in section I.A.2. of this proposed rule, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the Hospital OQR Program would reduce program complexity. In addition, as we discuss in section XIII.B.4.a. of this proposed rule, where we are proposing to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Therefore, due to the combination of factors of the costs of collecting data for this chart-abstracted measure, the preference for an outcomes measure in OQR that provides valuable data for the same procedure, and the existence of the same measure in the MIPS program, we believe that the burdens and costs associated with manual chart abstraction outweigh the limited benefit to beneficiaries of receiving this information. As a result, we are proposing to remove OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use beginning with the CY 2021 payment determination and for subsequent years. We note that we are also proposing to remove a similar measure in the ASCQR Program in section XIV.B.3.c. of this proposed rule.

- Proposed Removal of OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75103) where we adopted OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) beginning with the CY 2016 payment determination and subsequent years. This measure assesses the rate of patients 18 years and older (with a diagnosis of uncomplicated cataract) in a sample who had improvement in visual function achieved within 90 days following cataract surgery based on completing both a pre-operative and post-operative visual function survey.

Since the adoption of this measure, we came to believe that it can be operationally difficult for facilities to collect and report the measure (79 FR 66947). Specifically, we were concerned that the results of the survey used to assess the pre-operative and post-operative visual function of the patient may not be shared across clinicians and facilities, making it difficult for facilities to have knowledge of the visual function of the patient before and after surgery (79 FR 66947). We were also concerned about the surveys used to assess visual function; the measure allows for the use of any validated survey and results may be inconsistent should clinicians use different surveys (79 FR 66947). Therefore, on December 31, 2013, we issued guidance stating that we would delay data collection for OP–31 for 3 months (data collection would commence with April 1, 2014 encounters) for the CY 2016 payment determination (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772854917*). We issued additional guidance on April 2, 2014, stating that we would further delay the implementation of OP–31 for an additional 9 months, until January 1, 2015 for the CY 2016 payment

[77] CMS finalized that services furnished by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology will not be subject to the MIPS payments adjustments, but eligible clinicians payable under those methodologies may have the option to still voluntarily report on applicable measures and the data reported will not be used to determine future eligibility (82 FR 53586).

determination, due to continued concerns (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228773786593*). As a result of these concerns, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66948), we finalized our proposal to allow voluntary data collection and reporting of this measure beginning with the CY 2017 payment determination and for subsequent years.

In this proposed rule, we are proposing to remove OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2021 and for subsequent years under our proposed measure removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. We originally adopted OP–31 because we believe facilities should be a partner in care with physicians and other clinicians using their facility and that this measure would provide an opportunity to do so (79 FR 66947). However, in light of the history of complications and upon reviewing this measure within our Meaningful Measures framework, we have concluded that it is overly burdensome for facilities to report this measure due to the difficulty of tracking care that occurs outside of the HOPD setting. In order to report on this measure to CMS, a facility would need to obtain the visual function assessment results from the appropriate ophthalmologist and ensure that the assessment utilized is validated for the population for which it is being used. If the assessment is not able to be used or is not available, the facility would then need to administer the survey directly and ensure that the same visual function assessment tool is utilized preoperatively and postoperatively. There is no simple, preexisting means for information sharing between ophthalmologists and facilities, so a facility would need to obtain assessment results from each individual patient's ophthalmologist both preoperatively and postoperatively. The high administrative costs of the technical tracking of this information presents an undue cost, and also burden associated with submission and reporting of OP–31 to CMS, especially for small facilities with limited staffing capacity.

Furthermore, this measure currently provides limited benefits. Since making the measure voluntary, only 59 [78] facilities have reported this measure to CMS, compared to approximately 4,798 total facilities for all other measures, resulting in only 1.2 percent of facilities reporting. Consequently, we have been unable to uniformly offer pertinent information to beneficiaries on how the measure assesses facility performance. This reinforces comments made in the CY 2015 OPPS/ASC final rule with comment period in which commenters expressed concern that the incomplete display of data associated with voluntary reporting is confusing and not meaningful to beneficiaries and other consumers (79 FR 66947). The data are also hard to validate. Furthermore, commenters feared that the display of data from some hospitals, but not others, would lead some patients to conclude that some hospitals are more committed to improving cataract surgery. As described in section I.A.2. of this proposed rule, we strive to ensure that beneficiaries are empowered to make decisions about their health care using information from data-driven insights. Because of the lack of sufficient data, this measure may be difficult for beneficiaries to interpret or use to aid in their choice of where to obtain care; thus, the benefits of this measure are limited.

Thus, we believe the high technical and administrative costs of this measure, coupled with the high technical and administrative burden, outweigh the limited benefit associated with the measure's continued use in the Hospital OQR Program. As discussed in section I.A.2. of this proposed rule, above, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We believe that removing this measure from the Hospital OQR Program will reduce program burden, costs, and complexity. Therefore, we are proposing to remove OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2021 payment determination and for subsequent years. We note that we are also proposing to remove a similar measure under the ASCQR Program in section XIV.B.3.c. of this proposed rule.

(b) Proposed Measure Removal Under Removal Factor 3: OP–9: Mammography Follow-Up Rates

We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766) where we adopted OP–9: Mammography Follow-up Rates beginning with the CY 2010 payment determination. This claims-based measure assesses the percentage of patients with mammography screening studies that are followed by a diagnostic mammography, ultrasound, or MRI of the breast in an outpatient or office setting within 45 days. We are proposing to remove this measure under measure removal Factor 3, a measure does not align with current clinical guidelines or practice.

An examination of the measure specifications [79] shows that recent changes in clinical practice are not incorporated into the measure calculation. Since development of this measure in 2008, advancements in imaging technology and clinical practice for mammography warrant updating the measure's specifications to align with current clinical practice guidelines and peer-reviewed literature. Specifically, findings from the annual Literature Reviews and Environmental Scans conducted by the measure developer suggest that there is additional clinical benefit in performing adjuvant DBT concomitant with full-field digital mammography (FFDM) or conventional mammography (currently included in the measure denominator), especially in women with dense breast tissue.[80] [81] [82] In addition, in 2016, the American College of Radiology (ACR) updated its Breast Cancer Screening Appropriateness Criteria® to include DBT.[83] The ACR notes that DBT can better detect potential false-positive findings without the need for recall. Furthermore, the cancer detection rate is increased with use of DBT compared with traditional mammography alone.[84] A 2014 study published in the Journal of the American College of Radiology assessed the utilization of DBT among physician members of the Society of

[78] OQR Hospital Compare. Available at: *https://data.medicare.gov/Hospital-Compare/Timely-and-Effective-Care-Hospital/yv7e-xc69.*

[79] Hospital Outpatient Quality Reporting Specifications Manual. Version 11.0a. Available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228776146046.*

[80] Bernardi, D., Macaskill, P., Pellegrini, M., Valentini, M., Fanto, C., Ostillio, L., Houssami, N. (2016). Breast cancer screening with tomosynthesis (3D mammography) with acquired or synthetic 2D mammography compared with 2D mammography alone (STORM–2): A population-based prospective study. Lancet Oncol, 17(8), 1105–1113. doi: 10.1016/s1470–2045(16)30101–2.

[81] Bian, T., Lin, Q., Cui, C., Li, L., Qi, C., Fei, J., & Su, X. (2016). Digital Breast Tomosynthesis: A New Diagnostic Method for Mass-Like Lesions in Dense Breasts. Breast J, 22(5), 535–540. doi: 10.1111/tbj.12622.

[82] Pozz, A., Corte, A.D., Lakis, M. A., & Jeong, H. (2016). Digital Breast Tomosynthesis in Addition to Conventional 2DMammography Reduces Recall Rates and is Cost Effective. Asian Pac J Cancer Prev, 17(7), 3521–3526.

[83] Mainiero MB, Bailey L, D'Orsi C, Green ED, Holbrook AI, Lee SJ, Lourenco AP, Moy L, Sepulveda KA, Slanetz PJ, Trikha S, Yepes MM, Newell MS, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® breast cancer screening. Reston (VA): American College of Radiology (ACR); 2016. 7 p.

[84] Ibid.

Breast Imaging and found that 30 percent of respondents reported using DBT concurrent with traditional mammography.[85] With the update of the ACR clinical practice guidelines (that is, the Breast Cancer Screening Appropriateness Criteria®) to include DBT, use of this technology is expected to increase.

As currently specified, the measure does not adequately capture this shift in clinical practice. Thus, we believe this measure as specified does not align with current clinical guidelines or practice, and we are proposing to remove OP–9: Mammography Follow-up Rates from the program for the CY 2021 payment determination and subsequent years. We intend to investigate respecification of this measure and consider it for adoption to the program through future rulemaking. Specifically, we will consider ways to capture a broader, more comprehensive spectrum of mammography services including adding diagnostic digital breast tomosynthesis (DBT). We note that, in crafting our proposal, we considered removing this measure beginning with the CY 2020 payment determination, but decided on proposing to delay removal until the CY 2021 payment determination and subsequent years to be sensitive to facilities' planning and operational procedures given that data collection for this measure begins during CY 2018 for the CY 2020 payment determination.

(c) Proposed Measure Removals Under Removal Factor 1: OP–11 and OP–14

In this proposed rule, for the CY 2021 payment determination and subsequent years, we are proposing to remove OP–11 and OP–14 under removal Factor 1, measure performance among providers is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. The Hospital OQR Program previously finalized two criteria for determining when a measure is ''topped-out'': (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation is less than or equal to 0.10 (79 FR 66968 through 66969). We refer readers to section XIII.B.4.a.(6) of this proposed rule, above, where we clarify and discuss how we calculate the TCOV for measures that assess the rate of rare, undesired events for which a lower rate is preferred such as OP–11 and OP–14.

For each of these measures, we believe that removal from the Hospital OQR Program measure set is appropriate as there is little room for improvement. In addition, as discussed in section I.A.2. of this proposed rule above, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We believe that removing these measures from the Hospital OQR Program will reduce program burden, costs, and complexity. As such, we believe the burden associated with reporting these measures outweighs the benefits of keeping them in the Hospital OQR Program.

Each measure is discussed in more detail below. We also note that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination, but decided on proposing to delay removal until the CY 2021 payment determination and subsequent years to be sensitive to providers' planning and operational procedures given that data collection for the measures begins during CY 2018 for the CY 2020 payment determination.

• Proposed Removal of OP–11: Thorax CT Use of Contrast Material

We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766) where we adopted OP–11: Thorax CT Use of Contrast Material (NQF #0513) beginning with the CY 2010 payment determination. This claims-based measure assesses the percentage of thorax studies that are performed with and without contrast out of all thorax studies performed.

Based on our analysis of Hospital OQR Program measure data, we have determined that this measure meets our measure removal Factor 1. These analyses are captured in the table below.

OP–11—THORAX CT USE OF CONTRAST MATERIAL TOPPED-OUT ANALYSIS

Encounters	Number of hospitals	75th Percentile	90th Percentile	Truncated COV
CY 2012	867	96.9	98.4	0.081
CY 2013	869	97.1	98.5	0.074
CY 2014	796	97.2	98.4	0.065
CY 2015	711	97.4	98.5	0.054

As displayed in the table above, there is a statistically indistinguishable difference in hospital performance between the 75th and 90th percentiles, and the truncated coefficient of variation has been below 0.10 since 2012.

• Proposed Removal of OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT

We refer readers to the CY 2010 OPPS/ASC final rule with comment period (75 FR 72082) where we adopted OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT beginning with the CY 2012 payment determination and for subsequent years. This claims-based measure assesses the extent to which patients with a headache who have a brain CT also have a sinus CT performed on the same date at the same facility.

Based on our analysis of Hospital OQR Program measure data, we have determined that this measure meets our measure removal Factor 1. These analyses are captured in the table below.

OP–14: SIMULTANEOUS USE OF BRAIN COMPUTED TOMOGRAPHY (CT) AND SINUS CT TOPPED-OUT ANALYSIS

Encounters	Number of hospitals	75th percentile	90th percentile	Truncated COV
CY 2012	1,478	97.8	98.3	0.012

[85] Hardesty LA, Kreidler SM, Glueck DH. Digital breast tomosynthesis utilization in the United States: A survey of physician members of the Society of Breast Imaging. Journal of the American College of Radiology. 2014. 11(6): 594–599.

OP–14: SIMULTANEOUS USE OF BRAIN COMPUTED TOMOGRAPHY (CT) AND SINUS CT TOPPED-OUT ANALYSIS—Continued

Encounters	Number of hospitals	75th percentile	90th percentile	Truncated COV
CY 2013	1,939	97.7	98.2	0.010
CY 2014	2,023	97.6	98.2	0.011
CY 2015	1,101	98.5	98.8	0.007

As displayed in the table above, there is a statistically indistinguishable difference in hospital performance between the 75th and 90th percentiles, and the truncated coefficient of variation has been below 0.10 since 2012.

Therefore, we are inviting public comment on our proposals to remove: (1) OP–11: Thorax CT Use of Contrast Material, and (2) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT measure for the CY 2021 payment determination and subsequent years as discussed above.

(d) Proposed Removals Under Measure Removal Factor 2: OP–12 and OP–17

In this proposed rule, for the CY 2021 payment determination and subsequent years, we are proposing to remove two measures under our measure removal Factor 2, performance or improvement on a measure does not result in better patient outcomes: OP–12 and OP–17. The proposals are discussed in more detail below. As discussed in section I.A.2. of this proposed rule above, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We believe that removing these measures from the Hospital OQR Program will reduce program burden, costs, and complexity. In addition, we note that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination, but decided on proposing to delay removal until the CY 2021 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for this measure begins during CY 2018 for the CY 2020 payment determination.

• Proposed Removal of OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data

We refer readers to CY 2011 OPPS/ASC final rule with comment period (75 FR 72076) where we adopted OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data beginning with the CY 2012 payment determination. This web-based measure assesses the extent to which a provider uses an Office of the National Coordinator for Health Information Technology (ONC) certified electronic health record (EHR) system that incorporates an electronic data interchange with one or more laboratories allowing for direct electronic transmission of laboratory data in the EHR as discrete searchable data elements. In this proposed rule, we are proposing to remove OP–12 beginning with the CY 2021 payment determination and for subsequent years under our measure removal Factor 2, performance or improvement on a measure does not result in better patient outcomes.

OP–12 is a process measure that tracks the transmittal of data, but does not directly assess quality or patient outcomes. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72075), commenters expressed concern that the measure only assesses HIT functionality and does not assess the quality of care provided. As discussed in section I.A.2. of this proposed rule, one of the goals of our Meaningful Measures Initiative is to reduce burden associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology. As also discussed in section I.A.2. of this proposed rule, one of the goals of our Meaningful Measures Initiative is to utilize measures that are ''outcome-based where possible.'' We do not believe OP–12 adds to these goals. In fact, we believe that provider performance in the measure is not an indicator for patient outcomes and continued collection provides little benefit.

Therefore, we are proposing to remove OP–12 from the Hospital OQR Program beginning with the CY 2021 payment determination and for subsequent years.

• Proposed Removal of OP–17: Tracking Clinical Results Between Visits

We refer readers to CY 2011 OPPS/ASC final rule with comment period (75 FR 72085) where we adopted OP–17: Tracking Clinical Results between Visits beginning with the CY 2013 payment determination. This web-based measure assesses the extent to which a provider uses a certified/qualified EHR system to track pending laboratory tests, diagnostic studies (including common preventive screenings), or patient referrals. In this proposed rule, we are proposing to remove OP–17 beginning with the CY 2021 payment determination and for subsequent years under our measure removal Factor 2, performance or improvement on a measure does not result in better patient outcomes.

OP–17 is a process measure that tabulates only the ability for transmittal of data, but does not directly assess quality or patient outcomes. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72075), commenters expressed concern that the measure only assesses HIT functionality and does not assess the quality of care provided. As discussed in section I.A.2. of this proposed rule, one of the goals of our Meaningful Measures Initiative is to reduce burden associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology. As also discussed in section I.A.2. of this proposed rule, one of the goals of our Meaningful Measures Initiative is to utilize measures that ''outcome-based where possible.'' We do not believe OP–17 supports this goal. In fact, we believe that provider performance in the measure does not improve patient outcomes and continued collection provides little benefit. Therefore, we are proposing to remove OP–17 from the Hospital OQR Program beginning with the CY 2021 payment determination and for subsequent years.

5. Summary of Proposed Hospital OQR Program Measure Sets for the CY 2020 and CY 2021 Payment Determinations

In this proposed rule, we are not proposing any new measures for the Hospital OQR Program. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59434 through 59435) for the previously finalized measure set for the CY 2020 payment determination and subsequent years. The tables below summarize the

proposed Hospital OQR Program measure sets for the CY 2020 and 2021 payment determinations and subsequent years (including previously adopted measures and excluding measures proposed for removal in this proposed rule).

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2020 PAYMENT DETERMINATION

NQF No.	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
0289	OP–5: Median Time to ECG †
0514	OP–8: MRI Lumbar Spine for Low Back Pain
None	OP–9: Mammography Follow-up Rates
None	OP–10: Abdomen CT—Use of Contrast Material
0513	OP–11: Thorax CT—Use of Contrast Material
None	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
None	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
0491	OP–17: Tracking Clinical Results between Visits †
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 *
0659	OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use *
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
1822	OP–33: External Beam Radiotherapy for Bone Metastases
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.

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244.*

** We note that measure name was revised to reflect NQF title.

*** Measure voluntarily collected as set forth in section XIII.D.3.b. of 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 section XIII.B.5. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433).

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	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.
2539	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
1822	OP–33: External Beam Radiotherapy for Bone Metastases.
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.

[c] OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244.*

* We note that measure name was revised to reflect NQF title.

** Measure voluntarily collected as set forth in section XIII.D.3.b. of 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 section XIII.B.5. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433).

6. Hospital OQR Program Measures and Topics for Future Consideration

In this proposed rule, we are requesting public comment on future measure topics for the Hospital OQR Program. We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the hospital outpatient setting. The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED throughput efficiency, Health Information Technology (health IT) use, care coordination, and patient safety. Measures are of various types, including those of process, structure, outcome, and efficiency. Through future rulemaking, we intend to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in hospital outpatient settings, while aligning quality measures across the Medicare program to the extent possible.

We are moving towards greater use of outcome measures and away from use of clinical process measures across our Medicare quality reporting and value-based purchasing programs. We are inviting public comments on possible measure topics for future consideration in the Hospital OQR Program. We are specifically requesting comment on any outcome measures that would be useful to add to as well as any process measures that should be eliminated from the Hospital OQR Program.

7. 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.* In this proposed rule, we are proposing to change the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019 and for subsequent years and we refer readers to section XIII.D.2. of this proposed rule for more details.

8. Public Display of Quality Measures

We refer readers to the CY 2014 and CY 2017 OPPS/ASC final rules with comment period (78 FR 75092 and 81 FR 79791 respectively) for our previously finalized policies regarding public display of quality measures. In this proposed rule, we are not proposing any changes to our previously finalized public display policies.

C. Administrative Requirements

1. QualityNet Account and Security Administrator

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). In that final rule with comment period, we codified these procedural requirements at 42 CFR 419.46(a). In this proposed rule, we are not proposing any changes to our requirements for the QualityNet account and security administrator.

2. Requirements Regarding Participation Status

In this proposed rule, we are proposing to update our requirements related to the Notice of Participation (NOP) form.

a. Background

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519) for requirements for participation and withdrawal from the Hospital OQR Program. We also codified these procedural requirements at 42 CFR 419.46(a) and 42 CFR 419.46(b).

b. Proposal to Remove the Notice of Participation (NOP) Form Requirement

We finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) that participation in the Hospital OQR Program requires that hospitals must: (1) Register on the QualityNet website before beginning to report data; (2) identify and register a QualityNet security administrator; and (3) complete and submit an online participation form, the Notice of Participation (NOP) form, available at the QualityNet website if this form has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CMS Certification Number (CCN). In addition, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109), we finalized the requirement that that hospitals must submit the NOP according to the below deadlines. These requirements are also codified at 42 CFR 419.46(a).

- If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must complete and submit to CMS a completed Hospital OQR Notice of Participation Form by July 31 of the calendar year prior to the affected annual payment update.
- If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date. In this proposed rule, beginning with the CY 2018 reporting period/CY 2020 payment determination, we are proposing to remove submission of the NOP form as a requirement for the Hospital OQR Program. After reevaluating program requirements, we have concluded that this form does not provide CMS with any unique information, and as such, we believe it is unnecessarily burdensome for hospitals to complete and submit. In place of the NOP form, we are proposing that submission of any Hospital OQR Program data would indicate a hospital's status as a participant in the program. This includes submitting just one data element. That is, hospitals would no longer be required to submit the NOP form as was previously required. Instead, hospitals would need to do the following to be a participant in the Hospital OQR Program: (1) Register on the QualityNet website before beginning to report data; (2) identify and register a QualityNet security administrator; and (3) submit data. We are also proposing to update 42 CFR 419.46(a) to reflect these changes.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Payment Determinations

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 through 75111) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), we specified our data submission deadlines. We also codified our submission requirements at 42 CFR 419.46(c).

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), where we finalized our proposal to shift the quarters upon which the Hospital OQR Program payment determinations are based, beginning with the CY 2018 payment determination. The finalized deadlines for the CY 2020 payment

determination and subsequent years are illustrated in the table below.

CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Patient encounter quarter	Clinical data submission deadline
Q2 2018 (April 1–June 30)	11/1/2018
Q3 2018 (July 1–September 30)	2/1/2019
Q4 2018 (October 1–December 31)	5/1/2019
Q1 2019 (January 1–March 31)	8/1/2019

In the CY 2018 OPPS/ASC final rule with comment period, we finalized a policy to align the initial data submission timeline for all hospitals that did not participate in the previous year's Hospital OQR Program and made conforming revisions at 42 CFR 419.46(c)(3). In this proposed rule, we are not proposing any changes to these policies.

2. Proposal To Change Frequency of Hospital Outpatient Quality Reporting Specifications Manual Release Beginning With CY 2019 and for Subsequent Years

In this proposed rule, we are proposing to change the frequency of the Hospital Outpatient Quality Reporting Specifications Manual release beginning with CY 2019 and for subsequent years. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established a subregulatory process for making updates to the measures we have adopted for the Hospital OQR Program. As stated in CY 2014 OPPS/ASC final rule with comment period (78 FR 75091), we believe that a measure can be updated through this subregulatory process provided it is a nonsubstantive change. We expect to continue to make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis. Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that nonsubstantive changes may include updates to measures based upon changes to guidelines upon which the measures are based.

For a history of our policies regarding maintenance of technical specifications for quality measures, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60631), the CY 2011 OPPS/ASC final rule with comment period (75 FR 72069), and the CY 2013 OPPS/ASC final rule with comment period (77 FR 68469 through 68470). We note that we will continue to use rulemaking to adopt substantive updates to measures we have adopted for the Hospital OQR Program. We believe that this policy adequately balances our need to incorporate nonsubstantive updates to Hospital OQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.

As stated in CY 2014 OPPS/ASC final rule with comment period (78 FR 75091), under current policy, technical specifications for the Hospital OQR Program measures are listed in the Hospital Outpatient Quality Reporting Specifications Manual, which is posted on the CMS QualityNet website at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228772438492.* We maintain the technical specifications for the measures by updating this Hospital Outpatient Quality Reporting Specifications Manual and including detailed instructions and calculation algorithms. In some cases where the specifications are available elsewhere, we may include links to websites hosting technical specifications. These resources are for hospitals to use when collecting and submitting data on required measures. We revise the Hospital Outpatient Quality Reporting Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary. We generally release the Hospital Outpatient Quality Reporting Specifications Manual every 6 months and release addenda as necessary. This release schedule provides at least 3 months of advance notice for nonsubstantive changes such as changes to ICD–10, CPT, NUBC, and HCPCS codes, and at least 6 months of advance notice for changes to data elements that would require significant systems changes (78 FR 75091).

However, we believe that unnecessarily releasing two manuals a year has the potential to cause confusion for Hospital OQR Program participants. Therefore, in this proposed rule, we are proposing to update the frequency with which we release Hospital Outpatient Quality Reporting Specifications Manuals, such that instead of every 6 months, we would release Specifications Manuals every 6 to 12 months beginning with CY 2019 and for subsequent years. Under this proposal, we would release a Hospital Outpatient Quality Reporting Specifications Manual one to two times per calendar year, depending on the need for an updated release and consideration of our policy to provide at least 6 months' notice for substantive changes.

3. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of chart-abstracted measures for the CY 2014 payment determination and subsequent years. We are not proposing any changes to our policies regarding the submission of chart-abstracted measure data where patient-level data are submitted directly to CMS.

We note that, in section XIII.B.4.b. of this proposed rule, we are proposing to remove OP–5: Median Time to ECG for the CY 2021 payment determination and subsequent years. If that proposal is finalized as proposed, only the following previously finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2021 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).

4. Claims-Based Measure Data Requirements for the CY 2020 Payment Determination and Subsequent Years

In this proposed rule, we are proposing to extend the reporting

period [86] for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

a. General

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112) for a discussion of the general claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years.

We are not proposing changes to our general requirements for claims-based measure data, but refer readers to the section below for our proposal specific to OP–32.

We note that, in section XIII.B.4.b. of this proposed rule, we are proposing to remove OP–9: Mammography Follow-up Rates, OP–11: Thorax CT Use of Contrast Material, and OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT for the CY 2021 payment determination and subsequent years. If these removals are finalized as proposed, only the following previously finalized Hospital OQR Program claims-based measures will be required for the CY 2021 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).

b. Proposed Extension of the Reporting Period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66949), we finalized the adoption of OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy into the Hospital OQR Program for the CY 2018 payment determination and subsequent years, with public display to begin on or after December 1, 2017. This measure is calculated with data obtained from paid Medicare FFS claims (79 FR 66950). For this reason, facilities are not required to submit any additional information. In that final rule with comment period, we also finalized the reporting period for measure calculation as claims data from 2 calendar years prior to the payment determination year. Specifically, for the CY 2018 payment determination, we stated we would use paid Medicare FFS claims from January 1, 2016 to December 31, 2016 to calculate measure results (79 FR 66955). We finalized a 1-year reporting period, as it adequately balanced competing interests of measure reliability and timeliness for payment determination purposes, and explained that we would continue to assess this during the dry run (79 FR 66955).

We noted we would complete a dry run of the measure in 2015 using 3 or 4 years of data, and, from the results of this dry run, we would review the appropriate volume cutoff for facilities to ensure statistical reliability in reporting the measure score (79 FR 66953). Our analyses of the 2015 dry run using data from July 2011 through June 2014 showed that a reporting period of one year had moderate to high reliability for measure calculation. Specifically, using data from July 2013 through June 2014, we calculated facility-level reliability estimates as the ratio of true variance to observed variance.[87] Consistent with the original measure specifications as described in the 2014 technical report,[88] this calculation was performed combining the measure results for HOPDs and ASCs. We found that for a facility with median case size, the reliability estimate was high (over 0.90), but the minimum reliability estimate for facilities with 30 cases (the minimum case size chosen for public reporting) was only moderate (that is, between 0.40 and 0.60).[89]

However, after the 2015 dry run, CMS calculated the HOPD and ASC scores separately to compare similar types of providers to each other. During subsequent analysis of the 1-year period July 2013 through June 2014, we confirmed that a 1-year reporting period with separate calculations for HOPDs and ASCs was sufficient, but did result in lower reliability and decreased precision compared to these measures calculated from longer reporting periods (2 or 3 years). Based on analyses conducted using data from July 2013 through June 2014 (1-year reporting period) and 2017 measure specifications,[90] we found that the median facility-level reliability was 0.74 for ASCs and 0.51 for HOPDs. Using a 2-year reporting period (data from July 2012—June 2014), we found that median facility-level reliability was 0.81 for ASCs and 0.67 for HOPDs. When the reporting period was extended to 3 years (using data from July 2011 through June 2014), we found that median facility-level reliability was higher for both ASCs and HOPDs: 0.87 for ASCs and 0.75 for HOPDs. These results indicate that a larger portion of the included facilities have scores measured with higher reliability when 3 years of data are used rather than 1 year of data.

Using 3 years of data, compared to just 1 year, is estimated to increase the number of HOPDs with eligible cases for OP–32 by 5 percent, adding approximately 235 additional facilities to the measure calculation. Facilities reporting the measure would increase their sample sizes and, in turn, increase the precision and reliability of their measure scores. Thus, we believe extending the reporting period to 3 years from 1 year for purposes of increasing reliability would be beneficial for providing better information to beneficiaries regarding the quality of care associated with low-risk outpatient colonoscopy procedures. In crafting our proposal, we considered extending the reporting period to 2 years beginning with the CY 2020 payment determinations and subsequent years, but decided on proposing 3 years instead, because a higher level of reliability is achieved with a 3-year reporting period compared to 2 years.

Therefore, we are proposing to change the reporting period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from 1 year to 3 years beginning with the CY 2020 payment determination (which would use claims data from January 1, 2016 through December 31, 2018) and for subsequent years. Under this proposal, the annual reporting requirements for facilities would not change, because this is a claims-based measure. However, with a 3-year reporting period, the most current year

[86] We note that we previously referred to these reporting periods as ''collection periods'' (for example, 82 FR 59440); we now use the term ''reporting period'' in order to align the ASCQR Program terminology with the terminology we use in other CMS quality reporting and pay for performance (value-based purchasing) programs.

[87] Snijders TA, Bosker RJ. *Multilevel Analysis: An introduction to basic and advanced multilevel modeling.* SAGE Publications. 2000. London.

[88] Additional methodology details and information obtained from public comments for measure development are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Colonoscopy.''

[89] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159–174.

[90] Current and past measure specifications are available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775214597.*

of data would be supplemented by the addition of 2 prior years. For example, for the CY 2020 payment determination, we would use a reporting period of CY 2018 data plus 2 prior years of data (CYs 2016 and 2017). We note that since implementation of this measure began with the CY 2018 payment determination, we have already used paid Medicare fee-for-service claims from January 1, 2016 to December 31, 2016 to calculate measure scores, which have been previously previewed by facilities and publicly displayed. In crafting our proposal, we also considered timeliness related to payment determinations and public display. Because we would utilize data already collected to supplement current data, our proposal to use 3 years of data would not disrupt payment determinations or public display. We refer readers to the table below for example reporting periods and public display dates corresponding to the CY 2020, CY 2021, and CY 2022 payment determinations:

	CY 2020 payment determination	CY 2021 payment determination	CY 2022 payment determination
Public display	January 2020	January 2021	January 2022.
Reporting period	January 1, 2016–December 31, 2018.	January 1, 2017–December 31, 2019.	January 1, 2018–December 31, 2020.

5. 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 2020 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 are not proposing any changes to the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures.

6. Data Submission Requirements for Previously Finalized Measures for Data Submitted via a Web-Based Tool for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521) and the CMS QualityNet website (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1205442125082*) for a discussion of the requirements for measure data submitted via the CMS QualityNet website 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 are not proposing any changes to our policies regarding the submission of measure data submitted via a web-based tool.

We note that, in section XIII.B.4.b. of this proposed rule, we are proposing to remove of OP–27: Influenza Vaccination Coverage Among Healthcare Personnel beginning with the CY 2020 payment determination and for subsequent years. If this removal is finalized as proposed, for the CY 2020 payment determination, the following web-based quality measures would be required:

- OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data (via CMS' QualityNet website);
- OP–17: Tracking Clinical Results between Visits (NQF #0491) (via CMS' QualityNet website);
- OP–22: Left Without Being Seen (NQF #0499) (via CMS' QualityNet website);
- OP–29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) (via CMS' QualityNet website);
- OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659) (via CMS' QualityNet website);
- OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) (via CMS' QualityNet website); and
- OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) (via CMS' QualityNet website).

Furthermore, we note that in section XIII.B.4.b. of this proposed rule, for the CY 2021 payment determination and subsequent years, we are proposing to remove: OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; OP–17: Tracking Clinical Results between Visits; OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use; and OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2021 payment determination and for subsequent years. If these removals are finalized as proposed, only the following web-based quality measures would require data to be submitted via a web-based tool for the CY 2021 payment determination and subsequent years:

- OP–22: Left Without Being Seen (NQF #0499) (via CMS' QualityNet website); and
- OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) (via CMS' QualityNet website).

7. Population and Sampling Data Requirements for the CY 2020 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. In this proposed rule, we are not proposing any changes to our population and sampling requirements for chart-abstracted measures.

8. Hospital OQR Program Validation Requirements

We refer readers to 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 42 CFR 419.46(e) for our policies regarding validation. We are not proposing any changes to these policies in this proposed rule.

9. Extraordinary Circumstances Exception (ECE) Process for the CY 2020 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 are not proposing any changes to our ECE policy in this proposed rule.

10. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2020 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 42 CFR 419.46(f) for our reconsideration and appeals procedures. We are not proposing any changes to our reconsideration and appeals procedures in this proposed rule.

E. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2019 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 this 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).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule

increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2019

We are proposing 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 2019 annual payment update factor. For the CY 2019 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of 77.955 by the proposed full conversion factor of 79.546. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2019 OPPS, we are proposing 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 are proposing to continue to exclude services paid under New Technology APCs. We are proposing 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 are also proposing 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 are proposing 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.

XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIII.A.1. of this proposed rule for a general overview of our quality reporting programs and to section I.A.2. of this proposed rule for a discussion of our new Meaningful Measures Initiative.

2. Statutory History of the ASCQR Program

We refer readers to section XIV.K.1. of 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 seek to promote higher quality and more efficient health care for beneficiaries. This effort is supported by the adoption of widely-agreed-upon quality measures. We have worked with relevant stakeholders to define measures of quality in almost every healthcare setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and outcomes. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of ASC services and to make such information publicly available, we implemented the ASCQR Program. We refer readers to section XV.A.3. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75122), section XIV. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966 through 66987), section XIV. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70526 through 70538), section XIV. of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79797 through 79826) and section XIV. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59445 through 59476) for an overview of the regulatory history of the ASCQR Program.

4. Meaningful Measures Initiative

In this proposed rule, we are proposing a number of new policies for the ASCQR Program. We developed these proposals after conducting an overall review of the Program under our new Meaningful Measures Initiative, which is discussed in more detail in section I.A.2. of this proposed rule. The proposals reflect our efforts to ensure that the ASCQR Program measure set continues to promote improved health outcomes for our beneficiaries while minimizing costs, which can consist of several different types of costs, including, but not limited to: (1) Facility information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the facility cost associated with complying with other quality programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or State regulations (if applicable). They also reflect our efforts to improve the usefulness of the data that we publicly report in the ASCQR Program. Our goal is to improve the usefulness and usability of CMS quality program data by streamlining how facilities are reporting and accessing data, while maintaining or improving consumer understanding of the data publicly reported on a *Compare* website. We believe this framework will allow ASCs and patients to continue to obtain meaningful information about ASC performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to ASCs associated with participating in this program do not outweigh the benefits of improving beneficiary care.

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 ASCQR Program quality measure selection. We are not proposing any changes to these policies.

2. Accounting for Social Risk Factors in the ASCQR Program

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59445 through 59447), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[91] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[92] As we noted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59445 through 59447), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59446), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[93] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx.* The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF is now undertaking an extension of the socioeconomic status (SES) trial,[94] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or facility that would also allow for a comparison of those differences, or disparities, across facilities. Feedback we received through our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patients' backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public. We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for facilities to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower beneficiaries and other consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discourage the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to reduce health disparities among patient groups within and across healthcare settings by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital Inpatient Quality Reporting Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

3. Policies for Retention and Removal of Quality Measures From the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously adopted 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 they 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). In this proposed rule, we are not proposing any changes to this policy.

b. Removal Factors for ASCQR Program Measures

(1) Current Policy

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66969) and 42 CFR 416.320 for a detailed discussion of the process for removing adopted measures from the ASCQR Program. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66969), we finalized the ASCQR Program measure removal factors[95] for determining whether to

[91] See, for example, United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities;* or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[92] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[93] National Quality Forum. Final Report-Disparities Project. September 2017. Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx.*

[94] National Quality Forum. Health Equity Program: Social Risk Initiative 2.0. 2017. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357.*

[95] We note that we previously referred to these factors as ''criteria'' (for example, 82 FR 59474 through 59475); we now use the term ''factors'' in order to align the ASCQR Program terminology with the terminology we use in other CMS quality

remove ASCQR Program measures as follows:

- Factor 1. Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures).
- Factor 2. Availability of alternative measures with a stronger relationship to patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

In that final rule with comment period, we stated that the benefits of removing a measure from the ASCQR Program will be assessed on a case-by-case basis (79 FR 66969). Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor. We note that in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473), similar measure removal factors were finalized for the Hospital OQR Program.

In this proposed rule, we are proposing to: (1) Remove one factor; (2) add two new measure removal factors, and (3) update 42 CFR 416.320(c) to better reflect our measure removal policies. We are also making one clarification to measure removal Factor 1. These items are discussed in detail below.

(2) Proposal To Remove Factor 2

We received comments in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967) remarking the duplicative nature of the ASCQR Program's measure removal Factor 2, availability of alternative measures with a stronger relationship to patient outcomes, with measure removal Factor 6, the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic. In that final rule with comment period, we stated that ''criterion (2) applies when there is more than one alternative measure with a stronger relationship to patient outcomes that is available, and criterion (6) applies where there is only one measure that is strongly and specifically associated with desired patient outcomes for the particular topic that is available'' (79 FR 66967). Since reevaluating those comments, we have now come to agree that ASCQR measure removal Factor 2 is repetitive with Factor 6. Therefore, we are proposing to remove Factor 2, ''availability of alternative measures with a stronger relationship to patient outcomes,'' beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period.

(3) Proposals To Add Two New Measure Removal Factors

(a) Proposed Measure Removal Factor 2: Performance or Improvement on a Measure Does Not Result in Better Patient Outcomes

We would like the ASCQR Program measure removal factors to be fully aligned with the Hospital OQR Program to provide consistency across these two outpatient setting quality reporting programs. We believe it is important to evaluate the appropriateness of measures across programs using similar standards. In evaluating the two programs' removal factors, we became aware that the Hospital OQR Program includes one factor not currently in the ASCQR Program. The Hospital OQR Program's second measure removal factor specifies ''performance or improvement on a measure does not result in better patient outcomes'' (75 FR 50185).

Therefore, in this proposed rule, we are proposing to add ''performance or improvement on a measure does not result in better patient outcomes'' as the new removal Factor 2 for the ASCQR Program (replacing the previously adopted factor proposed for removal above). We believe that this factor is applicable in evaluating the ASCQR Program quality measures for removal because we have found it useful for evaluating measures in the Hospital OQR Program, which also evaluates the outpatient setting. We also note that this proposed factor is already included in the Hospital IQR (80 FR 49641 through 49642), the PCHQR (82 FR 38411), the LTCH QRP (77 FR 53614 through 53615), and the IPFQR (82 FR 38463) Programs. Therefore, we are proposing to add a new removal factor to the ASCQR Program: ''performance or improvement on a measure does not result in better patient outcomes'' beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period.

(b) Proposed New Measure Removal Factor 8

We are proposing to adopt an additional factor to consider when evaluating measures for removal from the ASCQR Program measure set:

- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

As we discuss in section I.A.2. of this proposed rule with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the ASCQR Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Facility information collection burden and related costs and burden associated with the submission/reporting of quality measures to CMS; (2) the facility cost associated with complying with other programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or State regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for ASCs to track confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

In weighing the costs against the benefits, we evaluate the benefits of the

reporting and pay for performance (value-based purchasing) programs.

measure as a whole, but in particular, we assess the benefits through the framework of our Meaningful Measures Initiative, as we discussed in section I.A.2. of this proposed rule. One key aspect of patient benefits is assessing the improved beneficiary health outcomes if a measure is retained in our measure set. We believe that these benefits are multifaceted, and are illustrated through the Meaningful Measures framework's 6 domains and 19 areas. For example, we assessed the Healthcare Worker Influenza Vaccination and patient Influenza Vaccination measures categorized in the Quality Priority ''Promote Effective Prevention and Treatment of Chronic Disease'' in the meaningful measure area of ''Preventive Care'' across multiple CMS programs, and considered: Patient outcomes, such as mortality and hospitalizations associated with influenza; CMS measure performance in a program; and other available and reported influenza process measures, such as population influenza vaccination coverage.

When these costs outweigh the evidence supporting the benefits to patients with the continued use of a measure in the ASCQR Program, we believe it may be appropriate to remove the measure from the Program. Although we recognize that one of the main goals of the ASCQR Program is to improve beneficiary outcomes by incentivizing health care facilities to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data (including percentage payment adjustment data) is of limited use because it cannot be easily interpreted by beneficiaries and used to inform their choice of facility. In these cases, removing the measure from the ASCQR Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are proposing that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for ASCs to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We are inviting public comment on our proposal to adopt an additional measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period and for subsequent years.

We refer readers to section XIV.B.3.c. of this proposed rule, where we are proposing to remove four measures based on this proposed measure removal factor. We note that we have also proposed this same removal factor for the Hospital OQR Program in section XIII.B.4.a.(4) of this proposed rule, as well as for other quality reporting and value-based purchasing programs for FY 2019 including: the Hospital VBP Program (83 FR 20409), the Hospital IQR Program (83 FR 20472); the PCHQR Program (83 FR 20501 through 20502); the LTCH QRP (83 FR 20512); the HQRP (83 FR 20956); the IRF QRP (83 FR 21000); the SNF QRP (83 FR 21082); and the IPFQR Program (83 FR 21118).

If our proposals to remove one and add two new removal factors are finalized as proposed, the new removal factors list would be:

- Factor 1. Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures).
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

(4) Proposed Revisions to 42 CFR 416.320(c)

We are proposing to revise 42 CFR 416.320(c) to better reflect our considerations for removing measures policy in light of the above proposals.

(5) Clarification for Removal Factor 1: ''Topped-Out'' Measures

We refer readers to the CY 2015 OPPS/ASC final rule with comment period where we finalized the criteria for determining when a measure is ''topped-out'' (79 FR 66968). In that final rule with comment period, we finalized two criteria for determining when a measure is ''topped-out'' under the ASCQR Program: (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10 (79 FR 66968 through 66969).

We are not proposing any changes to this policy; however, we are clarifying our process for calculating the truncated coefficient of variation (TCOV) for four of the measures (ASC–1, ASC–2, ASC–3, and ASC–4) proposed for removal from the ASCQR Program. Utilizing our finalized methodology (79 FR 66968), we determine the truncated coefficient of variation (TCOV) by calculating the truncated standard deviation (SD) divided by the truncated mean. As discussed above, our finalized removal criteria state that to be considered ''topped-out'', a measure must have a TCOV of less than 0.10. We utilize the TCOV because it is generally a good measure of variability and provides a relative methodology for comparing different types of measures.

Unlike the majority of our measures, for which a higher rate (indicating a higher proportion of a desired event) is the preferred outcome, some measures—in particular, ASC–1, ASC–2, ASC–3, and ASC–4—assess the rate of rare, undesired events for which a lower rate is preferred. For example, ASC–1 assesses the occurrence of patient burns, a patient safety issue. However, when determining the TCOV for a measure assessing rare, undesired events, the mean, or average rate of event occurrence, is very low and the result is a TCOV that increases rapidly and approaches infinity as the proportion of rare events declines.[96] We note that the SD, the variability statistic, is the same in magnitude for measures assessing rare and non-rare events.

In this proposed rule, we are proposing to remove a number of measures that assess the rate of rare, undesired events for which a lower rate is preferred—ASC–1, ASC–2, ASC–3, and ASC–4—and refer readers to section

[96] Rose-Hulman Institute of Technology. Denominator approaching zero. Retrieved from: *https://www.rose-hulman.edu/media/89584/lclimitsguide.pdf.*

XIV.B.3.c. of this proposed rule where these proposed measure removals are discussed in detail. Because by design these measures have maintained very low rates (indicating the preferred outcome), we utilized the mean of *non-adverse* events in our calculation of the TCOV. For example, for ASC–1, to calculate the TCOV we divide the SD by the average rate of patients *not* receiving burns (1 minus the rate of patients receiving burns) rather than the rate of patients receiving burns. Utilizing this methodology results in a TCOV that is comparable to that calculated for other measures and allows us to assess rare-event measures by still generally using our previously finalized topped-out criteria.

c. Proposed Removal of Quality Measures From the ASCQR Program Measure Set

In this proposed rule, we are proposing to remove a total of 8 measures from the ASCQR Program measure set across the CY 2020 and CY 2021 payment determinations. Specifically, beginning with the CY 2020 payment determination, we are proposing to remove: (1) ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and beginning with the CY 2021 payment determination, we are proposing to remove: (2) ASC–1: Patient Burn (NQF #0263); (3) ASC–2: Patient Fall (NQF #0266); (4) ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); (5) ASC–4: All-Cause Hospital Transfer/Admission (NQF #0265); (6) ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); (7) ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); and (8) ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536). We are proposing to remove these measures under the following measure removal factors: Factor 1—measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures); and proposed Factor 8—the costs associated with a measure outweigh the benefit of its continued use in the program.

These proposed measure removals are discussed in detail below.

(1) Proposed Measure Removal for the CY 2020 Payment Determination and Subsequent Years—Proposed Removal of ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel

For the CY 2020 payment determination and subsequent years, we are proposing to remove one NHSN measure under proposed measure removal Factor 8, the costs associated with this measure outweigh the benefit of its continued use in the program.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74510), where we adopted ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), beginning with the CY 2016 payment determination and for subsequent years. This process of care measure, also a National Healthcare Safety Network (NHSN) measure, assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. We initially adopted this measure based on our recognition that influenza immunization is an important public health issue and vital component to preventing healthcare associated infections. We believe that the measure addresses this public health concern by assessing influenza vaccination in the ASC among healthcare personnel (HCP), who can serve as vectors for influenza transmission.

In this proposed rule, we are proposing to remove ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel beginning with the CY 2020 payment determination under proposed measure removal Factor 8, because we have concluded that the costs associated with this measure outweigh the benefit of its continued use in the program.

The information collection burden for the Influenza Vaccination Coverage Among Healthcare Personnel measure is less than for measures that require chart abstraction of patient data because influenza vaccination among health care personnel can be calculated through review of records maintained in administrative systems and because facilities have fewer health care personnel than patients. As such, ASC–8 does not require review of as many records. However, this measure does still pose information collection burden on facilities due to the requirement to identify personnel who have been vaccinated against influenza and for those not vaccinated, the reason why.

Furthermore, as we stated in section XIV.B.3.b. of this proposed rule, costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For example, it may be costly for health care providers to maintain general administrative knowledge to report these measures. In addition, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information.

In our analysis of the ASCQR Program measure set, we recognized that some ASCs face challenges with respect to the administrative requirements of the NHSN in their reporting of the Influenza Vaccination Coverage Among Healthcare Personnel measure. These administrative requirements (which are unique to NHSN) include annually completing NHSN system user authentication. Enrolling in NHSN is a five-step process that the CDC estimates takes an average of 263 minutes per ASC.[97] Furthermore, submission via NHSN requires the system security administrator of participating facilities to reconsent electronically, ensure that contact information is kept current, ensure that the ASC has an active facility administrator account, keep Secure Access Management Service (SAMS) credentials active by logging in approximately every 2 months and changing their password, create a monthly reporting plan, and ensure the ASC's CCN information is up-to-date.

Unlike acute care hospitals which participate in other quality programs, such as the Hospital IQR and HAC Reduction Programs, ASCs are only required to participate in NHSN to submit data for this one measure. This may unduly disadvantage smaller ASCs, specifically those that are not part of larger hospital systems, because these ASCs do not have NHSN access for other quality reporting or value-based payment programs. It is our goal to ensure that the ASCQR Program is equitable to all ASCs and this measure may disproportionately affect small, independent ASCs. Especially for these small, independent ASCs, the incremental costs of this measure, as compared to other measures in the ASCQR Program measure set, are significant because of the requirements imposed by NHSN participation.

We continue to believe that the Influenza Vaccination Coverage Among Healthcare Personnel measure provides the benefit of protecting ASC patients

[97] Available at: *https://www.cdc.gov/nhsn/ambulatory-surgery/enroll.html* (the estimates for time to complete are 2 hours 45 minutes for step 1, 10 minutes for step 2, 16 minutes for step 3a, 35 minutes for step 3b, 32 minutes for step 4, and 5 minutes for step 5; totaling 263 minutes).

against influenza. However, we believe that these benefits are offset by other efforts to reduce influenza infection among ASC patients, such as numerous healthcare employer requirements for healthcare personnel to be vaccinated against influenza.[98] We also expect that a portion of MIPS-eligible clinicians nationwide will report on the Preventive Care and Screening: Influenza Immunization measure (NQF #0041) through the Quality Payment Program (QPP).[99] Although MIPS-eligible clinicians may voluntarily select measures from a list of options, ASC providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure. CMS remains responsive to the public health concern of influenza infection within the Medicare FFS population by collecting data on rates of influenza immunization among patients.[100] Thus, the public health concern is addressed via these other efforts to track influenza vaccination. The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area. In addition, as we discuss in section XIV.B.3.b. of this proposed rule, where we are proposing to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

We wish to minimize the level of cost of our programs for participating facilities, as discussed under the Meaningful Measures Initiative described in section I.A.2. of this proposed rule. In our assessment of the ASCQR Program measure set, we prioritized measures that align with this Framework as the most important to the ASC population. Our assessment concluded that while the Influenza Vaccination Coverage Among Healthcare Personnel measure continues to provide benefits, these benefits are diminished by other factors and are outweighed by the costs and burdens of reporting this measure.

For these reasons, we are proposing to remove ASC–8: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) from the ASCQR Program beginning with the CY 2020 payment determination and for subsequent years because the costs associated with the measure outweigh the benefit of its continued use in the program. We note that if proposed measure removal Factor 8 is not finalized, removal of this measure would also not be finalized. We note that this measure is also being proposed for removal from the Hospital OQR Program in section XIII.B.4.b. of this proposed rule and the IPFQR Program in the FY 2019 IPF PPS proposed rule (83 FR 21119 through 21120).

(2) Proposed Measure Removals for the CY 2021 Payment Determination and Subsequent Years

For the CY 2021 payment determination and subsequent years, we are proposing to remove: (1) Four claims-based measures under measure removal Factor 1, ''topped-out'' status; (2) two chart-abstracted measures and one web-based tool measure under proposed measure removal Factor 8.

(a) Proposed Measure Removals Under Removal Factor 1: ASC–1, ASC–2, ASC–3, and ASC–4

In this proposed rule, beginning with the CY 2021 payment determination and subsequent years, we are proposing to remove ASC–1, ASC–2, ASC–3, and ASC–4 under measure removal Factor 1, measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. The ASCQR Program previously finalized two criteria for determining when a measure is ''topped-out'': (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation is less than or equal to 0.10 (79 FR 66968 through 66969). We refer readers to section XIV.B.3.b. of this proposed rule, above, where we clarify and discuss how we calculate the TCOV for measures that assess the rate of rare, undesired events for which a lower rate is preferred, such as ASC–1, ASC–2, ASC–3, and ASC–4.

For each of these measures, we believe that removal from the ASCQR Program measure set is appropriate as there is little room for improvement. In addition, removal would alleviate the maintenance costs and administrative burden to ASCs associated with retaining the measures. As such, we believe the burden associated with reporting these measures outweighs the benefits of keeping them in the program.

Each measure is discussed in more detail below. We also note that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination, but opted to delay removal until the CY 2021 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for the measures begins during CY 2018 for the CY 2020 payment determination.

• Proposed Removal of ASC–1: Patient Burn

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74497 through 74498) where we adopted ASC–1: Patient Burn beginning with the CY 2014 payment determination (NQF #0263). This claims-based outcome measure assesses the percentage of ASC admissions experiencing a burn prior to discharge.

Based on our analysis of ASCQR Program measure data for CYs 2013 to 2017 encounters, the ASC–1 measure meets our measure removal Factor 1. These analyses are captured in the table below.

ASC–1—Patient Burn Topped-Out Analysis

Encounters	Number of ASCs	75th percentile	90th percentile	Truncated COV
Q1–Q4 2013	4,768	100.00	100.00	0.023
Q1–Q4 2014	4,794	100.00	100.00	0.015
Q1–Q4 2015	4,783	100.00	100.00	0.011
Q1–Q4 2016	4,788	100.00	100.00	0.010
Q1–Q4 2017	4,814	100.00	100.00	0.008

[98] CDC, Influenza Vaccination Information for Health Care Workers. Available at: *https://www.cdc.gov/flu/healthcareworkers.htm.*

[99] QPP 2017 Measures Selection: Influenza. Retrieved from: *https://qpp.cms.gov/mips/quality-measures.*

[100] Ibid.

As displayed in the analysis above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles, and the truncated coefficient of variation has been below 0.10 since 2013. We also note that NQF endorsement of this measure (NQF #0263) was removed on May 24, 2016.[101]

• Proposed Removal of ASC–2: Patient Fall

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498) where we adopted ASC–2: Patient Fall beginning with the CY 2014 payment determination. This NQF-endorsed (NQF #0266), claims-based measure assesses the percentage of ASC admissions experiencing a fall in the ASC.

Based on our analysis of ASCQR Program measure data for CYs 2013 to 2017 encounters, the ASC–2 measure meets our measure removal Factor 1. These analyses are captured in the table below.

ASC–2—PATIENT FALL TOPPED-OUT ANALYSIS

Encounters	Number of ASCs	75th percentile	90th percentile	Truncated COV
Q1–Q4 2013	4,769	100.00	100.00	0.011
Q1–Q4 2014	4,793	100.00	100.00	0.007
Q1–Q4 2015	4,783	100.00	100.00	0.006
Q1–Q4 2016	4,787	100.00	100.00	0.003
Q1–Q4 2017	4,815	100.00	100.00	0.001

As displayed in the analysis above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles and the truncated coefficient of variation has been below 0.10 since 2013.

• Proposed Removal of ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498 through 74499) where we adopted ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant beginning with the CY 2014 payment determination (NQF #0267). This claims-based outcome measure assesses the percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant.

Based on our analysis of ASCQR Program measure data for CYs 2013 to 2017 encounters, the ASC–3 measure meets our measure removal Factor 1. These analyses are captured in the table below.

ASC–3—WRONG SITE, WRONG SIDE, WRONG PATIENT, WRONG PROCEDURE, WRONG IMPLANT TOPPED-OUT ANALYSIS

Encounters	Number of ASCs	75th percentile	90th percentile	Truncated COV
Q1–Q4 2013	4,769	100.00	100.00	0.000
Q1–Q4 2014	4,793	100.00	100.00	0.000
Q1–Q4 2015	4,781	100.00	100.00	0.000
Q1–Q4 2016	4,787	100.00	100.00	0.000
Q1–Q4 2017	4,815	100.00	100.00	0.000

As displayed in the analysis above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles and the truncated coefficient of variation has been below 0.10 since 2013. We also note that NQF endorsement of this measure (NQF #0267) was removed on May 24, 2016.[102]

• Proposed Removal of ASC–4: All-Cause Hospital Transfer/Admission

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74499) where we adopted ASC–4: All-Cause Hospital Transfer/Admission beginning with the CY 2014 payment determination (NQF #0265). This claims-based outcome measure assesses the rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC.

Based on our analysis of ASCQR Program measure data for CYs 2013 to 2017 encounters, the ASC–4 measure meets our measure removal Factor 1. These analyses are captured in the table below.

ASC–4—ALL CAUSE HOSPITAL TRANSFER/ADMISSION TOPPED-OUT ANALYSIS

Encounters	Number of ASCs	75th percentile	90th percentile	Truncated COV
Q1–Q4 2013	4,768	100.00	100.00	0.059
Q1–Q4 2014	4,793	100.00	100.00	0.050
Q1–Q4 2015	4,781	100.00	100.00	0.041
Q1–Q4 2016	4,787	100.00	100.00	0.040
Q1–Q4 2017	4,814	100.00	100.00	0.037

[101] National Quality Forum. Available at: *http://www.qualityforum.org/QPS/0263.*

[102] National Quality Forum. Available at: *http://www.qualityforum.org/QPS/0267.*

As displayed in the analysis above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles and the truncated coefficient of variation has been below 0.10 since 2013. We also note that NQF endorsement of this measure (NQF #0265) was removed on February 4, 2016.[103]

Therefore, we are inviting public comment on our proposals to remove: (1) ASC–1: Patient Burn; (2) ASC–2: Patient Fall; (3) ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and (4) ASC–4: All-Cause Hospital Transfer/Admission beginning with the CY 2021 payment determination and for subsequent years as discussed above.

(b) Proposed Measure Removals Under Removal Factor 8: ASC–9, ASC–10, and ASC–11

In this proposed rule, we are proposing to remove three measures (ASC–9, ASC–10, and ASC–11) under proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, for the CY 2021 payment determination and subsequent years. We note that if proposed measure removal Factor 8 is not finalized, removal of these measures would also not be finalized.

The proposals are discussed in more detail below. We note that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination, but opted to delay removal until the CY 2021 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for these measures begins during CY 2018 for the CY 2020 payment determination.

• Proposed Removal of ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75127 through 75128) where we adopted ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0659) beginning with the CY 2016 payment determination. This chart-abstracted process measure assesses the ''[p]ercentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report'' (78 FR 75128). This measure aims to assess whether average risk patients with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is less than the recommended amount of 10 years.

In this proposed rule, we are proposing to remove ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and for subsequent years under our proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We adopted ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75127 through 75128) noting that performing colonoscopy too frequently increases patients' exposure to procedural harm. However, we now believe that the costs of this measure outweigh the benefit of its continued use in the program.

Chart-abstraction requires facilities to select a sample population, access historical records from several current and historic clinical data quarters, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. In addition to submission of manually chart-abstracted data, we take all burden and costs into account when evaluating a measure. Removing ASC–9 would reduce the burden and cost to facilities associated with collection of information and reviewing their data and performance associated with the measure.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities, especially when taking into consideration the availability of other CMS quality measures that are relevant in the clinical condition and highly correlated in performance across measures. Another colonoscopy-related measure required in the ASCQR Program, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) measures all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure (79 FR 66970). This claims-based outcome measure does not require chart-abstraction, and similarly contributes data on quality of care related to colonoscopy procedures, although the measure does not specifically track processes such as follow-up intervals. When we adopted ASC–12, we believed this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to facilities and patients all unplanned hospital visits following the procedure (79 FR 66970).

Furthermore, the potential benefits of keeping ASC–9 in the program are mitigated by the existence of the same measure (Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients)[104] for gastroenterologists in the Merit-Based Incentive Payment System (MIPS) for the 2019 performance period in the QPP (82 FR 30292). Thus, we believe the issue of preventing harm to patients from colonoscopy procedures that are performed too frequently is adequately addressed through MIPS in the QPP, because we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS. Although MIPS-eligible clinicians may voluntarily select measures from a list of options, ASC providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure without being penalized if they determine there is value for various quality improvement efforts.[105] The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area.

Furthermore, we seek to align our quality reporting work with the Patients Over Paperwork and the Meaningful Measures Initiatives described in section I.A.2. of this proposed rule. The purpose of this effort is to hold providers accountable for only the measures that are most important to patients and clinicians and those that are focused on patient outcomes in particular, because outcome measures

[103] National Quality Forum. Available at: *http://www.qualityforum.org/QPS/0265.*

[104] QPP Measure Selection: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients. Retrieved from: *https://qpp.cms.gov/mips/quality-measures.*

[105] CMS finalized that services furnished by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology will not be subject to the MIPS payments adjustments, but eligible clinicians payable under those methodologies may have the option to still voluntarily report on applicable measures and the data reported will not be used to determine future eligibility (82 FR 53586).

evaluate the actual results of care. As described in section I.A.2. of this proposed rule, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the ASCQR Program would reduce program complexity. In addition, as we discuss in section XIV.B.3.b. of this proposed rule, where we are proposing to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Therefore, due to the combination of factors of the costs of collecting data for this chart-abstracted measure, the preference for an outcomes measure in the ASCQR Program that provides valuable data for the same procedure, and the existence of the same measure in another CMS program, we believe that the burdens and costs associated with this measure outweigh the limited benefit to beneficiaries. As a result, we are proposing to remove ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and for subsequent years. We note that we are also proposing to remove a similar measure in the Hospital OQR Program in section XIII.B.4.b. of this proposed rule.

• Proposed Removal of ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use

We refer readers to CY 2014 OPPS/ASC final rule with comment period (78 FR 75128) where we adopted ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659) beginning with the CY 2016 payment determination. This chart-abstracted process measure assesses the percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report.

In this proposed rule, we are proposing to remove ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use beginning with the CY 2021 payment determination and for subsequent years under our proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We adopted ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75128) noting that colonoscopy screening for high risk patients is recommended based on risk factors, and one such factor is a history of adenomatous polyps. The frequency of colonoscopy screening varies depending on the size and amount of polyps found, with the general recommendation of a 3-year follow-up. We stated that this measure is appropriate for the measurement of quality of care furnished by ASCs, because colonoscopy screening is commonly performed in these settings (78 FR 75128). However, we now believe that the costs of this measure outweigh the benefit of its continued use in the program.

Chart-abstraction requires facilities to select a sample population, access historical records from several clinical data quarters past, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. In addition to submission of manually chart-abstracted data, we take all burden and costs into account when evaluating a measure. Removing ASC–10 would reduce the burden and cost to facilities associated with collection of information and reporting on their performance associated with the measure.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities especially when taking into consideration the availability of other CMS quality measures. Another colonoscopy-related measure required in the ASCQR Program, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) measures all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure (79 FR 66970). This claims-based outcome measure does not require chart-abstraction, and similarly contributes data on quality of care related to colonoscopy procedures, although the measure does not specifically track processes such as follow-up intervals. When we adopted ASC–12, we believed this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to facilities and patients all unplanned hospital visits following the procedure (79 FR 66970). Furthermore, the potential benefits of keeping ASC–10 in the ASCQR Program are mitigated by the existence of the same measure (Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients) [106] for gastroenterologists in the Merit-Based Incentive Payment System (MIPS) for the 2019 performance period in the QPP (82 FR 30292). Thus, we believe the issue of preventing harm to patients from colonoscopy procedures that are performed too frequently is adequately addressed through MIPS in the QPP, because we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS. Although MIPS-eligible clinicians may voluntarily select measures from a list of options, ASC providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure without being penalized if they determine there is value for various quality improvement efforts.[107] The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area.

Furthermore, we seek to align our quality reporting work with the Patients Over Paperwork and the Meaningful Measures Initiatives described in section I.A.2. of this proposed rule. The purpose of this effort is to hold providers accountable for only the measures that are most important to patients and clinicians and that are focused on patient outcomes in particular, because outcome measures evaluate the actual results of care. As described in section I.A.2. of this proposed rule, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the ASCQR Program would reduce program complexity. In addition, as we discuss in section

[106] QPP Measure Selection: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients. Retrieved from: *https://qpp.cms.gov/mips/quality-measures.*

[107] CMS finalized that services furnished by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology will not be subject to the MIPS payments adjustments, but eligible clinicians payable under those methodologies may have the option to still voluntarily report on applicable measures and the data reported will not be used to determine future eligibility (82 FR 53586).

XIV.B.3.b. of this proposed rule, where we are proposing to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Therefore, due to the combination of factors of the costs of collecting data for this chart-abstracted measure, the preference for an outcomes measure in the ASCQR Program that provides valuable data for the same procedure, and the existence of the same measure in the MIPS program, we believe that the burdens and costs associated with manual chart abstraction outweigh the limited benefit to beneficiaries of receiving this information. As a result, we are proposing to remove ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use beginning with the CY 2021 payment determination and for subsequent years. We note that we are also proposing to remove a similar measure in the Hospital OQR Program in section XIII.B.4.b. of this proposed rule.

- Proposed Removal of ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75129) where we adopted ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) beginning with the CY 2016 payment determination. This measure assesses the rate of patients 18 years and older (with a diagnosis of uncomplicated cataract) in a sample who had improvement in visual function achieved within 90 days following cataract surgery based on completing both a preoperative and postoperative visual function survey.

Since the adoption of this measure, we came to believe that it can be operationally difficult for ASCs to collect and report the measure (79 FR 66984). Specifically, we were concerned that the results of the survey used to assess the preoperative and post-operative visual function of the patient may not be shared across clinicians and facilities, making it difficult for ASCs to have knowledge of the visual function of the patient before and after surgery (79 FR 66984). We were also concerned about the surveys used to assess visual function; the measure allows for the use of any validated survey and results may be inconsistent should clinicians use different surveys (79 FR 66984). Therefore, on December 31, 2013, we issued guidance stating that we would delay data collection for ASC–11 for 3 months (data collection would commence with April 1, 2014 encounters) for the CY 2016 payment determination (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772879036*). We issued additional guidance on April 2, 2014, stating that we would further delay the implementation of ASC–11 for an additional 9 months, until January 1, 2015 for the CY 2016 payment determination, due to continued concerns (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228773811586*). As a result of these concerns, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985), we finalized our proposal to allow voluntary data collection and reporting of this measure beginning with the CY 2017 payment determination and for subsequent years.

In this proposed rule, we are proposing to remove ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery from the ASCQR Program beginning with the CY 2021 payment determination under proposed measure removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. We originally adopted ASC–11 because we believe ASCs should be a partner in care with physicians and other clinicians using their facility and that this measure would provide an opportunity to do so (79 FR 66984). However, in light of the history of complications and upon reviewing this measure within our Meaningful Measures framework, we have concluded that it is overly burdensome for facilities to report this measure due to the difficulty of tracking care that occurs outside of the ASC setting.

In order to report on this measure to CMS, a facility would need to obtain the visual function assessment results from the appropriate ophthalmologist and ensure that the assessment utilized is validated for the population for which it is being used. If the assessment is not able to be used or is not available, the ASC facility would then need to administer the survey directly and ensure that the same visual function assessment tool is utilized preoperatively and postoperatively. There is no simple, preexisting means for information sharing between ophthalmologists and ASCs, so an ASC would need to obtain assessment results from each individual patient's ophthalmologist both preoperatively and postoperatively. The high administrative costs of the technical tracking of this information presents an undue cost, and also burden associated with submission and reporting of ASC–11 to CMS, especially for small ASCs with limited staffing capacity.

Furthermore, this measure currently provides limited benefits. Since making the measure voluntary, only 118 facilities have reported this measure to CMS, compared to approximately 5,121 total facilities for all other measures, resulting in only 2.3 percent of facilities reporting.[108] Consequently, we have been unable to uniformly offer pertinent information to beneficiaries on how the measure assesses ASC performance. This reinforces comments made in the CY 2015 OPPS/ASC final rule with comment period, in which commenters expressed concern that the voluntary reporting of this measure would result in incomplete data that may be confusing to beneficiaries and other consumers (79 FR 66984). As we state in section I.A.2. of this proposed rule, we strive to ensure that beneficiaries are empowered to make decisions about their healthcare using information from data-driven insights. Because of the lack of sufficient data, this measure may be difficult for beneficiaries to interpret or use to aid in their choice of where to obtain care; thus, the benefits of this measure are limited.

Therefore, we believe the high technical and administrative costs of this measure outweigh the limited benefit associated with its continued use in the ASCQR Program. As discussed in section I.A.2. of this proposed rule, above, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We believe that removing this measure from the ASCQR Program will reduce program burden, costs, and complexity. As a result, we are proposing to remove ASC–11 beginning with the CY 2021 payment determination and for subsequent years. We are also proposing to remove a similar measure under the Hospital OQR Program in section XIII.B.4.b. of this proposed rule.

4. Summary of ASCQR Program Quality Measure Sets Proposed for the CY 2020, CY 2021, and CY 2022 Payment Determinations

In this CY 2019 OPPS/ASC proposed rule, we are not proposing any new measures for the ASCQR Program. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR

[108] ASCQR Compare Data. Available at: *https://data.medicare.gov/Hospital-Compare/Ambulatory-Surgical-Quality-Measures-Facility/4jcv-atw7/data.*

59470) for the previously finalized ASCQR Program measure set for the CY 2020 payment determination and subsequent years. We note that we are proposing to change the reporting period for one previously adopted measure, ASC–12, and refer readers to section XIV.D.4.b. of this proposed rule for details.

The tables below summarize the proposed ASCQR Program measure sets for the CY 2020, 2021, and 2022 payment determinations (including previously adopted measures and measures proposed for removal in this proposed rule).

PROPOSED ASCQR PROGRAM MEASURE SET FOR THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	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–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use.
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.**

† NQF endorsement was removed.

* Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of 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 section XIV.B.4. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).

PROPOSED ASCQR PROGRAM MEASURE SET FOR THE CY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	Measure name
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.*

* 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 section XIV.B.4. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).

PROPOSED ASCQR PROGRAM MEASURE SET FOR THE CY 2022 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	Measure name
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	None	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures.
ASC–18	None	Hospital Visits after Urology Ambulatory Surgical Center Procedures.

* 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 section XIV.B.4. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).

5. ASCQR Program Measures and Topics for Future Consideration: Possible Future Validation of ASCQR Program Measures

We are requesting public comment on the possible future validation of ASCQR Program measures. There is currently no validation of ASCQR measure data, and we believe ASCs may benefit from the opportunity to better understand their data and examine potential discrepancies. We believe the ASCQR Program may similarly benefit from the opportunity to produce a more reliable estimate of whether an ASC's submitted data have been abstracted correctly and provide more statistically reliable estimates of the quality of care delivered in each selected ASC as well as at the national level. We believe the Hospital OQR Program validation policy could be a good model for the ASCQR Program and are requesting comment on the validation methodology and identifying one measure with which to start.

The Hospital OQR Program requires validation of its chart-abstracted measures. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965) for a discussion of finalized policies regarding Hospital OQR Program validation requirements, which are also codified at 42 CFR 419.46(e). Under the Hospital OQR Program, CMS selects a random sample of 450 hospitals and an additional 50 hospitals based on the following criteria: (1) The hospital failing of the validation requirement that applies to the previous year's payment determination; or (2) the hospital having an outlier value for a measure based on data that it submits. An ''outlier value'' is defined as a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score. Then, CMS or its contractor provides written requests to the randomly selected hospitals by requesting supporting medical record documentation used for purposes of data submission under the program. The hospital must submit the supporting medical record documentation within 45 days of the date written in the request. A hospital meets the validation requirement with respect to a calendar year if it achieves at least a 75 percent reliability score, as determined by CMS.

Specifically for the ASCQR Program, we are interested in the validation of chart-abstracted measures. We believe it would be beneficial to start with validation of just one measure, such as ASC–13: Normothermia Outcome, prior to expanding to more measures. ASC–13: Normothermia Outcome was finalized in the 2017 OPPS/ASC final rule with comment period (81 FR 79798 through 79801) and assesses the percentage of patients having surgical procedures under general or neuraxial anesthesia of 60 minutes or more in duration who are normothermic within 15 minutes of arrival in the post-anesthesia care unit. We also considered starting with ASC–14: Unplanned Anterior Vitrectomy instead, which was finalized in the 2017 OPPS/ASC final rule with comment period (81 FR 79801 through 79803) and assesses the percentage of cataract surgery patients who have an unplanned anterior vitrectomy. However, we believe ASC–13 would be the most feasible measure for validation because it assesses surgical cases and would have a larger population of cases from which to sample. ASC–14, which assesses rare, unplanned events that are less common, would have a smaller population of cases from which to sample.

Therefore, we are inviting public comment on the possible future validation of ASCQR Program measures. We specifically request comment on whether Hospital OQR Program's validation policies could be an appropriate model for the ASCQR Program, the possible ASC sample size, sampling methodology, number of cases to sample, validation score methodology, and reduced annual payment updates for facilities that do not pass validation requirements. We also are requesting comment on possibly starting with only one measure, specifically ASC–13, before expanding to more measures.

6. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74513 through 74514), where we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures, including the subregulatory process for updating adopted measures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68496 through 68497), the CY 2014 OPPS/ASC final rule (78 FR 75131), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66981), we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy, including the processes for addressing nonsubstantive and substantive changes to adopted measures. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531), we provided clarification regarding our decision to not display the technical specifications for the ASCQR Program on the CMS website, but stated that we will continue to display the technical specifications for the ASCQR Program on the QualityNet website. In addition, our policies regarding the maintenance of technical specifications for the ASCQR Program are codified at 42 CFR 416.325. In this proposed rule, we are not proposing any changes to our policies regarding the maintenance of technical specifications for the ASCQR Program.

7. Public Reporting of ASCQR Program Data

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS website after providing an ASC an opportunity to review the data to be made public. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531 through 70533), we finalized our policy to publicly display data by the National Provider Identifier (NPI) when the data are submitted by the NPI and to publicly display data by the CCN when the data are submitted by the CCN. In addition, we codified our policies regarding the public reporting of ASCQR Program data at 42 CFR 416.315 (80 FR 70533). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79819 through 79820), we formalized our current public display practices regarding timing of public display and the preview period by finalizing our proposals to: Publicly display data on the *Hospital Compare* website, or other CMS website as soon as practicable after measure data have been submitted to CMS; to generally provide ASCs with approximately 30 days to review their data before publicly reporting the data; and to announce the timeframes for each preview period starting with the CY 2018 payment determination on a CMS website and/or on our applicable listservs. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59455 through 59470), we discussed specific public reporting policies associated with two measures beginning with the CY 2022 payment determination: ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, and ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures.

In this proposed rule, we are not proposing any changes to our public reporting policies.

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 maintenance of a QualityNet account and security administrator for the ASCQR Program at 42 CFR 416.310(c)(1)(i). In the CY 2018 OPPS/ASC final rule (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes to the 42 CFR 416.310(c)(1)(i). In this proposed rule, we are not proposing any changes to these policies.

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 and 70534), we codified these requirements regarding participation status for the ASCQR Program at 42 CFR 416.305. In this proposed rule, we are not proposing any changes to these policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(1) and (2).

In this proposed rule, we are not proposing any changes to these requirements. However, we note that in section XIV.B.3.c. of this proposed rule, beginning with the CY 2021 payment determination and for subsequent years, we are proposing to remove all four claims-based measures currently using QDCs:

- 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.

If the removal of these measures is finalized as proposed, no claims-based measures using QDCs would remain in the ASCQR Program. However, we are not proposing any changes to our requirements regarding data processing and collection periods for these types of measures. These requirements would apply to any future claims-based measures using QDCs adopted in the program.

2. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59472) (and the previous rulemakings cited therein), as well as 42 CFR 416.310(a)(3) and 42 CFR 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. In this proposed rule, we are not proposing any changes to these policies.

3. Requirements for Data Submitted via an Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59472) (and the previous rulemakings cited therein) and 42 CFR 416.310(c) for our previously finalized policies for data submitted via an online data submission tool. For more information on data submission using QualityNet, we refer readers to: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228773314768.*

a. 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 (that is, the CDC NHSN website). We codified our existing policies regarding the data collection time 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).

Currently, we only have one measure (ASC–8: Influenza Vaccination Coverage among Healthcare Personnel) that is submitted via a non-CMS online data submission tool. We note that we are proposing this measure for removal for the CY 2020 payment determination and subsequent years in section XIV.B.3.c. of this proposed rule. If the removal of ASC–8 is finalized as proposed, no measures submitted via a non-CMS online data submission tool would remain in the ASCQR Program. However, we are not proposing 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 program.

b. 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 QualityNet website as our CMS online data submission tool: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetHomepage&cid=1120143435383.* 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 to the 42 CFR 416.310(c)(1)(i).

In this proposed rule, we are not proposing any changes to this policy. However, we note that in sections XIV.B.3.c. of this proposed rule, we are proposing to remove three measures collected via a CMS online data submission tool–ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients, ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use, and ASC–11: Cataracts: Improvement in Patients' Visual Function within 90 Days Following

Cataract Surgery [109] beginning with the CY 2021 payment determination. If those measures are finalized for removal as proposed, only the following previously finalized measures will require data to be submitted via a CMS online data submission tool for the CY 2021 payment determination and subsequent years:

- ASC–13: Normothermia Outcome
- ASC–14: Unplanned Anterior Vitrectomy

4. Requirements for Non-QDC Based, Claims-Based Measure Data

In this proposed rule, we are not proposing any changes to our requirements for non-QDC based, claims-based measures. However, we are proposing to change the reporting period for the previously adopted measure, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. This proposal is discussed in more detail further below.

a. General

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70536) for our previously adopted policies regarding data processing and reporting periods for claims-based measures for the CY 2018 payment determination and subsequent years. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70536), we codified these policies at 42 CFR 416.310(b). We are not proposing any changes to these policies. We note that the non-QDC, claims-based measures in the program are as follows:

- CY 2020 payment determination and subsequent years: ASC 12: Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy (79 FR 66970 through 66978)
- CY 2022 payment determination and subsequent years:
  - •• ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (82 FR 59455 through 59470)
  - •• ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures (82 FR 59455 through 59470)

b. Proposed Extension of the Reporting Period for ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66970 through 66978), we finalized the adoption of ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy into the ASCQR Program for the CY 2018 payment determination and subsequent years, with public display to begin on or after December 1, 2017. This measure is calculated with data obtained from paid Medicare FFS claims (79 FR 66978). For this reason, facilities are not required to submit any additional information. In that final rule with comment period, we also finalized the reporting period for measure calculation as claims data from two calendar years prior to the payment determination year. Specifically, for the CY 2018 payment determination, we stated we would use paid Medicare FFS claims from January 1, 2016 to December 31, 2016 to calculate measure results (79 FR 66985). We finalized a 1-year reporting period as it adequately balanced competing interests of measure reliability and timeliness for payment determination purposes, and explained that we would continue to assess this during the dry run (79 FR 66973).

We noted we would complete a dry run of the measure in 2015 using 3 or 4 years of data, and, from the results of this dry run, we would review the appropriate volume cutoff for facilities to ensure statistical reliability in reporting the measure score (79 FR 66974). Our analyses of the 2015 dry run using data from July 2011 through June 2014 showed that a reporting period of 1 year had moderate to high reliability for measure calculation. Specifically, using data from July 2013 through June 2014, we calculated facility-level reliability estimates as the ratio of true variance to observed variance.[110] Consistent with the original measure specifications as described in the 2014 technical report,[111] this calculation was performed combining the measure results for HOPDs and ASCs. We found that for a facility with median case size, the reliability estimate was high (over 0.90), but the minimum reliability estimate for facilities with 30 cases (the minimum case size chosen for public reporting) was only moderate (that is, between 0.40 and 0.60).[112]

However, after the 2015 dry run, CMS calculated the HOPD and ASC scores separately to compare similar types of facilities to each other. During subsequent analysis of the 1-year period of July 2013 through June 2014, we confirmed that a 1-year reporting period with separate calculations for HOPDs and ASCs was sufficient, but did result in lower reliability and decreased precision, compared to results calculated with longer reporting periods (2 or 3 years). Based on analyses conducted using data from July 2013 through June 2014 (1-year reporting period) and 2017 measure specifications,[113] we found that the median facility-level reliability was 0.74 for ASCs and 0.51 for HOPDs. Using a 2-year reporting period (data from July 2012—June 2014), we found that median facility-level reliability was 0.81 for ASCs and 0.67 for HOPDs. When the reporting period was extended to 3 years (using data from July 2011 through June 2014), we found that median facility-level reliability was higher for both ASCs and HOPDs: 0.87 for ASCs and 0.75 for HOPDs. These results indicate that a larger portion of the included facilities have scores measured with higher reliability when 3 years of data are used rather than 1 year of data.

Using 3 years of data, compared to just 1 year, is estimated to increase the number of ASCs with eligible cases for ASC–12 by 10 percent, adding approximately 235 additional ASCs to the measure calculation. ASCs reporting the measure would increase their sample sizes and, in turn, increase the precision and reliability of their measure scores. Thus, we believe extending the reporting period to 3 years from 1 year for purposes of increasing reliability would be beneficial for providing better information to beneficiaries regarding the quality of care associated with low-risk outpatient colonoscopy procedures. In crafting our proposal, we considered extending the reporting period to 2 years beginning with the CY 2020 payment determinations and subsequent years, but decided on proposing 3 years instead, because a higher level of reliability is achieved with a 3-year reporting period compared to 2 years.

[109] We note that the ASC–11 measure is voluntarily collected effective beginning with the CY 2017 payment determination, as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

[110] Snijders TA, Bosker RJ. *Multilevel Analysis: An introduction to basic and advanced multilevel modeling.* SAGE Publications. 2000. London.

[111] Additional methodology details and information obtained from public comments for measure development are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Colonoscopy.''

[112] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159–174.

[113] Current and past measure specifications are available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775214597.*

Therefore, we are proposing to change the reporting period for ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from 1 year to 3 years beginning with the CY 2020 payment determination (which would use claims data from January 1, 2016 through December 31, 2018) and for subsequent years. Under this proposal, the annual reporting requirements for ASCs would not change because this is a claims-based measure. However, with a 3-year reporting period, the most current year of data would be supplemented by the addition of 2 prior years. For example, for the CY 2020 payment determination, we would use a reporting period of CY 2018 data plus 2 prior years of data (CYs 2016 and 2017). We note that since implementation of this measure began with the CY 2018 payment determination, we have already used paid Medicare FFS claims from January 1, 2016 to December 31, 2016 to calculate the measure scores, which have been previously previewed by ASCs and publicly displayed. In crafting our proposal, we also considered timeliness related to payment determinations and public display. Because we would utilize data already collected to supplement current data, our proposal to use 3 years of data would not disrupt payment determinations or public display. We refer readers to the table below for example reporting periods and public display dates corresponding to the CY 2020, CY 2021, and CY 2022 payment determinations:

	CY 2020 Payment determination	CY 2021 Payment determination	CY 2022 Payment determination
Public display	January 2020	January 2021	January 2022.
Reporting period	January 1, 2016–December 31, 2018.	January 1, 2017–December 31, 2019.	January 1, 2018–December 31, 2020.

5. 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 ASC–15a–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. In this proposed rule, we are not proposing any changes to this policy.

6. 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 also clarified that we will strive to complete our review of each request within 90 days of receipt. In this proposed rule, we are not proposing any changes to these policies.

7. 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. In this proposed rule, we are not proposing any changes to this policy.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to section XVI.D.1. of 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. Proposed 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 equal the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2019, the proposed 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 proposed annual update for the ASC payment system for an interim 5-year period (CY 2019 through CY 2023). As discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062), if the CPI–U update factor is a negative number, the CPI–U update factor would be held to zero. Consistent with past practice, in the event the percentage change in the hospital market basket for a year is negative, we are proposing to hold the hospital market basket update factor for the ASC payment system to zero. 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 proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to section XII.G. of this proposed rule.

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, certain radiology services and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (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 section XII.D.2.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for the new category of covered ancillary services (that is, certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS and when they are integral to covered ASC surgical procedures) 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. 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, CY 2016, CY 2017, and CY 2018 OPPS/ASC final rules with comment period (79 FR 66981 through 66982; 80 FR 70537 through 70538; 81 FR 79825 through 79826; and 82 FR 59475 through 59476, respectively), we did not make any other changes to these policies.

XV. Requests for Information (RFIs)

This section addresses three requests for information (RFIs). Upon reviewing the RFIs, respondents are encouraged to provide complete but concise responses. These RFIs are issued solely for information and planning purposes; neither RFI constitutes a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense.

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

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

Currently, Medicare- and Medicaid-participating providers and suppliers are at varying stages of adoption of health information technology (health IT). Many hospitals have adopted electronic health records (EHRs), and CMS has provided incentive payments to eligible hospitals, critical access hospitals (CAHs), and eligible professionals who have demonstrated meaningful use of certified EHR technology (CEHRT) under the Medicare EHR Incentive Program. As of 2015, 96 percent of Medicare- and Medicaid-participating non-Federal acute care hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care.[114] While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many localities and regions throughout the Nation.

CMS is firmly committed to the use of certified health IT and interoperable EHR systems for electronic healthcare information exchange to effectively help hospitals and other Medicare- and Medicaid-participating providers and suppliers improve internal care delivery practices, support the exchange of important information across care team members during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). The Office of the National Coordinator for Health Information Technology (ONC) acts as the principal Federal entity charged with coordination of nationwide efforts to implement and use health information technology and the electronic exchange of health information on behalf of the Department of Health and Human Services.

In 2015, ONC finalized the 2015 Edition health IT certification criteria (2015 Edition), the most recent criteria for health IT to be certified to under the ONC Health IT Certification Program. The 2015 Edition facilitates greater interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications. CMS requires eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs and eligible clinicians in the Quality Payment Program (QPP) to use EHR technology certified to the 2015 Edition beginning in CY 2019.

In addition, several important initiatives will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information. Section 4003 of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, and amending section 3000 of the Public Health Service Act (42 U.S.C. 300jj), requires HHS to take steps to advance the electronic exchange of health information and interoperability for participating providers and suppliers in various settings across the care continuum. Specifically, Congress directed that ONC ". . . for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally." In January 2018, ONC released a draft version of its proposal for the Trusted Exchange Framework and Common Agreement,[115] which outlines principles and minimum terms and conditions for trusted exchange to enable interoperability across disparate health information networks (HINs). The Trusted Exchange Framework (TEF) is focused on achieving the following four important outcomes in the long-term:

- Professional care providers, who deliver care across the continuum, can access health information about their patients, regardless of where the patient received care.
- Patients can find all of their health information from across the care continuum, even if they do not remember the name of the professional care provider they saw.
- Professional care providers and health systems, as well as public and private health care organizations and public and private payer organizations accountable for managing benefits and the health of populations, can receive necessary and appropriate information on groups of individuals without having to access one record at a time, allowing them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives.
- The health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation that will make health information more accessible and improve EHR usability.

ONC will revise the draft TEF based on public comment and ultimately release a final version of the TEF that will subsequently be available for adoption by HINs and their participants seeking to participate in nationwide health information exchange. The goal for stakeholders that participate in, or serve as, a HIN is to ensure that participants will have the ability to seamlessly share and receive a core set of data from other network participants in accordance with a set of permitted purposes and applicable privacy and security requirements. Broad adoption of this framework and its associated exchange standards is intended to both achieve the outcomes described above while creating an environment more conducive to innovation.

In light of the widespread adoption of EHRs along with the increasing availability of health information exchange infrastructure predominantly among hospitals, we are interested in hearing from stakeholders on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, CMS might consider revisions to the current CMS CoPs for hospitals, such as: Requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required

[114] These statistics can be accessed at: *https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php.*

[115] The draft version of the trusted Exchange Framework may be accessed at: *https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.*

discharge instructions) via electronic means if requested.

On November 3, 2015, we published a proposed rule (80 FR 68126) to implement the provisions of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113–185) and to revise the discharge planning CoP requirements that hospitals (including short-term acute care hospitals, long-term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, children's hospitals, and cancer hospitals), critical access hospitals (CAHs), and home health agencies (HHAs) would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. However, several of the proposed requirements directly address the issue of communication between providers and between providers and patients, as well as the issue of interoperability:

- Hospitals and CAHs would be required to transfer certain necessary medical information and a copy of the discharge instructions and discharge summary to the patient's practitioner, if the practitioner is known and has been clearly identified;
- Hospitals and CAHs would be required to send certain necessary medical information to the receiving facility/post-acute care providers, at the time of discharge; and
- Hospitals, CAHs, and HHAs would need to comply with the IMPACT Act requirements that would require hospitals, CAHs, and certain post-acute care providers to use data on quality measures and data on resource use measures to assist patients during the discharge planning process, while taking into account the patient's goals of care and treatment preferences.

We published another proposed rule (81 FR 39448) on June 16, 2016, that updated a number of CoP requirements that hospitals and CAHs would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. One of the proposed hospital CoP revisions in that rule directly addresses the issues of communication between providers and patients, patient access to their medical records, and interoperability. We proposed that patients have the right to access their medical records, upon an oral or written request, in the form and format requested by such patients, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, including current medical records, within a reasonable timeframe. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

We also published a final rule (81 FR 68688) on October 4, 2016, that revised the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. In this rule, we made a number of revisions based on the importance of effective communication between providers during transitions of care, such as transfers and discharges of residents to other facilities or providers, or to home. Among these revisions was a requirement that the transferring LTC facility must provide all necessary information to the resident's receiving provider, whether it is an acute care hospital, an LTCH, a psychiatric facility, another LTC facility, a hospice, a home health agency, or another community-based provider or practitioner (42 CFR 483.15(c)(2)(iii)). We specified that necessary information must include the following:

- Contact information of the practitioner responsible for the care of the resident;
- Resident representative information including contact information;
- Advance directive information;
- Special instructions or precautions for ongoing care;
- The resident's comprehensive care plan goals; and
- All other necessary information, including a copy of the resident's discharge or transfer summary and any other documentation to ensure a safe and effective transition of care.

We note that the discharge summary mentioned above must include reconciliation of the resident's medications, as well as a recapitulation of the resident's stay, a final summary of the resident's status, and the post-discharge plan of care. In addition, in the preamble to the rule, we encouraged LTC facilities to electronically exchange this information if possible and to identify opportunities to streamline the collection and exchange of resident information by using information that the facility is already capturing electronically.

Additionally, we specifically invite stakeholder feedback on the following questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?
- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–91), and implementation of relevant policies in the 21st Century Cures Act?
- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?
- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving

provider, supplier, or patient/resident cannot receive the information electronically?

• Are there any other operational or legal considerations (for example, implementing regulations related to the HIPAA privacy and security standards), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?

• What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP, including CEHRT hardship or small practices, be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

We would also like to directly address the issue of communication between hospitals (as well as the other providers and suppliers across the continuum of patient care) and their patients and caregivers. MyHealthEData is a government-wide initiative aimed at breaking down barriers that contribute to preventing patients from being able to access and control their medical records. Privacy and security of patient data will be at the center of all CMS efforts in this area. CMS must protect the confidentiality of patient data, and CMS is completely aligned with the Department of Veterans Affairs (VA), the National Institutes of Health (NIH), ONC, and the rest of the Federal Government, on this objective.

While some Medicare beneficiaries have had, for quite some time, the ability to download their Medicare claims information, in pdf or Excel formats, through the CMS Blue Button platform, the information was provided without any context or other information that would help beneficiaries understand what the data were really telling them. For beneficiaries, their claims information is useless if it is either too hard to obtain or, as was the case with the information provided through previous versions of Blue Button, hard to understand. In an effort to fully contribute to the Federal Government's MyHealthEData initiative, CMS developed and launched the new Blue Button 2.0, which represents a major step toward giving patients meaningful control of their health information in an easy-to-access and understandable way. Blue Button 2.0 is a developer-friendly, standards-based application programming interface (API) that enables Medicare beneficiaries to connect their claims data to secure applications, services, and research programs they trust. The possibilities for better care through Blue Button 2.0 data are exciting, and might include enabling the creation of health dashboards for Medicare beneficiaries to view their health information in a single portal, or allowing beneficiaries to share complete medication lists with their doctors to prevent dangerous drug interactions.

To fully understand all of these health IT interoperability issues, initiatives, and innovations through the lens of its regulatory authority, CMS invites members of the public to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. We are particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. We also welcome the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers. We have received stakeholder input through recent CMS Listening Sessions on the need to address health IT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and post-acute care providers, behavioral health providers, clinical laboratories and social service providers, and we would also welcome specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers as well.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20548 and 20549) and the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28169 and 79 FR 50146, respectively), we stated that we intend to continue to review and post relevant charge data in a consumer-friendly way, as we previously have done by posting hospital and physician charge information on the CMS website.[116] In the FY 2019 IPPS/LTCH PPS proposed rule, we also continued our discussion of the implementation of section 2718(e) of the Public Health Service Act, which aims to improve the transparency of hospital charges. This discussion in the FY 2019 IPPS/LTCH PPS proposed rule continued a discussion we began in the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28169 and 79 FR 50146, respectively). In all of these rules, we noted that section 2718(e) of the Public Health Service Act requires that each hospital operating within the United States, for each year, establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups (DRGs) established under section 1886(d)(4) of the Social Security Act. In the FY 2015 IPPS/LTCH PPS proposed and final rules, we reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the Public Health Service Act and provided guidelines for its implementation. We stated that hospitals are required to either make public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry. In the FY 2019 IPPS/LTCH PPS proposed rule, we took one step to further improve the public accessibility of charge information. Specifically, effective January 1, 2019, we are updating our guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate.

In general, we encourage all providers and suppliers of health care services to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services. We encourage providers and suppliers to update this information at least annually, or more often as appropriate, to reflect current charges.

We are concerned that challenges continue to exist for patients due to insufficient price transparency. Such challenges include patients being

[116] For example, Medicare Provider Utilization and Payment Data, available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html.*

surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in-network hospitals and other settings, and patients being surprised by facility fees, physician fees for emergency department visits, or by fees for provider and supplier services that the beneficiary might consider to be a part of an episode of care involving a hospitalization but that are not services furnished by the hospital. We also are concerned that, for providers and suppliers that maintain a list of standard charges, the charge data are not helpful to patients for determining what they are likely to pay for a particular service or facility encounter. In order to promote greater price transparency for patients, we are considering ways to improve the accessibility and usability of current charge information.

We also are considering potential actions that would be appropriate to further our objective of having providers and suppliers undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain from the provider or supplier, and to enable patients to compare charges for similar services across providers and suppliers, including when services could be offered in more than one setting, such as a freestanding physician office or a hospital outpatient department or an ambulatory surgical center. Therefore, we are seeking public comment from all providers and suppliers, including providers receiving payment under the OPPS, on the following:

- How should we define ''standard charges'' in provider and supplier settings? Is there one definition for those settings that maintain chargemasters, and potentially a different definition for those settings that do not maintain chargemasters? Should ''standard charges'' be defined to mean: Average or median rates for the items on a chargemaster or other price list or charge list; average or median rates for groups of items and/or services commonly billed together, as determined by the provider or supplier based on its billing patterns; or the average discount off the chargemaster, price list, or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together? Should ''standard charges'' be defined and reported for both some measure of the average contracted rate and the chargemaster, price list, or charge list? Or is the best measure of a provider's or supplier's standard charges its chargemaster, price list, or charge list?
- What types of information would be most beneficial to patients, how can health care providers and suppliers best enable patients to use charge and cost information in their decision-making, and how can CMS and providers and suppliers help third parties create patient-friendly interfaces with these data?
- Should providers and suppliers be required to inform patients how much their out-of- pocket costs for a service will be before those patients are furnished that service? How can information on out-of-pocket costs be provided to better support patient choice and decision-making? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? How can CMS help beneficiaries to better understand how copayment and coinsurance are applied to each service covered by Medicare? What can be done to better inform patients of their financial obligations? Should providers and suppliers play any role in helping to inform patients of what their out-of-pocket obligations will be?
- Can we require providers and suppliers to provide patients with information on what Medicare pays for a particular services performed by that provider or supplier. If so, what changes would need to be made by providers and suppliers. What burden would be added as a result of such a requirement?

In addition, we are seeking public comment on improving a Medigap patient's understanding of his or her out-of-pocket costs prior to receiving services, especially with respect to the following particular questions:

- How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care? What challenges do providers and suppliers face in providing information about out-of-pocket costs to patients with Medigap? What changes can Medicare make to support providers and suppliers that share out-of-pocket cost information with patients that reflects the patient's Medigap coverage? Who is best situated to provide patients with clear Medigap coverage information on their out-of-pocket costs prior to receipt of care? What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service? What State-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

C. Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Building on President Trump's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, the CMS Center for Medicare and Medicaid Innovation (Innovation Center) is soliciting public comment on key design considerations for developing a potential model that would test private market strategies and introduce competition to improve quality of care for beneficiaries, while reducing both Medicare expenditures and beneficiaries' out of pocket spending. CMS has sought similar feedback in a previous solicitation of comments [117] and, most recently, in the President's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.[118] Comments provided in response to these previous solicitations have been extremely helpful to CMS. In this request for information (RFI), we are seeking additional and more specific public feedback on a potential model design that would accelerate the move to a value-based health care system building upon the Competitive Acquisition Program (CAP) established under section 1847B of the Act, including but not limited to design features such as the potential model's scope, which providers and suppliers should be included or excluded from the model, the types of Medicare Part B drugs and biologicals that should be included or excluded from the potential model, the role of private-sector vendors in the model (''model vendors''), a defined population of beneficiaries to be addressed by the potential model,

[117] CMS included a solicitation of comments on the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals (81 FR 13247) in a proposed rule, on March 11, 2016, entitled ''Medicare Program; Part B Drug Payment Model'' (81 FR 13230). The solicitation of comments sought to help CMS determine if there was sufficient interest in the CAP program, and to gather public input if we were to consider developing and testing a future model that would be at least partly based on the authority for the CAP under section 1847B of the Act. The March 11, 2016 proposed rule was withdrawn on October 4, 2017 (82 FR 46182) to ensure agency flexibility in reexamining important issues related to the proposed payment model and exploring new options and alternatives with stakeholders as CMS develops potential payment models that support innovative approaches to improve quality, accessibility, and affordability, reduce Medicare program expenditures, and empower patients and doctors to make decisions about their health care.

[118] President Donald J. Trump's Blueprint to Lower Drug Prices, May 11, 2018. Available at: *https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/.*

appropriate beneficiary protections, possible inclusion of other payers, and options for model payments. We also are interested in how best to handle Medicare payment for the new high-cost therapies, and whether a potential CAP-like model could be an appropriate payment and delivery structure for these drugs and biologicals. We are soliciting comments on how a model could be structured to advance the goals of the President's blueprint, namely to increase competition, strengthen negotiation, create incentives for lower list prices, and lower out-of-pocket costs. Feedback on these questions will be important for shaping the potential model's design and operations. CMS appreciates the public's input on these important issues.

1. Current Medicare Payments for Part B Drugs

Medicare Part B covers and pays separately for a limited number of drugs. Drugs paid separately under Medicare Part B generally fall into three categories: Drugs, typically injectable, furnished incident to a physician's service in the physician office or other nonfacility setting (covered under sections 1832(a)(1) and 1861(s)(2)(A) of the Act), hospital outpatient settings (covered under sections 1832(a)(2)(B) and 1861(s)(2)(B) of the Act), or ambulatory surgical center (covered under sections 1832(a)(2)(F) and 1833(i)(1)(A) of the Act); drugs administered via a covered item of durable medical equipment (DME) (covered under section 1861(n) of the Act); and other categories of drugs specified by statute (generally in section 1861(s)(2) of the Act).

Many Medicare Part B drug expenditures are for drugs furnished ''incident to'' a physician's service. Sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act provide that ''incident to'' drugs are not usually self-administered; self-administered drugs, such as orally administered tablets and capsules, are not included in the ''incident to'' provisions. Payment for drugs furnished ''incident to'' a physician's service is specified at section 1842(o) of the Act. Drugs that are covered ''incident to'' a physician's service must represent a real cost to the physician (that is, the physician must incur a cost to obtain the drug); hence, the physician obtains these drugs using the ''buy and bill'' methodology.

In accordance with section 1842(o)(1)(C) of the Act, most ''incident to'' drugs are paid under the methodology in section 1847A of the Act. This means the Medicare payment is generally based on the average sales price (ASP) methodology, which includes a statutorily mandated 6-percent add-on. Under this methodology, expensive drugs receive higher add-on payment amounts than inexpensive drugs, potentially creating a financial incentive for providers and suppliers to furnish higher cost drugs. Specifically, because the 6-percent add-on results in increased Medicare payment for a higher-cost drug relative to a lower-cost drug, the use of more expensive drugs may generate more revenue for a health care provider, depending on the health care provider's acquisition costs for the drugs.[119] However, more expensive drugs generally result in greater cost-sharing for beneficiaries because patient cost-sharing is set at a percentage of the total Medicare payment amount. Meanwhile, the ASP-based methodology creates no direct incentives for furnishing high-value drug therapies.

The ASP payment amount determined under section 1847A of the Act reflects a weighted ASP for all National Drug Codes (NDCs) that are assigned to a Healthcare Common Procedure Coding System (HCPCS) code. The ASP payment amount does not vary based on the price an individual provider or supplier pays to acquire the drug, but reflects the price of all nonexcluded sales from all purchasers in the U.S. market. Payment determinations under the methodology in section 1847A of the Act also do not directly take into account the effectiveness of a particular drug. The payment determinations do not consider the cost of clinically comparable drugs that are billed for and paid under other HCPCS codes. The ASP is calculated quarterly using manufacturer-submitted data[120] on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act, such as sales to an entity that are merely nominal in amount and sales exempt from inclusion in the determination of Medicaid best price) with manufacturers' rebates, discounts, and price concessions included in the ASP calculation.

Medicare Part B also pays for drugs that are infused through a covered item of durable medical equipment (DME), such as drugs administered with an infusion pump and inhalation drugs administered through a nebulizer. Medicare payments for these drugs are described in section 1842(o)(1)(D) of the Act for DME infusion drugs and section 1842(o)(1)(G) of the Act for inhalation drugs.

Finally, Medicare Part B covers and pays for a number of drugs with specific benefit categories defined under section 1861(s) of the Act including: Immunosuppressive drugs; hemophilia blood clotting factors; certain oral anticancer drugs; certain oral anti-emetic drugs; pneumococcal pneumonia, influenza and hepatitis B vaccines; erythropoietin for trained home dialysis patients; and certain osteoporosis drugs. Payment for many of these drugs falls under section 1842(o) of the Act, and in accordance with section 1842(o)(1)(C) of the Act, most, but not all, drugs with specific benefit categories are paid under the methodology in section 1847A of the Act. A notable exception is that payment for pneumococcal pneumonia, influenza and hepatitis B vaccines is based on published AWP, specifically 95 percent AWP, if furnished in the physician office setting, payment is based on reasonable cost in the hospital outpatient setting.

Under Medicare Part B, drug payment depends on the site of care, the drug, and the statutory requirements. Beneficiaries' cost-sharing is generally 20 percent of the Medicare allowed amount. However, for a hospital outpatient service, beneficiaries are financially responsible for a copayment amount for a procedure up to the amount of the inpatient deductible for the year, which means that beneficiary cost-sharing for a separately payable drug or biological is limited to $1,340 in 2018 when the drug or biological is part of a covered outpatient hospital service, while the remaining portion of the Medicare allowed amount would be paid by the Medicare program.

From 2011 to 2016, Medicare drug spending increased from $17.6 billion to $28 billion under Medicare Part B, representing a compound annual growth rate (CAGR) of 9.8 percent, with per capita spending increasing 54 percent, from $532 to $818.[121] The number of Medicare Part B FFS beneficiaries and the number of these beneficiaries who received a Part B drug increased over the 5-year period (2011 through 2016). However, the increase in total Medicare drug spending during this period is more fully explained by increases in the prices of drugs for those beneficiaries

[119] MedPAC Report to the Congress Medicare and the Health Care Delivery System, June 2015, pp. 65–72. Available at: *http://medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0.*

[120] OMB Control Number 0938–0921.

[121] Spending and Enrollment Data from Centers for Medicare and Medicaid Services Office of Enterprise Data and Analytics.

who received them than by increases in enrollment and utilization.

Furthermore, the most recent National Health Expenditure Projections (2017–2026) noted ''among the largest health care goods and services, prescription drugs are projected to experience the fastest average annual spending growth in 2017–26 (6.3 percent per year).'' [122] This trend primarily reflects faster anticipated growth in drug prices, which is attributable to a larger share of drug spending being accounted for by specialty drugs over the coming decade.

2. Competitive Acquisition Program (CAP) for Part B Drugs

Section 1847B of the Act authorizes the CAP for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis. The CAP was established as an alternative to the average sales price (ASP) methodology that is specified in section 1847A of the Act described above. Instead of buying drugs for their offices, the CAP would allow physicians to voluntarily choose to participate in the CAP and place patient specific drug orders with an approved CAP vendor; the CAP vendor would acquire and distribute (or supply) the drugs to the physician's office and then bill Medicare and collect cost-sharing amounts from the beneficiary.

The CAP program was operational for a limited time. CMS conducted the initial bidding for CAP vendors in 2005. The first CAP contract period ran from July 1, 2006 until December 31, 2008. One entity participated in the program, as the CAP vendor, providing drugs assigned to approximately 180 HCPCS billing codes (including heavily utilized drugs in Medicare Part B) to physicians across the United States and certain Territories. Unlike the ''buy and bill'' process that is still used to obtain many Medicare Part B drugs, physicians who chose to participate in the CAP did not buy or take title to the drug. The CAP vendor supplied drugs in unopened containers (not pharmacy-prepared individualized doses like syringes containing a patient's prescribed dose). The CAP vendor's drug claims were processed by a designated Medicare claims processing contractor selected by CMS.

The parameters for the second round of the CAP vendor selection were essentially the same as those for the first round. While CMS received several qualified bids for the second contract period, contractual issues with the successful bidders led to the postponement of the program. The CAP has been suspended since January 1, 2009. After the CAP was suspended, we sought additional input from physicians and other interested parties about further improvements to the program. For example, we held Open Door Forums, met with stakeholders, and encouraged correspondence from stakeholders and physicians who participated in the CAP. Although we received some useful suggestions, several significant concerns could not be addressed under the existing statutory requirements. These concerns included uncertainty about the participation of non-pharmacy entities like wholesalers as approved CAP vendors under the statutory requirements, and the requirement for a beneficiary-specific drug order, which impacts use of a consignment approach to facilitate emergency/urgent access to drugs, and to manage inventory through automated dispensing systems in the office. Many stakeholders were also concerned about the complexity of the program and the level of financial risk, particularly for the entities selected as CAP vendors. Financial risks for vendors included unpaid beneficiary cost sharing, lost or damaged drugs, and unverified drug administrations (which prevented payment). The CAP also was hindered by low physician enrollment and that some physicians perceived physician election, drug ordering and billing processes, and post pay documentation as burdensome. Also, an evaluation of the CAP found that it was not associated with savings (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/CMS1234237.html*).

More detailed information about the CAP is available on the following CMS web page and links within the web page: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html.* The ''Downloads'' section of the following CMS web page includes a section with information about CAP vendor bidding, physician participation, and drugs provided under the CAP: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/vendorbackground.html.*

3. MedPAC Part B Drug Value Program (DVP) Proposal

In June 2017, the Medicare Payment Advisory Commission (MedPAC) recommended the development of a voluntary alternative to the ASP payment system, calling it the Part B Drug Value Program (DVP), along with changes to the existing Medicare payment policy for separately payable Part B drugs and biologicals. MedPAC stated in its June 2017 Report to Congress that the purpose of such a program would be to obtain lower prices for Medicare Part B drugs by using private vendors to negotiate with manufacturers and improve incentives for health care providers furnishing Medicare Part B drugs by making health care providers accountable for cost and quality through shared savings opportunities.[123] MedPAC noted that, although the CAP program faced challenges, the concept underlying the CAP—to create a voluntary alternative to the ASP system using private vendors to negotiate favorable prices and eliminate financial incentives for physicians to prescribe Medicare Part B drugs—still has appeal. The DVP would be designed differently from the CAP to address several issues encountered with the CAP program and to allow hospitals to obtain drugs through the DVP. MedPAC noted that CAP vendors had little leverage to negotiate discounts with manufacturers because they were required to offer a group of about 180 HCPCS codes, including many single-source drugs and biologicals used in Medicare Part B. By contrast, DVP vendors would be permitted to use tools (such as a formulary, step therapy, prior authorization, indication-based pricing, risk based contracting with savings passed back to the Medicare program, and, in certain circumstances, binding arbitration) to give the DVP vendors greater negotiating leverage with manufacturers.

MedPAC envisioned that the DVP would begin with a subset of drug classes. In addition, under the DVP, private vendors would negotiate prices for Medicare Part B drugs, but, unlike the CAP, DVP vendors would not purchase (take title of) or ship drugs to the voluntarily participating health care providers. Rather, participating health care providers would continue to buy drugs from established distribution channels, but at the DVP-negotiated prices, and the Medicare payment to participating health care providers would be at the same negotiated price. To encourage voluntary enrollment in the DVP, in addition to lowered financial risk associated with buying and billing for drugs at the set amounts established by a DVP vendor, participating health care providers

[122] National Health Expenditure Projections, 2017–26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth, available at: *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2017.1655.*

[123] The MedPAC June 2017 *Report to the Congress: Medicare and the Health Care Delivery System. http://medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0.*

would have shared savings opportunities through the DVP. According to MedPAC June 2017 report, the proposed shared savings opportunities for providers would not include providers taking on risk. Specifically, the shared savings with providers would occur ''if the DVP led to lower aggregate costs of Part B drugs, the savings would be shared with providers.'' Savings achieved through the DVP would also be shared with beneficiaries (through lower cost sharing), the DVP vendors, and the Medicare program. Nonparticipating health care providers would continue to buy drugs from traditional distribution channels and Medicare would pay based on the ASP system, although the ASP add-on would be reduced gradually. Other key elements of the DVP include its vendor structure, a shared savings component, tools to increase vendors' negotiating leverage, a reduction of the add-on in the ASP system, and exclusion of DVP prices from the ASP calculations.

In response to the Innovation Center New Direction RFI,[124] issued in September 2017, MedPAC encouraged the Innovation Center to consider its DVP proposal, suggesting that the Innovation Center could test use of private vendors to negotiate drug prices with manufacturers on a smaller scale in specific markets, and allow for voluntary provider participation, as a way to obtain lower prices for Medicare Part B drugs. The public comments that were received by the CMS Innovation Center in response to the New Direction RFI are available at: *https://innovation.cms.gov/initiatives/direction.* Numerous other stakeholders, such as the Coalition of State Rheumatology Organizations, CVS Health, and The Pew Charitable Trusts, also referenced or recommended similar approaches to MedPAC's DVP proposal in response to the New Direction RFI, involving the use of a private vendor to structure alternative payment arrangements for a small subset of therapies.[125]

4. Potential Model Goals and Considerations

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce program expenditures, while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. The CMS Innovation Center is exploring leveraging the authority for the CAP under section 1847B of the Act to test improvements to the CAP and to test whether allowing private-sector model vendors to enter into and administer value-based arrangements with manufacturers of separately payable Medicare Part B drugs and biologicals improves beneficiary access and quality of care while reducing Medicare expenditures. Such a CAP-like model would test an alternative to the current system, under which health care providers (physicians, hospital outpatient departments, and potentially other providers and suppliers) would acquire drugs through value-based agreements with manufacturers administered by CAP-like model vendors (''vendor-administered payment arrangements''), building on lessons learned from CMS' experience with the CAP. A potential benefit of a CAP-like model of this nature would be eliminating the financial risk to providers and suppliers of taking title to very high-cost drugs and biologicals.

Such a potential model would include competitively selected private-sector vendors that would establish vendor-administered payment arrangements with the manufacturers of separately payable Part B drugs and biologicals included in the model (''included drugs and biologicals''). CMS has considered that model vendors' vendor-administered payment arrangements under a potential model could be required to include value-based pricing strategies, such as outcomes-based agreements, indication-based pricing, payment over time, shared savings or performance-based payments based on the impact on total cost of care, and reduced beneficiary cost-sharing. This could more closely tie the Medicare payment and beneficiary cost-sharing for an included drug or biological to the value of such therapy, which we believe has the potential to reduce Medicare expenditures while preserving or enhancing the quality of care for beneficiaries. Such a model could start with a subset of therapies, with an increasing number of included drugs and biologicals over time. By introducing a competitive dynamic in Part B between manufacturers and model vendors and potentially among model vendors, such a model would aim to get lower drug prices for Medicare and for beneficiaries.

We are considering how to structure a model vendor role, and whether a CAP-like model test should include an approach similar to the CAP (where model vendors would purchase and take title to the included drugs and biologicals) or an approach similar to MedPAC's envisioned DVP (where providers and suppliers purchase and receive included drugs and biologicals through pricing arrangements and model vendors would not take title to the included drugs and biologicals). We also are considering, for example, whether testing either or both of these approaches may be appropriate for certain drugs and biologicals, such as testing one approach for high-cost drugs and biologicals, single source drugs and biologicals, or certain drug classes, and testing another approach for other types of drugs and biologicals.

We also are considering whether model vendors, if they did take title to included drugs and biologicals, would take possession of the included drugs and biologicals, or if existing distribution channels could be leveraged such that model vendors would take title to, but not possession of, the included drugs and biologicals and the included drugs and biologicals would be distributed directly to the providers and suppliers. In addition, we are considering whether, under a potential CAP-like model, providers and suppliers could have a formal custodial agreement with one or more model vendors, under which the model vendor would agree to ensure onsite availability of an included therapy without the provider or supplier taking ownership of the product, making payment, or otherwise being financially at risk for obtaining the product, subject to the provider's or supplier's obligation to ensure the physical safety and integrity of the included drug and biological until the included therapy is administered to an included beneficiary. In addition, we are considering how custodial agreements of this nature could address concerns with existing CAP requirements that CAP drugs could only be delivered upon receipt of a prescription, with limited exceptions. We are also considering whether providers and suppliers under such a custodial agreement with a model vendor could continue to collect beneficiary cost-sharing to address issues encountered under the CAP, such as eliminating the need for the provider or supplier to share beneficiary billing information with model vendors, reducing model vendors' financial risk for uncollected beneficiary cost-sharing, and lessening beneficiaries' burden associated with model vendors' billing for cost-sharing. However, potential financial relationships between providers and suppliers and model vendors could increase program risks, and we seek information on how CMS

[124] New Direction RFI and public comments are available at *https://innovation.cms.gov/initiatives/direction.*

might structure a potential model to avoid these risks while testing improvements to the CAP.

CMS is also considering how a potential CAP-like model could include other payers including Medicare Advantage organizations, State Medicaid agencies, as well as Medicaid Managed Care Organizations (MCOs). Specifically, we are considering ways to allow Medicare Advantage, State Medicaid agencies, and Medicaid MCOs to have access to the same or similar value-based vendor-administered payment arrangements available under a potential CAP-like model, such as by paying for included drugs and biologicals for their enrollees through model vendors.

We are soliciting public comments on these design considerations, on how to best initially test and then broaden the scope of a potential CAP-like model, and on the questions about a potential model identified below. These questions have been categorized into the following key areas: Included providers and suppliers; included drugs and biologicals; beneficiary cost-sharing, protections and fiscal considerations; model vendors; regulatory barriers and transparency issues; manufacturer participation; and model scope.

a. Included Providers and Suppliers

- Are there types of Part B providers and suppliers that should be included or excluded from a potential CAP-like model, and if so why?
- Certain physician specialties currently receive substantial revenue from Medicare payments for Part B drugs. For certain specialties (for example, rheumatology, ophthalmology and oncology) a significant portion of their overall Medicare payments are related to Part B drugs. Should a potential CAP-like model address concerns about a potential reduction in overall payments for physicians that currently rely on this revenue and, if so, how?
- What protections or incentives would be necessary for providers and suppliers to participate in a potential model that would require that included drugs and biologicals be acquired under a vendor-administered payment arrangement?

b. Included Drugs and Biologicals

- Which separately payable Part B drugs and biologicals or drug classes, would be appropriate to include in a potential CAP-like model in order to bring the greatest value to the Medicare program and to beneficiaries, and among these drugs and biologicals or classes thereof, which ones would be appropriate to include initially? Should separately payable Part B drugs and biologicals that are used in the treatment of substance use disorders and mental health disorders be included? Are there certain separately payable Part B drugs and biologicals or drug classes that should be excluded, and if so, why?
- Which specific drugs, drug classes, groups of drugs, or indications would be appropriate candidates for inclusion in a potential CAP-like model or in specific types of value-based pricing strategies? What rationale and supporting data are available to support adopting value-based payment for these candidates? For which of these candidates would claims data be an adequate information source for determining whether outcomes under a value-based agreement were met? Which drugs and biologicals or drug classes would be appropriate candidates for reducing or eliminating beneficiary coinsurance? How should modifications to beneficiary cost-sharing amounts be structured so that any reduced cost sharing does not lead to unintended competitive advantages?
- In addition to outcomes-based agreements, indication-based pricing arrangements, payment over time, shared savings or performance-based payment based on the impact on the total cost of care, what other potential value-based pricing strategies can CMS test that utilize market-based strategies in paying for Part B drugs? How could CMS ensure that payment arrangements are site neutral, where applicable? What current experience in the commercial or other markets should CMS consider?
- For outcomes-based agreements, what elements (*e.g.,* clinical measures, cost measures, quality measures, and other targets) should these agreements include? How would the outcomes of interest be measured? What information systems and infrastructure would be necessary for collection of outcomes data? Are there existing systems or data (such as claims data or quality measures) that could be leveraged to measure outcomes? What role could registries have in supporting outcomes-based agreements?

c. Beneficiary Cost Sharing, Protections and Fiscal Considerations

- How could a potential CAP-like model be structured to improve beneficiaries' access to Part B drugs and biologicals?
- How can access to and quality of care for beneficiaries be improved or maintained under a potential vendor-administered payment arrangement? Should these arrangements be constructed so beneficiaries share in the value created? How could the sharing of value with beneficiaries be structured?
- How can CMS ensure a potential CAP-like model includes beneficiary protections, including ensuring the quality of and access to care?
- What key considerations should CMS assess related to beneficiary cost-sharing, experience of care, choice of health care provider and drug or biological, and access to care in potentially designing such a model test?
- What challenges would need to be addressed to allow for collection of beneficiary outcomes data by model vendors or other CMS contractors?
- What tools and strategies should a potential model include to ensure program integrity and to minimize the potential for fraud, waste and abuse?

d. Model Vendors

- How could the role of the CAP vendor be improved such that model vendors, and included providers and suppliers, would not face unsurmountable challenges to model participation? What types of organizations should CMS consider as candidates to serve as the model vendors?
- As described above, CMS used a competitive process to select vendors for the CAP under section 1847B of the Act. What factors and selection criteria should CMS consider as part of a competitive selection process under a potential CAP-like model to identify those entities most likely to perform the responsibilities of a model vendor efficiently and effectively with minimal start up time? What methods should CMS consider for evaluation of submitted bids to obtain the best value for the Medicare program?
- What factors should CMS consider in setting the geographic areas that model vendors would serve? What are the benefits and challenges of setting larger geographic areas, or even a single nationwide geographic area, verses smaller geographic areas? If CMS establishes multiple geographic areas to be served by model vendors, should CMS allow entities that bid to perform model vendor responsibilities to submit a bid for one or more geographic areas or require entities that bid to perform model vendor responsibilities to do so for all areas included in a model? If bidders are allowed to choose to apply only for certain geographic areas, what strategies should CMS consider to ensure that qualified model vendors could be selected for each geographic area?
- How should CMS balance the need for potential model vendors to have

negotiating power (for example, sufficient volume) with the need to create competition across model vendors for developing vendor-based payment arrangements using innovative value-based pricing strategies? Should there be more than one model vendor that covers a specific geographic area? Should the number of model vendors in a specific geographic area be limited? Are there unique challenges that should be addressed for certain geographic areas, such as rural areas or the Territories, or for providers and suppliers in those areas?

- One suggested improvement to the CAP is to use a consignment approach. How could existing purchasing and distribution processes for included drugs and biologicals be leveraged to facilitate model vendor ownership prior to administration without a model vendor taking physical possession of the included drugs and biologicals, while ensuring timely onsite availability of included drugs and biologicals and flexibility for dosage changes?
- What are the potential risks with testing a consignment approach for model vendor-owned included drugs and biologicals, including high-cost therapies? What would be possible approaches for mitigating these risks?
- What terms and responsibilities should be included in formal custodial agreements between model vendors and included providers and suppliers to provide protections to model vendors, included providers and suppliers, and the Medicare program?
- What potential conflicts of interest might limit the success of a potential CAP-like model and what steps should CMS consider to mitigate this risk?
- What types of structures (such as group purchasing organizations, single or affiliated entities) could support a model vendor role for a potential CAP-like model for included drugs and biologicals?
- What financial protection(s) may be necessary to encourage private-sector vendor participation in a potential CAP-like model?
- How should CMS structure the payment arrangement between CMS and selected model vendors? Should CMS pay model vendors a fee that is not tied to the value of the included drugs and biologicals, discounts or rebates and, if so, how? Should the payment be tied to model vendor performance and, if so, how? How can CMS ensure that the payment arrangements with model vendors do not introduce perverse incentives?
- What, if any, formulary and/or utilization management strategies, such as step therapy, should model vendors be allowed to include in their value-based payment arrangements with manufacturers?

e. Regulatory Barriers and Transparency Issues

- What specific regulatory barriers currently exist under either the Medicare or Medicaid programs to value-based pricing strategies as part of a potential Medicare payment model that would test vendor-administered payment arrangements? How could CMS best address these barriers?
- What waivers of statutory and other requirements would need to be considered for purposes of testing a potential CAP-like model that would make included drugs and biologicals available to included providers and suppliers through vendor-administered payment arrangements?
- What specific engagement strategies, information sharing, and transparency would be necessary as part of a test of value-based vendor-administered payment arrangements with manufacturers in order to encourage participation and to provide beneficiaries, providers, and suppliers with important information in order for beneficiaries, providers, and suppliers to make person-centered health care decisions?
- What types of data would need to be shared with model vendors, manufacturers or other stakeholders to support model vendors' value-based payment arrangements with manufacturers?
- What are specific barriers that limit sharing data with model vendors or manufacturers? What safeguards should be in place regarding sharing data with potential model participants?
- How should the potential model be evaluated? What metrics should be reviewed or collected? What benchmarks should be used for purposes of the model for evaluation?

f. Manufacturer Participation

- What features should CMS consider that would incentivize manufacturers to participate in vendor-administered payment arrangements? Should participation by manufacturers be mandatory?
- How would drug prices and manufacturer price reporting for included drugs and biologicals be impacted by the potential CAP-like model test?

g. Model Scope

In designing models, CMS must consider the size and scope of the potential model, which impacts how many participants may be eligible for a model, to ensure an effective and valid model test and evaluation.

- What features should CMS consider to ensure a potential CAP-like model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures?
- Under a potential CAP-like model, how geographically broad should a model be in order to allow for a robust model test and evaluation?
- Are there certain states, localities, geographies, or other areas that should be excluded from the model? If so, what compelling reason exists for such exclusion?
- How could a CAP-like model be structured to allow for Medicare Advantage organizations, State Medicaid agencies, and Medicaid MCOs to have access to model vendor pricing under the model?
- Under what circumstances would allowing Medicare Advantage organizations, State Medicaid agencies, and Medicaid MCOs to pay for included drugs and biologicals for their enrollees through a model vendor's vendor-administered arrangement with a manufacturer not be appropriate?
- What are the potential interactions of a potential CAP-like model with existing CMS Innovation Center models? What steps should CMS consider to minimize potential overlap or impacts on existing models?

XVI. Proposed Additional Hospital Inpatient Quality Reporting (IQR) Program Policies

A. Background

We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38323 through 38411) for the measures and program policies we have adopted for the Hospital IQR Program through the FY 2020 payment determination and subsequent years. In addition to the proposal discussed in this section, we also refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20470 through 20500) for a full discussion of the Hospital IQR Program and its proposed policies.

B. Proposed Updates to the HCAHPS Survey Measure (NQF #0166) for the FY 2024 Payment Determination and Subsequent Years

1. Background of the HCAHPS Survey in the Hospital IQR Program

CMS partnered with the Agency for Healthcare Research and Quality (AHRQ) to develop the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey (NQF #0166) [126] (hereinafter referred to as the HCAHPS Survey). We adopted the HCAHPS Survey in the Hospital IQR Program (at the time called the Reporting Hospital Quality Data Annual Payment Update Program) in the CY 2007 OPPS final rule with comment period (71 FR 68202 through 68204) beginning with the FY 2008 payment determination and for subsequent years. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FY 43882), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220 through 50222), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 to 38342) for details on previously-adopted HCAHPS Survey requirements.

The HCAHPS Survey (OMB Control Number 0938–0981) is the first national, standardized, publicly reported survey of patients' experience of hospital care and asks discharged patients 32 questions about their recent hospital stay. The HCAHPS Survey is administered to a random sample of adult patients who receive medical, surgical, or maternity care between 48 hours and 6 weeks (42 calendar days) after discharge and is not restricted to Medicare beneficiaries.[127] Hospitals must survey patients throughout each month of the year.[128] The HCAHPS Survey is available in official English, Spanish, Chinese, Russian, Vietnamese, and Portuguese versions. The HCAHPS Survey and its protocols for sampling, data collection and coding, and file submission can be found in the current HCAHPS *Quality Assurance Guidelines,* which is available on the official HCAHPS website at: *http://www.hcahpsonline.org/en/quality-assurance/.* AHRQ carried out a rigorous scientific process to develop and test the HCAHPS Survey instrument. This process entailed multiple steps, including: A public call for measures; literature reviews; cognitive interviews; consumer focus groups; multiple opportunities for additional stakeholder input; a 3-State pilot test; small-scale field tests; and notice-and-comment rulemaking. In May 2005, the HCAHPS Survey was first endorsed by the NQF.[129]

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 through 38342), out of an abundance of caution, in the face of a nationwide epidemic of opioid overprescription, we finalized a refinement to the HCAHPS Survey measure as used in the Hospital IQR Program by removing the previously adopted pain management questions and incorporating new Communication About Pain questions beginning with patients discharged in January 2018, for the FY 2020 payment determination and subsequent years.[130] These three survey questions within the HCAHPS Survey, collectively known as the Communication About Pain questions,[131] address how providers communicate with patients about pain. These questions are as follows:

- HP1: ''During this hospital stay, did you have any pain?''

☐ Yes
☐ No

- HP2: ''During this hospital stay, how often did hospital staff talk with you about how much pain you had?''

☐ Never
☐ Sometimes
☐ Usually
☐ Always

- HP3: ''During this hospital stay, how often did hospital staff talk with you about how to treat your pain?''

☐ Never
☐ Sometimes
☐ Usually
☐ Always

In addition, we finalized public reporting on the Communication About Pain questions, such that hospital performance data on those questions would be publicly reported on the *Hospital Compare* website beginning October 2020, using CY 2019 data. We also stated that we would provide performance results based on CY 2018 data on the Communication About Pain questions to hospitals in confidential preview reports, upon the availability of four quarters of data, as early as July 2019. We believed implementing the Communication About Pain questions as soon as feasible was necessary to address any perceived conflict between appropriate management of opioid use and patient satisfaction by relieving any potential pressure physicians may feel to overprescribe opioids (82 FR 38333).

2. Proposed Updates to the HCAHPS Survey: Removal of Communication About Pain Questions

Since finalization of the Communication About Pain questions, we have received feedback that some stakeholders are concerned that, although the revised questions focus on communications with patients about their pain and treatment of that pain, rather than how well their pain was controlled, the questions still could potentially impose pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the HCAHPS Survey. In addition, in its final report, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended removal of the HCAHPS Pain Management questions in order to ensure providers are not incentivized to offer opioids to raise their HCAHPS Survey score.[132]

Other potential factors outside the control of CMS quality program requirements may contribute to the perception of a link between the Communication About Pain questions and opioid prescribing practices, including: misuse of the HCAHPS Survey (such as using it for outpatient emergency room care instead of inpatient care, or using it for determining individual physician performance); failure to recognize that the HCAHPS Survey excludes certain populations from the sampling frame (such as those with a primary substance use disorder diagnosis); and the addition of supplemental pain-related

[126] The HCAHPS measure also includes the NQF-endorsed Care Transition Measure (CTM–3) (NQF #0228), which we added in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53513 through 53516). We added the Communication About Pain composite measure in the FY 2018 IPPS/LTCH PPS final rule (38328 through 38342), and stated that we would seek NQF endorsement for this measure.

[127] We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 to 38342, 38398) and to the official HCAHPS website at: *http://www.hcahpsonline.org* for details on HCAHPS requirements.

[128] Ibid.

[129] Available at: *http://www.qualityforum.org/Publications/2008/08/National_Voluntary_Consensus_Standards_for_Hospital_Care_2007__Performance_Measures.aspx.*

[130] In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862), the Hospital VBP Program removed the Pain Management dimension of the HCAHPS Survey in the Patient and Caregiver-Centered Experience of Care/Care Coordination domain of the Hospital VBP Program beginning with the FY 2018 program year. Under the Hospital VBP Program, payment adjustments are tied to hospitals' performance on the measures that are used to calculate each hospital's Total Performance Score.

[131] Available at: *http://hcahpsonline.org/en/survey-instruments/.*

[132] Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf.*

survey questions by the hospital that are not formally part of the HCAHPS Survey or otherwise required by CMS.

Because some hospitals have identified patient experience of care as a potential source of competitive advantage, we have heard from stakeholders that some hospitals may be disaggregating their raw HCAHPS Survey data to compare, assess, and incentivize individual physicians, nurses, and other hospital staff. Some hospitals also may be using the HCAHPS Survey to assess their emergency and outpatient departments. To be clear, the HCAHPS Survey was never designed or intended to be used in these ways.[133] In our HCAHPS Quality Assurance Guidelines,[134] which sets forth current survey administration protocols, we strongly discourage the unofficial use of HCAHPS scores for comparisons within hospitals, such as for comparisons of particular wards, floors, and individual staff hospital members. We also support the standardization of HCAHPS Survey administration and data collection methodologies by requiring hospitals/survey vendors to participate in introductory and annual update trainings.

We continue to believe that pain management is a critical part of routine patient care on which hospitals should focus and an important concern for patients, their families, and their caregivers. It is important to reiterate that the HCAHPS Survey does not specify any particular type of pain control method. The revised questions focus entirely on communication about pain with patients and do not refer to, recommend, or imply that any particular type of treatment is appropriate (82 FR 38333). In addition, appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, proper prescription practices, and alternative treatments for pain management.

Although we are not aware of any scientific studies that support an association between scores on the prior or current iterations of the Communication About Pain questions and opioid prescribing practices, out of an abundance of caution and to avoid any potential unintended consequences, we are proposing to update the HCAHPS Survey by removing the Communication About Pain questions effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years. This would reduce the overall length of the HCAHPS Survey from 32 to 29 questions, and the final four quarters of reported Communication About Pain data (comprising data from the first, second, third, and fourth quarters 2021) would be publicly reported on *Hospital Compare* in October 2022 and then subsequently discontinued. As stated above, in its final report, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended removal of the HCAHPS Pain Management Survey questions in order to ensure providers are not incentivized to offer opioids to raise their HCAHPS Survey score.[135]

In proposing removal of the Communication About Pain questions, we are not proposing to change how performance scores are calculated for the remaining questions on the HCAHPS Survey. The Hospital IQR Program is a quality data reporting program; payments to hospitals will not be affected so long as hospitals timely submit data on required measures and meet all other program requirements. We would continue to use the remaining 29 questions of the HCAHPS Survey to assess patients' experience of care, and would continue to publicly report hospital scores on those questions in order to ensure patients and consumers have access to these data while making decisions about their care. Patients and providers can continue to review data from responses to the remaining 29 questions of the HCAHPS Survey on the *Hospital Compare* website.

In crafting our proposal, we considered whether the Communication About Pain questions should be retained in both the HCAHPS Survey and the Hospital IQR Program but with a further delay in public reporting. For example, instead of public reporting starting in October 2020 as previously finalized, we could delay public reporting of the Communication About Pain questions until October 2021. We are interested in feedback on whether the Communication About Pain questions should be retained in both the HCAHPS Survey and the Hospital IQR Program but with a further delay in public reporting. Delay in public reporting would allow further time to engage a broad range of stakeholders and assess their feedback regarding use of the Communication About Pain questions in the HCAHPS Survey and the Hospital IQR Program and to assess the impact of the new Communication About Pain questions. However, we chose to propose to remove the Communication About Pain questions as discussed above instead, so providers do not perceive that there are incentives for prescribing opioids to increase survey scores.

In crafting our proposal, we also considered proposing earlier removal of the Communication About Pain questions from the HCAHPS Survey effective as early as January 2020 discharges, for the FY 2022 payment determination and subsequent years. However, we believe removing the questions effective with January 2020 discharges would not allow sufficient time to make necessary updates to the data collection tools, including the CMS data submission warehouse and associated reporting tools, as well as to update the HCAHPS Survey administration protocols and the survey tool itself. In addition, our proposal to make these updates effective later, with January 2022 discharges, would allow time to assess the potential impact of using the Communication About Pain questions while monitoring unintended consequences. It would also allow time for empirical testing for any potential effect the removal of the Communication About Pain questions might have on responses to the remaining non-pain related survey items.

We are inviting public comment on our proposal as discussed above and whether the questions should be removed from the HCAHPS Survey and Hospital IQR Program. We are particularly interested in receiving feedback on any potential implications on patient care related to removing these questions. We also are interested in feedback from stakeholders on: (1) The importance of receiving feedback from patients related to communication about pain management and the importance of publicly reporting this information for use both by patients in healthcare decision-making and by hospitals in focusing their quality improvement efforts; (2) additional analyses demonstrating a relationship between the use of pain questions in patient surveys and prescribing behavior, including unpublished data, if available; (3) input from clinicians and other providers concerning whether it would be valuable for CMS to issue

[133] Tefera L, Lehrman WG, and Conway P. ''Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches.'' *Journal of the American Medical Association.* Available at: *http://jama.jamanetwork.com/article.aspx?articleid=2503222.*

[134] HCAHPS *Quality Assurance Guidelines* (v. 13.0), available at: *http://www.hcahpsonline.org/en/quality-assurance/.*

[135] Final Report, The President's Commission on Combating Drug Addiction and the Opioid Crisis, available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf.*

guidance suggesting that hospitals do not administer any surveys with pain-related questions, including adding hospital-specific supplemental items to HCAHPS, as well as the potential implementation of a third party quality assurance program to assure that hospitals are not misusing survey data by creating pressure on individual clinicians to provide inappropriate clinical care; (4) information from clinicians and other providers concerning instances of hospital administrators using results from the HCAHPS Survey to compare individual clinician performance directly to other clinicians at the same facility or institution and examples where, as a result, clinicians have felt pressured to prescribed opioids inappropriately (in terms of either quantity or appropriateness for particular patients); (5) suggestions for other measures that would capture facets of pain management and related patient education, for instance, for collecting data about a hospital's pain management plan, and provide that information back to consumers; and (6) how other measures could take into account provider-supplied information on appropriate pain management and whether patients are informed about the risks of opioid use and about non-opioid pain management alternatives.

XVII. 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. For CY 2019, we are proposing to change the format of the OPPS Addenda A, B, and C, by adding a column entitled ''Copayment Capped at the Inpatient Deductible of $1,340.00'' where we would 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). We are requesting public comments on this proposed change of the OPPS Addenda A, B, and C for CY 2019.

To view the Addenda to this proposed rule pertaining to proposed CY 2019 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 ''1695–P'' from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder entitled ''2019 OPPS 1695–P Addenda'' at the bottom of the page. To view the Addenda to this proposed rule period pertaining to CY 2019 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 ''1695–P'' from the list of regulations. All ASC Addenda to this proposed rule are contained in the zipped folders entitled ''Addendum AA, BB, DD1, DD2, and EE.''

XVIII. 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 this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

B. ICRs for the Hospital OQR Program

1. Background

The Hospital 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 2018 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; and 82 FR 59476 through 59479, respectively) for detailed discussions of Hospital OQR Program information collection requirements we have previously finalized. The information collection requirements associated with the Hospital OQR Program are currently approved under OMB control number 0938–1109. Below we discuss only the changes in burden that would result from the newly proposed provisions in this proposed rule.

In section XIII.B.4.b. of this proposed rule, we are proposing to remove a total of 10 measures. Specifically, beginning with the CY 2020 payment determination, we are proposing to remove: (1) OP–27: Influenza Vaccination Coverage Among Healthcare Personnel; and beginning with the CY 2021 payment determination, we are proposing to remove: (2) OP–5: Median Time to ECG; (3) OP–9: Mammography Follow-up Rates; (4) OP–11: Thorax CT Use of Contrast Material; (5) OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; (6) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT; (7) OP–17: Tracking Clinical Results between Visits; (8) OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; (9) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (10) OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. The reduction in burden associated with these proposals is discussed below in sections XVIII.B.3. and 4. of this proposed rule.

In section XIII.D.2. of this proposed rule, we are proposing to update the frequency with which we would release HOPD Specifications Manuals such that instead of every 6 months, we would release specifications manuals every 6 to 12 months beginning with CY 2019 and for subsequent years. In section XIII.C.2. of this proposed rule, beginning with the CY 2020 payment determination, we are proposing to remove the Notice of Participation (NOP) form as a requirement for the Hospital OQR Program and to update 42 CFR 419.46(a) to reflect these policies. As discussed below, we do not expect these proposals to affect our collection of information burden estimates.

2. Proposal To Update the Frequency of Releasing Hospital Outpatient Quality Reporting Specifications Manuals Beginning With CY 2019 and for Subsequent Years

In section XIII.D.2. of this proposed rule, we are proposing to update the frequency with which we would release Hospital Outpatient Quality Reporting Specifications Manuals, such that instead of every 6 months, we would release specifications manuals every 6 to 12 months beginning with CY 2019 and for subsequent years. We anticipate that this proposed change would reduce hospital confusion, as potentially releasing fewer manuals per year reduces the need to review updates as frequently as previously necessary. However, because this proposed change does not affect Hospital OQR Program participation requirements or data reporting requirements, we do not expect a change in the information collection burden experienced by hospitals.

3. Estimated Burden of Hospital OQR Program Proposals for the CY 2020 Payment Determination and Subsequent Years

a. Proposal To Remove the Notice of Participation (NOP) Form Requirement

In section XIII.C.2.b. of this proposed rule, beginning with the CY 2020 payment determination, we are proposing to remove the NOP form as a requirement. As a result, to be a participant in the Hospital OQR Program, hospitals would need to: (1) Register on the QualityNet website; (2) identify and register a QualityNet security administrator, and (3) submit data. In addition, we are proposing to update 42 CFR 419.46(a) to reflect these policies. We have previously estimated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171) that the burden associated with administrative requirements including completing program requirements, system requirements, and managing facility operations is 42 hours per hospital or 138,600 hours across 3,300 hospitals. We believe that the proposal to remove the NOP, if finalized, would reduce administrative burden experienced by hospitals by only a nominal amount, as it is not required every year, but only at the start of a hospital's participation. As a result, this proposal does not influence our information collection burden estimates.

b. Proposed Removal of OP–27 for the CY 2020 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove the OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure beginning with the CY 2020 payment determination and for subsequent years. The burden associated with OP–27, a National Healthcare Safety Network (NHSN) measure, is accounted for under a separate information collection request, OMB control number 0920–0666. Because burden associated with submitting data for this measure is captured under a separate OMB control number, we are not providing an estimate of the information collection burden associated with this measure for the Hospital OQR Program.

4. Estimated Burden of Hospital OQR Program Proposals for the CY 2021 Payment Determination and Subsequent Years

a. Proposed Removal of Chart-Abstracted Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove one chart-abstracted measure for the CY 2021 payment determination and subsequent years: OP–5: Median Time to ECG. With regard to chart-abstracted measures for which patient-level data is submitted directly to CMS, we have previously estimated it would take 2.9 minutes, or 0.049 hour, per measure to collect and submit the data for each submitted case (80 FR 70582). In addition, based on the most recent data, we estimate that 947 cases are reported per hospital for chart-abstracted measures. Therefore, we estimate that it will take approximately 46 hours (0.049 hours × 947 cases) to collect and report data for each chart-abstracted measure. Accordingly, we believe that the removal of this chart-abstracted measure for the CY 2021 payment determination would reduce burden by 151,800 hours (46 hours × 3,300 hospitals) and $5.6 million (151,800 hours × $36.58 [136]).

[136] In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59477), we finalized a hourly labor cost to hospitals of $36.58 and specified that this cost included both wage ($18.29) and 100 percent overhead and fringe benefit costs (an additional $18.29). The estimate for this duty is available in the Bureau of Labor Statistics report on Occupation Employment and Wages for May 2016, 29–2071 Medical Records and Health Information Technicians at: *https://www.bls.gov/oes/2016/may/oes292071.htm.*

b. Proposed Removal of Measures Submitted Via a Web-based Tool for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove five measures submitted via a web-based tool beginning with the CY 2021 payment determination and for subsequent years: OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; OP–17: Tracking Clinical Results between Visits; OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery, a voluntary measure.

As we stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582), we estimate that hospitals spend approximately 10 minutes, or 0.167 hours, per measure to report web-based measures. Accordingly, we believe that the proposal to remove OP–12, OP–17, OP–29, and OP–30 for the CY 2021 payment determination would reduce burden by 0.668 hours per hospital (4 measures × 0.167 hours per measure) and 2,204 hours (0.668 hours × 3,300 hospitals) across 3,300 hospitals. In addition, we estimate that OP–29 and OP–30 measures require 25 additional minutes (0.417 hours) per case per measure to chart-abstract and that a hospital would each abstract 384 cases per year (this number is based on previous analysis (78 FR 75171) where we estimate that each of the approximately 3,300 responding hospitals will have volume adequate to support quarterly sample sizes of 96 cases, for a total of 384 cases (96 cases per quarter × 4 quarters) to be abstracted by each hospital annually for one new measure) for each of these measures. Therefore, we estimated an additional burden reduction of 1,056,845 hours (3,300 hospitals × 0.417 hours × 384 cases per measure × 2 measures) for all participating hospitals for OP–29 and OP–30. In total, we estimate a burden reduction of 1,059,049 hours (2,204 hours for web submission + 1,056,845 hours for chart-abstraction of OP–29 and OP–30) and $38.7 million (1,059,049 hours × $36.58) for the proposed removal of those four web-based

measures from the Hospital OQR Program.

In addition, we estimate that approximately 20 percent of hospitals, or 660 hospitals (3,300 hospitals × 0.2), elect to report OP–31 on a voluntary basis, resulting in an additional burden reduction of 110 hours (0.167 hours per hospital × 660 hospitals) for web submission. We also estimate that OP–31 requires 25 additional minutes (0.417 hours) per case to chart-abstract and that a hospital would abstract 384 cases per year for this measure. Therefore, we estimate that the additional chart-abstraction burden reduction for this measure would be 105,684 hours (660 hospitals × 0.417 hours per case × 384 cases) for participating hospitals. In total, we anticipate a burden reduction of 105,794 hours (110 hours for web-submission + 105,684 hours for chart-abstraction) and $3.9 million (105,794 hours × $36.58) for the proposed removal of OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

In total, we estimate that the removal of five web-based measures (OP–12, OP–17, OP–29, OP–30, and OP–31) would reduce burden by 1,164,843 hours (1,059,049 hours for the removal of four measures + 105,794 hours for the removal of one voluntary measure) and $42.6 million (1,164,843 hours × $36.58).

c. Proposed Removal of Claims-Based Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove three claims-based measures beginning with the CY 2021 payment determination: OP–9: Mammography Follow-up Rates; OP–11: Thorax CT Use of Contrast Material; and OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT. Claims-based measures are derived through analysis of administrative claims data and do not require additional effort or burden on hospitals. As a result, we do not expect these proposals to affect collection of information burden for the CY 2021 payment determination.

In total for the CY 2021 payment determination, we expect the information collection burden would be reduced by 151,800 hours due to the proposed removal of one chart-abstracted measure, and 1,164,843 hours due to the proposed removal of five measures submitted via a web-based tool. In total, we estimate an information collection burden reduction of 1,316,643 hours (1,164,843 hours + 151,800 hours) and $48.2 million (1,316,643 hours × $36.58) for the CY 2021 payment determination.

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, and CY 2018 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; and 82 FR 59479 through 59481, respectively) for detailed discussions of the ASCQR Program information collection requirements we have previously finalized. The information collection requirements associated with the ASCQR Program are currently approved under OMB control number 0938–1270. Below we discuss only the changes in burden that would result from the newly proposed provisions in this proposed rule.

In section XIV.B.3.c. of this proposed rule, we are proposing to remove one measure beginning with the CY 2020 payment determination, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel, and seven measures beginning with the CY 2021 payment determination: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC–4: All-Cause Hospital Transfer/Admission; ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. We expect these proposals would reduce the overall burden of reporting data for the ASCQR Program, as discussed below.

2. Estimated Burden of ASCQR Program Proposals Beginning With CY 2020 Payment Determination and Subsequent Years: Proposed Removal of ASC–8 for the CY 2020 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule, we are proposing the removal of one measure beginning with the CY 2020 payment determination, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel. Data for ASC–8 are submitted via a non-CMS online data submission tool, to the NHSN. However, we note that the information collection burden associated with ASC–8, a NHSN measure, is accounted for under a separate information collection request, OMB control number 0920–0666. As such, we are not providing an estimate of the information collection burden associated with this measure under the ASCQR Program OMB control number.

3. Estimated Burden of ASCQR Program Proposed Measure Removals for the CY 2021 Payment Determination

In section XIV.B.3.c. of this proposed rule, we are proposing to remove seven measures beginning with the CY 2021 payment determination: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC–4: All-Cause Hospital Transfer/Admission; ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

a. Proposed Removal of QDC Claims-based Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule, we are proposing to remove four QDC claims-based measures from the ASCQR Program measure set beginning with the CY 2021 payment determination: ASC–1: Patient Burn; ASC–2, Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC–4: All-Cause Hospital Transfer/Admission. Data used to calculate scores for these measures are collected via Part A and Part B Medicare administrative claims and Medicare enrollment data; therefore, ASCs are not required to report any additional data. Because these measures do not require ASCs to submit any additional data, we do not believe there would be any information collection burden change associated with removing these measures.

b. Proposed Removal of Chart-Abstracted Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule, we are proposing to remove three chart-abstracted measures from the ASCQR Program measure set beginning

with the CY 2021 payment determination: ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. We believe 3,937 ASCs would experience a reduction in information collection burden associated with our proposals to remove ASC–9 and ASC–10 from the ASCQR Program measure set. For ASC–11, a voluntary measure, we previously estimated that approximately 20 percent of ASCs (5,260 ASCs nationwide × 0.20), 1,052, would elect to submit these data on a voluntary basis and, thus, would experience a reduction in information collection burden associated with reporting.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79864), we finalized our estimates that each participating ASC would spend 0.25 hours (15 minutes) per case per measure per year to collect and submit the required data for the ASC–9, ASC–10, and ASC–11 measures. We estimate that the average number of patients per ASC is 63 based on the historic average. In addition, we estimate the total annual information collection burden per ASC to be 15 hours and 45 minutes (15.75 hours) per measure (0.25 hours × 63 cases). Therefore, for ASC–9 and ASC–10, we estimate the total annualized information collection burden associated with each measure to be 62,008 hours (3,937 ASCs × 15.75 hours per ASC) and $2,268,253 (62,008 hours × $36.58 per hour [137]). For ASC–11, we estimate a total annual information collection burden of 16,569 hours (1,052 ASCs × 15.75 hours) and $606,094 (16,569 hours × $36.58 per hour). Therefore, we estimate a total reduction in information collection burden of 140,585 hours (62,008 hours + 62,008 hours + 16,569 hours) and $5,142,600 ($2,268,253 + $2,268,253 + $606,094) as a result of our proposals to remove ASC–9; ASC–10; and ASC–11.

Therefore, as a result of our proposals to remove seven measures from the ASCQR measure set for the CY 2021 payment determination, ASC–1; ASC–2; ASC–3; ASC–4; ASC–9; ASC–10; and ASC–11, we estimate a total annual reduction in information collection burden of 140,585 hours and $5,142,600. The reduction in information collection burden associated with these requirements is available for review and comment under OMB control number 0938–1270.

D. ICRs for the Proposed Update to the HCAHPS Survey Measure in the Hospital IQR Program

As described in section XVI. of this proposed rule, we are proposing to update the HCAHPS Survey measure by removing the Communication About Pain questions beginning with patients discharged in January 2022, for the FY 2024 payment determination and subsequent years. While we anticipate that the removal of these questions will reduce the burden associated with reporting this measure, as further discussed below, the burden estimate for the Hospital IQR Program excludes the burden associated with the HCAHPS Survey measure, which is submitted under a separate information collection request and approved under OMB control number 0938–0981. For discussion of the burden estimate for the Hospital IQR Program under OMB control number 0938–1022, we refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20555 through 20559). For details on the burden estimate specifically for the HCAHPS Survey, including use of the Communication About Pain questions, we refer readers to the notice published in the **Federal Register** on Information Collection for the National Implementation of the Hospital CAHPS Survey (83 FR 21296 through 21297). We note that a revised information collection request under OMB control number 0938–0981 will be submitted to OMB based on the proposed update to the HCAHPS Survey in accordance with this proposed rule.

As noted above, the proposal to remove the Communication About Pain questions does not change the estimated burden for the Hospital IQR Program under the program's OMB control number 0938–1022. However, we believe that overall cost and burden will change slightly for hospitals and HCAHPS Survey respondents. Under HCAHPS Survey OMB control number 0938–0981, it is estimated that the average cost and hour burdens for hospitals are $4,000 and 1 hour per hospital for HCAHPS data collection activities. Because these estimates include administrative activities and overhead costs, we believe our proposal to remove the Communication About Pain questions from the HCAHPS Survey would not reduce these estimates of hospital burden or would only nominally and temporarily increase the average cost and hour burdens associated with the removal of these questions from the survey given the need to adjust the survey instrument and instructional materials and, therefore, marginally reduce the burden due to the shortening of the survey instrument.

Under HCAHPS Survey OMB control number 0938–0981, the average time for a respondent to answer the 32 question survey is estimated at 8 minutes, which we estimate to be 0.25 minutes per question (8 minutes/32 questions = 0.25 minutes per question). In addition, under this OMB control number, the number of respondents is estimated at 3,104,200 respondents. In this proposed rule, we are proposing to remove 3 questions, which we estimate would reduce the time burden by 0.75 minutes (0.25 minutes per question × 3 questions), or 0.0125 hours (0.75 minutes/60 minutes) per respondent. We anticipate a total hourly burden reduction for respondents of 38,803 hours (0.0125 hours × 3,104,200 respondents). Further, under OMB control number 0938–0981, the cost of respondent time is based on the average hourly earnings of $26.71 per hour, as reported by the U.S. Bureau of Labor Statistics final January 2018 estimates available on the website at: *https://www.bls.gov/eag/eag.us.htm.*[138] We anticipate a total cost reduction for respondents associated with the proposal to remove the 3 Communication About Pain questions of $1,036,428 (38,803 total hours × respondent earnings estimate of $26.71 per hour).

E. Total Reduction in Burden Hours and in Costs

The total reduction in the burden hours for the above ICRs is 1,496,031 hours, and the reduction in cost is $54.3 million ($48.2 million + $5.1 million + $1 million).

XIX. 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 proposed rule, and, when we

[137] In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59479 through 59480), we finalized an hourly labor cost to hospitals of $36.58 and specified that this cost included both wage and overhead and fringe benefit costs. The estimate for this duty is available in the Bureau of Labor Statistics report on Occupation Employment and Wages for May 2016, 29–2071 Medical Records and Health Information Technicians at: *https://www.bls.gov/oes/2016/may/oes292071.htm.*

[138] Average hourly earnings of $26.71 per hour based on the average hourly earnings of all employees on private non-farm payrolls, seasonally adjusted, per the U.S. Bureau of Labor Statistics.

proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XX. Economic Analyses

A. Statement of Need

This proposed rule is necessary to make updates to the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2019. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are proposing to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2017, through and including December 31, 2017, and processed through December 31, 2017, and updated cost report information.

We note that we are proposing to control for unnecessary increases in the volume of outpatient services by paying for clinic visits furnished at off-campus PBDs at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). We expect that by removing the payment differential, we will control unnecessary volume increases both in terms of the number of covered outpatient services furnished and the costs of those services.

This proposed rule also is necessary to make updates to the ASC payment rates for CY 2019, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2019. 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 addition, for CYs 2019 through 2023, we are proposing to update the ASC payment system rates using the hospital market basket update instead of the CPI–U but are requesting evidence from commenters to justify this higher payment update. We believe that this proposal could 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 for Provisions of This Proposed Rule

We have examined the impacts of this proposed rule, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (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 proposed rule contains the impact and other economic analyses for the provisions we are proposing to make for CY 2019.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Congressional Review Act. Accordingly, this proposed rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this proposed rule. We are soliciting public comments on the regulatory impact analysis in this proposed rule, and we will address any public comments we receive in the final rule with comment period, as appropriate.

We estimate that the proposed total increase in Federal government expenditures under the OPPS for CY 2019, compared to CY 2018, due only to the proposed changes to OPPS in this proposed rule, would be approximately $90 million. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2019, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2019 would be approximately $74.6 billion; approximately $4.9 billion higher than estimated OPPS expenditures in CY 2018. We note that these spending estimates include the CY 2019 proposal to control for unnecessary increases in the volume of outpatient service by paying for clinic visits furnished at excepted off-campus PBDs at a PFS-equivalent rate. Because the proposed provisions of the OPPS are part of a proposed rule that is economically significant, as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 42 displays the distributional impact of the proposed CY 2019 changes in OPPS payment to various groups of hospitals and for CMHCs.

We are proposing for CY 2019 to pay for separately payable drugs and biological products that do not have pass-through payment status and are not acquired under the 340B program at WAC + 3 percent instead of WAC + 6 percent, if ASP data are unavailable for payment purposes. If WAC data are not available for a drug or biological product, we are proposing to continue our policy to pay separately payable drugs and biological products at 95 percent of the AWP. Drugs and biologicals that are acquired under the 340B Program would continue to be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable.

We estimate that the proposed update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through payment estimates, the application of the frontier State wage adjustment for CY 2018, and the proposal to control for unnecessary increases in the volume of covered outpatient department services described in section X.B. of this proposed rule) would increase total OPPS payments by 1.3 percent in CY 2019. The proposed changes to the APC relative payment weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase OPPS payments because

these proposed changes to the OPPS are budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system. We estimate that the total proposed change in payments between CY 2018 and CY 2019, considering all proposed budget neutral payment adjustments, proposed changes in estimated total outlier payments, proposed pass-through payments, the proposed application of the frontier State wage adjustment, and the proposal to control for unnecessary increases in the volume of outpatient as described in section X.B. of this proposed rule, in addition to the application of the proposed OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, would decrease total estimated OPPS payments by 0.1 percent.

We estimate the total increase (from proposed changes to the ASC provisions in this proposed rule as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2019 compared to CY 2018, to be approximately $240 million. Because the proposed provisions for the ASC payment system are part of a proposed rule that is economically significant, as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the proposed changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of this proposed rule. Tables 43 and 44 of this proposed rule display the redistributive impact of the proposed CY 2019 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 Proposed OPPS Changes in This Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2019 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2019 with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* At the website, select ''regulations and notices'' from the left side of the page and then select ''CMS–1695–P'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 42 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed 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 proposed policy changes in order to isolate the effects associated with specific policies or updates. 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 Proposal To Control for Unnecessary Increases in the Volume of Outpatient Services

In section X.B. of this proposed rule, we discuss our CY 2019 proposal to control for unnecessary increases in the volume of outpatient service by paying for clinic visits furnished at an off-campus provider-based department at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). Specifically, we are proposing to pay for HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) when billed with modifier ''PO'' at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). For a discussion of the PFS relativity adjuster that will now also be used to pay for all outpatient clinic visits provided at all off-campus PBDs, we refer readers to the CY 2018 PFS final rule with comment period discussion (82 FR 53023 through 53024), as well as the CY 2019 PFS proposed rule.

To develop an estimated impact of this proposal, we began with CY 2017 outpatient claims data used in ratesetting for the CY 2019 proposed OPPS. We then flagged all claim lines for HCPCS code G0463 that contained modifier ''PO'' because the presence of this modifier indicates that such claims were billed for services furnished by an off-campus department of a hospital paid under the OPPS. Next, we excluded those that were billed as a component of comprehensive APC 8011 (Comprehensive Observation Services) or packaged into another comprehensive APC because in those instances separate OPPS payment is made for a broader package of services. We then simulated payment for the remaining claim lines as if they were paid at the PFS-equivalent rate. An estimate of the proposed policy that includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2019 President's budget approximates the estimated decrease in total payment under the OPPS at $760 million, with Medicare OPPS payments decreasing by $610 million and beneficiary copayments decreasing by $150 million in CY 2019. This estimate is utilized for the accounting statement displayed in Table 45 of this proposed rule because the impact of this proposed CY 2019 policy, which is not budget neutral, is combined with the impact of the OPD update, which is also not budget neutral, to estimate changes in Medicare spending under the OPPS as a result of the changes proposed in this rule.

We note our estimates may differ from the actual effect of the proposed policy due to offsetting factors, such as changes in provider behavior. We note that by removing this payment differential that may influence site-of-service decision-making, we anticipate an associated decrease in the volume of clinic visits provided in the excepted off-campus PBD setting. We remind readers that this estimate could change in the final rule based on a number of factors such as the availability of updated data, changes in the final payment policy, and/or the method of assessing the payment impact in the final rule. As discussed in more detail in section X.B. of this proposed rule, we are seeking public comment on both our proposed payment policy for clinic visits furnished at off-campus provider based departments as well as how to apply methods for controlling overutilization of services more broadly.

c. Estimated Effects of Proposal To Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of Hospitals

In section X.C. of this proposed rule, we discuss our proposal to pay average sales price (ASP) minus 22.5 percent for 340B-acquired drugs furnished by nonexcepted, off-campus provider-based departments (PBDs) beginning in CY 2019. This is consistent with the payment methodology adopted in CY 2018 for 340B-acquired drugs furnished

in hospital departments paid under the OPPS.

To develop an estimated impact of this proposal, we began with CY 2017 outpatient claims data used in ratesetting for the CY 2019 proposed OPPS. We then flagged all claim lines that contained modifier ''PN'' because the presence of this modifier indicates that such claims were billed for services furnished by a nonexcepted off-campus department of a hospital paid under the PFS. We further subset this population by identifying 340B hospitals that billed for status indicator ''K'' drugs or biologicals (that is, nonpass-through, separately payable drugs) because such drugs may have been subject to the 340B discount. We found 115 unique nonexcepted off-campus PBDs associated with 340B hospitals billed for status indicator ''K'' drugs. Their ''K'' billing represents approximately $180 million in Medicare payments (including beneficiary copayments) based on a payment rate of ASP+6 percent. Based on our proposed adjustment, for CY 2019, we estimate that the Medicare Program and beneficiaries would save approximately $48.5 million, under the Physician Fee Schedule. This estimate represents an upper bound of potential savings under the Physician Fee Schedule for this proposed policy change and does not include adjustments for beneficiary enrollment, case-mix, or potential offsetting behaviors. Accordingly, this estimate could change in the final rule based on a number of factors such as the availability of updated data, changes in the final payment policy, and/or the method of assessing the payment impact in the final rule.

d. Estimated Effects of Proposed OPPS Changes on Hospitals

Table 42 below shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the proposed 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 42, 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 2019, we are proposing to pay CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs), and we are proposing to pay hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B. of this proposed rule.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase for FY 2019 is 2.8 percent (83 FR 20381). Section 1833(t)(3)(F)(i) of the Act reduces that 2.8 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.8 percentage point for FY 2019 (which is also the proposed MFP adjustment for FY 2019 in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20381 through 20382)), and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act further reduce the market basket percentage increase by 0.75 percentage point, resulting in the proposed OPD fee schedule increase factor of 1.25 percent. We are using the proposed OPD fee schedule increase factor of 1.25 percent in the calculation of the proposed CY 2019 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 2019 estimates in Table 42 of this proposed rule.

To illustrate the impact of the proposed CY 2019 changes, our analysis begins with a baseline simulation model that uses the CY 2018 relative payment weights, the FY 2018 final IPPS wage indexes that include reclassifications, and the final CY 2018 conversion factor. Table 42 shows the estimated redistribution of the proposed increase or decrease in payments for CY 2019 over CY 2018 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2018 and CY 2019 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the proposed changes described in the preceding columns plus the proposed 1.25 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the proposed off-campus provider-based departments visits payment policy (Column 5), and the estimated impact taking into account all proposed payments for CY 2019 relative to all payments for CY 2018, including the impact of proposed changes in estimated outlier payments, the proposed frontier State wage adjustment, and proposed changes to the pass-through payment estimate (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are proposing to maintain the current adjustment percentage for CY 2019. Because the proposed updates to the conversion factor (including the proposed update of the OPD fee schedule increase factor), the estimated cost of the proposed rural adjustment, and the estimated cost of projected pass-through payment for CY 2019 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 proposed wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule would redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2018 and CY 2019 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2019 would decrease Medicare OPPS payments by an estimated 0.1 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 0.1 percent decrease in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 42 shows the total number of facilities (3,806), including designated cancer and

children's hospitals and CMHCs, for which we were able to use CY 2017 hospital outpatient and CMHC claims data to model CY 2018 and CY 2019 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 2018 or CY 2019 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,695), 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 44 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Proposed Changes

Column 2 shows the estimated effect of proposed APC recalibration. Column 2 also reflects any proposed changes in multiple procedure discount patterns or conditional packaging that occur as a result of the proposed changes in the relative magnitude of payment weights. As a result of proposed APC recalibration, we estimate that urban hospitals would experience no change, with the impact ranging from an increase of 0.5 percent to a decrease of 0.3 percent, depending on the number of beds. Rural hospitals would experience an increase of 0.3 percent, with the impact ranging from a decrease of 0.2 percent to an increase of 0.5 percent, depending on the number of beds. Major teaching hospitals would experience a decrease of 0.3 percent.

Column 3: Proposed Wage Indexes and the Effect of the Proposed Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the proposed APC recalibration; the proposed updates for the wage indexes with the proposed FY 2019 IPPS post-reclassification wage indexes; the proposed rural adjustment; and the proposed cancer hospital payment adjustment. We modeled the independent effect of the proposed budget neutrality adjustments and the proposed OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2018 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the proposed updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the proposed frontier State wage index adjustment, which is not budget neutral and is included in Column 6. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2019, as described in section II.E. of this proposed rule. We also did not model a budget neutrality adjustment for the cancer hospital payment adjustment because we are using a payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2019 of 0.89, which is the same ratio that was reported for the CY 2018 OPPS/ASC final rule with comment period (82 FR 59266). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are proposing to apply a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.89, not the 0.88 target payment-to-cost ratio we are applying in section II.F. of this proposed rule.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the proposed CY 2019 scaled weights and a CY 2018 conversion factor that included a budget neutrality adjustment for the effect of the proposed changes to the wage indexes between CY 2018 and CY 2019. The proposed FY 2019 wage policy would result in modest redistributions.

Column 4: All Proposed Budget Neutrality Changes Combined With the Proposed Market Basket Update

Column 4 demonstrates the combined impact of all of the proposed changes previously described and the proposed update to the conversion factor of 1.25 percent. Overall, these proposed changes would increase payments to urban hospitals by 1.3 percent and to rural hospitals by 1.5 percent. Urban hospitals would receive an increase in line with the 1.3 percent overall increase for all facilities after the update is applied to the proposed budget neutrality adjustments. The increase for classes of rural hospitals would be more variable with sole community hospitals receiving a 1.3 percent increase and other rural hospitals receiving an increase of 1.7 percent.

Column 5—Proposed Off-Campus PBD Visits Payment Policy

Column 5 displays the estimated effect of our proposed CY 2019 policy to pay for clinic visit HCPCS code G0463 ((Hospital outpatient clinic visit for assessment and management of a patient) when billed with modifier ''PO'' at a PFS-equivalent rate. We note that the numbers provided in this column isolate the estimated effect of this proposed policy adjustment relative to the numerator of Column 4. Therefore, the numbers reported in Column 5 show how much of the difference between the estimates in Column 4 and the estimates in Column 6 are a result of the proposed off-campus PBD visits policy.

Column 6: All Proposed Changes for CY 2019

Column 6 depicts the full impact of the proposed CY 2018 policies on each hospital group by including the effect of all proposed changes for CY 2019 and comparing them to all estimated payments in CY 2018. Column 6 shows the combined budget neutral effects of Columns 2 through 3; the proposed OPD fee schedule increase; the effect of the proposed off-campus provider-based department visits policy, the impact of the proposed frontier State wage index adjustment; the impact of estimated OPPS outlier payments, as discussed in section II.G. of this proposed rule; the proposed 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 XIII. of this proposed rule); and the difference in proposed 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 2018 update (and assumed, for modeling purposes, to be the same number for CY 2019), we included 29 hospitals in our model because they had both CY 2017 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2019 would decrease payments to all facilities by 0.1 percent for CY 2019. We modeled the independent effect of all proposed changes in Column 6 using the final relative payment weights for CY 2018 and the proposed relative payment weights for CY 2019. We used the final conversion factor for CY 2018 of $78.636 and the proposed CY 2019 conversion factor of $79.546 discussed in section II.B. of this proposed rule.

Column 6 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the proposed FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20581) of 4.2 percent (1.04205) to increase individual costs on the CY 2017 claims, and we used the most recent overall CCR in the July 2018 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2018. Using the CY 2017 claims and a 4.2 percent charge inflation factor, we currently estimate that outlier payments for CY 2018, using a multiple threshold of 1.75 and a fixed-dollar threshold of $4,150, would be approximately 1.02 percent of total payments. The estimated current outlier payments of 1.02 percent are incorporated in the comparison in Column 6. We used the same set of claims and a charge inflation factor of 8.6 percent (1.085868) and the CCRs in the April 2018 OPSF, with an adjustment of 0.987842, to reflect relative changes in cost and charge inflation between CY 2017 and CY 2019, to model the proposed CY 2019 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $4,600. The charge inflation and CCR inflation factors are discussed in detail in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20582).

Overall, we estimate that facilities would experience a decrease of 0.1 percent under this proposed rule in CY 2019 relative to total spending in CY 2018. This projected increase (shown in Column 6) of Table 42 reflects the proposed 1.25 percent OPD fee schedule increase factor, minus 1.2 percent for the proposed off-campus provider-based department visits policy, minus 0.13 percent for the proposed change in the pass-through payment estimate between CY 2018 and CY 2019, plus a proposed increase of 0.02 percent for the difference in estimated outlier payments between CY 2018 (1.02 percent) and CY 2019 (proposed 1.00 percent). We estimate that the combined effect of all proposed changes for CY 2019 would decrease payments to urban hospitals by 0.1 percent. Overall, we estimate that rural hospitals would experience a 0.1 percent decrease as a result of the combined effects of all proposed changes for CY 2019. Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all proposed changes would include a decrease of 0.8 percent for major teaching hospitals and an increase of 0.5 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated decrease of 0.2 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience a decrease of 0.2 percent, proprietary hospitals would experience an increase of 0.7 percent, and governmental hospitals would experience a decrease of 0.3 percent.

TABLE 42—ESTIMATED IMPACT OF THE PROPOSED CY 2019 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	Proposed APC recalibration (all proposed changes)	Proposed new wage index and provider adjustments	All proposed budget neutral changes (combined cols 2 and 3) with market basket update	Proposed off-campus provider-based department visits policy	All proposed changes
	(1)	(2)	(3)	(4)	(5)	(6)
ALL FACILITIES*	3,806	0.0	0.0	1.3	−1.2	−0.1
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,695	0.0	0.0	1.3	−1.2	−0.1
URBAN HOSPITALS	2,900	0.0	0.0	1.3	−1.2	−0.1
LARGE URBAN (GT 1 MILL.)	1,534	0.0	−0.1	1.2	−1.0	0.1
OTHER URBAN (LE 1 MILL.)	1,366	0.0	0.1	1.3	−1.4	−0.2
RURAL HOSPITALS	795	0.3	0.0	1.5	−1.3	−0.1
SOLE COMMUNITY	367	0.2	−0.1	1.3	−1.5	−0.4
OTHER RURAL	428	0.4	0.0	1.7	−1.2	0.3
BEDS (URBAN):						
0—99 BEDS	980	0.5	−0.2	1.6	−0.8	0.7
100–199 BEDS	844	0.2	−0.2	1.3	−1.0	0.1
200–299 BEDS	463	0.1	0.1	1.4	−0.9	0.3
300–499 BEDS	399	−0.1	0.0	1.2	−1.2	−0.2
500 + BEDS	214	−0.3	0.1	1.1	−1.6	−0.6
BEDS (RURAL):						
0—49 BEDS	326	0.5	0.1	1.8	−0.5	1.1
50–100 BEDS	287	0.3	0.0	1.6	−1.6	−0.2
101–149 BEDS	96	0.3	0.0	1.6	−1.0	0.4
150–199 BEDS	48	0.3	−0.2	1.4	−2.1	−1.0
200 + BEDS	38	−0.2	−0.2	0.9	−1.2	−0.5
REGION (URBAN):						
NEW ENGLAND	140	0.2	0.3	1.7	−2.1	−0.4
MIDDLE ATLANTIC	336	0.0	−0.2	1.0	−0.9	0.0
SOUTH ATLANTIC	463	0.0	−0.2	1.1	−1.1	−0.1

TABLE 42—ESTIMATED IMPACT OF THE PROPOSED CY 2019 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	Proposed APC recalibration (all proposed changes)	Proposed new wage index and provider adjustments	All proposed budget neutral changes (combined cols 2 and 3) with market basket update	Proposed off-campus provider-based department visits policy	All proposed changes
	(1)	(2)	(3)	(4)	(5)	(6)
EAST NORTH CENT	468	0.0	−0.2	1.1	−1.6	−0.7
EAST SOUTH CENT	175	−0.1	0.1	1.2	−0.4	0.6
WEST NORTH CENT	180	−0.2	0.1	1.1	−1.3	−0.5
WEST SOUTH CENT	501	0.1	0.2	1.5	−1.0	0.3
MOUNTAIN	207	0.0	−0.6	0.7	−1.2	−0.6
PACIFIC	384	0.0	0.6	1.9	−1.1	0.5
PUERTO RICO	46	−0.8	−1.0	−0.5	0.0	−0.6
REGION (RURAL):						
NEW ENGLAND	21	0.0	−0.4	0.9	−4.1	−3.4
MIDDLE ATLANTIC	54	0.3	0.1	1.7	−2.0	−0.5
SOUTH ATLANTIC	121	0.2	−0.1	1.4	−0.4	0.9
EAST NORTH CENT	121	0.4	−0.1	1.6	−1.5	−0.2
EAST SOUTH CENT	154	0.2	0.2	1.6	−0.6	0.9
WEST NORTH CENT	96	0.0	0.0	1.2	−1.7	−0.8
WEST SOUTH CENT	152	0.7	0.2	2.1	−0.5	1.4
MOUNTAIN	53	0.1	−0.3	1.1	−0.8	0.7
PACIFIC	23	0.3	−0.6	1.0	−2.1	−1.3
TEACHING STATUS:						
NON-TEACHING	2,578	0.3	−0.1	1.4	−0.8	0.5
MINOR	769	0.0	0.1	1.3	−1.3	−0.2
MAJOR	348	−0.3	0.1	1.1	−1.8	−0.8
DSH PATIENT PERCENT:						
0	10	−0.9	0.2	0.5	0.0	0.9
GT 0–0.10	258	0.4	−0.2	1.4	−0.8	0.5
0.10–0.16	244	0.2	−0.3	1.1	−0.7	0.4
0.16–0.23	574	0.1	−0.1	1.2	−1.2	−0.1
0.23–0.35	1,110	0.0	0.1	1.4	−1.4	−0.2
GE 0.35	958	−0.1	0.0	1.2	−1.2	−0.2
DSH NOT AVAILABLE**	541	1.6	−0.1	2.8	−0.6	2.0
URBAN TEACHING/DSH:						
TEACHING & DSH	1,009	−0.1	0.1	1.2	−1.5	−0.4
NO TEACHING/DSH	1,366	0.2	−0.1	1.3	−0.7	0.5
NO TEACHING/NO DSH	9	1.2	−0.1	2.3	0.0	2.1
DSH NOT AVAILABLE**	515	1.5	−0.1	2.7	−0.6	1.9
TYPE OF OWNERSHIP:						
VOLUNTARY	1,970	0.0	0.0	1.3	−1.3	−0.2
PROPRIETARY	1,248	0.3	−0.2	1.4	−0.4	0.7
GOVERNMENT	477	−0.2	0.2	1.3	−1.4	−0.3
CMHCs	44	−19.1	0.3	−17.8	0.0	−17.9

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2019 OPPS policies and compares those to the CY 2018 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2019 hospital inpatient wage index. The proposed rural SCH adjustment would continue our current policy of 7.1 percent so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 1 because in CY 2019 the target payment-to-cost ratio is the same as it was in CY 2018 (0.88).

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 1.25 percent OPD fee schedule update factor (2.8 percent reduced by 0.8 percentage point for the productivity adjustment and further reduced by 0.75 percentage point as required by law).

Column (5) shows the impact of the proposal to pay for the visit service furnished at excepted off-campus provider-based departments at an MPFS equivalent rate.

Column (6) shows the additional proposed adjustments to the conversion factor resulting from the frontier adjustment, a change in the pass-through estimate, and adding estimated outlier payments.

*These 3,806 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.

e. Estimated Effects of Proposed OPPS Changes on CMHCs

The last line of Table 42 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2018, 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 data used for this proposed rule. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the

beneficiary. We estimate that CMHCs would experience an overall 17.9 percent decrease in payments from CY 2018 (shown in Column 6). We note that this includes the trimming methodology described in section VIII.B. of this proposed rule.

Column 3 shows that the estimated impact of adopting the proposed FY 2019 wage index values would result in a small increase of 0.3 percent to CMHCs. Column 4 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2019 and the proposed FY 2019 wage index updates, would result in an estimated decrease of 17.8 percent. Column 5 shows that the off-campus provider-based department visits payment proposal has no effect on CMHCs. Column 6 shows that adding the proposed changes in outlier and pass-through payments would result in a total 17.9 percent decrease in payment for CMHCs. This reflects all proposed changes to CMHCs for CY 2019.

f. Estimated Effect of Proposed OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments would rise and would decrease for services for which the OPPS payments would fall. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be 18.5 percent for all services paid under the OPPS in CY 2019. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2019 comprehensive APC payment policy discussed in section II.A.2.b. of this proposed rule.

g. Estimated Effects of Proposed 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 XII. of this proposed rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs would be affected by the proposed changes in this proposed rule.

h. Estimated Effects of Proposed OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $90 million in program payments for OPPS services furnished in CY 2019. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the proposed changes in this proposed rule would increase these Medicaid payments by approximately $7 million in CY 2019. This Medicaid impact is determined by starting with the estimated increase in Medicare payments of approximately $90 million, resulting in a beneficiary cost-sharing increase of approximtely $22 million. Currently, there are approximately 10 million dual-eligible beneficiaries, which represents approximtely one-third of Part B FFS beneficiaries. The impact on Medicaid was determined by taking one-third 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 $7 million Medicaid impact, approximately $4 million would be paid by the Federal Government and $3 million would be paid by the State programs. We refer readers to our discussion of the impact on beneficiaries in section XX.C.1.f. of this proposed rule.

i. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing to make and the reasons for our selected alternatives are discussed throughout this proposed rule.

• Alternatives Considered for the Methodology for Assigning Skin Substitutes to High or Low Cost Groups

We refer readers to section V.B.1.d. of this proposed rule for a discussion of our proposal to assign any skin substitute product that was assigned to the high cost group in CY 2018 to the high cost group in CY 2019, regardless of whether the product's mean unit cost (MUC) or the product's per day cost (PDC) exceeds or falls below the overall CY 2019 MUC or PDC threshold. We will continue to assign products that exceed either the overall CY 2019 MUC or PDC threshold to the high cost group. We also considered, but are not proposing, reinstating our methodology from CY 2017 and assigning skin substitutes to the high cost group based on whether an individual product's MUC or PDC exceeded the overall CY 2019 MUC or PDC threshold based on calculations done for either the proposed rule or the final rule with comment period.

• Alternatives Considered for the Methodology for Payment for Non-Opioid Pain Management Treatments

We refer readers to sections II.A.3.b. and XII.D.3. of this proposed rule for a discussion of our proposal to change the packaging policy for certain drugs when administered in the ASC setting and provide separate payment for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in an ASC. In those sections, we are also soliciting comments on whether we should pay separately for other non-opioid treatments for pain under the OPPS and the ASC payment system. We also considered and are soliciting comments on an alternative policy that would use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to establish an incentive payment for non-opioid alternatives that would apply to drugs and devices in the hospital and ASC settings that are not currently separately paid, are supported by evidence that demonstrates such drugs and devices are effective at treating acute or chronic pain, and would result in decreased use of prescription opioid drugs and any associated opioid addiction.

2. Estimated Effects of Proposed CY 2019 ASC Payment System Policies

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XII. of this proposed rule, we are proposing to set the CY 2019 ASC relative payment weights by scaling the proposed CY 2019 OPPS relative payment weights by the proposed ASC scalar of 0.8854. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 43 and 44 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which we are proposing will be the hospital market basket for CY 2019) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care 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, the CY 2019 payment determinations will be based on the application of a 2.0 percentage point reduction to the annual update factor, which we are proposing will be the hospital market basket for CY 2019. We calculated the proposed CY 2019 ASC conversion factor by adjusting the CY 2018 ASC conversion factor by 1.0003 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2018 and CY 2019 and by applying the proposed CY 2019 MFP-adjusted hospital market basket update factor of 2.0 percent (projected hospital market basket update of 2.8 percent minus a projected productivity adjustment proposed to be 0.8 percentage point). The proposed CY 2019 ASC conversion factor is $46.500.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2019 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2017 and CY 2019 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2019 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of Proposed ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the proposed update to the CY 2019 payments would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the proposed CY 2019 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2017 claims data. Table 43 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2018 payments to estimated proposed CY 2019 payments, and Table 44 shows a comparison of estimated CY 2018 payments to estimated proposed CY 2019 payments for procedures that we estimate would receive the most Medicare payment in CY 2018.

In Table 43, 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 43.

- 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 2018 ASC Payments were calculated using CY 2017 ASC utilization (the most recent full year of ASC utilization) and CY 2018 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2018 ASC payments.
- Column 3—Estimated CY 2019 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 are attributable to proposed updates to ASC payment rates for CY 2019 compared to CY 2018.

As shown in Table 43, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2019 would result in no change in aggregate payment amounts for eye and ocular adnexa procedures, a 4-percent increase in aggregate payment amounts for nervous system procedures, 3-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 genitourinary system procedures, and a 1-percent increase in aggregate payment amounts for integumentary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and proposed changes in policy. In general, spending in each of these categories of services increases due to the 2.0 percent proposed payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 2.0 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 no change in proposed aggregate eye and ocular adnexa procedure payments due to a reduction in hospital reported costs for the primary payment grouping for this category under the OPPS. This lowers the payment weights for eye and ocular adnexa procedure payments and, overall, offsets the proposed 2.0 percent ASC rate update for these procedures. For a table that includes estimated changes for selected procedures, we refer readers to Table 44 provided later in this section.

Also displayed in Table 43 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. We estimate that aggregate payments for these items and services would increase by 2 percent for CY 2019.

TABLE 43—ESTIMATED IMPACT OF THE PROPOSED CY 2019 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2019 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group (1)	Estimated CY 2018 ASC payments (in millions) (2)	Estimated CY 2019 percent change (3)
Total	$4,772	2
Eye and ocular adnexa	1,737	0
Nervous system	993	4
Digestive system	873	3
Musculoskeletal system	574	4
Genitourinary system	188	2
Integumentary system	145	1
Ancillary items and services	64	2

Table 44 below shows the estimated impact of the proposed updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2019. The table displays 30 of the procedures receiving the greatest estimated CY 2018 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2018 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2018 ASC Payments were calculated using CY 2017 ASC utilization (the most recent full year of ASC utilization) and the CY 2018 ASC payment rates. The estimated CY 2018 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2019 Percent Change reflects the percent differences between the estimated ASC payment for CY 2018 and the estimated payment for CY 2019 based on the proposed update.

TABLE 44—ESTIMATED IMPACT OF THE PROPOSED CY 2019 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code (1)	Short descriptor (2)	Estimated CY 2018 ASC payment (in millions) (3)	Estimated CY 2019 percent change (4)
66984	Cataract surg w/iol 1 stage	$1,206	0
45380	Colonoscopy and biopsy	228	4
63685	Insrt/redo spine n generator	221	−2
43239	Egd biopsy single/multiple	180	2
63650	Implant neuroelectrodes	166	0
45385	Colonoscopy w/lesion removal	156	4
64483	Inj foramen epidural l/s	101	14
0191T	Insert ant segment drain int	96	4
66982	Cataract surgery complex	89	0
64635	Destroy lumb/sac facet jnt	75	1
66821	After cataract laser surgery	69	1
29827	Arthroscop rotator cuff repr	65	2
64493	Inj paravert f jnt l/s 1 lev	63	14
62323	Njx interlaminar lmbr/sac	53	11
64590	Insrt/redo pn/gastr stimul	51	3
G0105	Colorectal scrn; hi risk ind	47	4
G0121	Colon ca scrn not hi rsk ind	42	4
45378	Diagnostic colonoscopy	41	4
64721	Carpal tunnel surgery	34	1
15823	Revision of upper eyelid	33	−1
29881	Knee arthroscopy/surgery	29	−1
C9740	Cysto impl 4 or more	28	2
64561	Implant neuroelectrodes	26	1
67042	Vit for macular hole	26	1
29880	Knee arthroscopy/surgery	25	−1
26055	Incise finger tendon sheath	25	−3
28285	Repair of hammertoe	24	−1
63655	Implant neuroelectrodes	24	5
52000	Cystoscopy	23	−1
G0260	Inj for sacroiliac jt anesth	22	12

c. Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2019 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures we are proposing to add to the ASC list of covered surgical procedures and for those we are proposing to designate as office-based for CY 2019. For example, using 2017 utilization data and proposed CY 2019 OPPS and ASC payment rates, we estimate that if 5 percent of cardiac catheterization procedures would migrate from the hospital outpatient setting to the ASC setting as a result of this proposed policy, Medicare payments would be reduced by approximately $35 million in CY 2019 and total beneficiary copayments would decline by approximately $14 million in CY 2019. 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). 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 would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised 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 OPPS payment rates, services that are performed a majority of the time in a physician office are paid the lesser of ASC charges or at the office-based amount payable under the PFS. Because ASC payment rates for services that are performed a majority of the time in the physician office are paid the lesser of ASC charges or at the office-based amount payable under the PFS, we do not believe that the increase in ASC payment rates that would result from this proposal would cause any significant migration of services from the physician office setting to the ASC setting. For those additional procedures that we are proposing to designate as office-based in CY 2019, the beneficiary coinsurance amount under the ASC payment system generally would 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).

d. Alternative ASC Payment Policies Considered

Alternatives to the ASC changes we are proposing to make and the reasons for our selected alternatives are discussed throughout this proposed rule.

• Alternatives Considered for the CY 2019 ASC Rate Update

As discussed in section XII. of this proposed rule with comment period, for CY 2019 through CY 2023 (5 years total), in response to stakeholder concerns regarding the application of CPI–U to update ASC payment rates, we are proposing to update ASC payment rates using the hospital market basket and to revise our regulations under 42 CFR 416.171(a), which address the annual update to the ASC conversion factor, to reflect this proposal.

As an alternative proposal, we are considering whether to continue applying the CPI–U as the update factor. If we were to update ASC payment rates for CY 2019 with an update factor based on CPI–U, the update would have been 1.3 percent (the 2.1 percent CPI–U less the 0.8 percent MFP update). This update factor would have resulted in increased payments to ASCs in CY 2019 of approximately $40 million, compared to the increased payments to ASCs in CY 2019 of approximately $70 million as a result of the 2.0 percent update based on the hospital market basket.

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/omb/circulars_a004_a-4#a*),we have prepared accounting statements to illustrate the impacts of the proposed OPPS and ASC changes in this proposed rule. The first accounting statement, Table 45 below, illustrates the classification of expenditures for the CY 2019 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2019 OPD fee schedule increase. This $90 million in additional Medicare spending estimate includes the $700 million in additional Medicare spending associated with updating the CY 2018 OPPS payment rates by the hospital market basket update for CY 2019, offset by the $610 million in Medicare savings associated with the proposal to pay for clinic visits furnished at off-campus PBDs at a PFS-equivalent rate. Additionally, we estimate that proposed OPPS changes in this proposed rule would increase copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries by approximately $7 million in CY 2019. The second accounting statement, Table 46 below, illustrates the classification of expenditures associated with the proposed 2.0 percent CY 2019 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers.

TABLE 45—ACCOUNTING STATEMENT: CY 2019 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2018 TO CY 2019 ASSOCIATED WITH THE PROPOSED CY 2019 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$90 million.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS.
Total	$90 million.

TABLE 46—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2018 TO CY 2019 AS A RESULT OF THE PROPOSED CY 2019 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$70 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Total	$70 million.

TABLE 47—ESTIMATED COSTS, COST SAVINGS, AND BENEFITS

Category	Costs	Cost savings
ICR Burden Savings		$54.3 million.*
Regulatory Familiarization	$2.9 million *	

* The annual estimates are in 2017 year dollars.
** Regulatory familiarization costs occur upfront only.

4. Effects of Proposed 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 OQR Program for the CY 2018, CY 2019, and CY 2020 payment determinations. Of the approximately 3,300 hospitals that met eligibility requirements for the CY 2018 payment determination, we determined that 36 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. Many of these hospitals (18 of the 36), chose not to participate in the Hospital OQR Program for the CY 2018 payment determination. We are not proposing to add any quality measures to the Hospital OQR Program measure set for the CY 2020 or CY 2021 payment determinations, and are proposing to remove 10 measures from the program measure set, as discussed in section XIII.B.4.b. of this proposed rule. Therefore, we do not believe that these proposals would increase the number of hospitals that do not receive a full annual payment update for the CY 2020 or CY 2021 payment determinations.

In section XIII.B.4.b. of this proposed rule, we are proposing to remove a total of 10 measures. Specifically, beginning with the CY 2020 payment determination, we are proposing to remove: (1) OP–27: Influenza Vaccination Coverage Among Healthcare Personnel; and beginning with the CY 2021 payment determination, we are proposing to remove: (2) OP–5: Median Time to ECG; (3) OP–9: Mammography Follow-up Rates; (4) OP–11: Thorax CT Use of Contrast Material; (5) OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; (6) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT; (7) OP–17: Tracking Clinical Results between Visits; (8) OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients; (9) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (10) OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. The reduction in burden associated with these proposals is discussed further below.

In section XIII.B.4.a. of this proposed rule, beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period, we are proposing to update one removal factor and to add one removal factor. We are also proposing to codify our measure removal policies and factors at proposed 42 CFR 419.46(h) effective upon finalization of the CY 2019 OPPS/ASC final rule and for subsequent years. In addition, in section XIII.D.2. of this proposed rule, we are proposing to update the frequency with which we will release Hospital Outpatient Quality Reporting Specifications Manuals, such that instead of every 6 months, we would release Specifications Manuals every 6 to 12 months beginning with CY 2019 and for subsequent years. In section XIII.C.2. of this proposed rule, beginning with the CY 2020 payment determination, we are proposing to remove the Notice of Participation (NOP) form as a requirement for the Hospital OQR Program and to update 42 CFR 419.46(a)(3) to reflect these policies. Finally, in section XIII.D.4.b. of this proposed rule, we are proposing to change the data collection period for OP–32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years beginning with the CY 2020 payment determination. As discussed below, we do not expect these proposals to affect our burden estimates. However, as further explained in section XVIII.B. of this proposed rule, we believe that there will be an overall decrease in the estimated information collection burden for hospitals due to the other proposed policies. We refer readers to section XVIII.B. of this proposed rule for a summary of our information collection burden estimate calculations. The effects of these proposals are discussed in more detail further below.

b. Estimated Effects of Hospital OQR Program Beginning With the Effective Date of the CY 2019 OPPS/ASC Final Rule With Comment Period

In section XIII.B.4.a. of this proposed rule, we are proposing to: (1) Update measure removal Factor 7; (2) add one new removal factor; and (3) codify our removal factors policy at 42 CFR 419.46(h). We do not expect a change in the information collection burden or other costs experienced by hospitals because these changes do not affect Hospital OQR Program participation requirements or data reporting requirements.

c. Proposal To Update the Frequency of Releasing the Hospital Outpatient Quality Reporting Specifications Manual Beginning With CY 2019 and for Subsequent Years

In section XIII.D.2. of this proposed rule, we are proposing to update the frequency with which we will release a Hospital Outpatient Quality Reporting Specifications Manual such that instead of every 6 months, we would release

Specifications Manuals every 6 to 12 months beginning with CY 2019. We anticipate that this proposed change will reduce hospital confusion, as potentially releasing fewer manuals per year reduces the need to review updates as frequently as previously necessary. However, because this change does not affect Hospital OQR Program participation requirements or data reporting requirements, we do not estimate a change in our calculation of the information collection burden experienced by hospitals.

d. Estimated Effects of Hospital OQR Program Proposals for the CY 2020 Payment Determination and Subsequent Years

(1) Proposal To Remove the Notice of Participation (NOP) Form Requirement

In section XIII.C.2. of this proposed rule, beginning with the CY 2020 payment determination, we are proposing to remove the NOP form as a requirement. As a result, to be a participant in the Hospital OQR Program, hospitals would need to: (1) Register on the QualityNet website, (2) identify and register a QualityNet security administrator, and (3) submit data. In addition, we are proposing to update 42 CFR 419.46(a) to reflect these policies. We believe that the proposal to remove the NOP, if finalized, would reduce administrative burden experienced by hospitals by only a nominal amount. As a result, this proposal does not influence our information collection burden estimates. We refer readers to section XVIII.B. of this proposed rule, where our burden calculations for the Hospital OQR Program are discussed in detail. In addition, we do anticipate that this proposal will reduce the possibility of hospitals failing to meet Hospital OQR Program requirements due to a failure to submit the NOP.

(2) Proposed Extension of the Collection Period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

In section XIII.D.4.b. of this proposed rule, we are proposing to increase the data collection period for OP–32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from 1 year to 3 years beginning with the CY 2020 payment determination. We expect this proposal to increase the reliability of OP–32 data allowing better information to be publicly reported. However, the proposal does not change our data reporting requirements, such that hospitals will be required to continue reporting claims data that are used to calculate this measure. Therefore, we do not expect a change in the information collection burden experienced by hospitals.

(3) Proposed Removal of OP–27 for the CY 2020 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) beginning with the CY 2020 payment determination and for subsequent years. The burden associated with OP–27, a NHSN measure, is accounted for under a separate Paperwork Reduction Act Package, OMB control number 0920–0666. Because burden associated with submitting data for this measure is captured under a separate OMB control number, we are not providing an estimate of the information collection burden associated with this measure for the Hospital OQR Program. Aside from burden associated with information collection however, we also anticipate that hospitals will experience a general burden and cost reduction associated with this proposal stemming from no longer having to review and track program requirements associated with this measure.

e. Estimated Effects of Hospital OQR Program Proposals for the CY 2021 Payment Determination and Subsequent Years

(1) Proposed Removal of Chart-Abstracted Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove OP–5: Median Time to ECG, a chart-abstracted measure, for the CY 2021 payment determination and subsequent years. We believe that the removal of this chart-abstracted measure for the CY 2021 payment determination would reduce collection of information burden by 153,130 hours and $5.6 million (153,130 hours × $36.58), as discussed in section XVIII.B. of this proposed rule. Aside from burden associated with information collection however, we also anticipate that hospitals will experience a general burden and cost reduction associated with this proposal stemming from no longer having to review and track program requirements associated with this measure.

(2) Proposed Removal of Measures Submitted Via a Web-Based Tool for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove five measures submitted via a web-based tool beginning with the CY 2021 payment determination and for subsequent years: OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; OP–17: Tracking Clinical Results between Visits; OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. As discussed in section XVIII.B. of this proposed rule, we anticipate a burden reduction of 1,164,843 hours and $42.6 million associated with the removal of OP–12, OP–17, OP–29, OP–30, and OP–31 for the CY 2021 payment determination. Aside from burden associated with information collection however, we also anticipate that hospitals will experience a general burden and cost reduction associated with these proposals stemming from no longer having to implement, review, track, and maintain program requirements associated with these measures.

(3) Proposed Removal of Claims-Based Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove three claims-based measures beginning with the CY 2021 payment determination: OP–9: Mammography Follow-up Rates; OP–11: Thorax CT Use of Contrast Material; and OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT. These claims-based measures are calculated using only data already reported to the Medicare program for payment purposes, therefore, we do not believe removing these measures will affect the information collection burden on hospitals. Nonetheless, we anticipate that hospitals would experience a general burden reduction associated with these proposals stemming from no longer having to review and track various associated program requirements.

In total for the CY 2021 payment determination, we expect information collection burden would be reduced by 151,800 hours due to our proposal to remove one chart-abstracted measure, and 1,164,843 hours due to our proposals to remove five measures submitted via a web-based tool. In total, we estimate an information collection burden reduction of 1,316,643 hours (1,164,843 hours + 151,800 hours) and $48.2 million (1,317,973 hours × $36.58) for the CY 2021 payment determination.

6. Effects of Proposed Requirements for the ASCQR Program

a. Background

In section XIV. of this proposed rule, we discuss our proposals to adopt policies affecting the ASCQR Program. For the CY 2018 payment determination, of the 6,683 ASCs that met eligibility requirements for the ASCQR Program, 233 ASCs did not meet the requirements to receive the full annual payment update. We note that, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79874), we used the CY 2016 payment determination numbers as a baseline, and estimated that approximately 200 ASCs will not receive the full annual payment update in CY 2019 due to failure to meet the ASCQR Program requirements (CY 2017 and CY 2018 payment determination information were not yet available). We are not proposing to add any new quality measures to the ASCQR Program measure set for the CY 2020 payment determination and subsequent determinations, and we do not believe that the other measures we previously adopted would cause any additional ASCs to fail to meet the ASCQR Program requirements. Therefore, we do not believe that these proposals would increase the number of ASCs that do not receive a full annual payment update for the CY 2020 payment determination. Below we discuss only the effects that would result from the newly proposed provisions in this proposed rule.

In section XIV.B.3.c. of this proposed rule, we are proposing to remove one measure beginning with the CY 2020 payment determination, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel, and to remove seven measures beginning with the CY 2021 payment determination: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC–4: All-Cause Hospital Transfer/Admission; ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. We expect these proposals would reduce the overall burden of reporting data for the ASCQR Program, as discussed further below.

In addition, in sections XIV.B.3.b. and XIV.D.4.b. of this proposed rule, beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period, we are proposing to: (1) Remove one measure removal factor; (2) add two new measure removal factors, and (3) update 42 CFR 416.320(c) to better reflect our measure removal policies; we are also proposing to: (4) Extend the reporting period for ASC–12: Facility Seven-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy from 1 to 3 years beginning with the CY 2020 payment determination. As discussed below, we do not expect these proposals would affect our burden estimates. However, as further explained in section XVIII.C. of this proposed rule, we believe that there would be an overall decrease in the estimated information collection burden for ASCs due to the other proposed policies. We refer readers to section XVIII.C. of this proposed rule for a summary of our information collection burden estimate calculations. The effects of these proposals are discussed in more detail below.

b. Estimated Effects of ASCQR Program Proposals Beginning With the Effective Date of the CY 2019 OPPS/ASC Final Rule With Comment Period

In section XIV.B.3.a. of this proposed rule, we are proposing, beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period, to remove one measure removal factor, add two new measure removal factors, and update 42 CFR 416.320(c) to better reflect our measure removal policies for the ASCQR Program. Because these changes do not affect ASCQR Program participation requirements or data reporting requirements, we do not expect these proposals would change the information collection burden or other costs experienced by ASCs.

c. Estimated Effects of ASCQR Program Proposals for the CY 2020 Payment Determination and Subsequent Years

(1) Proposed Extension of the Reporting Period for ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

In section XIV.D.4.b. of this proposed rule, we are proposing to increase the data reporting period for ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from 1 year to 3 years beginning with the CY 2020 payment determination. We expect this proposal to increase the reliability of ASC–12 data allowing better information to be publicly reported. However, the proposal does not change our data reporting requirements, because ASC–12 is a claims-based measure that is calculated based on claims data that facilities already submit to CMS. Therefore, we do not expect a change in the information collection burden or other costs experienced by ASCs.

(2) Proposed Removal of ASC–8 for the CY 2020 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule, we are proposing to remove one measure from the ASCQR Program measure set beginning with the CY 2020 payment determination, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel. As discussed in section XVIII.C.3.b. of this proposed rule, the information collection burden associated with ASC–8, a NHSN measure, is accounted for under a separate information collection request, OMB control number 0920–0666. As such, we are not providing an estimate of the information collection burden associated with this measure under the ASCQR Program control number. Aside from burden associated with information collection however, we anticipate that facilities would experience a general burden and cost reduction associated with this proposal stemming from no longer having to review and track program requirements associated with this measure.

d. Estimated Effects of ASCQR Program Proposals for the CY 2021 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule we are proposing to remove seven measures from the ASCQR Program measure set beginning with the CY 2021 payment determination: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC–4: All-Cause Hospital Transfer/

Admission; ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

(1) Proposed Removal of QDC Claims-based Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule, we are proposing to remove four QDC claims-based measures from the ASCQR Program measure set beginning with the CY 2021 payment determination: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC–4: All-Cause Hospital Transfer/Admission. As discussed in section XVIII.C.4.a. of this proposed rule, these measures do not require ASCs to report any additional data, and we do not believe there would be any information collection burden change associated with our proposals to remove these measures. Aside from burden associated with information collection however, we anticipate that facilities would experience a general burden and cost reduction associated with these proposals stemming from no longer having to review and track program requirements associated with these measures.

(2) Proposed Removal of Chart-Abstracted Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule, we are proposing to remove three chart-abstracted measures from the ASCQR Program measure set beginning with the CY 2021 payment determination: ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. As discussed in section XVIII.C.4.b. of this proposed rule, we believe our proposals to remove ASC–9; ASC–10; and ASC–11, if finalized, would result in a burden reduction for ASCs. For ASC–9 and ASC–10, we estimate the total annualized burden reduction associated with each measure to be 62,008 hours and $2,268,253 (62,008 hours × $36.58 per hour). For ASC–11, a voluntary measure, we estimate a total annual burden reduction of 16,569 hours and $606,094 (16,569 hours × $36.58 per hour). Aside from burden associated with information collection however, we anticipate that facilities would experience a general burden and cost reduction associated with these proposals stemming from no longer having to review and track program requirements associated with these measures.

Therefore, as noted in section XVIII.C.4. of this proposed rule, we believe our proposals to remove seven measures from the ASCQR measure set for the CY 2021 payment determination would result in a total annual reduction in information collection burden of 140,585 hours (62,008 hours + 62,008 hours + 16,569 hours) and $5,142,600 ($2,268,253 + $2,268,253 + $606,094).

D. Effects of the Proposed Update to the HCAHPS Survey Measure in the Hospital IQR Program

As discussed in section XVI. of this proposed rule, we are proposing to update the HCAHPS Survey measure by removing the ''Communication About Pain'' questions beginning with patients discharged in January 2022, for the FY 2024 payment determination and subsequent years. We anticipate that the removal of these questions will result in only a nominal and temporary increase on the information collection burden on providers associated with adjusting the survey instrument and instructional materials, and a burden decrease for survey respondents. We note that the burden estimate for the Hospital IQR Program under the program's OMB control number 0938–1022 excludes the burden associated with the HCAHPS Survey measure, which is submitted under a separate information collection request and approved under OMB control number 0938–0981. We address the anticipated information collection burden reduction in section XVIII.D. of this proposed rule.

E. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters will review this year's proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We welcome any comments on the approach in estimating the number of entities that will review this proposed rule.

We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of this proposed rule, and, therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. In this proposed rule, we are seeking public comments.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/naics4_621100.htm*). Assuming an average reading speed, we estimate that it will take approximately 8 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is $859.04 (8 hours × $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $2,912,146 ($859.04 × 3,390 reviewers).

F. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $38.5 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 $15 million or less in any single year. For details, see the Small Business Administration's ''Table of Small Business Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards.*

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of

a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule would increase payments to small rural hospitals by less than 3 percent; therefore, it should not have a significant impact on approximately 613 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

G. 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 $150 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

H. 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 proposed rule, if finalized, would be a deregulatory action for the purposes of Executive Order 13771. We estimate that this proposed rule would generate $43.5 million in annualized cost savings at a 7-percent discount rate, discounted relative to 2016, over a perpetual time horizon.

I. Conclusion

The changes we are proposing to make in this proposed rule would affect all classes of hospitals paid under the OPPS and would affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2019. Table 42 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 0.1 percent decrease in payments for all services paid under the OPPS in CY 2019, after considering all of the proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, proposed wage index changes, including the proposed frontier State wage index adjustment, estimated payment for outliers, the proposed off-campus provider-based department visits payment policy, and proposed changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2019.

The proposed updates to the ASC payment system for CY 2019 would affect each of the approximately 5,500 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 43 demonstrates the estimated distributional impact among ASC surgical specialties of the proposed MFP-adjusted hospital market basket update factor of 1.25 percent for CY 2019.

XXI. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 42 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would decrease by 0.3 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR chapter IV as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

■ 1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 2. Section 416.164 is amended by revising paragraph (a)(4) and adding paragraph (b)(6) to read as follows:

§ 416.164 Scope of ASC services.

(a) * * *

(4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS), with the exception of non-opioid pain management drugs that function as a supply when used in a surgical procedure;

* * * * *

(b) * * *

(6) Non-opioid pain management drugs that function as a supply when used in a surgical procedure.

* * * * *

■ 3. Section 416.171 is amended by revising paragraphs (a)(2) and (b)(1) and (2) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) *Conversion factor for CY 2009 and subsequent calendar years.* The conversion factor for a calendar year is equal to the conversion factor calculated for the previous year, updated as follows:

(i) For CY 2009, the update is equal to zero percent;

(ii) For CY 2010 through CY 2018, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(iii) For CY 2019 through CY 2023, the update is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(iv) For CY 2024 and subsequent years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(v) For CY 2014 through CY 2018, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(ii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vi) For CY 2019 through CY 2023, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vii) For CY 2024 and subsequent years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(iv) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(viii) *Productivity adjustment.* (A) For CY 2011 through CY 2018, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(iv) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) For CY 2019 through CY 2023, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section, after application of any reduction under paragraph (a)(2)(vi) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(C) For CY 2024 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(iv) of this section, after application of any reduction under paragraph (a)(2)(vii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(D) The application of the provisions of paragraph (a)(2)(viii)(A), (B), or (C) of this section may result in the update being less than zero percent for a year, and may result in payment rates for a year being less than the payment rates for the preceding year.

(b) * * *

(1) Covered ancillary services specified in § 416.164(b), with the exception of radiology services and certain diagnostic tests as provided in § 416.164(b)(5) and non-opioid pain management drugs that function as a supply when used in a surgical procedure as provided in § 416.164(b)(6).

(2) The device portion of device-intensive procedures, which are procedures that—

(i) Involve implantable devices assigned a CPT or HCPCS code;

(ii) Utilize devices (including single-use devices) that must be surgically inserted or implanted; and

(iii) Have a HCPCS code-level device offset of greater than 30 percent when calculated according to the standard OPPS ASC ratesetting methodology.

* * * * *

■ 4. Section 416.320 is amended by revising paragraph (c) to read as follows:

§ 416.320 Retention and removal of quality measures under the ASCQR Program.

* * * * *

(c) *Removal of quality measures*—(1) *General rule for the removal of quality measures.* Unless a measure raises specific safety concerns as set forth in paragraph (b) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the ASCQR Program to allow for public comment.

(2) *Factors for consideration of removal of quality measures.* CMS will weigh whether to remove measures based on the following factors:

(i) *Factor 1:* Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (topped-out measures);

(ii) *Factor 2:* Performance or improvement on a measure does not result in better patient outcomes;

(iii) *Factor 3:* A measure does not align with current clinical guidelines or practice;

(iv) *Factor 4:* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(v) *Factor 5:* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(vi) *Factor 6:* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(vii) *Factor 7:* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(viii) *Factor 8:* The costs associated with a measure outweigh the benefit of its continued use in the program.

(3) *Criteria to determine topped-out measures.* For the purposes of the ASCQR Program, a measure is considered to be topped-out under paragraph (c)(2)(i) of this section when it meets both of the following criteria:

(i) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an ASC's measure is within two times the standard error of the full data set); and

(ii) A truncated coefficient of variation less than or equal to 0.10.

(4) *Application of measure removal factors.* The benefits of removing a measure from the ASCQR Program will be assessed on a case-by-case basis. A measure will not be removed solely on the basis of meeting any specific factor or criterion.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 5. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

■ 6. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*10*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*10*) For calendar year 2019, a multifactor productivity adjustment (as determined by CMS) and 0.75 percentage point.

* * * * *

■ 7. Section 419.46 is amended by revising paragraphs (a)(1) through (3) and adding paragraph (h) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) * * *

(1) Register on the QualityNet website before beginning to report data;

(2) Identify and register a QualityNet security administrator as part of the registration process under paragraph (a)(1) of this section; and

(3) Submit at least one data element.

* * * * *

(h) *Retention and removal of quality measures under the Hospital OQR Program.* (1) *General rule for the retention of quality measures.* Quality measures adopted for the Hospital OQR Program measure set for a previous payment determination year are retained for use in subsequent payment determination years, except when they are removed, suspended, or replaced as set forth in paragraphs (h)(2) and (3) of this section.

(2) *Immediate measure removal.* For cases in which CMS believes that the continued use of a measure as specified raises patient safety concerns, CMS will immediately remove a quality measure from the Hospital OQR Program and will promptly notify hospitals and the public of the removal of the measure and the reasons for its removal through the Hospital OQR Program ListServ and the QualityNet website.

(3) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (h)(2) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the Hospital OQR Program to allow for public comment.

(i) *Factors for consideration of removal of quality measures.* CMS will weigh whether to remove measures based on the following factors:

(A) *Factor 1:* Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures);

(B) *Factor 2:* Performance or improvement on a measure does not result in better patient outcomes;

(C) *Factor 3:* A measure does not align with current clinical guidelines or practice;

(D) *Factor 4:* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) *Factor 5:* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) *Factor 6:* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(G) *Factor 7:* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(H) *Factor 8:* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Criteria to determine topped-out measures.* For the purposes of the Hospital OQR Program, a measure is considered to be topped-out under paragraph (h)(3)(i)(A) of this section when it meets both of the following criteria:

(A) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for a hospital's measure is within two times the standard error of the full data set); and

(B) A truncated coefficient of variation less than or equal to 0.10.

(iii) *Application of measure removal factors.* The benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis. Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor.

■ 8. Section 419.48 is amended by—

■ a. Revising paragraph (a);

■ b. Redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively;

■ c. Adding a new paragraph (b);

■ d. Revising redesignated paragraph (d); and

■ e. Adding paragraph (e).

The revisions and additions read as follows:

§ 419.48 Definition of excepted items and services.

(a) Excepted items and services are items or services that are furnished—

(1) On or after January 1, 2017—

(i) By a dedicated emergency department (as defined at § 489.24(b) of this chapter); or

(ii) By an excepted off-campus provider-based department defined in paragraph (c) of this section that has not impermissibly relocated or changed ownership.

(2) On or after January 1, 2019—

(i) By a dedicated emergency department (as defined at § 489.24(b) of this chapter); or

(ii) By an excepted off-campus provider-based department described in paragraph (a)(1)(ii) of this section only from those clinical families of services described in paragraph (b) of this section for which the excepted off-campus provider-based department furnished an item or service (and subsequently billed for that item or service under the OPPS) during the following baseline periods:

(A) For an off-campus provider-based department that first furnished a covered OPD service on or before November 1, 2014, November 1, 2014 through November 1, 2015;

(B) For an off-campus provider-based department that first furnished a covered OPD service between November 2, 2014 and November 1, 2015, during a 1-year baseline period that begins on the first date the off-campus provider-based department furnished a covered OPD service; or

(C) For an off-campus provider-based department that first furnished a covered OPD service after November 2, 2015, during a 1-year baseline period that begins on the first date the off-campus provider-based department furnished a covered OPD service. This paragraph (a)(2)(ii)(C) only applies to provider-based departments that met the exception criteria as defined at either section 1833(t)(21)(B)(iii) or section 1833(t)(21)(B)(iv) of the Act.

(b) For purposes of paragraph (a)(2)(ii) of this section, ''clinical families of services'' means the following:

(1) Airway endoscopy.

(2) Blood product exchange.

(3) Cardiac/pulmonary rehabilitation.

(4) Diagnostic/screening test and related procedures.

(5) Drug administration and clinical oncology.

(6) Ear, nose throat (ENT).

(7) General surgery and related procedures.

(8) Gastrointestinal (GI).

(9) Gynecology.

(10) Major imaging.

(11) Minor imaging.

(12) Musculoskeletal surgery.

(13) Nervous system procedures.

(14) Ophthalmology.

(15) Pathology.

(16) Radiation oncology.

(17) Urology.

(18) Vascular/endovascular/cardiovascular.

(19) Visits and related services.

* * * * *

(d) Payment for items and services that do not meet the definition in paragraph (a)(1) of this section will generally be made under the Medicare Physician Fee Schedule on or after January 1, 2017.

(e) Payment for items and services that do not meet the definition in paragraph (a)(2) of this section will generally be made under the Medicare Physician Fee Schedule on or after January 1, 2019.

Dated: June 26, 2018.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: June 28, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–15958 Filed 7–25–18; 4:15 pm]

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