

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

[CMS–1678–P]

RIN 0938–AT03

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

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 2018 to implement changes arising from our continuing experience with these systems and certain provisions under the 21st Century Cures Act (Pub. L. 114–255). 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.

DATES: *Comment period:* 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 11, 2017.

ADDRESSES: In commenting, please refer to file code CMS–1678–P when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

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–1678–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–1678–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

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.)

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 Elisabeth

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

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

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

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Twi Jackson at 410–786–1159 or via email Twi.Jackson@cms.hhs.gov.

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

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

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

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

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

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

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang

at 410-786-1816 or via email Erick.Chuang@cms.hhs.gov or contact Elisabeth Daniel at 410-786-0237 or via email Elisabeth.Daniel1@cms.hhs.gov.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Elisabeth Daniel at 410-786-0237 or via email Elisabeth.Daniel1@cms.hhs.gov.

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 at 410-786-4617 or via email Marjorie.Baldo@cms.hhs.gov.

OPPS Packaged Items/Services, contact Elisabeth Daniel at 410-786-0237 or via email Elisabeth.Daniel1@cms.hhs.gov.

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 at 410-786-2682 or via email Marina.Kushnirova@cms.hhs.gov.

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

Potential Revisions to the Laboratory Date of Service Policy, contact Rasheeda Johnson at 410-786-3434 or via email Rasheeda.Johnson1@cms.hhs.gov or Susan Janeczko at 410-786-4529 or via email Susan.Janeczko@cms.hhs.gov.

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

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

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Lela Strong at 410-786-3213 or via email Lela.Strong@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov/>. Follow the search instructions on that Web site 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.

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Addenda Available Only Through the Internet on the CMS Web Site

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 Web site. 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>.

Alphabetical List of Acronyms Appearing in This Federal Register Document

AHA American Hospital Association
 AMA American Medical Association
 AMI Acute myocardial infarction
 APC Ambulatory Payment Classification
 API Application programming interface
 APU Annual payment update
 ASC Ambulatory surgical center
 ASCQR Ambulatory Surgical Center Quality Reporting
 ASP Average sales price
 AUC Appropriate use criteria
 AWP Average wholesale price
 BBA Balanced Budget Act of 1997, Public Law 105-33
 BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106-113

BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106-554
 BLS Bureau of Labor Statistics
 CAH Critical access hospital
 CAHPS Consumer Assessment of Healthcare Providers and Systems
 CAP Competitive Acquisition Program
 C-APC Comprehensive Ambulatory Payment Classification
 CASPER Certification and Survey Provider Enhanced Reporting
 CAUTI Catheter-associated urinary tract infection
 CBSA Core-Based Statistical Area
 CCM Chronic care management
 CCN CMS Certification Number
 CCR Cost-to-charge ratio
 CDC Centers for Disease Control and Prevention
 CED Coverage with Evidence Development
 CERT Comprehensive Error Rate Testing
 CFR Code of Federal Regulations
 CI Comment indicator
 CLABSI Central Line [Catheter] Associated Blood Stream Infection
 CLFS Clinical Laboratory Fee Schedule
 CMHC Community mental health center
 CMS Centers for Medicare & Medicaid Services
 CoP Condition of participation
 CPI-U Consumer Price Index for All Urban Consumers
 CPT Current Procedural Terminology (copyrighted by the American Medical Association)
 CR Change request
 CRC Colorectal cancer
 CSAC Consensus Standards Approval Committee
 CT Computed tomography
 CV Coefficient of variation
 CY Calendar year
 DFO Designated Federal Official
 DME Durable medical equipment
 DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
 DOS Date of service
 DRA Deficit Reduction Act of 2005, Public Law 109-171
 DSH Disproportionate share hospital
 EACH Essential access community hospital
 EAM Extended assessment and management
 ECD Expanded criteria donor
 EBRT External beam radiotherapy
 ECG Electrocardiogram
 ED Emergency department
 EDTC Emergency department transfer communication
 EHR Electronic health record
 E/M Evaluation and management
 ESRD End-stage renal disease
 ESRD QIP End-Stage Renal Disease Quality Improvement Program
 FACA Federal Advisory Committee Act, Public Law 92-463
 FDA Food and Drug Administration
 FFS [Medicare] Fee-for-service
 FY Fiscal year
 GAO Government Accountability Office
 GI Gastrointestinal
 GME Graduate medical education
 HAI Healthcare-associated infection
 HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems

HCERA Health Care and Education Reconciliation Act of 2010, Public Law 111–152	MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173	SCH Sole community hospital
HCP Health care personnel	MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309	SCOD Specified covered outpatient drugs
HCPCS Healthcare Common Procedure Coding System	MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173	SES Socioeconomic status
HCRIS Healthcare Cost Report Information System	MPFS Medicare Physician Fee Schedule	SI Status indicator
HCUP Healthcare Cost and Utilization Project	MR Medical review	SIA Systems Improvement Agreement
HEU Highly enriched uranium	MRA Magnetic resonance angiography	SIR Standardized infection ratio
HH QRP Home Health Quality Reporting Program	MRgFUS Magnetic Resonance Image Guided Focused Ultrasound	SNF Skilled nursing facility
HHS Department of Health and Human Services	MRI Magnetic resonance imaging	SRS Stereotactic radiosurgery
HIE Health information exchange	MRSA Methicillin-Resistant Staphylococcus Aureus	SRTR Scientific Registry of Transplant Recipients
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191	MS–DRG Medicare severity diagnosis-related group	SSA Social Security Administration
HOP Hospital Outpatient Payment [Panel]	MSIS Medicaid Statistical Information System	SSI Surgical site infection
HOPD Hospital outpatient department	MUC Measure under consideration	TEP Technical Expert Panel
HOP QDRP Hospital Outpatient Quality Data Reporting Program	NCCI National Correct Coding Initiative	TOPs Transitional Outpatient Payments
HPMS Health Plan Management System	NEMA National Electrical Manufacturers Association	USPSTF United States Preventive Services Task Force
IBD Inflammatory bowel disease	NHSN National Healthcare Safety Network	VBP Value-based purchasing
ICC Interclass correlation coefficient	NOTA National Organ and Transplantation Act	WAC Wholesale acquisition cost
ICD Implantable cardioverter defibrillator	NOS Not otherwise specified	
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification	NPI National Provider Identifier	
ICD–10 International Classification of Diseases, Tenth Revision	NQF National Quality Forum	
ICH In-center hemodialysis	NQS National Quality Strategy	
ICR Information collection requirement	NTIOL New technology intraocular lens	
IDTF Independent diagnostic testing facility	NUBC National Uniform Billing Committee	
IGI IHS Global Insight, Inc.	OACT [CMS] Office of the Actuary	
IHS Indian Health Service	OBRA Omnibus Budget Reconciliation Act of 1996, Public Law 99–509	
I/OCE Integrated Outpatient Code Editor	O/E Observed to expected event	
IOL Intraocular lens	OIG [HHS] Office of the Inspector General	
IORT Intraoperative radiation treatment	OMB Office of Management and Budget	
IPFQR Inpatient Psychiatric Facility Quality Reporting	ONC Office of the National Coordinator for Health Information Technology	
IPPS [Hospital] Inpatient Prospective Payment System	OPD [Hospital] Outpatient Department	
IQR [Hospital] Inpatient Quality Reporting	OPPS [Hospital] Outpatient Prospective Payment System	
IRF Inpatient rehabilitation facility	OPSF Outpatient Provider-Specific File	
IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program	OQR [Hospital] Outpatient Quality Reporting	
IT Information technology	OT Occupational therapy	
LCD Local coverage determination	PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93	
LDR Low dose rate	PCHQR PPS-Exempt Cancer Hospital Quality Reporting	
LTCH Long-term care hospital	PCR Payment-to-cost ratio	
LTCHQR Long-Term Care Hospital Quality Reporting	PDC Per day cost	
MAC Medicare Administrative Contractor	PDE Prescription Drug Event	
MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114–10	PE Practice expense	
MAP Measure Application Partnership	PEPPER Program Evaluation Payment Patterns Electronic Report	
MDH Medicare-dependent, small rural hospital	PHP Partial hospitalization program	
MedPAC Medicare Payment Advisory Commission	PHSA Public Health Service Act, Public Law 96–88	
MEG Magnetoencephalography	PN Pneumonia	
MFP Multifactor productivity	POS Place of service	
MGCRB Medicare Geographic Classification Review Board	PPI Producer Price Index	
MIEA–TRHCA Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006, Public Law 109–432	PPS Prospective payment system	
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275	PQRI Physician Quality Reporting Initiative	
MLR Medical loss ratio	PQRS Physician Quality Reporting System	
	QDC Quality data code	
	QIO Quality Improvement Organization	
	RFA Regulatory Flexibility Act	
	RHQDAPU Reporting Hospital Quality Data for Annual Payment Update	
	RTI Research Triangle Institute, International	
	RVU Relative value unit	
	SAD Self-administered drug	
	SAMS Secure Access Management Services	

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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, 2018. 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.

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2018, we are proposing to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.75 percent. This proposed increase factor is based on the proposed hospital inpatient market basket percentage increase of 2.9 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.4 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act. Based on this proposed update, we estimate that proposed total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2018 would be approximately \$70 billion, an increase of approximately \$5.7 billion compared to estimated CY 2017 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 proposed reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

- *Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes:* As we did for CY 2017, we are proposing to assign skin substitutes with a geometric mean unit cost (MUC) or a per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, for CY 2018, we are proposing that a skin substitute product that does not exceed either the CY 2018 MUC or PDC threshold for CY 2018, but was assigned to the high cost group for CY 2017, will be assigned to the high cost group for CY 2018. The goal of our proposal is to maintain similar levels of

payment for skin substitute products for CY 2018 while we study our current skin substitute payment methodology to determine whether refinements to our existing methodologies may be warranted.

- *Supervision of Hospital Outpatient Therapeutic Services:* In the CY 2009 and CY 2010 OPPS/ASC proposed rule and final rule with comment period, we clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals, CAHs, and in provider-based departments (PBDs) of hospitals, as set forth in the CY 2000 OPPS final rule with comment period. For several years, there has been a moratorium on the enforcement of the direct supervision requirement for CAHs and small rural hospitals, with the latest moratorium on enforcement expiring on December 31, 2016. In this proposed rule, we are proposing to reinstate the nonenforcement of direct supervision enforcement instruction for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for CY 2018 and CY 2019.

- *340B Drug Pricing:* We are proposing changes to our current Medicare Part B drug payment methodology for 340B hospitals that we believe would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. Such changes would allow the Medicare program and Medicare beneficiaries to share in some of the savings realized by hospitals participating in the 340B program. For CY 2018, we are proposing to exercise the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through and vaccines) acquired under the 340B program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. In addition, in this proposed rule, we state our intent to establish a modifier to identify whether a drug billed under the OPPS was purchased under the 340B Drug Discount Program.

- *Device Pass-Through Applications:* For CY 2018, we evaluate five devices for eligibility to receive pass through payments and are seeking comments on whether each of these items meet the criteria for device pass-through status.

- *Rural Adjustment:* We are proposing to continue the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This proposed adjustment would apply to all services 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 cost.

- *Cancer Hospital Payment Adjustment:* For CY 2018, 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, beginning CY 2018, section 16002(b) of the 21st Century Cures Act requires this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, a proposed target PCR of 0.89 would be used to determine the CY 2018 cancer hospital payment adjustment to be paid at cost report settlement. That is, the proposed payment adjustments would be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

- *Changes to the Inpatient Only List:* In CY 2017 OPPS/ASC rulemaking, we solicited comment from the public on whether total knee arthroplasty should be removed from the inpatient only list. Several commenters to the CY 2017 OPPS/ASC proposed rule were supportive of the removal. In addition, the Advisory Panel on Hospital Outpatient Payment recommended at its Summer 2016 meeting that this procedure be removed from the inpatient only list. After evaluating the procedure, for CY 2018, we are proposing to remove total knee arthroplasty from the inpatient-only list. In addition, we are soliciting comment on whether partial and total hip should also be removed from the inpatient only list and added to the ASC Covered Surgical Procedures List.

- *Comprehensive APCs:* For CY 2018, we are not proposing to create any new C-APCs or any extensive changes to the already established methodology used for C-APCs. There will be a total number of 62 C-APCs as of January 1, 2018. We note that for CY 2018, for the C-APC for Stereotactic Radio Surgery (SRS), specifically, C-APC 5627 (Level 7 Radiation Therapy), we are proposing to continue to make separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 30 days of the SRS treatment. In addition, the data collection period for SRS claims with modifier "CP" is set to conclude on December 31, 2017.

Accordingly, for CY 2018, we are deleting this modifier and discontinuing its required use.

- *Packaging Policies*: In CY 2015, we implemented a policy to conditionally package ancillary services assigned to APCs with a geometric mean cost of \$100 or less prior to packaging, with some exceptions, including drug administration services. For CY 2018, we are proposing to remove the exception for certain drug administration services and conditionally package payment for low-cost drug administration services. We are not proposing to package drug administration add-on codes for CY 2018, but are soliciting comments on this policy. In addition, we are broadly soliciting comments on existing packaging policies that exist under the OPPS, including those related to drugs that function as a supply in a diagnostic test or procedure or in a surgical procedure.

- *Payment Changes for X-rays Taken Using Computed Radiography Technology*: Section 502(b) of Division O, Title V of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1833(t)(16) of the Act by adding new subparagraph (F). New section 1833(t)(16)(F)(ii) of the Act provides for a phased-in reduction of payments for imaging services that are taken using computed radiography technology. That section provides that payments for such services furnished during CYs 2018 through 2022 shall be reduced by 7 percent, and if such services are furnished during CY 2023 or a subsequent year, payments for such services shall be reduced by 10 percent. We are establishing a new modifier that would be reported on claims to identify those HCPCS codes that describe X-rays taken using computed radiography technology. Specifically, this modifier, as allowed under the provisions of new section 1833(t)(16)(F)(ii) of the Act, would be reported with the applicable HCPCS code to describe imaging services that are taken using computed radiography technology/cassette-based imaging beginning January 1, 2018.

- *ASC Payment Update*: For CY 2018, we are proposing to increase payment rates under the ASC payment system by 1.9 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed increase is based on a projected CPI-U update of 2.3 percent minus a multifactor productivity adjustment required by the Affordable Care Act of 0.4 percentage point. Based on this proposed update, we estimate that proposed total payments to ASCs (including beneficiary cost sharing and

estimated changes in enrollment, utilization, and case-mix), for CY 2018 would be approximately \$4.68 billion, an increase of approximately \$155 million compared to estimated CY 2017 Medicare payments. In addition, we are soliciting comment on payment reform for ASCs, including the collection of cost data which may support a rate update other than CPI-U.

- *Comment Solicitation on ASC Payment Reform*: We are broadly interested in feedback from stakeholders and other interested parties on potential reforms to the current payment system, including, but not limited to (1) the rate update factor applied to ASC payments, (2) whether and how ASCs should submit data relating to costs, (3) whether ASCs should bill on the institutional claim form rather than the professional claim form, and (4) other ideas to improve payment accuracy for ASCs.

- *Changes to the List of ASC Covered Surgical Procedures*: For CY 2018, we are proposing to add three procedures to the ASC Covered Procedures List. In addition, we are soliciting comment on whether total knee arthroplasty, partial hip arthroplasty and total hip arthroplasty meet the criteria to be added to the ASC-CPL. We also are soliciting comments from stakeholders on whether there are codes that are outside the AMA-CPT surgical code range that nonetheless, should be considered to be a covered surgical procedure.

- *Potential Revisions to the Laboratory Date of Service Policy*: To better understand the potential impact of the current date of service (DOS) policy on billing for molecular pathology tests and advance diagnostic laboratory tests (ADLTs) under the new private payor rate-based Clinical Laboratory Fee Schedule (CLFS), we are soliciting public comments on billing for molecular pathology tests and ADLTs ordered less than 14 days of a hospital outpatient discharge.

- *Hospital Outpatient Quality Reporting (OQR) Program*: For the Hospital OQR Program, we are proposing to remove and delay certain measures for the CY 2020 payment determination and the CY 2021 payment determination and subsequent years. For the CY 2020 payment determination and subsequent years, we are proposing to remove OP–21: Median Time to Pain Management for Long Bone Fracture and OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures. We are also proposing to delay the OAS CAHPS Survey measures (OP–37–a–e) beginning with the CY 2020 payment determination (CY 2018

reporting). In addition, for the CY 2020 payment determination and subsequent years we are: (1) Providing clarification on our procedures for validation of chart-abstracted measures to note that the 50 poorest performing outlier hospitals will be targeted for validation; (2) proposing to formalize the validation educational review process, update it to allow corrections of incorrect validation results for chart-abstracted measures, and modify the CFR accordingly; (3) proposing to change the Notice of Participation (NOP) deadline and make corresponding changes to the CFR; (4) proposing to align the first quarter for which to submit data for hospitals that did not participate in the previous year's Hospital OQR Program and make corresponding changes to the CFR; (5) proposing to publicly report OP–18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients; and (6) proposing to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy with that used in our other quality reporting and value-based payment programs and make corresponding changes to the CFR. For the CY 2021 payment determination and subsequent years, we are proposing to remove: (1) OP–1: Median Time to Fibrinolysis; (2) OP–4: Aspirin at Arrival; (3) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional; and, (4) OP–25: Safe Surgery Checklist Use.

- *Ambulatory Surgical Center Quality Reporting (ASCQR) Program*: For the ASCQR Program, we are proposing to adopt measures and policies for the CY 2019 payment determination, 2021 payment determination, and CY 2022 payment determination and subsequent years. Specifically, we are proposing, beginning with the CY 2019 payment determination, to remove three measures from the ASCQR Program measure set: (1) ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing; (2) ASC–6: Safe Surgery Checklist Use; and, (3) ASC–7: Ambulatory Surgical Center Facility Volume Data on Selected Ambulatory Surgical Center Surgical Procedures. In addition, we are also proposing to delay the OAS CAHPS Survey measures (ASC–15a–e) beginning with the CY 2020 payment determination (CY 2018 data collection). Furthermore, starting with CY 2018 and beyond, we are proposing to: (1) Expand the CMS online tool to also allow for batch submission of measure data and make corresponding changes to the CFR; and (2) align the naming of the

Extraordinary Circumstances Exceptions (ECE) policy with that used in our other quality reporting and value-based payment programs and make corresponding changes to the CFR. We are also proposing, beginning with the CY 2021 payment determination, to adopt one new measure, ASC-16: Toxic Anterior Segment Syndrome. In addition, we are proposing, beginning with the CY 2022 payment determination, to adopt two new measures collected via claims, ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures and ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures.

3. Summary of Costs and Benefits

In sections XIX. and XX. 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 OPSS Update

(1) Impacts of All OPSS Proposed Changes

Table 38 in section XIX. of this proposed rule displays the distributional impact of all the proposed OPSS changes on various groups of hospitals and CMHCs for CY 2018 compared to all estimated OPSS payments in CY 2017. We estimate that the proposed policies in this proposed rule would result in a 1.9 percent overall increase in OPSS payments to providers. We estimate that proposed total OPSS payments for CY 2018, including beneficiary cost-sharing, to the approximate 3,900 facilities paid under the OPSS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately \$897 million compared to CY 2017 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our proposed OPSS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPSS. Continuing the provider-specific structure that we adopted beginning in CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate a 2.1 percent increase in CY 2018 payments to CMHCs relative to their CY 2017 payments.

(2) Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY

2018 IPPS proposed rule wage indexes results in no change for urban and rural hospitals under the OPSS. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data.

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

There are no significant impacts of our proposed CY 2018 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 2018, the adjustment amounts do not significantly impact the budget neutrality adjustments for these policies.

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

We estimate that, for most hospitals, the application of the proposed OPD fee schedule increase factor of 1.75 percent to the conversion factor for CY 2018 would mitigate the impacts of the budget neutrality adjustments. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that rural and urban hospitals would experience increases of approximately 2.0 percent for urban hospitals and 2.0 percent for rural hospitals. Classifying hospitals by teaching status or type of ownership suggests that these hospitals would receive similar increases.

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 proposed percentage change in estimated total payments by specialty groups under the proposed CY 2018 payment rates compared to estimated CY 2017 payment rates ranges between 5 percent for integumentary system procedures and 1 percent for genitourinary system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our proposed CY 2018 policies to significantly affect the number of hospitals that do not receive a full annual payment update.

d. Impacts of the ASCQR Program

We do not expect our proposed CY 2018 policies to significantly affect the number of ASCs that do not receive a full annual payment update.

B. Legislative and Regulatory Authority for the Hospital OPSS

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 OPSS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPSS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) made major changes in the hospital OPSS. The following Acts made additional changes to the OPSS: The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA) (Pub. L. 109-432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110-173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111-309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112-78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012

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

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

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

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. 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 Web site 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 PHS Act which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary

expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel, or the Panel). The 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 HOP 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), reviews clinical data, and advises 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 panel 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 Web site at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/>

FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.

3. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on August 22, 2016. 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 that the public should be aware of. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). Further information on this summer's 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 21–22, 2017" (82 FR 24128).

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 are the Data Subcommittee, the Visits and Observation Subcommittee, and the Subcommittee for APC Groups and Status Indicator (SI) Assignments. The Data Subcommittee is responsible for studying the data issues confronting the Panel and for recommending options for resolving them. The Visits and Observation Subcommittee reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPSS (for example, APC configurations and APC relative payment weights). The Subcommittee for APC Groups and SI Assignments advises the Panel on the following issues: 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; and the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made. The Panel recommended at the August 22, 2016 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the August 22, 2016 Panel meeting, namely conditional packaging, allogeneic hematopoietic stem cell transplantation, and outpatient total knee arthroplasty, were discussed in the CY 2017 OPSS/ASC final rule with comment period (81 FR 79562), the CY 2017 OPSS/ASC correction notice (82 FR 24), or are included in the sections

of this proposed rule that are specific to each recommendation. For discussions of past Panel meetings and recommendations, we refer readers to previously published OPSS/ASC proposed and final rules, the CMS Advisory Panel on Hospital Outpatient Payment Web site mentioned earlier in this section, and the FACA database at: <http://facadatabase.gov/>.

F. Public Comments Received on the CY 2017 OPSS/ASC Final Rule With Comment Period

We received 39 timely pieces of correspondence on the CY 2017 OPSS/ASC final rule with comment period that appeared in the **Federal Register** on November 14, 2016 (81 FR 79562), 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 OPSS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule), the potential limitation on clinical service line expansion or volume of services increases by nonexcepted off campus provider-based departments, and the Medicare Physician Fee Schedule (MPFS) payment rates for nonexcepted items and services furnished and billed by nonexcepted off-campus provider-based departments of hospitals. Summaries of the public comments are set forth in this proposed rule under the appropriate subject matter headings. Summaries of public comments on the MPFS payment rates for nonexcepted items and services will be set forth in the CY 2018 MPFS final rule with comment period.

II. Proposed Updates Affecting OPSS 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 OPSS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

In this CY 2018 OPSS/ASC proposed rule, for CY 2018, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2018, and before January 1, 2019 (CY 2018), using the same basic methodology that we described in the

CY 2017 OPPTS/ASC final rule with comment period (81 FR 79574 through 79595). 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 proposed APC relative payment weights for CY 2018, 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, 2016, and before January 1, 2017, 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 2018 OPPTS 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 2018 OPPTS/ASC proposed rule on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

Addendum N to this proposed rule includes the proposed list of bypass codes for CY 2018. The proposed list of bypass codes contains codes that were reported on claims for services in CY 2016 and, therefore, includes codes that were in effect in CY 2016 and used for billing, but were deleted for CY 2017. We retained these deleted bypass codes on the proposed CY 2018 bypass list because these codes existed in CY 2016 and were covered OPD services in that period, and CY 2016 claims data are used to calculate CY 2018 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 2018 are identified by asterisks (*) in the fourth column of Addendum N.

Table 1 below contains the list of codes that we are proposing to remove from the CY 2018 bypass list.

TABLE 1—PROPOSED HCPCS CODES TO BE REMOVED FROM THE CY 2018 BYPASS LIST

HCPCS code	HCPCS short descriptor
77305	Teletx isodose plan simple.
77310	Teletx isodose plan intermed.
77315	Teletx isodose plan complex.
77327	Brachytx isodose calc intern.
90801	Psy dx interview.
90802	Intac psy dx interview.
90804	Psytx office 20–30 min.
90805	Psytx off 20–30 min w/e&m.
90806	Psytx off 45–50 min.
90807	Psytx off 45–50 min w/e&m.
90808	Psytx office 75–80 min.
90809	Psytx off 75–80 w/e&m.
90810	Intac psytx off 20–30 min.
90811	Intac psytx 20–40 w/e&m.
90812	Intac psytx off 45–50 min.
90857	Intac group psytx.
90862	Medication management.
99201	Office/outpatient visit new.
99202	Office/outpatient visit new.
99203	Office/outpatient visit new.
99204	Office/outpatient visit new.
99205	Office/outpatient visit new.
99212	Office/outpatient visit est.
99213	Office/outpatient visit est.
99214	Office/outpatient visit est.
C1300	Hyperbaric oxygen.
G0340	Robt lin-radsurg fractx 2–5.
G9141	Influenza A H1N1, admin w cou.
M0064	Visit for drug monitoring.

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

For CY 2018, in this CY 2018 OPPTS/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 2018 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 2016 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2015. For the proposed CY 2018 OPPTS payment rates, we used the set of claims processed during CY 2016. 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 Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/index.html](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 2016 (the year of claims data we used to calculate the proposed CY 2018 OPPTS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2016 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 OPPTS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPTS) 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 OPPTS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of this proposed rule.

In the CY 2014 OPPTS/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, MRIs, CT scans, and cardiac catheterization. However, in response to the CY 2014 OPPTS/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 OPPTS to remove claims from providers that use a cost allocation method of “square feet” to calculate CCRs used to estimate costs associated with the CT and MRI APCs (78 FR 74847). Further, we finalized a transitional policy to estimate 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 weight using cost data from all providers, regardless of the cost allocation statistic employed.

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 imaging APC payment rates.

Table 2 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 3 below provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods.

TABLE 2—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	–4.3
5522	Level 2 Imaging without Contrast	6.1
5523	Level 3 Imaging without Contrast	1.1
5524	Level 4 Imaging without Contrast	7.3
5525	Level 5 Imaging without Contrast	4.5
5571	Level 1 Imaging with Contrast	10.1
5572	Level 2 Imaging with Contrast	9.4
5573	Level 3 Imaging with Contrast	6.0
8005	CT and CTA without Contrast Composite	13.5
8006	CT and CTA with Contrast Composite	10.5
8007	MRI and MRA without Contrast Composite	6.8
8008	MRI and MRA with Contrast Composite	7.2

TABLE 3—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	0.0397	0.0559	0.0828	0.1072
Square Feet Only	0.0332	0.0493	0.0726	0.0972
Direct Assign	0.0591	0.0680	0.1039	0.1247
Dollar Value	0.0485	0.0644	0.0941	0.1203
Direct Assign and Dollar Value	0.0485	0.0644	0.0949	0.1200

Our analysis shows that since the CY 2014 OPSS in which we established the transition policy, the number of valid MRI CCRs has increased by 15.6 percent to 2,142 providers and the number of valid CT CCRs has increased by 13.4 percent to 2,219 providers. However, we note that, as shown in Table 2 above, nearly all imaging APCs would see an increase in payment rates for CY 2018 if claims from providers that report “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 3 above. We believe that the imaging CCRs that we have are appropriate for ratesetting. However, in response to provider concerns and to provide added flexibility for hospitals to improve their cost allocation methods, we are proposing to extend the transition policy an additional year, for the CY 2018 OPSS.

For the CY 2018 OPSS, we are proposing to continue to remove claims from providers that use a cost allocation method of “square feet” to calculate CCRs used to estimate costs with the CT and MRI APCs identified in Table 2 above. Beginning in CY 2019, we would estimate the imaging APC relative payment weights using cost data from all providers, regardless of the cost allocation statistic 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 OPSS payment rates for CY 2018. The Hospital OPSS page on the CMS Web site 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 Web site, <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>, includes information about obtaining the “OPSS Limited Data Set,” which now includes the additional variables previously available only in the OPSS Identifiable Data Set, including ICD–10–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2016 claims that were used to calculate the proposed payment rates for the CY 2018 OPSS.

In the history of the OPSS, 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 2018, in this CY 2018 OPPS/ASC proposed rule, we are proposing to continue to use geometric mean costs to calculate the proposed relative weights on which the CY 2018 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 2018 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). 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.

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 2018 OPPS/ASC proposed rule on the CMS Web site 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.

For CY 2018, in this CY 2018 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 2018 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 2018 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.e. of the CYs 2014 through 2017 OPPS/ASC final rules with comment period (78 FR 74861 through 74910, 79 FR 66798 through 66810, 80 FR 70325

through 70339, and 81 FR 79580 through 79585, respectively), we defined a comprehensive APC (C-APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C-APCs. We 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 Web site) for the proposed CY 2018 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).

We are inviting public comments on our proposals.

(b) Pathogen-Reduced Platelets and Rapid Bacterial Testing for Platelets

In March 2016, the Food and Drug Administration (FDA) issued draft guidance for the health care industry entitled "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion" (available at: <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>). This draft guidance recommended the use of rapid bacterial testing devices secondary to testing using a culture-based bacterial detection device or pathogen-reduction technology for platelets to adequately control the risk of bacterial contamination of platelets.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70322), we

established HCPCS code P9072 (Platelets, pheresis, pathogen reduced, each unit). The CMS HCPCS Workgroup later revised HCPCS code P9072 to include the use of pathogen-reduction technology or rapid bacterial testing. Specifically, the descriptor for this code was revised, effective January 1, 2017, to read as follows: HCPCS code P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit). The payment rate for HCPCS code P9072 is based on a crosswalk to HCPCS code P9037 (Platelets, pheresis, leukocyte reduced, irradiated, each unit). We refer readers to the CY 2016 OPPS/ASC final rule with comment period for a further discussion of crosswalks for pathogen-reduced blood products (80 FR 70323).

After the release of the CY 2017 OPPS/ASC final rule with comment period, several blood and blood product stakeholders expressed concerns about the revised code descriptor for HCPCS code P9072. The stakeholders believed that the revision to HCPCS code P9072 to describe both pathogen reduction and rapid bacterial testing was an inappropriate code descriptor. They stated that separate coding is needed to describe each service because each service is distinct. The stakeholders also noted that the code descriptor for HCPCS code P9072 results in hospitals receiving the same payment rate for platelets undergoing rapid bacterial testing that the hospitals receive for platelets treated with pathogen reduction technology, despite the fact that pathogen reduction is significantly more expensive than rapid bacterial testing.

After review of the concerns expressed by the blood and blood product stakeholders, the CMS HCPCS Workgroup deactivated HCPCS code P9072 for Medicare reporting and replaced the code with two new HCPCS codes effective July 1, 2017. Specifically, effective July 1, 2017, HCPCS code Q9988 (Platelets, pheresis, pathogen reduced, each unit) shall be used to report the use of pathogen-reduction technology and HCPCS code Q9987 (Pathogen(s) test for platelets) shall be used to report rapid bacterial testing or other pathogen tests for platelets, instead of HCPCS code P9072. We note that HCPCS code Q9987 should be reported to describe the test used for the detection of bacterial contamination in platelets as well as any other test that may be used to detect pathogen contamination. HCPCS code Q9987 should not be used for reporting donation testing for infectious agents such as viruses. The coding changes associated with these codes were published on the CMS HCPCS Quarterly

Update Web site, effective July 2017, at: <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.html>. In addition, for OPPS, we announced the new HCPCS codes that were effective July 1, 2017 through the July 2017 OPPS quarterly update Change Request (Transmittal 3783, Change Request 10122, dated May 26, 2017). We note that, effective July 1, 2017, HCPCS code Q9988 is assigned to APC 9536 (Pathogen Reduced Platelets), with a payment rate of \$647.12, and HCPCS code Q9987 is assigned to New Technology APC 1493, with a payment rate of \$25.50.

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 was new for CY 2016, there were no claims data 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 this HCPCS code based on a crosswalk to existing blood product HCPCS code P9037, 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.

Although our standard practice for new codes involves using claims data to set payment rates once claims data become available, we are 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 much less costly technology than pathogen reduction. In addition, as noted above, effective January 2017, the code descriptor for HCPCS code P9072 was, in fact, changed to also describe rapid bacterial testing of platelets and, effective July 1, 2017, the descriptor for the temporary successor code for HCPCS code P9072 (that is, 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 believe that claims for pathogen reduced platelets may potentially reflect certain claims for rapid bacterial testing of platelets. The geometric mean costs based on submitted claims for HCPCS code P9072 based on available claims data from CY 2016 is \$491.53, which is a 24-percent reduction from the CY 2017 payment rate of \$647.12. Because we believe that there may have been confusion related to ongoing discussions about changes to the original code descriptor for HCPCS code P9072, we believe it is appropriate to continue to crosswalk the payment amount for at least 1 additional year. Therefore, we are proposing for CY 2018 to determine the payment rate for HCPCS code Q9988 (the successor code to HCPCS code P9072) by continuing to use the payment rate that has been crosswalked from HCPCS code P9037 of \$647.12.

In this CY 2018 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for HCPCS codes Q9987 and Q9988 for the CY 2018 OPPS update. The proposed payment rates for HCPCS codes Q9987 and Q9988 can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

(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 OPSS. We refer readers to the CY 2016 OPSS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPSS payment for brachytherapy sources.

In this CY 2018 OPSS/ASC proposed rule, for CY 2018, we are proposing to use the costs derived from CY 2016 claims data to set the proposed CY 2018 payment rates for brachytherapy sources because CY 2016 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 2018 OPSS. 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 OPSS, 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 OPSS/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 and C2699, 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 OPSS/ASC final rule with comment period (72 FR 66785). For CY 2018 and subsequent years, we also are proposing to continue the policy we first implemented in the CY 2010 OPSS/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 OPSS/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 2018 payment rates for brachytherapy sources are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) and are identified with status indicator "U". For CY 2018, we are proposing to assign status indicator "E2" (Items and Services for Which Pricing Information and Claims Data Are Not Available) to HCPCS code C2645 (Brachytherapy planar, p-103) because this code was not reported on CY 2016 claims. Therefore, we are unable to calculate a proposed payment rate based on the general OPSS ratesetting methodology described earlier. Although HCPCS code C2645 became effective January 1, 2016, and although we would expect that if a hospital furnished a brachytherapy source described by this code in CY 2016, HCPCS code C2645 should appear on the CY 2016 claims, there are no CY 2016 claims reporting this code. In addition, unlike new brachytherapy sources HCPCS codes, we will not consider external data to determine a proposed payment rate for HCPCS code C2645 for CY 2018. Therefore, we are proposing to assign status indicator "E2" to HCPCS code C2645.

In addition, we assigned status indicator "E2" to HCPCS code C2644 (Brachytherapy cesium-131 chloride) because this code was not reported on any CY 2015 claims (that is, there were no Medicare claims submitted by any hospitals in 2015 that reported this HCPCS code). In our review of CY 2016 claims (which are used to set rates for CY 2018), we found that one hospital submitted one claim reporting HCPCS code C2644. Therefore, we are proposing to assign status indicator "U" to HCPCS code 2644, and our payment rates for HCPCS code C2644 will be based on this information.

We are inviting public comments on our proposals.

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 2018

(1) Background

In the CY 2014 OPSS/ASC final rule with comment period (78 FR 74861

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

A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C-APCs as a category broadly for OPSS payment and implemented 25 C-APCs beginning in CY 2015 (79 FR 66809 through 66810). In the CY 2016 OPSS/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. In the CY 2017 OPSS/ASC final rule with comment period (81 FR 79584 through 79585), we finalized another 25 C-APCs.

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

Services excluded from the C-APC policy under the OPSS include services that are not covered OPD services, services that cannot by statute be paid for under the OPSS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in

accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through 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 Web site).

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 to be not 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). We sum all line item charges for services included on the C-APC claim, convert the charges to costs, and calculate the comprehensive geometric mean cost of one unit of each service assigned to status indicator “J1”. (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 their 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 reported 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 OPPI/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

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

Once we have determined that a particular code combination of “J1” services (or combinations of “J1” services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C-APC within the clinical family unless the primary service is already assigned to the highest cost APC within the C-APC clinical family or assigned to the only C-APC in a clinical family. We do

not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C-APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family (79 FR 66802).

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

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2018, in this CY 2018 OPPI/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 2018, 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 Web site).

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 2018

For CY 2018 and subsequent years, in this CY 2018 OPPI/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. A

discussion of the C-APC payment policy methodology can be found at 81 FR 79583.

As a result of our annual review of the services and APC assignments under the OPPI, we are not proposing any additional C-APCs to be paid under the existing C-APC payment policy beginning in CY 2018. Table 4 below lists the proposed C-APCs for CY 2018, all of which were established in past rules. All C-APCs are displayed in Addendum J to this proposed rule. Addendum J to this proposed rule (which is available via the Internet on the CMS Web site) 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 4—PROPOSED CY 2018 C-APCs

C-APC	CY 2018 APC title	Clinical family
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
5164	Level 4 ENT Procedures	ENTXX
5165	Level 5 ENT Procedures	ENTXX
5166	Cochlear Implant Procedure	COCHL
5191	Level 1 Endovascular Procedures	VASCX
5192	Level 2 Endovascular Procedures	VASCX
5193	Level 3 Endovascular Procedures	VASCX
5194	Level 4 Endovascular Procedures	VASCX
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
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

TABLE 4—PROPOSED CY 2018 C-APCs—Continued

C-APC	CY 2018 APC title	Clinical family
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.

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) Brachytherapy Insertion Procedures

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584), we finalized 25 new C-APCs. Some of the HCPCS codes assigned to the C-APCs established for CY 2017 described surgical procedures for inserting brachytherapy catheters/needles and other related brachytherapy procedures such as the insertion of tandem and/or ovoids and the insertion of Heyman capsules. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583), we stated that we received public comments which noted that claims that included several insertion codes for brachytherapy devices (namely CPT codes 57155 (Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy); 20555 (Placement of needles or catheters into muscle and/or soft tissue for subsequent interstitial radioelement application (at the time of or subsequent to the procedure)); 31643 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application); 41019 (Placement of needles, catheters, or

other device(s) into the head and/or neck region (percutaneous, transoral, or transnasal) for subsequent interstitial radioelement application); 43241 (Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube catheter); 55920 (Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application); and 58346 (Insertion of Heyman capsules for clinical brachytherapy)) often did not also contain a brachytherapy treatment delivery code (CPT codes 77750 through 77799). The commenters concluded that brachytherapy delivery charges are being underrepresented in ratesetting under the C-APC methodology because a correctly coded claim should typically include an insertion and treatment delivery code combination. The commenters stated that the insertion procedure and brachytherapy treatment delivery generally occur on the same day or within the same week and therefore the services should appear on a claim together. We indicated that we would not exclude claims from the CY 2017 ratesetting calculation because we

generally do not remove claims from the claims accounting when stakeholders believe that hospitals included incorrect information on some claims. However, we stated that we would examine the claims for the brachytherapy insertion codes in question and determine if any future adjustment to the methodology (or possibly code edits) would be appropriate.

We analyzed the claims that include brachytherapy insertion codes assigned to status indicator “J1” and that received payment through a C-APC, and we determined that several of these codes are frequently billed without an associated brachytherapy treatment code. As mentioned above, stakeholders have expressed concerns that using claims for ratesetting for brachytherapy insertion procedures that do not also include a brachytherapy treatment code may not capture all of the costs associated with the insertion procedure. To address this issue and base payment on claims for the most common clinical scenario, for CY 2018 and subsequent years, we are establishing a code edit that requires a brachytherapy treatment

code when a brachytherapy insertion code is billed.

As noted in section II.A.2.c. of this proposed rule, we also are proposing to delete composite APC 8001 (LDR Prostate Brachytherapy Composite) and assign HCPCS code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to status indicator “J1” and to provide payment for this procedure through the C-APC payment

methodology similar to the payment methodology for other surgical insertion procedures related to brachytherapy. Specifically, when HCPCS code 55875 is the primary service reported on a hospital outpatient claim, we are proposing to package payments for all adjunctive services reported on the claim into the payment for HCPCS code 55875. We are proposing to assign HCPCS code 55875 to C-APC 5375 (Level 5 Urology and Related Services). The code edit for claims with

brachytherapy services described above that will be effective January 1, 2018 will require the brachytherapy application HCPCS code 77778 (Interstitial radiation source application; complex) to be included on the claim with the brachytherapy insertion procedure (HCPCS code 55875). The brachytherapy insertion codes that will be required to be billed with a brachytherapy treatment code are listed in Table 5 listed below.

TABLE 5—PROPOSED BRACHYTHERAPY INSERTION PROCEDURES ASSIGNED TO STATUS INDICATOR “J1”

HCPCS code	Long descriptor
19296	Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy.
19298	Placement of radiotherapy after loading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance.
19499	Unlisted procedure, breast.
20555	Placement of needles or catheters into muscle and/or soft tissue for subsequent interstitial radioelement application (at the time of or subsequent to the procedure).
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application.
41019	Placement of needles, catheters, or other device(s) into the head and/or neck region (percutaneous, transoral, or transnasal) for subsequent interstitial radioelement application.
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube catheter.
55875	Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy.
55920	Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application.
57155	Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy.
58346	Insertion of Heyman capsules for clinical brachytherapy.

(4) C-APC 5627 (Level 7 Radiation Therapy) Stereotactic Radiosurgery (SRS)

Stereotactic radiosurgery (SRS) is a type of radiation therapy that targets multiple beams of radiation to precisely deliver radiation to a brain tumor while sparing the surrounding normal tissue. SRS treatment can be delivered by Cobalt-60-based (also referred to as gamma knife) technology or robotic linear accelerator-based (LINAC)-based technology. As stated in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70336), section 634 of the American Taxpayer Relief Act (ATRA) of 2012 (Pub. L. 112-240) amended section 1833(t)(16) of the Act by adding a new subparagraph (D) to require that OPPTS payments for Cobalt-60-based SRS be reduced to equal that of payments for LINAC-based SRS for covered OPD services furnished on or after April 1, 2013. Because section 1833(t)(16)(D) of the Act requires equal payment for SRS treatment delivered by Cobalt-60-based or LINAC-based technology, the two types of services involving SRS delivery instruments (which are described by HCPCS code 77371 (Radiation treatment delivery, stereotactic radiosurgery [SRS], complete course of treatment cranial lesion(s) consisting of 1 session;

multi-source Cobalt 60-based) and HCPCS code 77372 (Linear accelerator-based)) are assigned to the same C-APC (C-APC 5627 Level 7 Radiation Therapy).

In the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70336), we stated that we had identified differences in the billing patterns for SRS procedures delivered using Cobalt-60-based and LINAC-based technologies. In particular, our claims data analysis revealed that services involving SRS delivered by Cobalt-60-based technologies (as described by HCPCS code 77371) typically included SRS treatment planning services (for example, imaging studies, radiation treatment aids, and treatment planning) and the actual deliveries of SRS treatment on the same date of service and reported on the same claim. In contrast, claims data analysis results revealed that services involving SRS delivered by LINAC-based technologies (as described by HCPCS code 77372) frequently included services related to SRS treatment (for example, imaging studies, radiation treatment aids, and treatment planning) that were provided on different dates of service and reported on claims separate from the actual delivery of SRS treatment.

We stated in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70336) that the intent of the C-APC policy is to package payment for all services adjunctive to the primary “J1” procedure and that we believed that all essential planning and preparation services related to the SRS treatment are adjunctive to the SRS treatment delivery procedure. Therefore, payment for these adjunctive services should be packaged into the C-APC payment for the SRS treatment instead of reported on a different claim and paid separately. To identify services that are adjunctive to the primary SRS treatment described by HCPCS codes 77371 and 77372, but reported on a different claim, we established modifier “CP” which became effective in CY 2016 and required the use of the modifier for CY 2016 and CY 2017.

To ensure appropriate ratesetting for the SRS C-APC, we believed it was necessary to unbundle payment for the adjunctive services for CY 2016 and CY 2017. Therefore, we finalized a policy to change the payment for SRS treatment for the 10 SRS planning and preparation services identified in our claims data (HCPCS codes 70551, 70552, 70553, 77011, 77014, 77280, 77285, 77290, 77295, and 77336) that were reported

differentially using HCPCS codes 77371 and 77372 both on the same claim as the SRS services and on claims 1 month prior to the delivery of SRS services. These codes were removed from the geometric mean cost calculations for C-APC 5627. In addition, for CY 2016 and CY 2017, we provided separate payment for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology, even when the planning service was included on the same claim as the primary "J1" SRS treatment service. The use of the modifier "CP" was not required to identify these 10 planning and preparation codes.

The data collection period for SRS claims with modifier "CP" began on January 1, 2016 and concludes on December 31, 2017. Based on our analysis of preliminary data collected with modifier "CP", we have identified some additional services that are adjunctive to the primary SRS treatment and reported on a different claim outside of the 10 SRS planning and preparation codes that were removed from the SRS C-APC costs calculations and paid separately.

However, the "CP" modifier has been used by a small number of providers since its establishment. In addition, our analysis showed that several of the HCPCS codes that were billed with modifier "CP" belonged to the group of 10 SRS planning and preparation codes that we pay separately and do not require the use of modifier "CP". Also, some providers erroneously included the modifier when reporting the HCPCS code for the delivery of the LINAC-based SRS treatment. As stated above, the data collection period for SRS claims with modifier "CP" was set to conclude on December 31, 2017. Accordingly, for CY 2018, we are deleting this modifier and discontinuing its required use.

For CY 2018, we also are proposing to continue to make separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 1 month of the SRS treatment. The continued separate payment of these services will allow us to complete our analysis of the claims data including modifier "CP" from both CY 2016 and CY 2017 claims. As stated in the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79583), we will consider in the future whether repackaging all adjunctive services (planning, preparation, and imaging,

among others) back into cranial single session SRS is appropriate.

We are inviting public comments on these proposals.

(5) Proposed Complexity Adjustment for Blue Light Cystoscopy Procedures

As discussed in prior OPPTS/ASC final rules with comment period, and most recently in the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79668), we continue to believe that Cysview® (hexaminolevulinate HCl) (described by HCPCS code C9275) is a drug that functions as a supply in a diagnostic test or procedure and is therefore packaged with payment for the primary procedure. In addition, as discussed in section II.A.2.b.(1) of this proposed rule, drugs that are not eligible for pass-through payment are always packaged when billed with a comprehensive service. To maintain the integrity of a prospective payment system, we believe it is generally not appropriate to allow exceptions to our drug packaging policy or comprehensive APC policy that would result in separate payment for the drug based on the product's ASP+6 percent payment rate. While we are not proposing to pay separately for Cysview®, we have heard concerns from stakeholders that the payment for blue light cystoscopy procedures involving Cysview® may be creating a barrier to access reasonable and necessary care for which there may not be a clinically comparable alternative. Therefore, we are revisiting our payment policy for blue light cystoscopy procedures. As described in more detail below, we believe certain code combinations for blue light cystoscopy procedures should be eligible to qualify for a complexity adjustment, given the unique properties of the procedure and resource costs.

Traditionally, white light (or standard) cystoscopy, typically performed by urologists, has been the gold standard for diagnosing bladder cancer. Enhanced bladder cancer diagnostics, such as narrow band imaging or blue light cystoscopy, increase tumor detection in nonmuscle invasive bladder cancer over white light cystoscopy alone, thus enabling more precise tumor removal by the urologist. Blue light cystoscopy can only be performed after performance of white light cystoscopy. Because blue light cystoscopy requires specialized imaging equipment to view cellular uptake of the dye that is not otherwise used in white light cystoscopy procedures, some practitioners consider blue light cystoscopy to be a distinct and adjunctive procedure to white light cystoscopy. However, the current CPT

coding structure for cystoscopy procedures does not identify blue light cystoscopy in the coding descriptions separate from white light cystoscopy. Therefore, the existing cystoscopy CPT codes do not distinguish cystoscopy procedures involving only white light cystoscopy from those involving both white and blue light procedures, which require additional resources compared to white light cystoscopy alone.

After discussion with our clinical advisors (including a urologist), we believe that blue light cystoscopy represents an additional elective but distinguishable service as compared to white light cystoscopy that in some cases may allow greater detection of bladder tumors in beneficiaries relative to white light cystoscopy alone. Given the additional equipment, supplies, operating room time, and other resources required to perform blue light cystoscopy in addition to white light cystoscopy, for CY 2018, we are proposing to create a new HCPCS C-code to describe blue light cystoscopy (HCPCS code C97XX (Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure)) and to allow for a complexity adjustment to APC 5374 (Level 4 Urology and Related Services) for certain code combinations in APC 5373 (Level 3 Urology and Related Services). Specifically, to determine which code pair combinations of proposed new HCPCS code C97XX and cystoscopy procedure would qualify for a complexity adjustment, we first crosswalked the costs of HCPCS code C9275 (Hexaminolevulinate hcl) to the proposed new HCPCS code C97XX assigned status indicator "N". Next, we identified the procedure codes used to describe white light cystoscopy of the bladder which include the following CPT codes and APC assignments:

- APC 5372 (Level 2 Urology and Related Services)
 - CPT code 52000
- APC 5373 (Level 3 Urology and Related Services)
 - CPT code 52204
 - CPT code 52214
 - CPT code 52224
- APC 5374 (Level 4 Urology and Related Services)
 - CPT code 52234
 - CPT code 52235
- APC 5375 (Level 5 Urology and Related Services)
 - CPT code 52240

Because APC 5372 is not a C-APC, cystoscopy procedures assigned to Level 2 Urology are not eligible for a complexity adjustment, and therefore,

we did not analyze these codes to determine whether they were eligible for a complexity adjustment. We modeled the data to determine which code pair combinations exceed the claim frequency and cost threshold in APC 5373, APC 5374, and APC 5375, which are all C-APCs. Results of our analysis indicate that the code pair combination of proposed new HCPCS code C97XX and cystoscopy procedures assigned to APC 5373 would be eligible for a complexity adjustment based on current criteria and cost data because they meet the frequency and cost criteria thresholds. Likewise, our results indicate that the combination of proposed new HCPCS code C97XX and cystoscopy procedures assigned to APC 5374 and APC 5375 would not qualify for a complexity adjustment because they do not meet the frequency and cost criteria thresholds.

Under the C-APC policy, blue light cystoscopy would be packaged, but when performed with a cystoscopy procedure in APC 5373 and reported with proposed new HCPCS code C97XX in addition to the cystoscopy CPT code, there would be a complexity adjustment to the next higher level APC in the series, resulting in a higher payment than for the white light cystoscopy procedure alone. That is, if the code pair combination of proposed new HCPCS code C97XX with CPT code 52204, 52214, or 52224 is reported on a claim, the claim will qualify for payment reassignment from APC 5373 to APC 5374. We plan to track the utilization and the costs associated with white light/blue light cystoscopy procedure combinations that will receive a complexity adjustment.

We are inviting public comments on our CY 2018 proposal to allow for a complexity adjustment when a white light followed by blue light cystoscopy procedure is performed. In addition, we are seeking public comments on whether alternative procedures, such as narrow band imaging, may be disadvantaged by this proposed policy.

(6) Analysis of C-APC Packaging under the OPSS

In the CY 2017 OPSS/ASC final rule with comment period (81 FR 79584), we accepted a recommendation made at the August 22, 2016 HOP Panel meeting to analyze the effects of C-APCs. The HOP panel recommendation did not elucidate specific concerns with the C-APC policy or provide detailed recommendations on particular aspects of the policy to analyze. Therefore, we took a broad approach in studying HCPCS codes and APCs subject to the C-APC policy to determine whether

aberrant trends in the data existed. Overall, we observed no such aberrancies and believe that the C-APC policy is working as intended.

Specifically, using OPSS claims data from the CY 2016 final rule, the CY 2017 final rule, and the CY 2018 proposed rule, which reflect an observation period of CY 2014 to CY 2016, we examined the effects of C-APCs and their impact on OPSS payments. We started with all hospital outpatient claims billed on the 13X claim-type and from that, separately identified HCPCS codes and APCs that were subject to the comprehensive methodology in CYs 2015 and 2016 (that is, HCPCS codes or APCs assigned status indicator "J1" or "J2"). Next, we analyzed the claims to create a subset of claims that contain the HCPCS codes and APCs that were subject to the comprehensive methodology. Using the claims noted above, we analyzed claim frequency, line frequency, number of billing units, and the total OPSS payment between CYs 2014 and 2016 for each HCPCS and APC that had been previously identified. In reviewing the cost statistics for HCPCS codes for procedures with status indicator "S", "T", or "V" in CY 2014 that were assigned to a C-APC in either CY 2015 or CY 2016, overall, we observed an increase in claim line frequency, units billed, and Medicare payment, which suggest that the C-APC payment policy did not adversely affect access or reduce payments to hospitals. Decreases in these cost statistics would suggest our comprehensive packaging logic is not working as intended and/or the C-APC payment rates were inadequate, resulting in lower volume due to migration of services to other settings or the cessation of providing these services. Likewise, because the cost statistics of major separately payable codes (that is, HCPCS codes with status indicator "S", "T", or "V") that were packaged into a C-APC prospectively were consistent with the cost statistics of the codes packaged on the claim in actuality, indicate that costs were appropriately redistributed, we believe the C-APC payment methodology is working as intended.

c. Proposed Calculation of Composite APC Criteria-Based Costs

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

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

In this CY 2018 OPSS/ASC proposed rule, for CY 2018 and subsequent years, we are proposing to continue our composite APC payment policies for mental health services and multiple imaging services, as discussed below. As discussed in section II.A.2.b. of this proposed rule, we are proposing to assign CPT code 55875 (Transperineal placement of needs or catheters into prostate for interstitial radioelement application, with or without cystoscopy) a status indicator of "J1" and assign it to a C-APC. In conjunction with this proposal, we also are proposing to delete the low dose rate (LDR) prostate brachytherapy composite APC for CY 2018 and subsequent years.

(1) Mental Health Services Composite APC

In this CY 2018 OPSS/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 OPSS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPSS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2017 OPPTS/ASC final rule (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 new APC 5863 (Partial Hospitalization (3 or more services per day)). For CY 2018, and subsequent years, 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 (Mental Health Services Composite) for CY 2018. In addition, we are proposing to set the payment rate for composite APC 8010 for CY 2018 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 payment rate for composite APC 8010. Under this policy, the I/OCE would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 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 OPPTS than the highest partial hospitalization per diem payment rate for hospitals.

(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 OPPTS/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 OPPTS 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 OPPTS/ASC final rule with comment period (73 FR 68559 through 68569).

In this CY 2018 OPPTS/ASC proposed rule, we are proposing, for CY 2018 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 2018 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 2016 claims available for this CY 2018 OPPTS/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 used to calculate the final geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPTS/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 OPPTS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this CY 2018 OPPTS/ASC proposed rule (which is available via the Internet on the CMS Web site) and are discussed in more detail in section II.A.1.b. of this CY 2018 OPPTS/ASC proposed rule.

For this CY 2018 OPPTS/ASC proposed rule, we were able to identify approximately 634,918 “single session” claims out of an estimated 1.7 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 36 percent of all eligible claims, to calculate the proposed CY 2018 geometric mean costs for the multiple imaging composite APCs. Table 6 of this CY 2018 OPPTS/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 2018.

TABLE 6—PROPOSED OPPTS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs

Family 1—Ultrasound	
Proposed CY 2018 APC 8004 (Ultrasound Composite)	
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.
Family 2—CT and CTA with and without Contrast	
Proposed CY 2018 APC 8005 (CT and CTA without Contrast Composite)*	Proposed CY 2018 Approximate APC Geometric Mean Cost = \$280
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 2018 APC 8006 (CT and CTA with Contrast Composite)	Proposed CY 2018 Approximate APC Geometric Mean Cost = \$503
70487	Ct maxillofacial w/dye.
70460	Ct head/brain w/dye.
70470	Ct head/brain w/o & w/dye.
70481	Ct orbit/ear/fossa w/dye.
70482	Ct orbit/ear/fossa w/o & w/dye.
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.

TABLE 6—PROPOSED OPPTS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs—Continued

Family 3—MRI and MRA with and without Contrast	
Proposed CY 2018 APC 8007 (MRI and MRA without Contrast Composite)*	Proposed CY 2018 Approximate APC Geometric Mean Cost = \$571
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.
C8904	MRI w/o cont, breast, uni.
C8907	MRI w/o cont, breast, bi.
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 2018 APC 8008 (MRI and MRA with Contrast Composite)	Proposed CY 2018 Approximate APC Geometric Mean Cost = \$888
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.

TABLE 6—PROPOSED OPSS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs—Continued

C8912	MRA w/cont, lwr ext.
C8914	MRA w/o fol w/cont, lwr ext.
C8918	MRA w/cont, pelvis.
C8920	MRA w/o fol w/cont, pelvis.
C8931	MRA, w/dye, spinal canal.
C8933	MRA, w/o&w/dye, spinal canal.
C8934	MRA, w/dye, upper extremity.
C8936	MRA, w/o&w/dye, upper extr.

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

3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPSS

Like other prospective payment systems, the OPSS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular patient. The OPSS packages payment for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPSS to maximize hospitals’ incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient’s needs, rather than to routinely use a more expensive item, which 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 payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPSS since its implementation in August 2000. For an extensive discussion of the history and background of the OPSS packaging policy, we refer readers to the CY 2000 OPSS final rule (65 FR 18434), the CY 2008 OPSS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPSS/ASC final rule with comment period (78 FR 74925), the CY 2015 OPSS/ASC final rule with comment period (79 FR 66817), the CY 2016 OPSS/ASC final rule with comment period (80 FR 70343), and the CY 2017 OPSS/ASC final rule with comment period (81 FR 79592). As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPSS packaging policies. Most, but not necessarily all, items and services currently packaged in the OPSS are listed in 42 CFR 419.2(b). Our overarching goal is to make OPSS payments for all services paid under the OPSS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPSS to determine which OPSS services can be packaged to further achieve the objective of advancing the OPSS toward a more prospective payment system.

For CY 2018, we examined the items and services currently provided under the OPSS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment

would be appropriately packaged into payment 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 OPSS packaging policies or a logical expansion of those existing OPSS packaging policies. In this proposed rule, for CY 2018, 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 proposed packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code. Below we discuss the items and services that we are proposing to package beginning in CY 2018.

b. CY 2018 Drug Administration Packaging Proposal

(1) Background of Drug Administration Packaging Policy

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

in response to stakeholder comments on the appropriateness of packaging drug administration add-on codes, we did not finalize our proposal to package drug administration add-on codes (78 FR 74945).

In the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66819 through 66822), we conditionally packaged payment for ancillary services assigned to APCs with a geometric mean cost of less than or equal to \$100 (prior to application of the conditional packaging status indicator). The ancillary services that we identified are primarily minor diagnostic tests and procedures that are often performed with a primary service, although there are instances where hospitals provide such services alone and without another primary service during the same encounter. Under this policy, we assigned the conditionally packaged services to status indicator “Q1”, which indicates that the service is separately payable when not billed on the same claim as a HCPCS code assigned status indicator “S”, “T”, or “V”. Exclusions to this ancillary service packaging policy include preventive services, certain psychiatric and counseling-related services, and certain low-cost drug administration services. In the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66819), we indicated that we did not propose to package certain low-cost drug administration services because we were examining various alternative payment policies for drug administration, including the associated drug administration add-on codes.

(2) Proposed Packaging of Level 1 and Level 2 Drug Administration Services

As stated earlier, our overarching goal is to make OPPTS payments for all services paid under the OPPTS more consistent with those of a prospective payment system and less like those of a per-service fee schedule. To achieve this goal, it is important that we are consistent in our approach to packaging items and services under the established packaging categories. Although we excluded packaging of low-cost drug

administration services from the ancillary services packaging policy in the CY 2015 rulemaking, separate payment for drug administration services is an example of inconsistent application of our packaging policy where we are continuing to pay separately for a service, regardless of cost and performance with another service. Given the frequency of drug administration in hospital outpatient care, we believe it is appropriate for us to reconsider whether payment for drug administration services with a geometric mean cost of less than or equal to \$100 (prior to application of the conditional packaging status indicator) should continue to be excluded from the ancillary services packaging policy.

As part of our review of CY 2016 claims data used for ratesetting in this CY 2018 OPPTS/ASC proposed rule, we examined drug administration billing patterns and payment for drug administration services under the OPPTS. Based on our analysis of CY 2016 claims data (used for the CY 2018 OPPTS/ASC proposed rule ratesetting), we found that the geometric mean cost for APC 5691 (Level 1 Drug Administration) is approximately \$37 and the geometric mean cost for APC 5692 (Level 2 Drug Administration) is approximately \$59. In addition, we observed that drug administration services in APC 5692 are frequently reported on the same claim with other separately payable services, such as an emergency department or clinic visit, while drug administration services in APC 5691 are sometimes reported with other separately payable services. Accordingly, Medicare data show that these drug administration services are currently being provided as part of another separately payable service for which two separate payments are made, and support that packaging these services, when they are reported with another separately payable services, is appropriate. Further, packaging for Levels 1 and 2 Drug Administration services is consistent with the ancillary packaging policy that was adopted in CY 2015, as noted earlier in this section. Therefore, given the low geometric mean costs of

drug administration services in APC 5691 and APC 5692 as well as their associated billing patterns, we believe that when these services are performed with another separately payable service, they should be packaged, but that they should be separately paid when performed alone. That is, we believe it is no longer necessary to exclude low-cost drug administration services from packaging under the ancillary services packaging policy adopted in CY 2015.

In addition, as we examine payment differences between the hospital outpatient department and the physician office for similar services, under the OPPTS, hospitals may receive separate payments for a clinic (office) visit and a drug administration service. In contrast, physicians are not eligible to receive payment for an office visit when a drug administration service is also provided. As a result, hospitals receive a higher payment than a physician office for furnishing the same drug administration service. We believe that conditional packaging of drug administration services would promote equitable payment between the physician office and the hospital outpatient hospital department. Accordingly, for CY 2018, we are proposing to conditionally package payment for HCPCS codes describing drug administration services in APC 5691 and APC 5692, except for add-on codes and preventive services, when these services are performed with another service.

Because preventive services are excluded from our packaging policies, we are proposing to continue to pay separately for Medicare Part B vaccine administration services. In addition, at this time, we are not proposing to package any drug administration services in APC 5693 (Level 3 Drug Administration) or APC 5694 (Level 4 Drug Administration), but are interested in public comments pertaining to whether services in these APCs may be appropriate for packaging. The proposed status indicators for drug administration services in APC 5691 and APC 5692 are listed in Table 7 below.

TABLE 7—PROPOSED CY 2018 STATUS INDICATORS FOR DRUG ADMINISTRATION SERVICES IN LEVEL 1 AND LEVEL 2 DRUG ADMINISTRATION APCs

HCPCS code	Short descriptor	Proposed CY 2018 status indicator
APC 5691—Level 1 Drug Administration		
95115	Immunotherapy one injection	Q1
95117	Immunotherapy injections	Q1
95144	Antigen therapy services	Q1

TABLE 7—PROPOSED CY 2018 STATUS INDICATORS FOR DRUG ADMINISTRATION SERVICES IN LEVEL 1 AND LEVEL 2—
Continued
DRUG ADMINISTRATION APCs

HCPCS code	Short descriptor	Proposed CY 2018 status indicator
95145	Antigen therapy services	Q1
95146	Antigen therapy services	Q1
95165	Antigen therapy services	Q1
95170	Antigen therapy services	Q1
96361	Hydrate iv infusion add-on	S
96366	Ther/proph/diag iv inf add-on	S
96370	Sc ther infusion addl hr	S
96375	Tx/pro/dx inj new drug add-on	S
96377	Application on-body injector	Q1
96379	Ther/prop/diag inj/inf proc	Q1
96423	Chemo ia infuse each addl hr	S
96549	Chemotherapy unspecified	Q1
G0008	Admin influenza virus vac	S
G0009	Admin pneumococcal vaccine	S
G0010	Admin hepatitis b vaccine	S
APC 5692—Level 2 Drug Administration		
90471	Immunization admin	Q1
90473	Immune admin oral/nasal	Q1
95147	Antigen therapy services	Q1
95148	Antigen therapy services	Q1
95149	Antigen therapy services	Q1
96367	Tx/proph/dg addl seq iv inf	S
96371	Sc ther infusion reset pump	Q1
96372	Ther/proph/diag inj sc/im	Q1
96401	Chemo anti-neopl sq/im	Q1
96402	Chemo hormon antineopl sq/im	Q1
96405	Chemo intralesional up to 7	Q1
96411	Chemo iv push addl drug	S
96415	Chemo iv infusion addl hr	S
96417	Chemo iv infus each addl seq	S

(3) Comment Solicitation Regarding Unconditionally Packaging Drug Administration Add-on Codes

With respect to drug administration add-on codes, as discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43573), we proposed to unconditionally package all drug administration services described by add-on codes. In response to the proposal, commenters objected to packaging drug administration add-on codes, which typically describe each additional hour of infusion or each additional intravenous push, among others, in addition to the initial drug administration service. The commenters believed that such a policy could disadvantage providers of longer drug administration services, which are often protocol-driven and are not necessarily dictated by the hospital, but by the characteristics of the specific drug or biological being administered to the patient. In response to these comments, we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74945) that, given the frequency of drug administration services in the hospital

outpatient department and their use in such a wide variety of different drug treatment protocols for various diseases in all types of hospitals, further study of the payment methodology for these services was warranted at that time. Therefore, we did not finalize our proposal to package the drug administration add-on codes in CY 2014. However, we stated we would continue to explore other payment options, including packaging and variations on packaging, in future years.

We are not proposing to package drug administration add-on codes for CY 2018 in this proposed rule because we want stakeholder input on a payment methodology that supports the principles of a prospective payment system while ensuring patient access to prolonged infusion services. Instead, we are soliciting public comment on whether conditionally or unconditionally packaging such codes would create access to care issues or have other unintended consequences. Specifically, we are requesting public comments on the following: (1) Whether we should conditionally or

unconditionally package drug administration services add-on codes; (2) how we should consider or incorporate the varied clinical drug protocols that result in different infusion times into a drug administration service add-on code payment proposal; and (3) other recommendations on an encounter-based payment approach for drug administration services that are described by add-on codes when furnished in the hospital outpatient setting.

c. Analysis of Packaging of Pathology Services in the OPPS

At the August 22, 2016 HOP Panel meeting, a stakeholder expressed concern regarding conditional packaging of multiple pathology services. When multiple conditionally packaged services are billed on the same claim, the costs of the lowest paying services are bundled into the cost of the highest paying service and payment is made based on the highest single payable service. The stakeholder requested that CMS create a pathology

composite to more appropriately pay for claims with only multiple pathology services and no other separately payable service such as a surgical procedure or a clinic visit. The HOP panel recommended that CMS develop a composite APC for pathology services when multiple pathology services are provided on a claim with no other payable services. The HOP Panel also requested that CMS take into consideration the stakeholder presentation comments made at the August 22, 2016 panel meeting regarding hospital pathology laboratories as CMS evaluates conditional packaging to determine

whether an accommodation can be made. Specifically, the stakeholder expressed concern with conditional packaging of pathology services, particularly when payment is limited to the single highest paying code, regardless of the number of services provided or specimens tested.

In response to these HOP Panel requests and recommendation, we stated that we may consider the stakeholders' request for a pathology composite APC as well as additional composite APCs for future rulemaking (81 FR 79588). In light of these requests and recommendation, in development of this CY 2018 OPPTS/ASC proposed

rule, we evaluated and considered a pathology composite APC when multiple pathology services are performed and billed without a separately payable service on the same claim. To understand the frequency of billing multiple pathology services and no other separately payable codes on the same claim by hospital outpatient departments, we examined currently available claims data to identify the frequency distribution of pathology codes within the CPT code range 88300 to 88361. The claim frequency breakdown is displayed in Table 8 below.

TABLE 8—DISTRIBUTION OF PATHOLOGY ONLY OPPTS CLAIMS

Claim subset	Number of claims	Percent of claims
Claims having 1 pathology code	464,039	74.29
Claims having 2 pathology codes	101,954	16.32
Claims having 3 pathology codes	38,163	6.11
Claims having 4 or more pathology codes	20,435	3.27

Based on our claims analysis, the majority of pathology-only OPPTS claims are reported with one pathology code. Therefore, we believe that it is neither a frequent occurrence nor a common occurrence for a provider to submit a claim for payment under the OPPTS with multiple pathology services and no other separately payable service.

With regard to the HOP Panel's recommendation to develop a composite APC for pathology services when multiple pathology services are provided on a claim with no other payable services, we used CY 2016 claims data available for the CY 2018 OPPTS/ASC proposed rule to model four hypothetical pathology composite APCs. That is, following our standard packaging methodology, we modeled four hypothetical pathology composite

APCs based on the following clinical scenarios that were specifically requested by a stakeholder at the August 2016 HOP Panel meeting:

- *Hypothetical Composite APC A:* Claims that contain 2–4 pathology units (CPT codes 88302 through 88309) with or without special stains (CPT codes 88312–88314);
- *Hypothetical Composite APC B:* Claims that contain 5 or more pathology units (CPT codes 88302 through 88309) with or without special stains (CPT codes 88312–88314);
- *Hypothetical Composite APC C:* Claims that contain 2–4 pathology units (CPT codes 88302 through 88309) with immunostains (CPT codes 88341, 88342, 88346, 88350, 88360, 88361); and
- *Hypothetical Composite APC D:* Claims that contain 5 or more pathology

units (CPT codes 88302 through 88309) with immunostains (CPT codes 88341, 88342, 88346, 88350, 88360, 88361).

In addition, we evaluated the volume of services and costs for each hypothetical composite. Results from modeling the four composite scenarios show low claim volume, which indicates that the suggested pathology code combinations are infrequently billed by hospital outpatient departments, which may mean that these are not likely clinical scenarios in hospital outpatient departments. A summary of the results from our composite analysis are presented in Table 9 below. We refer readers to Addendum B to the CY 2018 OPPTS/ASC proposed rule (which is available via the Internet on the CMS Web site) for the CPT code descriptors.

TABLE 9—COST AND UTILIZATION STATISTICS OF FOUR HYPOTHETICAL COMPOSITE APCS

Hypothetical composite APC	Number of claims	Geometric mean unit cost	Mean pathology units per claim	Mean special stains units per claim	Mean immunostain units per claim
A	139,238	\$95.82	2.42	0.19	0.02
B	14,388	265.36	6.78	0.24	0.03
C	877	544.71	2.46	0.14	3.98
D	214	1,531.87	6.56	0.12	4.28

As we move toward larger payment bundles under the OPPTS, the necessity of composite APCs diminishes. For example, in this CY 2018 OPPTS/ASC proposed rule, we are proposing to delete composite APC 8001 (LDR Prostate Brachytherapy Composite) and

to provide payment for the component procedures through the C-APC payment methodology. Composite APCs were a precursor to C-APCs. In CY 2008, we implemented 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 (72 FR 66650 through 66652). Because a C-APC would treat all individually reported codes as representing components of the comprehensive service, all of the

elements of the composite service are included in the C-APC payment. In addition, given the infrequent occurrence of multiple pathology services on the same claim without a separately payable service, we do not believe a composite APC is necessary or warranted.

Therefore, for CY 2018, we are not proposing to create a pathology composite APC or additional composite APCs for stakeholder-requested services, such as X-ray services, respiratory services, cardiology services, or allergy testing services. However, we are soliciting public comments on our packaging policies below.

d. Comment Solicitation on Packaging of Items and Services Under the OPSS

As previously noted, packaging is an inherent principle of a prospective payment system. The OPSS, like other prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated costs of providing a service or package of services for a particular patient, but with the exception of outlier cases, is adequate to ensure access to appropriate care. Packaging and bundling payment for multiple interrelated services into a single payment creates incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment. Decisions about packaging and bundling payment involve a balance between ensuring some separate payment for individual services or items while establishing incentives for efficiency through larger units of payment.

As the OPSS continues to move towards a prospectively determined encounter-based payments and away from separate fee schedule-like payments, we continue to hear concerns from stakeholders that our packaging policies may be hampering patient access or resulting in other undesirable consequences. However, we have not observed significant fluctuations in our data that show a sharp decline of the volume of packaged services, nor have we heard from Medicare beneficiaries specifically about access issues or other concerns with packaged items and services. However, given that aggregate spending and utilization continue to increase for covered outpatient services, it is unclear what, if any, adverse effect packaging has on beneficiary access to care. Specifically, within the framework of existing packaging categories, such as drugs that function as supplies in a surgical procedure or diagnostic test or

procedure, we are interested in stakeholder feedback on common clinical scenarios involving currently packaged HCPCS codes for which stakeholders believe packaged payment is not appropriate under the OPSS. Likewise, outside the framework of existing packaging categories, we are interested in stakeholder feedback on common clinical scenarios involving separately payable HCPCS codes for which payment would be most appropriately packaged under the OPSS. We are soliciting public comments from a broad cross-section of stakeholders, including beneficiaries, patient advocates, hospital providers, clinicians, manufacturers, and other interested parties.

4. Proposed Calculation of OPSS Scaled Payment Weights

We established a policy in the CY 2013 OPSS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPSS. In the CY 2017 OPSS/ASC final rule with comment period (81 FR 79594 through 79595), we applied this policy and calculated the relative payment weights for each APC for CY 2017 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 Web site) using the APC costs discussed in sections II.A.1. and II.A.2. of that final rule with comment period. For CY 2018, as we did for CY 2017, we are proposing to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2018 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 OPSS/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 OPSS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPSS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPSS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a

distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70351). For CY 2018, as we did for CY 2017, 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 OPSS services. For CY 2018, as we did for CY 2017, 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 OPSS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPSS for CY 2018 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 2017 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2018 unscaled relative payment weights.

For CY 2017, we multiplied the CY 2017 scaled APC relative payment weight applicable to a service paid under the OPSS by the volume of that service from CY 2016 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 2018, we are proposing to apply the same process using the estimated CY 2018 unscaled relative payment weights rather than scaled relative payment weights. We are proposing to calculate the weight scalar by dividing the CY 2017 estimated aggregate weight by the unscaled CY 2018 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPSS claims accounting

document available on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. Click on the CY 2018 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 2018 to the estimated total relative payment weights in CY 2017 using CY 2016 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 2018 unscaled relative payment weights for purposes of budget neutrality. We are proposing to adjust the estimated CY 2018 unscaled relative payment weights by multiplying them by a proposed weight scaler of 1.328 to ensure that the proposed CY 2018 relative payment weights are scaled to be budget neutral. The proposed CY 2018 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) were scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.3. of this proposed rule) is included in the proposed budget neutrality calculations for the CY 2018 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 2018 IPPS/LTCH PPS proposed rule (82 FR 19931), consistent with current law, based on IHS Global Insight, Inc.'s

fourth quarter 2016 forecast of the FY 2018 market basket increase, the proposed FY 2018 IPPS market basket update is 2.9 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 2018.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the “MFP adjustment”). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment, and then revised this methodology as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19931 through 19932), we discussed the calculation of the proposed MFP adjustment for FY 2018, which is -0.4 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 2018 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 2018 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 2018, 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 2018.

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 1.75 percent for the CY 2018 OPPS (which is 2.9 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.4 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 2018 OPPS/ASC proposed rule, we are proposing to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (9) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2018, 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 2018.

To set the OPPS conversion factor for this CY 2018 proposed rule, we are proposing to increase the CY 2017 conversion factor of \$75.001 by 1.75 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing further to adjust the conversion factor for CY 2018 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 0.9999 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2018 IPPS wage indexes to those

payments using the FY 2017 IPPS wage indexes, as adopted on a calendar year basis for the OPSS.

For CY 2018, 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 CY 2018, 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 2018 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2018 payments under section 1833(t) of the Act, including the proposed CY 2018 cancer hospital payment adjustment, to estimated CY 2018 total payments using the CY 2017 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The CY 2018 proposed estimated payments applying the proposed CY 2018 cancer hospital payment adjustment are less than estimated payments applying the CY 2017 final cancer hospital payment adjustment. Therefore, we are proposing to apply a budget neutrality adjustment factor of 1.0003 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 0.90, not the 0.89 target payment-to-cost ratio we are applying in section II.F. of this proposed rule.

For this proposed rule, we estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2018 would equal approximately \$26.2 million, which represents 0.04 percent of total projected CY 2018 OPSS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.26 percent estimate of pass-through spending for CY 2017 and the 0.04 percent estimate of proposed pass-through spending for CY 2018, resulting in a proposed adjustment for CY 2018 of 0.22 percent. Proposed estimated payments for outliers would remain at 1.0 percent of total OPSS payments for CY 2018. We estimate for this proposed rule that outlier payments would be 1.04 percent of total OPSS payments in CY 2017; the 1.0 percent for proposed outlier payments in CY 2018 would constitute a 0.04 percent decrease in payment in CY 2018 relative to CY 2017.

For this 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 -0.25 percent (that is, the proposed OPD fee schedule increase factor of 1.75 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2018 of \$74.953 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.530 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2018, we are proposing to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (9) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2018 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 \$74.953 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.530 in the conversion factor relative to hospitals that met the requirements).

For CY 2018, we are proposing to use a conversion factor of \$76.483 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 1.75 percent for CY 2018, the required proposed wage index budget neutrality adjustment of approximately 0.9999, the proposed cancer hospital payment adjustment of 1.0003, and the proposed adjustment of 0.22 percentage point of projected OPSS spending for the difference in the pass-through spending and outlier payments that result in a proposed conversion factor for CY 2018 of \$76.483.

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 OPSS payment rate is called the OPSS labor-related share. Budget neutrality is

discussed in section II.B. of this proposed rule.

The OPSS labor-related share is 60 percent of the national OPSS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPSS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPSS final rule with comment period (70 FR 68553). We are proposing to continue this policy for the CY 2018 OPSS. We refer readers to section II.H. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting documentation for this proposed rule (which is available via the Internet on the CMS Web site), for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same proposed FY 2018 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 OPSS payment rate and copayment amount.

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

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPSS/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 2018 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 2018 and subsequent 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 following sections in the FY 2011 through FY 2017 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; and for FY 2017, 81 FR 56922. We are inviting public comments on this proposal.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2018 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 note that in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19905), we proposed not to apply the imputed floor to the IPPS wage index computations for FY 2018 and subsequent fiscal years. We refer readers to the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19898 through 19915) for a detailed discussion of all proposed changes to the FY 2018 IPPS wage indexes (including our proposal not to extend the imputed floor for FY

2018 and subsequent fiscal years). In addition, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65842 through 65844) and subsequent OPPS rules for a detailed discussion of the history of these wage index adjustments as applied under the OPPS.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49488 through 49489 and 49494 through 49496), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), 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), we adopted the use of the OMB labor market area delineations contained in OMB Bulletin No. 13–01, effective October 1, 2014. 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. 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. Therefore, 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.

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 proposed rule (82 FR 19898 through 19899) discusses the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS has 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 proposed rule (81 FR 19898), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we proposed 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, we are proposing to discontinue the use of SSA county codes and begin using only the FIPS county codes. We are inviting public comments on this proposal.

The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the Web site at: <https://www.census.gov/geo/reference/county-changes.html>. In our proposed transition to using only FIPS codes for counties for the IPPS wage index, we proposed to update the FIPS codes used for crosswalking counties to CBSAs for the IPPS wage index to incorporate changes to the counties or county equivalent entities included in the Census Bureau’s most recent list. Based on information included in the Census Bureau’s Web site, since 2010, the Census Bureau has made the following updates to the FIPS codes for counties or county equivalent entities:

- Petersburg Borough, AK (FIPS State County Code 02–195), CBSA 02, was created from part of former Petersburg Census Area (02–195) and part of Hoonah-Angoon Census Area (02–105). The CBSA code remains 02.
- The name of La Salle Parish, LA (FIPS State County Code 22–059), CBSA 14, is now LaSalle Parish, LA (FIPS State County Code 22–059). The CBSA code remains as 14.
- The name of Shannon County, SD (FIPS State County Code 46–113), CBSA 43, is now Oglala Lakota County, SD (FIPS State County Code 46–102). The CBSA code remains as 43.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19898 through 19899), for the IPPS, we proposed to implement these FIPS code updates, effective October 1, 2017, beginning with the FY 2018 wage indexes. We proposed to include these updates to calculate area 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. We noted that while the county update changes listed earlier changed the county names, the CBSAs to which these counties map did not change from the prior counties. Therefore, there would be no impact or change to hospitals in these counties; they would continue to be considered rural for the IPPS wage index under these changes. Consistent with the FY 2018 IPPS/LTCH PPS proposed rule, for purposes of the OPSS, we are proposing to implement these revisions effective January 1, 2018, beginning with the CY 2018 OPSS wage indexes. We believe it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the OPSS wage index. In addition, we believe that using the latest FIPS codes will allow us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. Tables 2 and 3 for the FY 2018 IPPS/LTCH PPS proposed rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS Web site reflect these county changes. We are inviting public comments on our proposals.

For this CY 2018 OPSS/ASC proposed rule, we are proposing to use the FY 2018 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPSS to determine the wage adjustments for both the OPSS payment rate and the copayment standardized amount for CY 2018. Therefore, any adjustments for the FY 2018 IPPS post-reclassified wage index would be reflected in the final CY 2018 OPSS wage index. (We refer readers to the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19898 through 19915) and the proposed FY 2018 hospital wage index files posted on the CMS Web site). We are inviting public comments on this proposal.

Hospitals that are paid under the OPSS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPSS, it is our longstanding policy to assign the wage index that would be applicable if the hospital 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 2018. The following is a brief summary of the major proposed FY 2018 IPPS wage index policies and adjustments that we are proposing to apply to these hospitals under the OPSS for CY 2018. We are inviting public comments on these proposals. We

further refer readers to the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19898 through 19915) for a detailed discussion of the proposed changes to the FY 2018 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPSS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPSS. We note that, because non-IPPS hospitals cannot reclassify, they would be 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 would apply if the hospital were paid under the IPPS. For CY 2018, we are proposing to continue our policy of allowing non-IPPS hospitals paid under the OPSS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the 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 OPSS but not under the IPPS so that such hospitals will maintain 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 will end in CY 2017, it will no longer be applied in CY 2018.

In addition, under the IPPS, the imputed floor policy is set to expire effective October 1, 2017, and in the IPPS/LTCH PPS proposed rule, we proposed not to extend the imputed floor policy for FY 2018 and subsequent fiscal years (82 FR 19904 through 19905). For purposes of the CY 2018 OPSS, the imputed floor policy is set to expire effective December 31, 2017, and consistent with the IPPS, we are

proposing not to extend the imputed floor policy beyond this date.

For CMHCs, for CY 2018, 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 OPSS 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 will end in CY 2017, it will not be applied in CY 2018. Consistent with our current policy, the wage index that applies to CMHCs 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, 2017. The wage index that applies to CMHCs also would not include the out-migration adjustment because that adjustment only applies to hospitals.

Table 2 associated with the FY 2018 IPPS/LTCH PPS proposed rule (available via the Internet on the CMS Web site 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 2018. We are including the out-migration adjustment information from Table 2 associated with the FY 2018 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 2018 OPSS. Addendum L is available via the Internet on the CMS Web site. We refer readers to the CMS Web site for the OPSS 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 2018 IPPS wage index tables and Addendum L.

D. Proposed Statewide Average Default 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 OPPI 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. 100-04), Chapter 4, Section 10.11).

In this proposed rule, we are proposing to update the default ratios for CY 2018 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 OPPI/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 2018 OPPI proposed rule Claims Accounting Narrative that is posted on the CMS Web site. Table 10 below lists the proposed statewide average default CCRs for OPPI services furnished on or after January 1, 2018, based on proposed rule data.

TABLE 10—PROPOSED CY 2018 STATEWIDE AVERAGE CCRS

State	Urban/rural	Proposed CY 2018 default CCR	Previous default CCR (CY 2017 OPPI Final rule)
ALASKA	RURAL	0.582	0.449
ALASKA	URBAN	0.238	0.237
ALABAMA	RURAL	0.191	0.196
ALABAMA	URBAN	0.158	0.158
ARKANSAS	RURAL	0.192	0.196
ARKANSAS	URBAN	0.201	0.205
ARIZONA	RURAL	0.237	0.238
ARIZONA	URBAN	0.171	0.176
CALIFORNIA	RURAL	0.176	0.179
CALIFORNIA	URBAN	0.190	0.188
COLORADO	RURAL	0.351	0.354
COLORADO	URBAN	0.204	0.208
CONNECTICUT	RURAL	0.402	0.402
CONNECTICUT	URBAN	0.253	0.253
DISTRICT OF COLUMBIA	URBAN	0.279	0.286
DELAWARE	URBAN	0.296	0.288
FLORIDA	RURAL	0.170	0.169
FLORIDA	URBAN	0.141	0.143
GEORGIA	RURAL	0.226	0.230
GEORGIA	URBAN	0.187	0.196
HAWAII	RURAL	0.333	0.338
HAWAII	URBAN	0.314	0.319
IOWA	RURAL	0.297	0.291
IOWA	URBAN	0.247	0.252
IDAHO	RURAL	0.341	0.341
IDAHO	URBAN	0.404	0.401
ILLINOIS	RURAL	0.232	0.241
ILLINOIS	URBAN	0.216	0.209
INDIANA	RURAL	0.305	0.272
INDIANA	URBAN	0.217	0.218
KANSAS	RURAL	0.272	0.269
KANSAS	URBAN	0.202	0.194
KENTUCKY	RURAL	0.192	0.194
KENTUCKY	URBAN	0.188	0.189
LOUISIANA	RURAL	0.273	0.217
LOUISIANA	URBAN	0.200	0.201
MASSACHUSETTS	RURAL	0.315	0.316
MASSACHUSETTS	URBAN	0.349	0.345
MAINE	RURAL	0.419	0.425
MAINE	URBAN	0.412	0.413
MARYLAND	RURAL	0.263	0.264
MARYLAND	URBAN	0.228	0.229
MICHIGAN	RURAL	0.308	0.295
MICHIGAN	URBAN	0.323	0.324
MINNESOTA	RURAL	0.374	0.398
MINNESOTA	URBAN	0.304	0.319
MISSOURI	RURAL	0.226	0.222
MISSOURI	URBAN	0.243	0.261
MISSISSIPPI	RURAL	0.227	0.224
MISSISSIPPI	URBAN	0.165	0.167

TABLE 10—PROPOSED CY 2018 STATEWIDE AVERAGE CCRs—Continued

State	Urban/rural	Proposed CY 2018 default CCR	Previous default CCR (CY 2017 OPPS Final rule)
MONTANA	RURAL	0.475	0.450
MONTANA	URBAN	0.376	0.368
NORTH CAROLINA	RURAL	0.207	0.216
NORTH CAROLINA	URBAN	0.215	0.223
NORTH DAKOTA	RURAL	0.366	0.411
NORTH DAKOTA	URBAN	0.372	0.334
NEBRASKA	RURAL	0.298	0.294
NEBRASKA	URBAN	0.231	0.238
NEW HAMPSHIRE	RURAL	0.311	0.320
NEW HAMPSHIRE	URBAN	0.262	0.279
NEW JERSEY	URBAN	0.201	0.195
NEW MEXICO	RURAL	0.220	0.225
NEW MEXICO	URBAN	0.284	0.280
NEVADA	RURAL	0.194	0.196
NEVADA	URBAN	0.114	0.123
NEW YORK	RURAL	0.309	0.309
NEW YORK	URBAN	0.286	0.292
OHIO	RURAL	0.289	0.292
OHIO	URBAN	0.208	0.207
OKLAHOMA	RURAL	0.220	0.231
OKLAHOMA	URBAN	0.173	0.180
OREGON	RURAL	0.280	0.280
OREGON	URBAN	0.336	0.344
PENNSYLVANIA	RURAL	0.263	0.274
PENNSYLVANIA	URBAN	0.176	0.179
PUERTO RICO	URBAN	0.549	0.527
RHODE ISLAND	URBAN	0.292	0.291
SOUTH CAROLINA	RURAL	0.187	0.185
SOUTH CAROLINA	URBAN	0.186	0.190
SOUTH DAKOTA	RURAL	0.391	0.383
SOUTH DAKOTA	URBAN	0.238	0.229
TENNESSEE	RURAL	0.170	0.181
TENNESSEE	URBAN	0.177	0.180
TEXAS	RURAL	0.209	0.214
TEXAS	URBAN	0.171	0.177
UTAH	RURAL	0.351	0.349
UTAH	URBAN	0.303	0.315
VIRGINIA	RURAL	0.193	0.191
VIRGINIA	URBAN	0.222	0.226
VERMONT	RURAL	0.424	0.426
VERMONT	URBAN	0.340	0.340
WASHINGTON	RURAL	0.269	0.271
WASHINGTON	URBAN	0.295	0.294
WISCONSIN	RURAL	0.349	0.354
WISCONSIN	URBAN	0.311	0.290
WEST VIRGINIA	RURAL	0.259	0.266
WEST VIRGINIA	URBAN	0.292	0.285
WYOMING	RURAL	0.406	0.429
WYOMING	URBAN	0.326	0.311

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 2018

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) (Public Law 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 OPSS 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 2017. Further, in the CY 2009 OPSS/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.

In this CY 2018 OPSS/ASC proposed rule, for the CY 2018 OPSS, we are proposing to continue our 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 OPSS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2018

1. Background

Since the inception of the OPSS, 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 OPSS 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 OPSS 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 OPSS and a “pre-BBA amount.” That is, cancer hospitals are permanently held harmless to their “pre-BBA amount,” and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPSS than the payment amount they would have received before implementation of the OPSS, as set forth in section 1833(t)(7)(F) of the Act. The “pre-BBA amount” is the product of the hospital’s reasonable costs for covered outpatient 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 OPSS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals’ costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPSS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPSS/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 OPSS/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 OPSS. The target PCR is set in advance of the calendar year and is calculated using the most recent 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 OPSS/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 OPSS/ASC final rule with comment period (81 FR 79603 through 7960).

2. Proposed Policy for CY 2018

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. In this CY 2018 OPPS/ASC proposed rule, for CY 2018, 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 2018. To calculate the proposed CY 2018 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 2018 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 2016 claims data that we used to model the impact of the proposed CY 2018 APC relative payment weights (3,701 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2018 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2013 to 2016. We then removed the cost report data of the 49 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 16 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 3,636 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 90 percent of reasonable cost (weighted average PCR of 0.90). Therefore, after applying the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act, we 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 0.89 for each cancer hospital. Table 11 below indicates the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2018 due to the proposed cancer hospital payment adjustment policy. The actual amount of the CY 2018 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2018 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 11—PROPOSED ESTIMATED CY 2018 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider No.	Hospital name	Proposed estimated percentage increase in OPPS payments for CY 2018 due to payment adjustment (%)
050146	City of Hope Comprehensive Cancer Center	32.9
050660	USC Norris Cancer Hospital	11.5
100079	Sylvester Comprehensive Cancer Center	24.3
100271	H. Lee Moffitt Cancer Center & Research Institute	23.1
220162	Dana-Farber Cancer Institute	45.8
330154	Memorial Sloan-Kettering Cancer Center	47.1
330354	Roswell Park Cancer Institute	21.4
360242	James Cancer Hospital & Solove Research Institute	28.9
390196	Fox Chase Cancer Center	8.8
450076	M.D. Anderson Cancer Center	76.9
500138	Seattle Cancer Care Alliance	53.9

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 2017, 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 \$3,825 (the fixed-dollar amount threshold) (81 FR 79604 through 79606). 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 OPSS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPSS. Our estimate of total outlier payments as a percent of total CY 2016 OPSS payment, using CY 2016 claims available for this proposed rule, is approximately 1.0 percent of the total aggregated OPSS payments. Therefore, for CY 2016, we estimate that we paid the outlier target of 1.0 percent of total aggregated OPSS payments.

For this proposed rule, using CY 2016 claims data and CY 2017 payment rates, we estimate that the aggregate outlier payments for CY 2017 would be approximately 1.0 percent of the total CY 2017 OPSS payments. We are providing estimated CY 2018 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 Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

2. Proposed Outlier Calculation for CY 2018

In this CY 2018 OPSS/ASC proposed rule, for CY 2018, we are proposing to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPSS. 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 OPSS 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 OPSS 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 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.D. of this proposed rule.

To ensure that the estimated CY 2018 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPSS, 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 \$4,325.

We calculated this proposed fixed-dollar threshold of \$4,325 using the standard methodology most recently used for CY 2017 (81 FR 79604 through 79605). For purposes of estimating outlier payments for this proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2017 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPSS Pricer to pay claims. The claims that we use to model each OPSS update lag by 2 years.

In order to estimate the CY 2018 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2016 claims using the same inflation factor of 1.104055 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20173). We used an inflation factor of 1.05074 to estimate CY 2017 charges from the CY 2016 charges reported on CY 2016 claims. The methodology for determining this charge inflation factor is discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57286). As we stated in the CY 2005 OPSS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPSS 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 OPSS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPSS hospital outlier threshold if we did not

apply a CCR inflation adjustment factor. Therefore, we are proposing to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2018 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2018 OPSS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2018, we proposed to apply an adjustment factor of 0.979187 to the CCRs that were in the April 2017 OPSF to trend them forward from CY 2017 to CY 2018. The methodology for calculating this proposed adjustment was discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20173).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2017 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.979187 to approximate CY 2018 CCRs) to charges on CY 2016 claims that were adjusted (using the proposed charge inflation factor of 1.104055 to approximate CY 2018 charges). We simulated aggregated CY 2018 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 2018 OPSS payments. We estimated that a proposed fixed-dollar threshold of \$4,325, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPSS payments to outlier payments. For CMHCs, we proposed that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that will

apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, 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 refer 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 OPSS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2018 OPSS/ASC proposed rule, the proposed payment rate for most services and procedures for which payment is made under the OPSS is the product of the proposed 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 Web site) and for most HCPCS codes to which separate payment under the OPSS has been assigned in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) was calculated by multiplying the proposed CY 2018 scaled weight for the APC by the proposed CY 2018 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 will be made in a calendar year under the OPSS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: "J1", "J2", "P", "Q1", "Q2", "Q3", "Q4", "R", "S", "T", "U", or "V" (as defined in Addendum D1 to this proposed rule, which is available via the Internet on the CMS Web site), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of "Q1" and "Q2") qualify for separate payment. We note that, although blood and blood products with status indicator "R" and brachytherapy sources with status indicator "U" are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) 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 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 2018 OPSS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPSS, we

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

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

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

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that, under the proposed CY 2018 OPSS 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 proposed to be assigned for FY 2018 under the IPPS, reclassifications through the 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 2018 IPPS wage indexes, as applied to the CY 2018 OPSS, 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 Web site) contains the qualifying counties and the associated wage index increase developed for the FY 2018 IPPS, which

are listed in Table 2 in the FY 2018 IPPS/LTCH PPS proposed rule available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>. 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.

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

Adjusted Medicare Payment = $Y + X_a$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

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

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined

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 2018 full national unadjusted payment rate for APC 5071 is approximately \$552.34. The proposed reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is approximately \$541.29. 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 2018 wage index for a provider located in CBSA 35614 in New York is 1.2892. The labor-related portion of the proposed full national unadjusted payment is approximately \$427.25 (.60 * \$552.34 * 1.2892). The labor-related portion of the proposed reduced national unadjusted payment is approximately \$418.70 (.60 * \$541.29 * 1.2892). The nonlabor-related portion of the proposed full national unadjusted payment is approximately \$220.94 (.40 * \$552.34). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately \$216.52 (.40 * \$541.29). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately \$648.19 (\$427.25 + \$220.94). The sum of the portions of the proposed reduced national adjusted payment is approximately \$635.22 (\$418.70 + \$216.52).

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

2. Proposed OPSS Copayment Policy

For CY 2018, 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 OPSS 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 OPSS/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 OPSS that would be effective January 1, 2018 are included in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

As discussed in section XIII.E. of this proposed, for CY 2018, 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 OPSS copayments may increase or decrease each year based on changes in the calculated APC payment rates due to updated cost report and claims data, and any changes to the OPSS cost modeling process. However, as described in the CY 2004 OPSS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPSS APC payments (68 FR 63458 through 63459).

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

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

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

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

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

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

- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the

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

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

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

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

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, \$110.47 is approximately 20 percent of the proposed full national unadjusted payment rate of \$552.34. 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 Web site), the beneficiary payment percentage is 20 percent.

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

B is the beneficiary payment percentage.
 $B = \text{National unadjusted copayment for APC} / \text{National unadjusted payment rate for APC}.$

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as

indicated in Steps 2 through 4 under section II.H. of this proposed rule. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this proposed rule.

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

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

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

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

The proposed unadjusted copayments for services payable under the OPSS that would be effective January 1, 2018, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). 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 2018 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

In addition, as noted above, 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 OPSS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPSS 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 OPSS. Specifically, CMS recognizes the following codes on OPSS 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 12 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 12—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2017	Level II HCPCS Codes	April 1, 2017	CY 2018 OPPS/ASC proposed rule.	CY 2018 OPPS/ASC final rule with comment period.
July 1, 2017	Level II HCPCS Codes	July 1, 2017	CY 2018 OPPS/ASC proposed rule.	CY 2018 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2017	CY 2018 OPPS/ASC proposed rule.	CY 2018 OPPS/ASC final rule with comment period.
October 1, 2017	Level II HCPCS Codes	October 1, 2017	CY 2018 OPPS/ASC final rule with comment period.	CY 2019 OPPS/ASC final rule with comment period.
January 1, 2018	Level II HCPCS Codes	January 1, 2018	CY 2018 OPPS/ASC final rule with comment period.	CY 2019 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2018	CY 2018 OPPS/ASC proposed rule.	CY 2018 OPPS/ASC final rule with comment period.

1. Proposed Treatment of New HCPCS Codes That Were Effective April 1, 2017 for Which We Are Soliciting Public Comments in This CY 2018 OPPS/ASC Proposed Rule

Through the April 2017 OPPS quarterly update CR (Transmittal 3728,

Change Request 10005, dated March 3, 2017), we made effective six new Level II HCPCS codes for separate payment under the OPPS. In this CY 2018 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 13 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 Web site).

TABLE 13—NEW LEVEL II HCPCS CODES EFFECTIVE APRIL 1, 2017

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2018 SI	Proposed CY 2018 APC
C9484	Injection, eteplirsen, 10 mg	G	9484
C9485	Injection, olaratumab, 10 mg	G	9485
C9486	Injection, granisetron extended release, 0.1 mg	G	9486
C9487*	Ustekinumab, for intravenous injection, 1 mg	G	9487
C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488

* HCPCS code C9487, which was effective April 1, 2017, was deleted June 30, 2017 and replaced with HCPCS code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017.

2. Proposed Treatment of New HCPCS Codes That Were Effective July 1, 2017 for Which We Are Soliciting Public Comments in This CY 2018 OPPTS/ASC Proposed Rule

Through the July 2017 OPPTS quarterly update CR (Transmittal 3783, Change Request 10122, dated May 26, 2017), we made 10 new Category III CPT codes and 13 Level II HCPCS codes effective July 1, 2017 and assigned them to appropriate interim OPPTS status indicators and APCs.

Three HCPCS codes are no longer payable under the OPPTS because they have been replaced with more specific or different codes effective July 1, 2017. In particular, the coverage indicator for

HCPCS codes J1725 (Injection, hydroxyprogesterone caproate, 1 mg) and P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit) was revised to “Not Payable by Medicare” because these codes were replaced with more specific HCPCS codes. HCPCS code J1725 was replaced with HCPCS codes Q9986, and HCPCS code P9072 was replaced with HCPCS code Q9988 (Platelets, pheresis, pathogen reduced, each unit). Further, HCPCS code C9487 (Ustekinumab, for intravenous injection, 1 mg) was deleted June 30, 2017 and replaced with HCPCS code Q9989 effective July 1, 2017. Because HCPCS code Q9989 describes the same drug as HCPCS code C9487, we are proposing to continue the drug’s

pass-through payment status and to assign HCPCS code Q9989 to the same APC and status indicators as its predecessor HCPCS code C9487, as shown in Table 14.

In this CY 2018 OPPTS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for CY 2018 for the CPT and Level II HCPCS codes implemented on July 1, 2017, all of which are listed in Table 14 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 Web site).

TABLE 14—NEW CATEGORY III CPT AND LEVEL II HCPCS CODES EFFECTIVE JULY 1, 2017

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2018 SI	Proposed CY 2018 APC
C9489	Injection, nusinersen, 0.1 mg	G	9489
C9490	Injection, bezlotoxumab, 10 mg	G	9490
C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube	J1	5165
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed.	J1	5377
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance.	J1	5376
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit Of Service.	Y	N/A
K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system.	Y	N/A
Q9984	Levonorgestrel-releasing intrauterine contraceptive system (Kyleena), 19.5 mg ..	E1	N/A
Q9985	Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg	N	N/A
Q9986*	Injection, hydroxyprogesterone caproate (Makena), 10 mg	K	9074
Q9987	Pathogen(s) test for platelets	S	1493
Q9988	Platelets, pheresis, pathogen reduced, each unit	R	9536
Q9989#	Ustekinumab, for intravenous injection, 1 mg	G	9487
0469T	Retinal polarization scan, ocular screening with on-site automated results, bilateral.	E1	N/A
0470T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; first lesion.	M	N/A
0471T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; each additional lesion (List separately in addition to code for primary procedure).	N	N/A
0472T	Device evaluation, interrogation, and initial programming of intra-ocular retinal electrode array (eg, retinal prosthesis), in person, with iterative adjustment of the implantable device to test functionality, select optimal permanent programmed values with analysis, including visual training, with review and report by a qualified health care professional.	Q1	5743
0473T	Device evaluation and interrogation of intra-ocular retinal electrode array (eg, retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional.	Q1	5742
0474T	Insertion of anterior segment aqueous drainage device, with creation of intra-ocular reservoir, internal approach, into the supraciliary space.	J1	5492
0475T	Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording and storage, data scanning with signal extraction, technical analysis and result, as well as supervision, review, and interpretation of report by a physician or other qualified health care professional.	M	N/A
0476T	Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording, data scanning, with raw electronic signal transfer of data and storage.	Q1	5734
0477T	Recording of fetal magnetic cardiac signal using at least 3 channels; signal extraction, technical analysis, and result.	Q1	5734
0478T	Recording of fetal magnetic cardiac signal using at least 3 channels; review, interpretation, report by physician or other qualified health care professional.	M	N/A

*HCPCS code J1725 (Injection, hydroxyprogesterone caproate, 1 mg) was replaced with HCPCS code Q9986 effective July 1, 2017.

#HCPCS code C9487, which was effective April 1, 2017, was replaced with HCPCS code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017.

3. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2017 and January 1, 2018 for Which We Will Be Soliciting Public Comments in the CY 2018 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, 2017 and January 1, 2018 in the CY 2018 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 2019 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 Web site (for Level II HCPCS codes).

For CY 2018, 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, 2017 and January 1, 2018 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 2018 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 2019 OPPS/ASC final rule with comment period.

4. Proposed Treatment of New and Revised CY 2018 Category I and III CPT Codes That Will Be Effective January 1, 2018 for Which We Are Soliciting Public Comments in This CY 2018 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 MPFS 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 2018 OPPS update, we received the CY 2018 CPT codes from AMA in time for inclusion in this CY 2018 OPPS/ASC proposed rule. The new, revised, and deleted CY 2018 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 Web site). 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 2018 CPT codes in Addendum O to this proposed rule (which is available via the Internet on

the CMS Web site) 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 2018 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code,” to this proposed rule. The final CPT code numbers will be included in the CY 2018 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 2018 status indicators and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2018. 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 2018 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 Web site).

5. Proposed Care Management Coding Changes Effective January 1, 2018 (APCs 5821 and 5822)

As noted in the CY 2018 MPFS proposed rule, we continue to be interested in the ongoing work of the medical community to refine the set of codes used to describe care management services, including chronic care management. We are proposing to adopt CPT replacement codes for CY 2018 for several of the care management services finalized last year and are seeking public comment on ways we might further reduce burden on reporting providers, including through stronger alignment between CMS requirements and CPT guidance for existing and potential new codes. Table 15 below details the proposed care management coding changes. We refer readers to Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2018 payment rates for the replacement codes.

TABLE 15—PROPOSED CARE MANAGEMENT CODING CHANGES EFFECTIVE JANUARY 1, 2018

CY 2017 HCPCS code	CY2017 HCPCS short descriptor	CY 2017 OPPTS SI	CY 2017 OPPTS ASC	Proposed CY 2018 replacement CPT code*	Proposed CY 2018 replacement HCPCS short descriptor	Proposed CY 2018 OPPTS SI	Proposed CY 2018 OPPTS APC
G0502	Init psych care Manag, 70min.	S	5822	994X1	1st psyc collab care mgmt.	S	5822
G0503	Subseq psych care man, 60mi.	S	5822	994X2	Sbsg psyc collab care mgmt.	S	5822
G0504	Init/sub psych Care add 30 m.	N	N/A	994X3	1st/sbsq psyc collab care.	N	N/A
G0505	Cog/func assess-ment outpt.	S	5822	99XX3	Assmt & care pln pt cog imp.	S	5822
G0507	Care manage serv minimum 20.	S	5821	99XX5	Care mgmt. svc bhvl hlth cond.	S	5821

*These are the 5-digit placeholder CPT codes. The final CPT code numbers will be included in the CY 2018 OPPTS/ASC final rule with comment period. The long descriptors for the codes can be found in Addendum O (New Category I and Category III CPT Codes Effective January 1, 2018) to this proposed rule, which is available via the Internet on the CMS Web site.

B. Proposed OPPTS 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 § 419.2(b) of the regulations. A further discussion of packaged services is included in section II.A.3. of this proposed rule.

Under the OPPTS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2018, 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

In accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine, with respect to comparability of the use of resources, if the highest cost for an item or service in the APC group is more than 2 times greater than the lowest cost for an item or service within the same APC 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 2018, 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 2018 OPPTS, 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 2018 OPPTS/ASC proposed rule. Rather, it is published and made available via the Internet on the CMS Web site 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 2018 included in this proposed rule are related to changes in costs of services that were observed in the CY 2016 claims data newly available for CY 2018 ratesetting. Addendum B to this CY 2018 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, 2017 OPPS Addendum B Update (available via the Internet on the CMS Web site 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 for CY 2018, 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.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18457 and 18458).

Based on the CY 2016 claims data available for this CY 2018 proposed rule, we found 12 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 2018, and found that all of the 12 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2016 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 2 times rule violations.

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 16 of this proposed rule lists the 12 APCs that we are proposing to except from the 2 times rule for CY 2018 based on the criteria cited above and claims data submitted between January 1, 2016 and December 31, 2016, and processed on or before December 31, 2016. For the final rule with comment period, we intend to use claims data for dates of service between January 1, 2016 and December 31, 2016 that were processed on or before June 30, 2017, and updated CCRs, if available. The 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 Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>.

TABLE 16—PROPOSED APC EXCEPTIONS TO THE TWO TIMES RULE FOR CY 2018

Proposed CY 2018 APC	Proposed CY 2018 APC title
5112	Level 2 Musculoskeletal Procedures.
5161	Level 1 ENT Procedures.
5311	Level 1 Lower GI Procedures.
5461	Level 1 Neurostimulator and Related Procedures.
5521	Level 1 Imaging without Contrast.
5573	Level 3 Imaging with Contrast.
5611	Level 1 Therapeutic Radiation Treatment Preparation.
5691	Level 1 Drug Administration.
5731	Level 1 Minor Procedures.
5735	Level 5 Minor Procedures.
5771	Cardiac Rehabilitation.
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.

For CY 2017, there are 51 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 1906 (New Technology—Level 51 (\$140,001–\$160,000)). 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.

We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1906, vary with increments ranging from \$10 to \$19,999. 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.

Every year we receive several requests for higher payment amounts under the New Technology APCs for specific procedures paid under the OPPS because they require the use of expensive equipment. We are taking this opportunity to reiterate our response in general to the issue of hospitals’ capital expenditures as they relate to the OPPS and Medicare, as specified in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70374).

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

We note that, in a budget neutral environment, 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 OPSS 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 OPSS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314).

2. Proposed Revised and Additional New Technology APC Groups

As stated above, for CY 2017 there are currently 51 levels of New Technology APCs. To improve our ability to have payments for services over \$100,000 more closely match the cost of the service, for CY 2018 we are proposing to narrow the increments for New Technology APCs 1901–1906 from \$19,999 cost bands to \$14,999 cost bands. We also are proposing to add New Technology APCs 1907 and 1908 (New Technology Level 52 (\$145,001–\$160,000), which would allow for an appropriate payment of retinal prosthesis implantation procedures, which is discussed in later in this section. Table 17 below includes the complete list of the proposed modified and additional New Technology APC groups for CY 2018.

TABLE 17—PROPOSED CY 2018 ADDITIONAL NEW TECHNOLOGY APC GROUPS

Proposed CY 2018 APC	Proposed CY 2018 APC Title	Proposed CY 2018 SI	Updated or new APC
1901	New Technology—Level 49 (\$100,001–\$115,000)	S	Updated.
1902	New Technology—Level 49 (\$100,001–\$115,000)	T	Updated.
1903	New Technology—Level 50 (\$115,001–\$130,000)	S	Updated.
1904	New Technology—Level 50 (\$115,001–\$130,000)	T	Updated.
1905	New Technology—Level 51 (\$130,001–\$145,000)	S	Updated.
1906	New Technology—Level 51 (\$130,001–\$145,000)	T	Updated.
1907	New Technology—Level 52 (\$145,001–\$160,000)	S	New.
1908	New Technology—Level 52 (\$145,001–\$160,000)	T	New.

The proposed payment rates for New Technology APCs 1901 through 1908 can be found in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site).

3. Proposed Procedures Assigned to New Technology APC Groups for CY 2018

a. Overall Proposal

As we explained in the CY 2002 OPSS 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 2018, in this CY 2018 OPSS/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).

b. 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 of which we are proposing to continue to assign to a New Technology APC. These codes include CPT codes 0071T, 0072T, and 0398T, and HCPCS code C9734. CPT codes 0071T and 0072T are used for the treatment of uterine fibroids, CPT code 0398T is used for the treatment of essential tremor, and HCPCS code C9734 is used for pain palliation for metastatic bone cancer.

As shown in Table 18 below, and as listed in Addendum B of this CY 2018

OPPS/ASC proposed rule, we are proposing to continue to assign CPT codes 0071T and 0072T to APC 5414 (Level 4 Gynecologic Procedures), with a proposed payment rate of approximately \$2,189 for CY 2018. 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 all covered Part B services 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 HCPCS code C9734 to APC 5114 (Level 4

Musculoskeletal Procedures), with a proposed payment rate of approximately \$5,385 for CY 2018. We also are proposing to continue to assign HCPCS code C9734 to status indicator as “J1”.

Further, we are proposing to continue to assign CPT code 0398T to APC 1537 (New Technology—Level 37 (\$9501–\$10000)), with a proposed payment rate of approximately \$9,751 for CY 2018. We have only received one claim for CPT code 0398T, and, based on this limited information, are not proposing to assign this MRgFUS procedure to a standard APC. We refer readers to Addendum B of 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 Web site.

TABLE 18—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRGFUS) PROCEDURES

CPT/HCPCS Code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
0071T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue.	J1	5414	\$2,084.59	J1	5414	\$2,188.97
0072T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue.	J1	5414	2,084.59	J1	5414	2,188.97
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	1537	9,750.50	S	1537	9,750.50
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	J1	5114	5,219.36	J1	5114	5,385.23

c. 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 FDA in 2013 for adult patients diagnosed with advanced 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, 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 which has a 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 showed 9 single claims (out of 13 total claims) for 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 and our understanding of the Argus® II procedure, we reassigned 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 includes the cost of both the surgical procedure (CPT code 0100T) and the retinal prosthesis device (HCPCS code C1841).

For the CY 2018 update, analysis of the CY 2016 OPPS claims data used for the CY 2018 proposed rule showed 3 single claims (out of 3 total claims) for CPT code 0100T, with a geometric mean cost of approximately \$116,239 based on the claims submitted between January 1, 2016 through December 31, 2016, and processed through December 31, 2016. For the CY 2018 OPPS/ASC final rule with comment period, the final payment rate will be based on claims submitted between January 1, 2016 and December 31, 2016, and processed through June 30, 2017.

Based on the CY 2016 OPPS claims data available, which show a geometric mean cost of approximately \$116,239, we are proposing to assign the Argus® II procedure to a New Technology APC with a payment band that covers the geometric mean of the procedure. Therefore, we are proposing to assign CPT code 0100T to APC 1904 (New Technology—Level 50 \$115,001–\$130,000), with a proposed payment of \$122,000.50 for CY 2018. We are inviting public comments on this proposal.

d. Pathogen Test for Platelets

The CMS HCPCS Workgroup has established HCPCS code Q9987 (Pathogen(s) test for platelets) effective July 1, 2017. HCPCS code Q9987 will be used to report any test used to identify bacterial or other pathogen contamination in blood platelets. Currently, there is one test approved by the FDA that is described by HCPCS code Q9987. The test is a rapid bacterial test and the manufacturer estimates the cost of the test to be between \$26 and \$35. HCPCS code Q9987 was established after concerns from blood and blood product stakeholders that the previous CPT code used to describe pathogen tests for platelets, CPT code

P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit), inappropriately described rapid bacterial testing by combining the test with the pathogen reduction of platelets. CPT code P9072 is inactive effective July 1, 2017.

We are seeking more information on the actual costs of pathogen tests for platelets before assigning HCPCS code Q9987 to a clinical APC. Effective July 1, 2017, HCPCS code Q9987 is assigned to New Technology APC 1493 (New Technology—Level 1C (\$21–\$30)), with a payment rate of \$25.50. We are proposing to continue to assign HCPCS code Q9987 to New Technology APC 1493, with a proposed payment rate of \$25.50, until such time as claims data are available to support assignment to a clinical APC. We are inviting public comments on this proposal.

D. Proposed OPPS APC-Specific Policies

1. Blood-Derived Hematopoietic Cell Harvesting

HCPCS code 38205 describes blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic. This code represents a donor acquisition cost for an allogeneic hematopoietic stem cell transplant (HSCT). In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60575), we assigned this code to status indicator “B”, which indicates that this code is not recognized by the OPPS when submitted on an outpatient hospital Part B bill (type 12x and 13x).

In CY 2017, we finalized a comprehensive APC (C-APC) for HSCT (81 FR 79586 through 79587). Payment for donor acquisition services for HSCT is included in the C-APC payment for the allogeneic stem cell transplant when the transplant occurs in the hospital outpatient setting. All donor acquisition costs, including the costs for HCPCS code 38205, should be reported on the same date of service as the transplant procedure (HCPCS code 38240 (Hematopoietic progenitor (HPC); allogeneic transplantation per donor)) in order to be appropriately packaged for payment purposes. Hospitals are instructed to identify services required to acquire stem cells from a donor for allogeneic HSCT separately in Field 42 on Form CMS-1450 (or UB-04), with revenue code 0815 when an allogeneic stem cell transplant occurs. (We refer readers to the Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 4, Section 231.11 and Chapter 3, Section 90.3.1.)

There other donor acquisition costs, namely those costs for the procedure

described by HCPCS code 38230 (Bone marrow harvesting for transplantation; allogeneic), which are assigned to status indicator “S”. For consistency and to ensure that the donor acquisition costs are captured accurately, for CY 2018, we are proposing to change the status indicator assignment for the procedure described by HCPCS code 38205 from “B” to “S”, which indicates that the procedure is paid under the OPPS and receives separate payment.

Our latest claims data used for this proposed rule, which include claims submitted between January 1, 2016, and December 31, 2016, and processed on or before December 31, 2016, show a geometric mean cost of approximately \$580 for HCPCS code 38205 based on 2 single claims (out of 8 total claims). The procedure described by HCPCS code 38205 has resource and clinical similarities to procedures assigned to APC 5242 (Level 2 Blood Product Exchange and Related Services). Therefore, we are proposing to assign HCPCS code 38205 to APC 5242. We are inviting public comments on these proposals.

2. Radiology and Imaging Procedures and Services

a. Imaging APCs

Section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually, and revise the APC group assignments, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. In addition, 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.

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 APCs without contrast and three imaging APCs with contrast.

For this CY 2018 proposed rule, we reviewed the services assigned to the imaging without contrast APCs and imaging with contrast APCs. 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 and corrected any 2 times rule violations as discussed in section III.B.2. of this CY 2018 OPPS/ASC proposed rule. In addition, we reviewed and considered stakeholder recommendations to make additional refinements to the structure of the APC groupings of the imaging procedures classified within the imaging APCs that would maintain clinical homogeneity while more appropriately addressing resource cost fluctuation and volatility. As a result of our analysis and review of the claims data used for CY 2018 ratesetting, we believe a Level 5 Imaging without Contrast APC is needed to more appropriately group certain imaging services with higher resource costs. Specifically, we believe the data support splitting the current 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 are proposing to add a fifth level within the Imaging without Contrast APCs. Below in Table 19, we list the CY 2017 imaging APCs, and in Table 20, we list the proposed CY 2018 imaging APCs with the addition of a fifth level within the Imaging without Contrast APCs. The specific APC assignments for each service grouping are listed in Addendum B to the proposed rule, which is available via the Internet on the CMS Web site. This proposal would increase the imaging APCs from 7 APCs in CY 2017 to 8 in CY 2018. The specific APC assignments for each imaging service HCPCS code are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We note that some of the imaging procedures are assigned to APCs that are not listed in the tables below (for example, the vascular procedures APCs). Also, the nuclear medicine services APCs are not

included in this proposal. These imaging services are not included in this proposal because we are not proposing changes to their APC structure.

We are inviting public comments on our proposal to add a Level 5 Imaging without Contrast APC in CY 2018.

TABLE 19—CY 2017 IMAGING APCS

CY 2017 APC	CY 2017 APC Group Title
5521	Level 1 Imaging without Contrast.
5522	Level 2 Imaging without Contrast.
5523	Level 3 Imaging without Contrast.
5524	Level 4 Imaging without Contrast.
5571	Level 1 Imaging with Contrast.
5572	Level 2 Imaging with Contrast.
5573	Level 3 Imaging with Contrast.

TABLE 20—PROPOSED CY 2018 IMAGING APCS

Proposed CY 2017 APC	Proposed CY 2017 APC Group Title
5521	Level 1 Imaging without Contrast.
5522	Level 2 Imaging without Contrast.
5523	Level 3 Imaging without Contrast.
5524	Level 4 Imaging without Contrast.
5525	Level 5 Imaging without Contrast.
5571	Level 1 Imaging with Contrast.
5572	Level 2 Imaging with Contrast.
5573	Level 3 Imaging with Contrast.

b. Non-Ophthalmic Fluorescent Vascular Angiography (APC 5524)

For the CY 2018 OPPS update, we are proposing to reassign HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography) from APC 5523 (Level 3 Imaging without Contrast) to APC 5524 (Level 4 Imaging without Contrast) based on the latest claims data available for this proposed rule. We are proposing to maintain the status indicator assignment of “Q2” (T-packaged) to indicate that the service is conditionally packaged when performed in conjunction with other procedures on the same day but paid separately when performed as a stand-alone service.

Our latest claims data used for this proposed rule, which include claims submitted between January 1, 2016, and December 31, 2016, and processed on or before December 31, 2016, show a geometric mean cost of approximately \$236 for HCPCS code C9733 based on 216 single claims (out of 953 total claims), which is closely aligned with the geometric mean cost of approximately \$275 for APC 5524. Because HCPCS code C9733 is an imaging service which is similar to the codes assigned to APC 5524, we are proposing to reassign HCPCS code

C9733 from APC 5523 to APC 5524. We believe this proposed reassignment would improve the clinical homogeneity of APC 5524 and appropriately align the resource costs of HCPCS code C9733 to the resource costs of those procedures assigned to APC 5524.

As we have stated in previous OPPS/ASC final rules, specifically, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68345 through 68346), CY 2014 OPPS/ASC final rule with comment period (78 FR 74976 through 74977), and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79632), the service described by HCPCS code C9733 is primarily an intraoperative imaging service that is performed in combination with a number of primary procedures, including facial reconstruction and reanimation, muscle flaps, trauma reconstruction, digital and limb reattachment, and breast reconstruction. Therefore, HCPCS code C9733 is conditionally packaged under § 419.2(b)(14), which contains the policies governing packaging of intraoperative items and services. Consequently, we are proposing to maintain the status indicator assignment of “Q2” to indicate that the payment for the service will be packaged in the APC payment if billed on the same date of service as a HCPCS code assigned to status indicator “T”, but in all other circumstances, a separate APC payment for the service will be made. We believe that the OPPS payments, separate or packaged, for surgical procedures with which this service is performed are more than adequate to cover the cost of the service described by HCPCS code C9733 for Medicare beneficiaries in need of this service.

In summary, for the CY 2018 OPPS update, we are proposing to reassign HCPCS code C9733 to APC 5524 based on the latest claims data used for this proposed rule. In addition, we are proposing to maintain its status indicator assignment of “Q2” to indicate that the service is conditionally packaged. The proposed CY 2018 OPPS payment rate for HCPCS C9733 can be found in OPPS Addendum B to this proposed rule, which is available via the Internet on the CMS Web site.

3. Comment Solicitation on Intraocular Procedure APCs

As part of our CY 2018 comprehensive review of the structure of the APCs and procedure code assignments, we evaluated the intraocular procedure APCs with a particular focus on C-APC 5491 (Level 1 Intraocular Procedures) that contains

cataract surgery procedures. We strive to maintain APCs that contain procedures that are relatively homogenous in resource costs and clinical characteristics. While it is impracticable and contrary to the principles of a prospective payment system to assign each procedure to its own APC, thus resulting in a cost-based, fee schedule payment system, we seek to ensure our clinical groupings appropriately group like items and services while maintaining the integrity of a prospective payment system under which bundled, encounter-based payments are essential.

For CY 2018, we considered proposing a new intraocular procedure APC that would further distinguish the resource costs and clinical characteristics between cataract surgery and complex cataract surgery. As listed in Addendum B of this CY 2018 OPPS/ASC proposed rule, we are proposing to continue to assign CPT code 66984 (Cataract surgery with IOL 1 stage procedure) and CPT code 66982 (Cataract surgery complex) to C-APC 5491. However, because the 2017 AMA CPT Code manual describes a complex cataract surgery case as “requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis),” we believe it may be more appropriate to assign CPT code 66982 to a C-APC that is separate from the C-APC assignment for CPT code 66984. However, because this potential APC grouping would assign CPT code 66982 to a higher paying C-APC than CPT code 66984, we would monitor claims data for changes in the distribution of coding complex cataract surgery and routine cataract surgery if we were to adopt this change. We are seeking public comments from stakeholders, including ophthalmologists, organizations representing ophthalmologists, beneficiaries, hospitals, and all other interested parties on whether we should create a new C-APC that includes complex cataract surgeries identified by CPT code 66982 (along with other intraocular procedures that are similar in resources) in a newly created C-APC that is separate from those identified by CPT code 66984. That is, we are considering whether to establish a new Level 2 Intraocular Procedures C-APC in between existing C-APCs 5491 and 5492.

IV. Proposed OPPS Payment for Devices

A. Proposed 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 has 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 three device categories eligible for pass-through payment: (1) HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser), which was established effective April 1, 2015; (2) HCPCS code C2613 (Lung biopsy plug with delivery system), which was established effective July 1, 2015; and (3) HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), which was established effective January 1, 2016. The pass-through payment status of the device categories for HCPCS codes C2623, C2613, and C1822 will end on December 31, 2017. We note that our new policy adopted in the CY 2017 OPPS/ASC final rule with comment period to allow for quarterly expiration of pass-through payment status for devices applies to devices approved in CY 2017 and subsequent years. As all the devices in these three device categories were approved prior to CY 2017, we are applying our policy to expire them at the end of the calendar year when at least 2 years of pass-through payments have been made. Therefore, we are proposing, beginning in CY 2018, to package the costs of each of the devices described by HCPCS codes C2623, C2613, and C1822 into the costs related to the procedure with which each device is reported in the hospital claims data.

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 OPPTS, 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 OPPTS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPTS 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 OPPTS 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 Web site 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 2018

We received five applications by the March 1, 2017 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included for this CY 2018 OPPTS/ASC proposed rule. All applications were received in the second quarter of 2016. None of the five applications were approved for device pass-through payment during the quarterly review process.

Applications received for the later deadlines for the remaining 2017 quarters (June 1, September 1, and December 1), if any, will be presented in the CY 2019 OPPTS/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 Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>. A discussion of the five applications received by the March 1, 2017 deadline is presented below.

(1) Architect® Px

Harbor MedTech, Inc. submitted an application for a new device category for transitional pass-through payment status for Architect® Px. Architect® Px is a collagen biomatrix comprised of a stabilized extracellular matrix derived from equine pericardium. The equine pericardium is stabilized to become a catalyst and scaffold for use by autologous tissue regeneration factors. Architect® Px is packaged as an individual unit in sizes ranging from 2cm x 2cm up to 10cm x 15cm and is approximately 0.75mm thick. Architect® Px typically requires only one application. The applicant asserted

that it is clinically superior to other skin substitutes that work by flooding the wound with nonautologous collagen and growth factors because Architect® Px attracts and concentrates the patient's own autologous collagen and growth factors to support healing.

With respect to the newness criterion at § 419.66(b)(1), the applicant received FDA clearance for Architect® Px on September 12, 2014, and its June 1, 2016 application was submitted within 3 years of FDA clearance. However, Unite BioMatrix, cleared by the FDA on June 20, 2007, is claimed as a predicate of Architect® Px. The Architect® Px application states that “. . . while packaged differently, Architect® Px and Unite BioMatrix are identical . . . they are both stabilized equine pericardium manufactured using the same processes . . .” If the date for FDA clearance for Unite BioMatrix is used to evaluate the newness criterion, Architect® Px may not meet the newness criterion. We are inviting public comments on this issue.

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

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 Architect® Px. Harbor MedTech, Inc. proposes a new device category descriptor of “Stabilized Skin Substitute for Autologous Tissue Regeneration” for Architect® Px. 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 only identifies two references, neither of which we believe provide evidence of substantial clinical improvement. One reference is a 2012 summary report¹ of skin substitute products that can be used to treat chronic wounds that only describes characteristics of the predecessor product to Architect® Px with no efficacy or performance information. The second reference² is a small observational study of 34 subjects with no comparison group. We are inviting public comments on whether Architect® Px 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. Architect® Px 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 CY 2016 payment rate of \$1,411.21 and a device offset of \$4.52, or APC 5055 (Level 5 Skin Procedures), with a CY 2016 payment rate of \$2,137.49 and a device offset of \$25.44. According to the applicant, the cost of the substitute graft procedures when performed with Architect® Px is \$5,495.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of \$5,495 for Architect® Px exceeds the applicable APC amount for the service related to the category of devices of \$1,411.21 by 389 percent ($\$5,495/\$1,411.21 \times 100$ percent = 389 percent). Therefore, it

appears that Architect® Px 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 \$5,495 for Architect® Px exceeds the device-related portion of the APC payment amount for the related service of \$4.52 by 121,571 percent ($\$5,495/\4.52×100 percent = 121,571 percent). Therefore, it appears that Architect® Px 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 \$5,495 for Architect® Px and the portion of the APC payment amount for the device of \$4.52 exceeds 10 percent at 389 percent ($(\$5,495 - \$4.52)/\$1,411.21 \times 100$ percent = 389 percent). Therefore, it appears that Architect® Px meets the third cost significance test. Based on the costs submitted by the applicant and the calculations noted earlier, we believe that Architect® Px meets the cost criterion at § 419.66(c)(3) for new device categories.

We are inviting public comments on whether Architect® Px meets the device pass-through payment criteria discussed in this section.

(2) Dermavest and Plurivest Human Placental Connective Tissue Matrix (HPCTM)

Aedicell, Inc. submitted an application for a new device category for transitional pass-through payment status for Dermavest and Plurivest human placental connective tissue matrix (HPCTM). Dermavest and Plurivest HPCTM use tissue sourced from the placental disk, amnion/chorion, and umbilical cord to replace or supplement damaged tissue. The applicant stated that Dermavest and Plurivest replace or supplement damaged or inadequate integumental tissue by providing a scaffold to entrap migrating cells for repopulation. The applicant stated that the products may be clinically indicated for the following conditions: Partial and full thickness

¹ Snyder, D.L. *et al.* Skin Substitutes for Treating Chronic Wounds. Technology Assessment Report. Project ID: HCPR0610. AHRQ. December 18, 2012.

² Alexander JH, Yeager DA, *et al.* Equine Pericardium as a Biological Covering for the Treatment of Diabetic Foot Wounds; a Prospective Study. *J Am Podiatric Assoc.*, 2012 Sep-Oct.;102 (5): 352–358.

wounds; pressure ulcers; venous ulcers; chronic vascular ulcers; diabetic ulcers; trauma wounds (abrasions, lacerations, second degree burns, and skin tears); drainage wounds; and surgical wounds (donor sites/grafts post mohs surgery, post laser surgery, and podiatric). Dermavest and Plurivest HPCTM are applied to the area of inadequate or damaged tissue, moistened if necessary and covered with a nonadherent secondary dressing. While the application does not distinguish between the Dermavest and Plurivest products, the AediCell Inc. Web site states that the two products differ by dosage. According to information on the Web site at www.aedicell.com, each product contains different tissue cell attachment proteins (CAP) and cytokine/growth factors (GF) profiles. There is a lower cytokine/GF concentration profile in Plurivest and a higher concentration of CAP and cytokine/GF in Dermavest.

With respect to the newness criterion at § 419.66(b)(1), the applicant indicated that the product conforms to the FDA regulatory path under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Under this regulatory path, FDA requires the manufacturer to register and list its HCT/Ps with the Center for Biologics Evaluation and Research (CBER) within 5 days after beginning operations and to update their registrations annually. AediCell Inc. has an FDA field establishment identifier (FEI) under the HHS–FDA–Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) and submitted with its application the annual registration/listing for Dermavest and Plurivest dated November 9, 2015. The applicant noted that the initial registration for the manufacture of Dermavest was submitted to the CBER on October 28, 2013, and the registration of Plurivest was submitted the following year on November 14, 2014. The registration forms including these dates were not included in the application. Therefore, it is unclear if the newness criterion is met.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Dermavest and Plurivest are skin substitute products that are integral to the service provided, are used for one patient only, come in contact with human skin, and are applied in or on a wound or other skin lesion. The applicant also claimed Dermavest and Plurivest meet the device eligibility requirements of § 419.66(b)(4) because they are not instruments, apparatuses,

implements, or items for which depreciation and financing expenses are recovered, and they are not supplies or materials 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 Dermavest and Plurivest HPCTM. The applicant proposed a category descriptor for Dermavest and Plurivest of “Human placental connective tissue matrix (HPCTM), comprised of tissue sourced from the placental disk, amnion/chorion, and umbilical cord for the intention of replacing or supplementing damaged or inadequate integumental issue.” 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 provided several background studies showing general evidence that placental tissue, umbilical cord, and amnion membrane products are effective in the treatment of various wounds and ulcers. However, these studies were not specific to Dermavest and Plurivest HPCTM. The applicant submitted two poster presentations describing case studies that evaluated the wound healing time and wound characteristics of patients with diabetic and venous ulcers treated with Dermavest and Plurivest HPCTM. Both studies were described as case series and, as such, lacked blinding, randomization, and control groups. The first poster,³ presented in 2015, described a prospective, multi-center case series with a small number of participants (n = 15). The study evaluated wound healing time and wound characteristics of patients with various etiologies. The patients were

treated with up to two six cm² pieces of Dermavest per application on wounds up to 44 cm². Results were presented for diabetic and venous ulcer cases and showed a week 4 percent area reduction (PAR) of 71 percent for diabetic ulcers and 50 percent for venous ulcers. Eighty percent of the diabetic ulcer cases and 50 percent of the venous ulcer cases had a week 4 PAR of greater than 40 percent.

The second poster,⁴ presented in 2016, also described a case series that evaluated wound healing time and wound characteristics of patients with various etiologies (n = 8). The poster stated that the patients were treated with pieces of HPCTM according to manufacturer guidelines on wounds ranging in size up to 3.8 cm². The methods presented in the poster do not specify whether the patients were treated with Dermavest or Plurivest, or both. The results presented in the poster compile Dermavest data from two case series presented at the Society for Advanced Wound Care (SAWC) annual meeting. It was unclear whether there was overlap between the patients used in the 2015 and 2016 case series included in the application. The compiled Dermavest data were compared to the 4-week PAR results for diabetic and venous ulcers from two other noncontemporaneous studies evaluating different skin replacement products. The results showed, at week 4, approximately 80 percent of the Dermavest-treated diabetic ulcer cases had a PAR of greater than 50 percent in comparison to approximately 60 percent of cases and approximately 30 percent of cases, respectively, in the comparison studies using other skin replacement products. The results also showed that, at week 4, approximately 60 percent of the Dermavest-treated venous ulcer cases had a PAR of greater than 40 percent in comparison to approximately 50 percent of cases and approximately 30 percent of cases in the comparison studies treated with other skin replacement products. There were multiple differences between the Dermavest studies included in the poster presentations and these two additional studies presented as comparators, including the number of patients included in the studies, the number of wounds treated, and the purpose of the study. Based on the results presented in the poster, the applicant concluded that HPCTM

³ Connell et al., Human placental connective tissue matrix in the treatment of chronic wounds: A prospective multi-center case series. 2015 at Society of Advanced Wound Healing (SAWC) Spring meeting.

⁴ McGuire and Sebag, The use of a new placental acellular tissue product in the management of chronic wounds: A case series. 2016 at the Society of Advanced Wound Healing (SAWC) Spring meeting.

provides an effective alternative to other skin replacement products.

We are concerned that the research provided did not clinically demonstrate the active ingredients of the product(s) that might distinguish the product from others, the correct dosing of the product(s), the amount of durable wound closure with the product(s) compared to standard of care in studies with rigorous trial design/ implementation, and the amount of durable wound closure with the product(s) compared to other products in studies with rigorous trial design/ implementation. Based on the evidence submitted with the application, we are not yet convinced that the Dermavest and Plurivest HPCTM provide a substantial clinical improvement over other treatments for wound care. We are inviting public comments on whether the Dermavest and Plurivest HPCTM meet this criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that Dermavest and Plurivest HPCTM would be reported with CPT codes 15271, 15272, 15273, 15274, 15275, 15276, 15277, and 15278. CPT codes 15272, 15274, 15276, and 15278 are add-on codes assigned status indicator “N”, which means payment is packaged under the OPPS. CPT codes 15271 and 15275 are assigned to APC 5054 (Level 4 Skin Procedures), and CPT codes 15273 and 15277 are assigned to APC 5055 (Level 5 Skin 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 5054 (Level 4 Skin Procedures), which had a CY 2016 payment rate of \$1,411 and a device offset amount of \$4.52 at the time the application was received. According to the applicant, the cost of a sheet of 2x3 cm Dermavest is \$550, and the cost of a sheet of 2x3 cm Plurivest is \$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 \$550 for Dermavest and Plurivest exceeds 39 percent of the applicable APC payment amount for the service related to the

category of devices of \$1,411 ($\$550 / \$1,411 \times 100 = 39$ percent). Therefore, we believe Dermavest and Plurivest meet 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 \$550 for Dermavest and Plurivest exceeds the cost of the device-related portion of the APC payment amount for the related service of \$4.52 by 12,168 percent ($\$550 / \$4.52 \times 100 = 12,168$ percent). Therefore, we believe that Dermavest and Plurivest meet 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 \$550 for Dermavest and Plurivest and the portion of the APC payment amount for the device of \$4.52 exceeds the APC payment amount for the related service of \$1,411 by 38.6 percent ($(\$550 - \$4.52) / \$1,411 \times 100 = 38.6$ percent). Therefore, we believe that Dermavest and Plurivest meet the third cost significance test.

We are inviting public comments on whether Dermavest and Plurivest meet the device pass-through payment criteria discussed in this section.

(3) FlōGraft®/Flōgraft Neogenesis®

Applied Biologics, LLC submitted an application for a new device category for transitional pass-through payment status for FlōGraft®/Flōgraft Neogenesis®. FlōGraft®/Flōgraft Neogenesis® is an injectable, human placental amniotic fluid. It is an allograft derived from human birth tissue recovered from a live, healthy C-section birth. The allograft is used to augment tissue to bone and tissue to tissue repairs. The allograft is implanted at the surgical site at the end of the procedure using a needle and syringe under direct visualization. The applicant claimed that the product helps drive healing towards native tissue regeneration and away from scar formation. FlōGraft® has a standardized potency of 2 million cells. FlōGraft

Neogenesis® has a standardized potency of 1.5 million cells. The applicant indicated that the product may be used with several surgical procedures, including joint replacement procedures, traumatic bone and soft tissue injury, meniscal repairs, meniscal transplantation, articular cartilage restoration, foot and ankle repairs, and chronic wounds.

With respect to the newness criterion at § 419.66(b)(1), the applicant indicated that FlōGraft® and Flōgraft Neogenesis® conform to the FDA regulatory path under section 361 of the PHS Act and 21 CFR part 1271 for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Under this regulatory path, FDA requires the manufacturer to register and list their HCT/Ps with the Center for Biologics Evaluation and Research (CBER) within 5 days after beginning operations and update their registrations annually. Applied Biologics, LLC has two FDA field establishment identifiers (FEI) under the HHS–FDA–Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Both registration forms list the product as “FlōGraft®”. The applicant submitted an initial registration/listing for one FEI dated June 8, 2015, as well as an annual registration/listing for a different FEI dated December 1, 2014. The first date of U.S. sale for FlōGraft® was May 23, 2013. It is not clear when the initial CBER filing occurred for the FlōGraft® product. Therefore, it is unclear if the newness criterion for the FlōGraft® product is met.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, FlōGraft® and Flōgraft Neogenesis® are integral to the service provided, are used for one patient only, come in contact with human skin, and are applied in or on a wound or other skin lesion. The applicant also claimed FlōGraft® and Flōgraft Neogenesis meet the device eligibility requirements of § 419.66(b)(4) because they are not instruments, apparatuses, implements, or items for which depreciation and financing expenses are recovered, and they are not supplies or materials 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 device category that describes FlōGraft®/Flōgraft Neogenesis®. The application proposed a payment device category for FlōGraft®/Flōgraft Neogenesis® with a category descriptor of “Injectable Amniotic Fluid Allograft”. 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 the substantial clinical improvement criterion, the applicant submitted several peer-reviewed publications that provided general evidence that amniotic fluid and amniotic membrane-based products significantly reduce recovery time. However, these studies did not include the use of the FlōGraft®/Flōgraft Neogenesis® product. The applicant did list several studies in the application that involved the use of the FlōGraft®/Flōgraft Neogenesis® product. Of these studies, five unpublished studies were available for review. The five studies submitted with the application were described as case studies, case series, or retrospective cohort studies. The studies lacked random allocation, blinding, and a comparison group. The first study⁵ described a retrospective cohort study of 30 patients. The studies showed that 93 percent of the patients (n=14) who received a FlōGraft® injection, coupled with conservative, nonsurgical treatment plan to treat their Morton’s Nerve entrapment condition, had their issue resolved compared to 20 percent of patients (n=3) who did not receive FlōGraft® injection, coupled with conservative, nonsurgical treatment plan to treat their Morton’s Nerve entrapment condition. A greater percentage of patients who did not receive a FlōGraft® injection with their conservative treatment required surgery (80 percent versus 7 percent). Patients who required surgery had a 95-percent success rate when surgery was coupled with a FlōGraft® injection.

The next study⁶ was a retrospective analysis that involved 27 patients who were treated for stalled wounds. The patients had a broad spectrum of

etiologies. Over a 12-month period, the applicant indicated that 96 percent of wounds that had stalled demonstrated rapid acceleration towards closure within a 21-day period when treated with FlōGraft®. The article recommended a randomized controlled trial (RCT) to confirm the results. The applicant also submitted two case studies,^{7,8} each involving one patient, which described the use of FlōGraft® to treat distal fibula fracture and tarsal tunnel compression neuropathy. Lastly, the application included a study⁹ which presented the results from a case study of one patient as well as a retrospective cohort of 34 patients who received a Broström-Evans procedure with the FlōGraft® product. In general, the studies submitted lacked a clear description of the outcome variable and study population, and did not include statistical analysis.

Based on the evidence submitted, we believe there is insufficient data to determine whether FlōGraft®/Flōgraft Neogenesis® offers a substantial clinical improvement over other treatments for wound care. We are inviting public comments on whether the FlōGraft®/Flōgraft Neogenesis® 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 several CPT codes would be used to report FlōGraft®/Flōgraft Neogenesis®, including CPT codes 29826, 29827, 29828, 23473, 23420, 23412, 27605, 27650, 29891, 29888, 29889, 28008, 22551, 22856, 27179, 29861, and 29862. 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. These CPT codes are assigned to APCs 5121 through 5125 (Level 1 through Level 5 Musculoskeletal Procedures). For our calculations, we used APC 5121 (Level 1 Musculoskeletal Procedures), which had a CY 2016 payment rate of \$1,455 and

a device offset of \$15.86 at the time the application was received. According to the applicant, the FlōGraft®/Flōgraft Neogenesis® product is available in a variety of vial sizes, the largest size being 18 cc with a cost of \$19,925.

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. We used the highest priced product for this determination. The estimated average reasonable cost of \$19,925 for FlōGraft®/Flōgraft Neogenesis® exceeds the applicable APC payment amount for the service related to the category of devices of \$1,455 by 1,369 percent ($\$19,925/\$1,455 \times 100 = 1,369$ percent). Therefore, we believe FlōGraft®/Flōgraft Neogenesis® 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 average reasonable cost of \$19,925 for FlōGraft®/Flōgraft Neogenesis® exceeds the device-related portion of the APC payment amount of \$15.86 by 125,360 percent ($\$19,925/\$15.86 \times 100 = 125,360$ percent). Therefore, we believe that FlōGraft®/Flōgraft Neogenesis® 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 average reasonable cost of \$19,925 for FlōGraft®/Flōgraft Neogenesis® and the portion of the APC payment amount for the device of \$15.86 exceeds the APC payment amount for the related service of \$1,455 by 1,368 percent ($(\$19,925 - \$15.86)/\$1,455 \times 100 = 1,368$ percent). Therefore, we believe FlōGraft®/Flōgraft Neogenesis® meets the third cost significance test.

We are inviting public comments on whether FlōGraft®/Flōgraft Neogenesis® meets the device pass-through payment criteria discussed in this section.

⁷ Jacoby, Richard. Case Study 221: Non-surgical Resolution of Distal Fibula Fracture with Flograft Implant; 82 YO Male.

⁸ Jacoby, Richard. Tarsal Tunnel Compression Neuropathy Case Study Using Flograft.

⁹ Maling, Scott. A Case Series: A retrospective analysis of 34 patients receiving modified Bronstrom-Evans procedure with Flograft reduce time to full mobility by 52%

⁵ Bregman, Peter. (2014). Addressing Morton’s Nerve Entrapment Surgically and Non-surgically with FloGraft.

⁶ Gottlieb, et al. FloGraft Rapidly Moves Stalled Wounds Into the Proliferative Phase.

(4) Kerecis™ Omega3 Wound (Skin Substitute)

Kerecis, LLC submitted an application for a new device category for transitional pass-through payment status for Kerecis™ Omega3 Wound. Kerecis™ Omega3 Wound is made from acellular fish skin from wild Atlantic cod (*Gadus morhua*) caught in the North Atlantic Ocean that is used to regenerate damaged human tissue in chronic wounds. The applicant claimed that there is no disease transmission risk and noted that the fish skin is not required to undergo the viral inactivation process that the FDA dictates for tissues from farm animals. The applicant noted that the Omega3 fatty acids offer multiple health benefits, including anti-inflammation. Kerecis™ Omega3 Wound is supplied as a sterile, single-use sheet in peel-open pouches. Kerecis™ Omega3 Wound does not elicit an immune response because the major antigenic components present within cell membranes are removed in a gentle manner during processing. Unlike mammalian and human sourced products, the fish skin possesses extremely low risk of disease transmission and offers no known cultural or religious constraints for usage. The fish skin product is both halal and kosher compatible and avoids potential conflicts with Sikhism and Hinduism (Vaishnavism).

With respect to the newness criterion at § 419.66(b)(1), the applicant received FDA clearance for Kerecis™ Omega3 Wound through the premarket notification section 510(k) process on October 23, 2013 and its June 1, 2016 application was within 3 years of FDA clearance.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Kerecis™ Omega3 Wound is a skin substitute 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 applicant also claimed Kerecis™ Omega3 Wound 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.

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 Kerecis™ Omega3 Wound. The applicant proposed a pass-through payment device category for Kerecis™ Omega3 Wound with category descriptor of “Piscine skin substitute.” 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 stated that individuals who would normally refuse to use skin substitute products from animal sources, including pigs, cows, horses, and sheep, would use Kerecis™ Omega3 Wound because it is a fish-based skin substitute. The applicant also asserted that Kerecis™ Omega3 Wound provides several beneficial outcomes, including faster resolution of the disease process compared to similar products, decreased antibiotic use, decreased pain, and reduced amounts of device-related complications.

The applicant cited three studies in support of the application. The first study¹⁰ was a parallel-group, double-blinded, randomized controlled trial undertaken to determine if healing time of whole thickness biopsy wounds treated with Kerecis Omega3 Wound is noninferior to that of wounds treated with porcine SIS ECM (Oasis). The study was an intention-to-treat study. Participants had two 4-mm full thickness punch wounds made on the proximal anterolateral aspect of their nondominant arm. The study population was comprised of volunteers aged between 18 and 67 years with most volunteers between the ages of 18 and 30. There were 80 volunteers who received Kerecis Omega3 Wound and 82 volunteers who received porcine SIS ECM (Oasis).

The results showed that, at 21 days, 58 (72.5 percent) of the fish skin ADM group were healed, compared with 46 (56 percent) of the porcine SIS ECM

group. At 25 days, 62 (77.5 percent) of the fish skin ADM and 53 (65 percent) of the porcine SIS ECM group had healed. At the completion of the trial (28 days), 76 of the 80 wounds treated with fish skin ADM (95 percent) and 79 of the 82 wounds treated with porcine SIS ECM (96.3 percent) were healed. The odds ratio of a fish skin ADM-treated wound being healed as compared with that treated with porcine SIS ECM at any given time point was estimated to be 4.75. The difference between the treatments was significant ($P = .041$). The immunological part of the study was designed to detect autoimmune reactions in those individuals treated with Kerecis Omega3 Wound. There was no evidence of antibodies forming in the presence of Kerecis Omega3 Wound.

There were issues with this study that may limit its usefulness to determine substantial clinical improvement including the use of nonpatient volunteers; studying the healing of biopsy sites rather than actual wounds requiring treatment; and the use of an unrealistic 1-month endpoint of care instead of a 6-month endpoint of care.

The second study¹¹ was a case series study of 18 patients to assess the percentage of wound closure area from baseline after 5 weekly fish-skin graft applications with at least one “hard-to-heal” criterion. Patients underwent application of the fish skin for 5 sequential weeks, followed by 3 weeks of standard care. Wound area, skin assessments, and pain were analyzed weekly.

The study results showed a 40-percent decrease in wound surface area ($P < 0.05$) and a 48-percent decrease in wound depth was seen with 5 weekly applications of the fish-skin graft and secondary dressing ($P < 0.05$). Complete closure was seen in 3 of 18 patients by the end of the study phase. This study did not use a comparator group to measure whether there is substantial clinical improvement with Kerecis Omega3 Wound compared to other skin substitute products.

The third study¹² was a case series study of five patients with diabetes mellitus and complicated wounds in the lower limbs with exposed bone segments. The five patients had a total of seven wounds. Initial debridement

¹¹ Yang, C.K. et al. A Prospective, Postmarket, Compassionate Clinical Evaluation of a Novel Acellular Fish-skin Graft Which Contains Omega-3 Fatty Acids for the Closure of Hard-to-heal Lower Extremity Chronic Ulcers. *Wounds* 2016;28(4): 112–118.

¹⁰ Tumi Balduresson, T, MD, Ph.D. et al. Healing Rate and Autoimmune Safety of Full-Thickness Wounds Treated With Fish Skin Acellular Dermal Matrix Versus Porcine Small-Intestine Submucosa: A Noninferiority Study; *The International Journal of Lower Extremity Wounds* 2015, Vol. 14(1) 37–43.

¹² Trinh, T.T., et al. Marine Omega3 wound matrix for: the treatment of complicated wounds; *Phlebologie* 2016; 45: 93–98.

occurred in the operating room, followed by application of wound matrix and covered with silicone mesh. All seven wounds healed and the patients did not have to have planned amputations on the limbs with the wounds. The mean duration of treatment to achieve full closure of the wound was 25 ± 10 weeks and ranged from 13 to 41 weeks. This study did not have a comparator group to determine if there was substantial clinical improvement with Kerecis Omega3 Wound compared to other skin substitute products.

There is no clinical data provided by the applicant to suggest that Kerecis Omega3 Wound provides a substantial clinical improvement over other similar skin substitute products. We are inviting public comments on whether Kerecis Omega3 Wound 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. With respect to the cost criterion, the applicant stated that Kerecis™ Omega3 Wound 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 CY 2016 payment rate of \$1,411.21 and a device offset amount of \$4.52, or APC 5055 (Level 5 Skin Procedures), with a CY 2016 payment rate of \$2,137.49 and a device offset amount of \$25.44. According to the applicant, the cost of substitute graft procedures when performed with Kerecis™ Omega3 Wound is \$2,030.

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 \$2,030 for Kerecis™ Omega3 Wound exceeds the applicable APC payment amount for the service related to the category of devices of \$1,411.21 by 144 percent ($\$2,030 / \$1,411.21 \times 100$ percent = 144 percent). Therefore, it appears that Kerecis™

Omega3 Wound 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 average reasonable cost of \$2,030 for Kerecis™ Omega3 Wound exceeds the device-related portion of the APC payment amount of \$4.52 by 44,911 percent ($\$2,030 / \4.52×100 percent = 449 percent). Therefore, it appears that Kerecis™ Omega3 Wound 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 average reasonable cost of \$2,030 for Kerecis™ Omega3 Wound and the portion of the APC payment amount for the device of \$4.52 exceeds the APC payment amount for the related service of \$1,411 by 144 percent ($(\$2,030 - \$4.52) / \$1,411.21 \times 100$ percent = 144 percent). Therefore, it appears that Kerecis™ Omega3 Wound meets the third cost significance test. Based on the costs submitted by the applicant and the calculations noted earlier, it appears that Kerecis™ Omega3 Wound meets the cost criterion.

We are inviting public comments on whether Kerecis™ Omega3 Wound meets the device pass-through payment criteria discussed in this section.

(5) X-WRAP®

Applied Biologics, LLC submitted an application for a new device category for transitional pass-through payment status for X-WRAP®. X-WRAP® is a chorion-free, amnion membrane allograft that can be used as a biological wrap or patch at any surgical site. It is used as a treatment for surgical or traumatic injury to bone or soft tissue. It is used to minimize adhesions, reduce inflammation, and promote soft tissue healing. The X-WRAP® is made from the intermediate amniotic epithelial layer of the placenta, recovered from a Cesarean delivery of pre-screened donors. It is available in a variety of sizes and is used as a biologic augmentation to a variety of orthopedic repairs.

With respect to the newness criterion at § 419.66(b)(1), the applicant indicated that X-WRAP® conforms to the FDA regulatory path under section 361 of the PHS Act and 21 CFR part 1271 for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Under this regulatory path, FDA requires the manufacturer to register and list their HCT/Ps with the Center for Biologics Evaluation and Research (CBER) within 5 days after beginning operations and to update their registrations annually. Applied Biologics, LLC has a FDA field establishment identifier (FEI) under the HHS-FDA-Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). The applicant submitted an annual registration/listing for dated December 30, 2015. It is not clear when the initial CBER filing occurred for the X-WRAP® product, and therefore, it is unclear if the newness criterion for X-WRAP® is met.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, X-WRAP® 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 X-WRAP® 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 device category that describes X-WRAP®. The applicant proposed a pass-through device category for X-WRAP® with a category descriptor of "Amniotic Membrane Soft Tissue Allografts". 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 a list of studies in the application that showed general effectiveness of amniotic fluid and amniotic membrane-based products. However, these studies were not specific to the X-WRAP® product. The applicant also submitted one study¹³ that was a retrospective review with prospective follow-up of patients (n=8) with recurrent surgical primary cubital tunnel syndrome (CuTS) who had undergone at least two previous ulnar nerve surgeries before having an ulnar neurolysis with X-WRAP® dry amniotic membrane barrier. The results showed that the participants experienced significant improvement in VAS pain scores, QuickDASH outcome scores, and grip strength in comparison to these scores prior to the surgery. Mean VAS improved by 3.5 from, 7.3 to 3.8 (P < .0001). Mean QuickDASH improved by 30 from, 80 to 50 (P < .0001). Grip strength improved by 25 pounds on average (P < .0001), a mean improvement of 38 percent relative to the contralateral side compared with preoperative measurements. Also, none of the patients reported progression or worsening of their symptoms compared with preoperatively. The applicant's conclusions from the article were that using the X-WRAP® amniotic membrane with revision neurolysis was a safe and effective treatment for primary cubital syndrome. The study lacked a comparison arm and did not include group assignment or blinding of patients.

Based on the evidence submitted, we believe there is insufficient data to determine whether X-WRAP® offers a substantial clinical improvement over other treatments for wound care. We are inviting public comments on whether the X-WRAP® 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 several CPT codes would be used to report X-WRAP®, including: CPT codes 29826, 29827, 29828, 23473, 23420, 23412, 27605, 27650, 29891, 29888, 29889, 28008, 22551, 22856, 27179, 29861, 29862,

15271, 15272, 15273, and 15277. To meet the cost criterion for device pass-through payment, a device must pass all three tests for cost threshold for at least one APC. These CPT codes are assigned to APCs 5121 through 5125 (Level 1 through Level 5 Musculoskeletal Procedures) and APCs 5054 and 5055 (Level 4 and Level 5 Skin Procedures). For our calculations, we used APC 5121 (Level 1 Musculoskeletal Procedures), which had a CY 2016 payment rate of \$1,455 and a device offset amount of \$15.86 at the time the application was received. According to the applicant, the X-WRAP® product is available in several sizes, the largest being 4x8 cm with a cost of \$5,280.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of \$5,280 for X-WRAP® exceeds the applicable APC payment amount for the service related to the category of devices of \$1,455 by 363 percent ($\$5,280/\$1,455 \times 100 = 363$ percent). Therefore, it appears that X-WRAP® 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 average reasonable cost of \$5,280 for X-WRAP® exceeds the device-related portion of the APC payment amount of \$15.86 by 33,291 percent ($\$5,280/\$15.86 \times 100 = 33,291$ percent). Therefore, it appears that X-WRAP® 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 average reasonable cost of \$5,280 for X-WRAP® and the portion of the APC payment amount for the device of \$15.86 exceeds the APC payment amount for the related service of \$1,455 by 361 percent ($(\$5,280 - \$15.86)/\$1,455 \times 100 = 361$ percent). Therefore, it appears that X-WRAP® meets the third cost significance test.

We are inviting public comments on whether X-WRAP® meets the device pass-through payment criteria discussed in this section.

B. Proposed Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive APCs were defined as those APCs with a device offset greater than 40 percent (79 FR 66795). In assigning device-intensive status to an APC, the device costs of all of 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 utilize devices, and the device costs for the associated HCPCS codes exceed 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).

2. HCPCS Code-Level Device-Intensive Determination

As stated above, prior to CY 2017, the device-intensive methodology assigned device-intensive status to all procedures requiring the implantation of a device, which were assigned to an APC with a device offset greater than 40 percent. 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 to all procedures that require the implantation of a device and have an individual HCPCS code-level device offset of greater than 40 percent, regardless of the APC assignment. Under this policy, all procedures with significant device costs (defined as a device offset of more than 40 percent) are assigned device-intensive status, regardless of their APC placement. Also, 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

¹³ Gaspar, M.P., et al. (2016). Recurrent cubital tunnel syndrome treated with revision neurolysis and amniotic membrane nerve wrapping. *Journal of Shoulder and Elbow surgery*, 25, 2057-2065.

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 such a 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 to procedures without a significant device cost but which are granted such status because of APC assignment.

Under our CY 2017 finalized policy, procedures that have an individual HCPCS code-level device offset of greater than 40 percent 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 device credits. Therefore, all procedures requiring the implantation of a medical device and that have an individual HCPCS code-level device offset of greater than 40 percent are subject to the device edit and no cost/full credit and partial credit device policies, discussed in sections IV.B.3. and IV.B.4. of this proposed rule, respectively.

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 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 medical devices is 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 may temporarily assign 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 40 percent, according to our finalized policy of determining device-intensive status by calculating the HCPCS code-level device offset.

The full listing of proposed CY 2018 device-intensive procedures is included in Addendum P to this proposed rule (which is available via the Internet on the CMS Web site).

In response to comments received in the CY 2017 OPPS/ASC final rule with comment period, we specified that additional information for our consideration of an offset percentage higher than the default of 41 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.

3. Changes to the Device Edit Policy for CY 2017 and Subsequent Years

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 (individual HCPCS code-level device offset greater than 40 percent) 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 2018.

4. Proposed 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. Policy for CY 2017 and Subsequent Years

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.

In addition, for CY 2017 and subsequent years, we finalized our policy to use the following three criteria for determining the procedures to which our final policy will apply: (1) All procedures must involve implantable devices that would be reported if device insertion procedures were performed; (2) 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 (3) the procedure must be device intensive; that is, the device offset amount must be significant, which is defined as exceeding 40 percent of the procedure’s mean cost.

We are not proposing any changes to this policy for CY 2018.

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

For 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 2017 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 2017 payment rate (calculated using the median cost) is approximately \$18,984.

For CY 2018, 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 2018, this policy would continue to apply only to a procedure described by CPT code 0308T in APC 5495 because this APC is the only APC containing a device-intensive procedure with fewer than 100 total claims in the APC. As we have stated before (81 FR 79660), we believe that this approach will help to mitigate significant year-to-year payment rate fluctuations while preserving accurate claims data-based payment rates for

low-volume device-intensive procedures. The CY 2018 proposed rule median cost for the procedure described by CPT code 0308T is approximately \$17,643.75. The proposed CY 2018 payment rate (calculated using the median cost and the claims that reported the device consistent with our device edit policy for device intensive procedures) is approximately \$16,963.69.

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

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

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biologicals. Throughout this proposed rule, the term “biological” is used because this is the term that appears in section 1861(t) of the Act. A “biological” as used in this proposed rule includes (but is not necessarily limited to) a “biological product” or a “biologic” as defined 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 OPSS was implemented.

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

for the product as a hospital outpatient service under Medicare Part B. Proposed CY 2018 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 Web site).

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 OPSS, 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 Web site 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 Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.

2. 3-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 OPSS 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 OPSS/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 and biologicals 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 believe that the timing of a pass-through payment application should not determine the duration of pass-through payment status, and this approach allows 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 2017

We are proposing that the pass-through payment status of 19 drugs and biologicals would expire on December 31, 2017, as listed in Table 21 below. All of these drugs and biologicals will have received OPSS pass-through payment for at least 2 years and no more than 3 years by December 31, 2017. These drugs and biologicals were approved for pass-through payment status on or before January 1, 2016. In accordance with the policy finalized last year and described above, 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 \$120 for CY 2018), 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 2018, as discussed further in section V.B.3. of this proposed rule).

TABLE 21—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2017

CY 2017 HCPCS Code	CY 2017 Long descriptor	CY 2017 Status indicator	CY 2017 APC	Pass-through payment effective date
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664	01/01/2015
C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663	01/01/2015
J0596	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445	04/01/2015
J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	9452	04/01/2015
J0875	Injection, dalbavancin, 5 mg	G	1823	01/01/2015
J1833	Injection, isavuconazonium sulfate, 1 mg	G	9456	10/01/2015
J2407	Injection, oritavancin, 10 mg	G	1660	01/01/2015
J2502	Injection, pasireotide long acting, 1 mg	G	9454	07/01/2015
J2547	Injection, peramivir, 1 mg	G	9451	04/01/2015
J2860	Injection, siltuximab, 10 mg	G	9455	07/01/2015
J3090	Injection, tedizolid phosphate, 1 mg	G	1662	01/01/2015
J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450	04/01/2015
J8655	Netupitant (300 mg) and palonosetron (0.5 mg)	G	9448	04/01/2015
J9032	Injection, belinostat, 10 mg	G	1658	01/01/2015
J9039	Injection, blinatumomab, 1 mcg	G	9449	04/01/2015
J9271	Injection, pembrolizumab, 1 mg	G	1490	01/01/2015
J9299	Injection, nivolumab, 1 mg	G	9453	07/01/2015
Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter.	G	1657	01/01/2015
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9457	10/01/2015

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 Web site).

4. Proposed Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Payment Status in CY 2018

We are proposing to continue pass-through payment status in CY 2018 for 38 drugs and biologicals. None 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, 2017. These drugs and biologicals, which were approved for pass-through status between January 1, 2016, and July 1, 2017, are listed in Table 22 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status through July 1, 2017 are assigned status indicator "G" in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

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 2018, 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 2018. We are proposing that a \$0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2018 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 2018 because, if not for their pass-through status, payment for these products would be packaged into the associated procedure.

In addition, we are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2018 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).

For CY 2018, consistent with our CY 2017 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 OPPTS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2018, 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+6 percent, the equivalent payment provided to pass-through 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 38 drugs and biologicals that we are proposing to continue to have pass-through payment status for CY 2018 or have been granted pass-through payment status as of July 2017 are shown in Table 22 below.

TABLE 22—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2018

CY 2017 HCPCS code	CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2018 status indicator	Proposed CY 2018 APC	Pass-through payment effective date
A9515	A9515	Choline C 11, diagnostic, per study dose	G	9461	04/01/2016
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
C9140	C9140	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 I.U..	G	9043	01/01/2017
C9460	C9460	Injection, cangrelor, 1 mg	G	9460	01/01/2016
C9482	C9482	Injection, sotalol hydrochloride, 1 mg	G	9482	10/01/2016
C9483	C9483	Injection, atezolizumab, 10 mg	G	9483	10/01/2016
C9484	C9484	Injection, eteplirsen, 10 mg	G	9484	04/01/2017
C9485	C9485	Injection, olaratumab, 10 mg	G	9485	04/01/2017
C9486	C9486	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017
Q9989	Q9989	Ustekinumab, for Intravenous Injection, 1 mg	G	9487	04/01/2017
C9488	C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017
C9489	C9489	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017
C9490	C9490	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017
J0570	J0570	Buprenorphine implant, 74.2 mg	G	9058	01/01/2017
J1942	J1942	Injection, aripiprazole lauroxil, 1 mg	G	9470	04/01/2016
J2182	J2182	Injection, mepolizumab, 1 mg	G	9473	04/01/2016
J2786	J2786	Injection, reslizumab, 1 mg	G	9481	10/01/2016
J2840	J2840	Injection, sebelipase alfa, 1 mg	G	9478	07/01/2016
J7179	J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rho.	G	9059	01/01/2017
J7202	J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u..	G	9171	10/01/2016
J7207	J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U..	G	1844	04/01/2016
J7209	J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u..	G	1846	04/01/2016
J7322	J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg.	G	9471	04/01/2016
J7328	J7328	Hyaluronan or derivative, gel-syn, for intra-articular injection, 0.1 mg.	G	1862	04/01/2017
J7342	J7342	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479	07/01/2016
J7503	J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg.	G	1845	04/01/2016
J9034	J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017
J9145	J9145	Injection, daratumumab, 10 mg	G	9476	07/01/2016
J9176	J9176	Injection, elotuzumab, 1 mg	G	9477	07/01/2016
J9205	J9205	Injection, irinotecan liposome, 1 mg	G	9474	04/01/2016
J9295	J9295	Injection, necitumumab, 1 mg	G	9475	04/01/2016
J9325	J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU).	G	9472	04/01/2016
J9352	J9352	Injection, trabectedin, 0.1 mg	G	9480	07/01/2016
Q5101	Q5101	Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram	G	1822	01/01/2016
Q5102	Q5102	Injection, Infliximab, Biosimilar, 10 mg	G	1847	04/01/2017
Q9982	Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries.	G	9459	01/01/2016
Q9983	Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries.	G	9458	01/01/2016

5. 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 2018, as we did in CY 2017, 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 23 below.

TABLE 23—PROPOSED APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2018

Proposed CY 2018 APC	Proposed CY 2018 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 Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.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 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 \$110 for CY 2017 (81 FR 79665).

Following the CY 2007 methodology, for this CY 2018 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 2018 and rounded the resulting dollar amount (\$117.98) to the nearest \$5 increment, which yielded a figure of \$120. 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 (BLS) series code WPUSI07003) from CMS' Office of the Actuary. Based on these calculations, we are proposing a packaging threshold for CY 2018 of \$120.

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 2018 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 2016 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2016 claims processed before January 1, 2017 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 2018: 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 2018, 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

2018, as discussed in more detail in section V.B.2.b. of this proposed rule) to calculate the CY 2018 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2016 (data that were used for payment purposes in the physician's office setting, effective April 1, 2017) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2018, we are proposing to use payment rates based on the ASP data from the first quarter of CY 2017 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 Web site) 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, 2017. 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 2016 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 \$120, and identify items with a per day cost greater than \$120 as separately payable. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2016 HCPCS codes that were reported to the CY 2017 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for proposed payment in CY 2018.

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 2018 OPPS/ASC proposed rule, we are proposing to use ASP data from the fourth quarter of CY 2016, 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, 2017,

along with updated hospital claims data from CY 2016. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for this CY 2018 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 second quarter of CY 2017. 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, 2017. These payment rates would then be updated in the January 2018 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2018. 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 2016 claims data and updated cost report information available for the CY 2018 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 2018 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2017. 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 2018, 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 2017 and that were proposed for separate payment in CY 2018, and that then have per day costs equal to or less than the CY 2018 final rule drug packaging threshold, based on the updated ASPs and hospital claims data

used for the CY 2018 final rule, would continue to receive separate payment in CY 2018.

- HCPCS codes for drugs and biologicals that were packaged in CY 2017 and that were proposed for separate payment in CY 2018, and that then have per day costs equal to or less than the CY 2018 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2018 final rule, would remain packaged in CY 2018.

- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2018 but then have per day costs greater than the CY 2018 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2018 final rule, would receive separate payment in CY 2018.

c. Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned briefly earlier, in the OPPTS, 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 OPPTS 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 OPPTS/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 OPPTS/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 codes 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high cost group, and claims billed with HCPCS codes C5271, C5273, C5275, and 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 2017, the payment rate for APC 5053 (Level 3 Skin Procedures) was \$466, the payment rate for APC 5054 (Level 4 Skin Procedures) was \$1,468, and the payment rate for APC 5055 (Level 5 Skin Procedures) was \$2,575.

This information also is available in Addenda A and B of the CY 2017 OPPTS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

We have continued the high cost/low cost categories policy since CY 2014, and are proposing to continue it for CY 2018 with the modification discussed below. 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 OPPTS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high cost/low cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70434 through 70435). For CY 2018, as in CY 2016 and CY 2017, we are proposing to continue to determine the high/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 2018, as for CY 2017, 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 2018, as for CY 2017, we are proposing to assign any skin substitute with an MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group. For CY 2018, we are proposing that any skin substitute product that was assigned to the high cost group in CY 2017 will be assigned to the high cost group for CY 2018, regardless of whether it exceeds or falls below the CY 2018 MUC or PDC threshold.

For this CY 2018 OPPTS/ASC proposed rule, and consistent with previous methodology as established in the CY 2014 through CY 2017 final rules with comment period, we analyzed CY 2016 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 2018 MUC threshold is \$47 per cm² (rounded to the nearest \$1) and the proposed CY 2018 PDC threshold is \$755 (rounded to the nearest \$1).

For CY 2018, we are proposing to continue to assign skin substitutes with pass-through payment status to the high cost category. However, there are no skin substitutes that are proposed to have pass-through payment status for CY 2018. 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 would use WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2018 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 also 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).

In order to allow additional time to evaluate concerns and suggestions from stakeholders about the volatility of the MUC and PDC thresholds, for CY 2018, we are proposing 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. Our analysis has found that seven skin substitute products that would have otherwise been assigned to the low cost group for CY 2018 will instead be assigned to the high cost group under this proposed policy. The skin substitute products affected by this proposed policy are identified with an "*" in Table 24. For CY 2019 and subsequent years, we are seeking public comment on how we should calculate data for products in determining the MUC and PDC thresholds that are included in the high cost group solely based on assignment to the high cost group in CY 2017.

The goal of our proposal to retain the same skin substitute cost group assignments in CY 2018 as in CY 2017

is to maintain similar levels of payment for skin substitute products for CY 2018 while we study our current 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 are seeking public comments on the methodologies that are used to calculate pricing thresholds as well as the payment groupings that recognize a low cost group and a high cost group. We are especially interested in suggestions that are based on analysis of Medicare claims data from hospital outpatient departments that might better promote improved payment stability for skin substitute products under the OPPS. This proposal is intended to apply for CY 2018 to allow time for the public to submit other ideas that could be evaluated for the CY 2019 rulemaking.

In summary, we are proposing to assign skin substitutes 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 2017, in which case we are proposing to assign the product to the high cost group for CY 2018, regardless of whether it exceeds the CY 2018 MUC or PDC threshold. We also are proposing to assign to the high cost group skin substitute products that exceed the CY 2018 MUC or PDC threshold and assign to the low cost group skin substitute products that did not exceed either the CY 2017 or CY 2018 MUC or PDC thresholds and were not assigned to the high cost group in CY 2017. We are proposing to continue to use payment methodologies including ASP+6 percent, WAC+6 percent, or 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 2018 MUC threshold. Finally, we are proposing to continue to assign new skin substitute products without pricing information to the low cost group.

Table 24 below displays the proposed CY 2018 high cost or low cost category assignment for each skin substitute product.

TABLE 24—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2018

CY 2018 HCPCS code	CY 2018 short descriptor	Current CY 2017 high/low assignment	Proposed CY 2018 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 BMWWD	High	High.

TABLE 24—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2018—Continued

CY 2018 HCPCS code	CY 2018 short descriptor	Current CY 2017 high/low assignment	Proposed CY 2018 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	High	High.
Q4133	Grafix Prime	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 1k, 1cm	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 1 square cm	High	High.
Q4157	Revitalon 1 square cm	High	High.
Q4158	MariGen 1 square cm	High	High.*
Q4159	Affinity 1 square cm	High	High.
Q4160	NuShield 1 square cm	High	High.
Q4161	Bio-Connekt per square cm	High	High.*
Q4162	Amnio bio and woundex flow	Low	High.
Q4163	Amnion bio and woundex sq cm	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.

* These products do not exceed either the MUC or PDC threshold for CY 2018, but are proposed to be assigned to the high cost group since they were assigned to the high cost group in CY 2017.

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

In the CY 2010 OPPI/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we 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 2018.

For CY 2018, 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 2016 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 2018 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 2016 claims data to make the proposed packaging determinations for these drugs: 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 2018 drug packaging threshold of \$120 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2018 drug packaging threshold of \$120 (so that all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2018 is displayed in Table 25 below.

TABLE 25—PROPOSED HCPCS CODES TO WHICH THE CY 2018 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2018 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. 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 OPSS 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.¹⁴

It has been our longstanding policy 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 2018 OPSS/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 OPSS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPSS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPSS/ASC final

rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+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 CY 2014, CY 2015, CY 2016, and CY 2017 (81 FR 79673).

b. Proposed CY 2018 Payment Policy

For CY 2018, we are proposing to continue our payment policy that has been in effect from CY 2013 to present and 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 that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. We also 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, and that the budget neutral weight scalar is not applied in determining payments for these separately paid drugs and biologicals.

We note that we are proposing below 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 the full discussion of this proposal in section V.B.7. of this proposed rule.

Also, 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 Web site), which illustrate the proposed CY 2018 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, 2017, or WAC, AWP, or mean unit cost from CY 2016 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 2018 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2018 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of

2017 (July 1, 2017 through September 30, 2017) will be used to set the payment rates that are released for the quarter beginning in January 2018 near the end of December 2017. 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 2017 are based on mean unit cost in the available CY 2016 claims data. If ASP information becomes available for payment for the quarter beginning in January 2018, 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 2017 ASP data) that do not have ASP information available for the quarter beginning in January 2018. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2016 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2018 payment purposes and are only illustrative of the proposed CY 2018 OPSS 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 (80 FR 70445 through 70446). For CY 2018, we are proposing to continue this same payment policy for biosimilar biological products.

Public comments on the Medicare Part B biosimilar biological product payment policy should be submitted in response to the biosimilar payment policy comment solicitation in the CY 2018 MPFS proposed rule.

3. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2018, we are proposing to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately paid 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

¹⁴ 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.

from hospital claims. We believe that the rationale outlined in the CY 2010 OPSS/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 2018. Therefore, we are proposing for CY 2018 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 OPSS/ASC final rule with comment period (74 FR 60520 through 60521). We also are proposing to rely on CY 2016 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 OPSS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPSS final rule with comment period (69 FR 65811), the CY 2006 OPSS final rule with comment period (70 FR 68655), and the CY 2010 OPSS/ASC final rule with comment period (74 FR 60524). The proposed CY 2018 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

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 OPSS/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). We have reassessed this payment for CY 2018 and did not identify any new information that would cause us to modify payment. Therefore, for CY 2018, we are proposing to continue to provide an additional \$10 payment for radioisotopes produced by non-HEU sources.

5. Proposed Payment for Blood Clotting Factors

For CY 2017, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPSS and continued paying an updated furnishing fee (81 FR 79676). That is, for CY 2017, we provided payment for blood clotting factors under the OPSS 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 2017 updated furnishing fee was \$0.209 per unit.

For CY 2018, 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 OPSS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPSS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPSS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPSS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPSS/ASC final rule with comment period (72 FR 66765), we are proposing to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site 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 OPSS Hospital Claims Data

For CY 2018, we are proposing to continue to use the same payment policy as in CY 2017 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPSS 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 OPSS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2018 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPSS hospital claims data is listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site.

7. Alternative Payment Methodology for Drugs Purchased Under the 340B Drug Discount Program

a. Background

The 340B Drug Discount 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. The statutory intent of the 340B program is to maximize scarce Federal resources as much as possible, reaching more eligible patients, and providing care that is more comprehensive.¹⁵

The 340B statute defines which health care providers are eligible to participate in the program (“covered entities”). In addition to Federal health care grant recipients, covered entities include hospitals with a Medicare disproportionate share hospital (DSH) percentage above 11.75 percent. However, under Pub. L. 111–148, section 7101 expanded eligibility to critical access hospitals (CAHs), children’s hospitals with a DSH adjustment greater than 11.75 percent, sole community hospitals with a DSH adjustment percentage of 8.0 percent or higher, rural referral centers with a DSH adjustment percentage of 8.0 percent or higher, and freestanding cancer hospitals with a DSH adjustment percentage above 11.75 percent. In accordance with section 340B(a)(4)(L) of the Public Health Service Act, DSH hospitals and CAH participants must meet other criteria, such as being owned by a State or local government, or be a nonprofit hospital under contract with a State or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid.

HRSA calculates the ceiling price for each covered outpatient drug. The ceiling price is the drug’s average manufacturer price (AMP) minus the unit rebate amount (URA), which is a statutory formula that varies depending on whether the drug is an innovator single source drug (no generic

available), an innovator multiple source drug (a brand drug with available generic(s)), or a noninnovator multiple source (generic) drug. The ceiling price represents the maximum price a drug manufacturer can charge a covered entity for the drug. However, covered entities also have the option to participate in HRSA’s Prime Vendor Program (PVP), under which the prime vendor, in some circumstances, can negotiate even deeper discounts (known as “subceiling prices”) on many covered outpatient drugs. By the end of FY 2014, the PVP had nearly 7,000 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the 340B ceiling price.¹⁶

Several recent studies and reports on Medicare Part B payments for 340B purchased 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.^{17 18 19} Links to the full reports referenced in this section can be found in the footnotes.

In its May 2015 Report to Congress, MedPAC analyzed Medicare hospital outpatient claims (excluding CAHs) along with information from HRSA on which hospitals participate in the 340B program. MedPAC included data on all separately payable drugs under the OPSS except for vaccines and orphan drugs provided by freestanding cancer hospitals, rural referral centers, and sole community hospitals. To estimate costs that 340B hospitals incur to acquire drugs covered under the OPSS, it generally used the formula for calculating the 340B ceiling price: (average manufacturer price (AMP) – unit rebate amount (URA)) × drug package size. Because MedPAC did not have access to AMP data, it used

¹⁶ Department of Health and Human Services. 2016. Fiscal Year 2017. Health Resources and Services Administration justification of estimates for appropriations committees. Washington, DC: HHS. <https://www.hrsa.gov/about/budget/budgetjustification2017.pdf>.

¹⁷ Office of Inspector General. “Part B Payment for 340B Purchased Drugs OEI-12-14-00030”. November 2015. Available at: <https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf>.

¹⁸ Medicare Payment Advisory Commission. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015. Available at: <http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0>

¹⁹ Government Accountability Office. “Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals GAO-15-442”. June 2015. Available at: <https://www.gao.gov/assets/680/670676.pdf>.

each drug’s ASP as a proxy for AMP. MedPAC notes that ASP is typically slightly lower than AMP. In addition, MedPAC noted that, due to data limitations, its estimates of ceiling prices are conservative and likely higher (possibly much higher) than actual ceiling prices. Further details on the methodology used to calculate the average minimum discount for separately payable drugs can be found in Appendix A of its May 2015 Report to Congress. In this report, MedPAC estimated that, on average, hospitals in the 340B program “receive a minimum discount of 22.5 percent of the [ASP] for drugs paid under the [OPSS].”

In its March 2016 MedPAC Report to Congress, MedPAC noted that the OIG recently estimated that discounts across all 340B providers (hospitals and certain clinics) average 33.6 percent of ASP, allowing these providers to generate significant profits when they administer Part B drugs (MedPAC March 2016, page 79). According to the U.S. Government Accountability Office (GAO) report, the amount of the 340B discount ranges from an estimated 20 to 50 percent discount, compared to what the entity would have otherwise paid. In addition, participation in the PVP often results in a covered entity paying a subceiling price (estimated to be approximately 10 percent below the ceiling price). (U.S. Department of Health and Human Services, HRSA FY 2015 Budget Justification.) Participation in the PVP is voluntary and free.

With respect to chemotherapy drugs and drug administration services, MedPAC examined Part B spending for 340B and non-340B hospitals for a 5-year period from 2008 to 2012 and found that “Medicare spending grew faster among hospitals that participated in the 340B program for all five years than among hospitals that did not participate in the 340B program at any time during [the study] period.” (MedPAC May 2015, page 14). This is just one example of drug spending increases that is correlated with participation in the 340B program and calls into question whether Medicare’s current payment policy for separately payable drugs at ASP+ 6 percent is appropriate in light of the discounted rates at which 340B hospitals acquire such drugs, especially because beneficiary cost-sharing for these drugs is based on the Medicare payment rate.

Further, GAO found that “. . . in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals.” According to the GAO report, this

¹⁵ The House report that accompanied the authorizing legislation for the 340B program stated, “In giving these “covered entities” access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” (H.R. Rep No. 102–384(II), at 12 (1992)).

indicates that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis. For example, in 2012, average per beneficiary spending at 340B DSH hospitals was \$144, compared to approximately \$60 at non-340B hospitals. The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status. (GAO 15-442, page 20)

Under the OPSS, all hospitals (other than CAHs, which are paid based on 101 percent of reasonable costs as required by section 1834(g) of the Act) are currently paid the same rate for separately payable drugs (ASP plus 6 percent), regardless of whether the hospital purchased the drug at a discount through the 340B program. Medicare beneficiaries are liable for a copayment that is equal to 20 percent of the OPSS payment rate, which is currently ASP+6 percent (regardless of the 340B purchase price for the drug). Based on an analysis of almost 500 drugs billed in the hospital outpatient setting in 2013, the OIG found that, for 35 drugs, the "difference between the Part B amount and the 340B ceiling price was so large that, in a least one quarter of 2013, the beneficiary's coinsurance alone . . . was greater than the amount a covered entity spent to acquire the drug" (OIG November 2015, OEI-12-14-00030, page 9).

In the CY 2009 OPSS/ASC final rule with comment period, we requested comment regarding the drug costs of hospitals that participate in the 340B program and whether we should consider an alternative drug payment methodology for participating 340B hospitals (73 FR 68655). As noted above, in the time since that comment solicitation, access to the 340B program was expanded under section 7101 of Public Law 111-148, which amended section 340B(a)(4) of the Public Health Service Act to expand the types of covered entities eligible to participate in the 340B program. In addition, in its March 2016 Report to Congress, MedPAC recommended a legislative proposal related to payment for Part B drugs furnished by 340B hospitals under which Medicare would reduce payment rates for 340B hospitals' separately payable 340B drugs by 10 percent of the ASP and direct the program savings from reducing Part B drug payment rates to the Medicare funded uncompensated care pool.²⁰ In

²⁰ Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare

its November 2015 report entitled "Part B Payments for 340B-Purchased Drugs," the Office of the Inspector General (OIG) found that Part B payments were 58 percent more than 340B ceiling prices, which allowed covered entities to retain approximately \$1.3 billion in 2013 (OEI-12-14-00030, page 8). In the same report, the OIG described three options under which both the Medicare program and Medicare beneficiaries would be able to share in the savings realized by hospitals and other covered entities that participate in the 340B program (OEI-12-14-00030, pages 11-12). These options ranged from paying ASP with no additional add-on percentage, to making payment based on the 340B ceiling price plus 6 percent of ASP for each 340B purchased drug (OEI-12-14-00030, page 11). Analysis in several of these reports notes limitations in estimating 340B purchased drugs acquisition costs and the inability to identify which drugs were purchased through the 340B program within Medicare claims data was another limitation.

It is estimated that covered entities saved \$3.8 billion on outpatient drugs purchased through the 340B program in 2013.²¹ In addition, the number of hospitals participating in the program has grown from 583 in 2005 to 1,365 in 2010 and 2,140 in 2014 (MedPAC May 2015). Given the growth in the number of providers participating in the 340B program and recent trends in high and growing prices of several separately payable drugs administered under Medicare Part B to hospital outpatients, we believe it is timely to reexamine the appropriateness of continuing to pay the current OPSS methodology of ASP+6 percent to hospitals that have acquired those drugs under the 340B program at significantly discounted rates. This is especially important because of the inextricable link of the Medicare payment rate to the beneficiary cost-sharing amount. In addition, we are concerned about the rising prices of certain drugs and that Medicare beneficiaries, including low-income seniors, are responsible for paying 20 percent of the Medicare payment rate for these drugs. We are concerned that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs.

Payment Policy. March 2016. Available at: <http://www.medpac.gov/docs/default-source/reports/chapter-3-hospital-inpatient-and-outpatient-services-march-2016-report.pdf?sfvrsn=0>.

²¹ U.S. Department of Health and Human Services, HRSA FY 2015 Budget Justification, p. 342.

b. Proposed OPSS Payment Rate for 340B Purchased Drugs

In this proposed rule, we are proposing changes to our current Medicare Part B drug payment methodology for 340B hospitals that we believe 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 to Medicare beneficiaries that are purchased under the 340B program.

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 while continuing to provide access to care. Medicare expenditures on Part B drugs are rising due to underlying factors such as growth of the 340B program, higher price drugs, or price increases for drugs.²² We believe that any payment changes we adopt should be limited to separately payable drugs under the OPSS, with other additional exclusions. These exclusions include (1) drugs on pass-through status, which are required to be paid based on the ASP methodology and (2) vaccines, which are excluded from the 340B program. Also, as stated later in this section, we are soliciting comment on whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment.

Current data limitations inhibit identification of which drugs were acquired under the 340B program in the Medicare OPSS 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, we intend 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 OPSS participate in the 340B program, we believe it is appropriate to presume that a separately payable drug reported on an OPSS claim was purchased under the

²² Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. Issue Brief: Medicare Part B Drugs: Pricing and Incentives. 2016. <https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf>.

340B program, unless the hospital identifies that the drug was not purchased under the 340B program. We intend 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.

Further, we note that the confidentiality of ceiling and subceiling prices limits our ability to precisely calculate the price paid by 340B hospitals for a particular covered outpatient drug. Accordingly, we believe using an average discounted price is appropriate for our proposal. Therefore, for CY 2018, we are proposing to apply an average discount of 22.5 percent of the average sales price for nonpass-through separately payable drugs purchased under the 340B program, as estimated by MedPAC (MedPAC's May 2015 Report to Congress, page 7).

In the near-term, we believe that the estimated average minimum discount MedPAC calculated—22.5 percent of the ASP—adequately represents the average minimum discount that a 340B participating hospital receives for separately payable drugs under the OPPS. Given the limitations in calculating a precise discount for each separately payable drug, we have not attempted to do so for this proposed rule. Instead, we believe that using the analysis from the MedPAC report is appropriate and note that the analysis is spelled out in detail and can be replicated by interested parties. As MedPAC noted, its estimate was conservative and the actual average discount experienced by 340B hospitals is likely much higher than 22.5 percent. As GAO mentioned, discounts under 340B range from 20 to 50 percent (GAO-11-836, page 2). We believe that such reduced payment would meet the requirements under section 1833(t)(14)(A)(iii)(II) of the Act, which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary. We do not have hospital acquisition cost data for 340B drugs and, therefore, are proposing to continue to pay for these drugs under our authority at section 1833(t)(14)(A)(iii)(II) of the Act at ASP, and then to adjust that amount by

applying a reduction of 22.5 percent, which, as explained throughout this section, is the adjustment we believe is necessary for drugs acquired under the 340B program.

Specifically, in this CY 2018 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. However, we are proposing to exercise the Secretary's authority to adjust the applicable payment rate as necessary and, for separately payable drugs and biologicals (other than drugs on pass-through and vaccines) acquired under the 340B program, are proposing to adjust the rate to ASP minus 22.5 percent which we believe better represents the average acquisition cost for these drugs and biologicals.

As indicated above, because ceiling prices are confidential, we are unable to publicly disclose those prices or set payment rates in a way that would allow the public to determine the ceiling price for a particular drug. We believe that the MedPAC analysis that found the average minimum discount of 22.5 percent of ASP adequately reflects the average minimum discount that 340B hospitals paid under the OPPS receive. Additionally, we believe that using an average discount to set payment rates for separately payable drugs would achieve the dual goals of (1) adjusting payments to better reflect resources expended to acquire such drugs while (2) also protecting the confidential nature of discounts applied to a specific drug. Moreover, we do not believe that Medicare beneficiaries should be liable for a copayment rate that is tied to the current methodology of ASP+6 percent when the actual cost to the hospital to purchase the drug is much lower than the ASP for the drug.

We note that MedPAC excluded vaccines from its analysis since vaccines are not covered under 340B, but it did not exclude drugs on pass-through status. Further, because data used to calculate ceiling prices is not publicly available, MedPAC instead estimated "the lower bound of the average discount received by 340B hospitals for drugs paid under the [OPPS]" (MedPAC 2015, page 6). Accordingly, it is likely that the average discount is higher, potentially significantly higher, than the average minimum of 22.5 percent that MedPAC found through its analysis. We encourage the public to analyze the analysis presented in Appendix A of MedPAC's May 2015 Report to Congress.

As noted above, we believe that the discount amount of 22.5 percent below the ASP reflects the average minimum

discount that 340B hospitals receive for drugs acquired under the 340B program, and it is likely that the average discount may be higher due to participation in the PVP, substitution of ASP (which includes additional rebates) for AMP, and that drugs with pass-through status were included rather than excluded from the MedPAC analysis. We believe that a payment rate of ASP+6 percent does not sufficiently recognize the significantly lower acquisition costs of such drugs incurred by a 340B hospital. Accordingly, as noted above, we are proposing to reduce payment for separately payable drugs, excluding drugs on pass-through status and vaccines that were acquired under the 340B program, by 22.5 percent of ASP for all drugs for which a hospital does not append on the claim the modifier proposed above.

Finally, as detailed in the impact analysis section (section XIX.) of this proposed rule, we also are proposing that the reduced payments for separately payable drugs and biologicals purchased under the 340B program are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scalar is not applied in determining payments for these separately paid drugs and biologicals purchased under the 340B program. In that section, we also are soliciting public comments on whether we should apply all or part of the savings generated by this payment reduction to increase payments for specific services paid under the OPPS, or under Part B generally, in CY 2018, rather than simply increasing the conversion factor. In particular, we are seeking comments on whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured. In addition, we are seeking comments on whether the redistribution of savings associated with this proposal would result in unnecessary increases in the volume of covered services paid under the OPPS which should be adjusted in accordance with section 1833(t)(2)(F) of the Act. More information on the impact estimate associated with this proposal is included in section XIX. of this proposed rule.

c. Comment Solicitation on Additional 340B Considerations

As discussed above, we recognize there are data limitations in estimating the average discount of 340B drugs. We welcome stakeholder input with regard to MedPAC's May 2015 analysis and the resulting estimate of ASP minus 22.5

percent as the proposed payment rate for separately payable, nonpass-through OPPTS drugs purchased under the 340B drug discount program in CY 2018. We also are requesting comment on whether we should adopt a different payment rate to account for the average minimum discount of OPPTS drugs purchased under the 340B drug discount program. Also, we are seeking comment on whether the proposal to pay ASP minus 22.5 percent for 340B purchased drugs should be phased in over time (such as over a period of 2 to 3 years).

In addition, we recognize that the acquisition costs for drugs may vary among hospitals, depending on a number of factors such as size, patient volume, labor market area and case-mix. Accordingly, in the longer term, we are interested in exploring ways to identify the actual acquisition costs that each hospital incurs rather than using an average minimum discounted rate that would apply uniformly across all 340B hospitals. We are seeking public comment on whether, as a longer term option, Medicare should require 340B hospitals to report their acquisition costs in addition to charges for each drug on the Medicare claim. Having the acquisition cost on a drug-specific basis would enable us to pay a rate under the OPPTS that is directly tied to the acquisition costs for each separately payable drug. To the extent that the acquisition costs for some drugs may equal the ceiling price for a drug, we recognize that there may be challenges with keeping the ceiling price confidential as required by section 1927(b)(3)(D) of the Act and are seeking comment on this point.

Lastly, for consideration for future policy refinements, we are seeking public comment on (1) whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPPTS (for example, rural sole-community hospitals or PPS-exempt cancer hospitals) if a policy were adopted to adjust OPPTS payments to 340B participating hospitals (if so, describe how adjusted rates for drugs purchased under the 340B program would disproportionately affect access in these provider settings); (2) whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment; and (3) whether hospital-owned or affiliated ASCs have access to 340B discounted drugs.

VI. Proposed Estimate of OPPTS 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 OPPTS 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 2018 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 2018. The CY 2008 OPPTS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2017 or beginning in CY 2018. The sum of the proposed CY 2018 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2018 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 OPPTS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment 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 2018, 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. Because we are proposing to pay for most nonpass-through separately payable drugs and biologicals under the CY 2018 OPPTS at ASP+6 percent, and because we are proposing to pay for CY 2018 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of this proposed rule, our estimate of drug and biological pass-through payment for CY 2018 for this group of items is \$0, as discussed below. We note that our estimate does not reflect the proposed payment policy for drugs purchased through the 340B program, as we discuss in section V.B.7. 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 2018. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2018 is not \$0, as discussed below. In section V.A.5. of this proposed rule, we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we 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 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 2018. 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 2017 or beginning in CY 2018. The sum of the CY 2018 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2018 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. 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 2018, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2017 (81 FR 79676 through 79678).

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 2018, there are no active categories for CY 2018. Because there are no device active categories for CY 2018, we are proposing an estimate for the first group of devices of \$0.

In estimating our proposed CY 2018 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 2018; 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, 2018; and contingent projections for new device categories established in the second through fourth quarters of CY 2018. 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 2018 pass-through spending for this second group of device categories is \$10 million.

To estimate proposed CY 2018 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 2018, 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 2018 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 2018, 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 2018 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 2018 proposed spending estimate for this first group of drugs and biologicals of approximately \$7.7 million.

To estimate proposed CY 2018 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 2018, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2017, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2018), 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 2018 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 2018 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 \$8.5 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 2018 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2018 is approximately \$26.2 million (approximately \$10 million for device categories and approximately \$16.2 million for drugs and biologicals), which represents 0.24 percent of total projected OPPS payments for CY 2018. Therefore, we estimate that pass-through spending in CY 2018 will not amount to 2.0 percent of total projected OPPS CY 2018 program spending.

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

As we did in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79678), for CY 2018, we are proposing to continue with and not make any changes to 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 with and not propose any change to our payment policy for critical care services for CY 2018. 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 encourage those parties who comment to provide the data and analysis necessary to justify any suggested changes.

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 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 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, 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-tiered 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-tiered 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 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 (CCR>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.

For a comprehensive description on the background of PHP payment policy, 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 2018

1. Proposed PHP APC Geometric Mean Per Diem Costs

For CY 2018, 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 would continue to calculate the geometric mean per diem costs for CY 2018 for APC 5853 for CMHCs using only CY 2016 CMHC claims data and the most recent CMHC cost data, and the CY 2018 geometric mean per diem costs for APC 5863 for hospital-based PHPs using only CY 2016 hospital-based PHP claims data and the most recent hospital cost data.

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

For CY 2018 and subsequent years, we are proposing 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, 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 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>5 hospital service day trim for hospital-based PHP providers. These two trims were finalized in our 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 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, there were 47 CMHCs in the data. Under the ± 2 standard deviation trim policy, we excluded any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day is more than ± 2 standard deviations from the geometric mean cost per day for all CMHCs. By applying this trim for CY 2018 ratesetting, in this proposed rule, 4 CMHCs with geometric mean per diem costs per day below the trim's lower limit of \$49.33 and 2 CMHCs above the trim's upper limit of \$361.02 were excluded from the proposed ratesetting for CY 2018. This standard deviation trim removed 6 providers from ratesetting whose data would have skewed the calculated proposed geometric mean per diem cost.

In accordance with our PHP ratesetting methodology, in this proposed rule, we also removed 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). In this CY 2018 proposed rule ratesetting,

two CMHCs were excluded because they were missing wage index data for all of their service days.

In addition to our trims and data exclusions, before determining the PHP APC geometric mean per diem costs, we also assess CCRs (80 FR 70463). Our longstanding PHP OPPS ratesetting methodology defaults any CMHC CCR>1 to the statewide hospital ancillary CCR (80 FR 70457). In our CY 2018 proposed rule ratesetting, we identified one CMHC that had a CCR>1. This CMHC's CCR was 1.002, and it was defaulted to its appropriate statewide hospital ancillary CCR for CY 2018 ratesetting purposes.

In summary, these data preparation steps adjusted the CCR for 1 CMHC and excluded 8 CMHCs, resulting in the inclusion of a total of 39 CMHCs in our CY 2018 proposed rule ratesetting modeling. The trims removed 1,733 CMHC claims from the 14,400 total CMHC claims, resulting in 12,667 CMHC claims used in ratesetting. 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 CMHC APC geometric mean per diem cost. Moreover, we believe that these trims, exclusions, and adjustments help prevent inappropriate fluctuations in the PHP APC geometric mean per diem payment rates.

After applying all of the above trims, exclusions, or adjustments, the proposed CY 2018 geometric mean per diem cost for all CMHCs for providing 3 or more services per day (APC 5853) is \$128.81.

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

For this CY 2018 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, in this proposed rule there were 420 hospital-based PHP providers in the claims data. 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. The CCR>5 hospital service day trim removed hospital-based PHP service days that use a CCR>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>5 trim excluded any hospital-based PHP service day where any of the services provided on that day are associated with a CCR>5. Applying this trim removed service days from 4 hospital-based PHP providers with CCRs ranging from 6.6494 to 17.4803 from our proposed rule ratesetting. However, all of the service days for these 4 hospital-based PHP providers had at least one service associated with a CCR>5, so the trim removed these providers entirely from our proposed rule ratesetting. In addition, 1 hospital-based PHP was removed for missing wage index data, and 3 hospital-based

PHPs were removed by the OPPTS ±3 standard deviation trim on costs per day. Finally, in our proposed rule ratesetting, we excluded 19 hospital-based PHP providers that reported zero daily costs on their claims, in accordance with established PHP ratesetting policy (80 FR 70465). Therefore, we excluded a total of 27 hospital-based PHP providers, resulting in 393 hospital-based PHP providers in the data used for proposed rule ratesetting. After completing these data preparation steps, we calculated the proposed geometric mean per diem cost

for hospital-based PHP APC 5863 for hospital-based PHP services. The proposed 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 \$213.60. The proposed CY 2018 PHP APC geometric mean per diem costs for the CMHC and hospital-based PHP APCs are shown in Table 26 of this proposed rule. The proposed PHP APC payment rates are included in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 26—CY 2018 PROPOSED PHP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2018 APC	Group title	Proposed PHP APC geometric mean per diem costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	\$128.81
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	213.60

3. PHP Service Utilization Updates

In the CY 2016 OPPTS/ASC final rule with comment, we expressed concern over the low frequency of individual therapy provided to beneficiaries (81 FR 79684 through 79685). The CY 2016 claims data used for this CY 2018 proposed rule revealed some increases in the provision of individual therapy. In CY 2016, hospital-based PHPs provided individual therapy on 4.7 percent of days with only 3 services and 5.6 percent of days with 4 or more services (compared to 4.0 percent and

6.2 percent, respectively, in CY 2015). Similarly, in CY 2016, CMHCs provided individual therapy on 9.0 percent of days with only 3 services provided and 4.9 percent of days with 4 or more services provided (compared to 7.9 percent and 4.4 percent, respectively, in CY 2015 claims). 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 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. For this CY 2018 proposed rule, we used CY 2016 claims. The CY 2016 claims data showed that PHPs maintained an appropriately low utilization of 3 service days compared to CY 2015:

TABLE 27—PERCENTAGE OF PHP DAYS BY SERVICE UNIT FREQUENCY

	CY 2015 %	CY 2016 %	Change %
CMHCs:			
Percent of Days with 3 services	4.7	4.1	-0.6
Percent of Days with 4 services	62.9	72.6	9.7
Percent of Days with 5 or more services	32.4	23.3	-9.1
Hospital-based PHPs:			
Percent of Days with 3 services	12.4	10.2	-2.2
Percent of Days with 4 services	69.8	67.5	-2.3
Percent of Days with 5 or more services	17.8	22.3	4.5

As we noted in the CY 2017 OPPTS/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 combined PHP APCs 5853 and 5863 are in place for providing 3 or more services per day to CMHCs and hospital-based PHPs, respectively.

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 OPPTS/ASC final rule 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 include 5 to 6 hours of services (73 FR 68687 through 68694). 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, that patients must require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care (73 FR 68689).

4. Minimum Service Requirement: 20 Hours per Week

In the CY 2009 OPPTS/ASC final rule with comment period, we codified patient eligibility criteria to reflect the intensive nature of a PHP. At that time, we noted that many of the patient eligibility criteria had been longstanding policy requirements that did not reflect a change in policy. The added regulatory text was intended to strengthen and enhance the integrity of the PHP benefit (73 FR 68694). We further stated that because PHP is provided in lieu of inpatient care, it should be a highly structured and clinically intensive program. Our goal was to improve the level of service furnished in a day of PHP, while also ensuring that the appropriate population utilizes the PHP benefit (73 FR 68695).

When we codified these eligibility criteria, we acknowledged commenters' concerns related to the eligibility requirement that a patient must require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care. For example, we recognized commenters' concerns that it

may sometimes be difficult for patients to receive 20 hours per week of therapeutic services, such as when transitioning into or out of a PHP program (73 FR 68695). Therefore, to permit flexibility in treating PHP patients, we required a minimum of 20 hours per week of therapeutic services, with the understanding that patients may not always meet this minimum, such as during the week of admission and the week of discharge, and qualified the requirement by adding "as evidenced in their plan of care." This eligibility requirement only addresses the minimum amount of PHP services beneficiaries must require as evidenced in their plan of care. It does not address whether or not beneficiaries receive a particular number of therapeutic services per week. However, we have noted in multiple prior OPPTS/ASC final rules with comment periods that a typical PHP day would include 5 to 6 hours per day of PHP services (70 FR 68548, 71 FR 67999, 72 FR 66671, and 73 FR 68687).

Most recently, we discussed the 20 hours of services requirement in the CY 2017 rulemaking when we reminded providers that our regulations at §§ 410.43(a)(3) and (c)(1) continue to require that PHP beneficiaries must require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care, and that PHP services must be furnished in accordance with a physician certification and the beneficiary's plan of care reflecting that need.

We analyzed CY 2015 and CY 2016 PHP claims data to assess the intensity of PHP services provided, using PHP-allowable HCPCS codes and provider

and service date information. To calculate the number of hours of PHP services provided to each beneficiary each day, we assumed each unit of service equaled one hour of time. Each service day was then mapped to its Sunday-through-Saturday calendar week, and the number of PHP hours per week was calculated for each beneficiary. Next, the service weeks for each beneficiary were sorted chronologically and assessed: The first service week in a continuous series of service weeks was flagged as an "Admission" week, and the last service week in a continuous series of service weeks was flagged as a "Discharge" week. We removed from the analysis the admission and discharge weeks for each beneficiary to permit us to assess the intensity of services provided to beneficiaries fully engaged in PHPs (that is, those in "nontransitional" weeks). We then calculated the total number of service weeks and the number of service weeks with at least 20 PHP hours for each beneficiary. These two values were then used to determine the percentage of nontransitional service weeks that met the 20-hour PHP threshold for each beneficiary.

We found that a majority of PHP patients did not receive at least 20 hours of PHP services per week. Just over half of PHP beneficiaries received 20 hours or more of services in 50 percent or more of nontransitional weeks. In CY 2016 claims data, only 16.4 percent of beneficiaries in CMHCs and 34.8 percent of beneficiaries in hospital-based PHPs received at least 20 hours of PHP services in 100 percent of nontransitional weeks.

TABLE 28—NUMBER AND PERCENTAGE OF BENEFICIARIES RECEIVING AT LEAST 20 HOURS OF PHP SERVICES PER WEEK [CY 2015 Through CY 2016]

	Beneficiaries receiving 20 or more hours of PHP services per nontransitional week *	CY 2015 (%)	CY 2016 (%)
Number/Percentage of CMHC Beneficiaries	In 50% or more of weeks	1,205/53.1	1,016/57.3
	In 100% of weeks	319/14.1	291/16.4
Number/Percentage of Hospital-based PHP Beneficiaries.	In 50% or more of weeks	8,610/51.0	8,333/56.7
	In 100% of weeks	5,003/29.6	5,115/34.8

* Weeks are trimmed to exclude admission and discharge weeks based on a Sunday through Saturday week. Nontransitional weeks are weeks that are not admission or discharge weeks.

Overall, the data suggest that some PHPs may not provide the intensive services that eligible beneficiaries actually need. We are concerned about these findings, and encourage PHPs to review their admission practices and ensure they are providing the services beneficiaries need.

Given these concerns, in the CY 2017 OPPTS/ASC final rule with comment

period, we solicited public comments on potential future editing of PHP claims for the 20 hours per week minimum eligibility requirement and on strengthening the tie between a beneficiary's receipt of 20 hours per week of PHP services and payment for those services (81 FR 79686). We received nine comments in response to our solicitation. Overall, commenters

requested that we monitor data for a year before implementing any payment edits. A number of commenters suggested that if CMS chose to edit PHP claims for the 20-hour minimum requirement, CMS should: (1) Provide exceptions to the editing; (2) not require weekly billing; and (3) implement the edits in a fashion that is not administratively burdensome.

A number of commenters were not supportive of editing that would lead to payment denial. A few commenters indicated that attending a PHP for 20 hours per week is not a condition of payment. Several commenters suggested that editing would be premature until CMS could analyze monitoring data, consider the effect of the newly implemented single APC payment tier, and seek engagement from the PHP provider community. Some commenters also noted that the current PHP HCPCS codes may require some refinement to fully enable providers to record service times.

Several commenters expressed concerns that edits to deny payment for weeks with fewer than 20 hours of PHP services could reduce access to the PHP benefit. Several commenters suggested that noncompliance with a 20-hour requirement could be addressed through medical review, and suggested that PHPs' documenting the reasons for absences in the medical record should be sufficient. Another commenter questioned the necessity of an edit for occasional beneficiary absences beyond the PHP's control. We will consider these comments as we evaluate our options for possible future editing.

In addition, in this CY 2018 OPPS/ASC proposed rule, we are soliciting public comments on the advisability of applying a payment requirement conditioned on a beneficiary's receipt of a minimum of 20 hours of therapeutic services per week. We also are soliciting public comments addressing the need for exceptions to such a policy. Specifically, we want to know and understand the type of occurrences or circumstances that would cause a PHP patient to not receive at least 20 hours of PHP services per week, particularly where payment would still be appropriate.

Our goal is for PHP providers to continue to have flexibility in providing PHP services. However, we must ensure that beneficiaries enrolled in PHPs are legitimately eligible for PHP services and receive appropriately intensive treatment. As we seek to understand the usage of PHP services by Medicare patients, we also will continue to monitor the intensity of services provided on a weekly basis, and look forward to reviewing stakeholder comments when considering options to address situations where an appropriately intensive level of service is not provided.

C. Proposed Outlier Policy for CMHCs

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), after examining

the costs, charges, and outlier payments for CMHCs, we concluded that establishing a separate OPPS outlier policy for CMHCs would be appropriate. 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.

The 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. In contrast, in CY 2003, more than \$30 million was paid to CMHCs in outlier payments. We note that, in the CY 2009 OPPS/ASC final rule with comment period, we also established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments (73 FR 68594 through 68599). In CY 2017, 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). This outlier payment cap only affects CMHCs, and does not affect other provider types. This outlier payment cap is in addition to and separate from the current outlier policy and reconciliation policy in effect. 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).

In this CY 2018 OPPS/ASC proposed rule, we are proposing to continue 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 in CY 2018, excluding outlier payments. This policy results in CMHC outliers being paid under limited circumstances associated with costs from complex cases, rather than as a substitute for the standard PHP payment to CMHCs. CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2018, excluding outlier payments. Therefore, we are proposing to designate approximately 0.0027 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs. As we do for each rulemaking cycle, we have updated the CMHC CCRs and

claims data used to model the PHP payments rates.

Based on our simulations of CMHC payments for CY 2018, in this proposed rule, we are proposing to continue to set the cutoff point for outlier payments for CY 2018 at 3.4 times the highest CMHC APC payment rate implemented for that calendar year, which for CY 2018 is the payment rate for CMHC APC 5853. In addition, we are proposing to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2018, we are proposing to continue to pay 50 percent of CMHC 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 APC 5853 exceeds 3.4 times the proposed payment rate for CMHC APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the payment rate for CMHC APC 5853.

In section II.G. of this proposed rule, for the hospital outpatient outlier payment policy, we are proposing to set a fixed dollar threshold in addition to an APC multiplier threshold. 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. As such, it is not necessary to also impose a fixed dollar threshold on CMHCs. Therefore, we are not proposing to set a dollar threshold for CMHC outlier payments.

In summary, we are proposing to continue to calculate our CMHC outlier threshold and CMHC outlier payments according to our established policies.

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 proposed list of codes that would be paid by Medicare in CY 2018 as inpatient only procedures (the proposed IPO list) is included as Addendum E to this proposed rule (which is available via the Internet on the CMS Web site).

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

In this proposed rule, for CY 2018, 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 OPPI/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 OPPI 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, we are proposing to remove the procedures described by the following codes from the IPO list for CY 2018: CPT code 27447 (Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)) and CPT code 55866 (Laparoscopy, surgical prostatectomy, retroperitoneal radical, including nerve sparing, includes robotic assistance, when performed).

For a number of years, total knee arthroplasty (TKA) has been a topic of discussion for removal from the IPO list with both stakeholder support and opposition. Most recently, in the CY 2017 OPPI/ASC proposed rule (81 FR 45679 through 45681), we sought public comments on the removal of the TKA procedure from the IPO list from interested parties, including specifically: Medicare beneficiaries and

advocate associations for Medicare beneficiaries; orthopedic surgeons and physician specialty societies that represent orthopedic surgeons who perform TKA procedures; hospitals and hospital trade associations; and any other interested stakeholders. In the comment solicitation, we requested stakeholder input on whether the TKA procedure met the established criteria used to identify procedures to remove from the IPO list. We also requested input regarding how to modify current Medicare payment models that include TKA, such as the Bundled Payments for Care Improvement (BPCI) and the Comprehensive Care for Joint Replacement (CJR) initiatives, if the procedure was removed from the IPO list.

The public comments we received were varied and nuanced. A number of commenters believed that continued refinements in the TKA surgical procedure allowed it to be performed safely on properly selected Medicare beneficiaries in the outpatient setting. A number of facilities indicated that they were currently performing TKA procedures on an outpatient basis in both the HOPD and ASC on non-Medicare patients. Commenters who supported removing the TKA procedure from the IPO list also noted recent peer-reviewed publications that reported on investigations of the feasibility of outpatient TKA with positive results; that is, TKA outpatients did not experience higher rates of complications or readmissions in comparison to TKA inpatients.

A minority of commenters (including teaching hospital stakeholders and some professional organizations representing orthopedic surgeons) stated that the risk of postsurgical complications was too high for patients with the TKA procedure performed in the outpatient setting for the Medicare population and noted that patients appropriate for the TKA procedure performed on an outpatient basis tend to be younger, more active, have fewer complications, and have more at home support than most Medicare beneficiaries. These commenters also believed there was insufficient research on the TKA procedure performed on an outpatient basis to definitively claim that the procedure could be safely performed in the outpatient setting.

Some commenters noted that if the TKA procedure was removed from the IPO list, inpatient TKA cases should not be subject to Recovery Audit Contractor (RAC) review for appropriate site-of-service. In addition, some commenters expressed concerns about the effect that removing the TKA procedure from the

IPO list could have on the BPCI and CJR Medicare payment models. We stated in the CY 2017 OPPI/ASC final rule with comment period (81 FR 79699) that we would consider all public comments received in future policymaking.

We have reviewed the clinical characteristics of the TKA procedure and related evidence, including current length-of-stay (LOS) data for inpatient TKA procedures and peer-reviewed literature related to outpatient TKA procedures. We also have considered input from the comment solicitation in the CY 2017 OPPI/ASC final rule with comment period and the professional opinions of orthopedic surgeons and CMS clinical advisors. In addition, we have taken into account the recommendation from the summer 2016 Advisory Panel on Hospital Outpatient Payment (HOP Panel) meeting to remove the TKA procedure from the IPO list. Based on this information, we have determined that the TKA procedure would be an appropriate candidate for removal from the IPO list. We expect providers to carefully develop evidence-based patient selection criteria to identify patients who are appropriate candidates for an outpatient TKA procedure as well as exclusionary criteria that would disqualify a patient from receiving an outpatient TKA procedure. We believe that the subset of Medicare beneficiaries who meet patient selection criteria for performance of the TKA procedure on an outpatient basis may have the procedure performed safely in the outpatient setting.

We believe that the TKA procedure meets a number of criteria for removal from the IPO list, including criteria 1, 2, and 4. We are seeking comments on whether the public believes that these criteria are met and whether the TKA procedure meets any other of the five criteria stated in the beginning of this section.

We are proposing that CPT code 27447 would be assigned to C-APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator "J1".

We also note, as stated in the CY 2017 OPPI/ASC final rule with comment period (81 FR 79697), that removal from the IPO list does *not* require the covered surgical procedures to be performed only on an outpatient basis. Removal of a procedure from the IPO list allows for Medicare coverage and payment for the procedure when it is furnished either in an inpatient or outpatient hospital setting. IPO list procedures must be performed on an inpatient basis (regardless of the expected length of the hospital stay) in order to qualify for Medicare payment, but procedures that are not on the IPO list may still be

covered and paid for by Medicare when they are performed on individuals who are inpatients. The decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary. Therefore, if we finalize our proposal to remove the TKA procedure from the IPO list, we would also prohibit Recovery Audit Contractor (RAC) review for patient status for TKA procedures performed in the inpatient setting for a period of 2 years to allow time and experience for these procedures under this setting. We

would not want hospitals to err on the side of inappropriately performing the procedure on an outpatient basis due to concerns about the possibility of an inpatient TKA claim being denied for patient status. That is, given that this surgical procedure would be newly eligible for payment under either the IPPS or the OPSS, RAC denial of a hospital claim for patient status would be prohibited. We note that contractor reviews for issues other than patient status as an inpatient or outpatient would continue to be permitted, including those for underlying medical necessity.

We also are proposing to remove the procedure described by CPT code 55866 from the IPO list for CY 2018. We are

proposing that CPT code 55866 would be assigned to C-APC 5362 (Level 2 Laparoscopy & Related Services) with status indicator "J1". After consulting with stakeholders and our clinical advisors regarding this procedure, we believe that this procedure meets criteria 1 and 2. We are seeking comment on whether the public believes that these criteria are met and whether CPT code 55866 meets any other of the five criteria stated in the beginning of this section.

The procedures that we are proposing to remove from the IPO list for CY 2018 and subsequent years, including the HCPCS code, long descriptors, and the proposed CY 2018 payment indicators, are displayed in Table 29 below.

TABLE 29—PROPOSED PROCEDURES TO BE REMOVED FROM THE INPATIENT ONLY LIST FOR CY 2018

CY 2018 CPT code	CY 2018 long descriptor	Proposed CY 2018 OPSS APC assignment	Proposed CY 2018 OPSS status indicator
27447	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty).	5115	J1
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed.	5362	J1

We are inviting public comments on our proposals to remove the procedures described by CPT code 27447 and CPT code 55866 from the IPO list beginning in CY 2018. In addition, in section XII.C.1.b. of this proposed rule, we are soliciting public comments on whether the TKA procedure meets the criteria to be added to the list of ASC covered surgical procedures.

The complete proposed list of codes (the IPO list) that would be paid by Medicare in CY 2018 as inpatient only procedures is included as Addendum E to this proposed rule (which is available via the Internet on the CMS Web site).

C. Solicitation of Public Comments on the Possible Removal of Partial Hip Arthroplasty (PHA) and Total Hip Arthroplasty (THA) Procedures From the IPO List

1. Background

Partial hip arthroplasty (PHA), CPT code 27125 (Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)), and total hip arthroplasty (THA) or total hip replacement, CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft), have traditionally been considered inpatient surgical procedures. The procedures were placed on the original IPO list in the CY 2001

OPSS final rule (65 FR 18780). In 2000, the primary factors that were used to determine the assignment of a procedure to the IPO list were as follows: (1) The invasive nature of the procedure; (2) the need for at least 24 hours of postoperative care; and (3) the underlying physical condition of the patient who would require the surgery (65 FR 18455). In 2000, the geometric mean average length of stay for the DRG to which uncomplicated PHA and THA procedures were assigned was 4.6 days, and in 2016, the average length of stay for current uncomplicated PHA and THA procedures for the MS-DRG was 2.7 days.

In the CY 2017 OPSS/ASC proposed rule, we solicited public comments on the possible removal of total knee arthroplasty (TKA) from the IPO list (81 FR 45679 through 45681). Included in the public comments received related to the removal of TKA from the IPO list were several comments in support of removal of THA from the IPO list as well. Among those commenters expressing support for removal of THA from the IPO list were several surgeons and other stakeholders who believed that, given thorough preoperative screening by medical teams with significant experience and expertise involving hip replacement procedures, the THA procedure could be provided on an outpatient basis for some

Medicare beneficiaries. These commenters noted significant success involving same day discharge for patients who met the screening criteria and whose experienced medical teams were able to perform the procedure early enough in the day for the patients to achieve postoperative goals, allowing home discharge by the end of the day. The commenters believed that the benefits of providing the THA procedure on an outpatient basis will lead to significant enhancements in patient well-being, improved efficiency, and cost savings to the Medicare program, including shorter hospital stays resulting in fewer medical complications, improved results, and enhanced patient satisfaction.

Recent innovations have enabled surgeons to perform the PHA and THA procedures on an outpatient basis on non-Medicare patients (both in the HOPD and in the ASC). These innovations in PHA and THA care include minimally invasive techniques, improved perioperative anesthesia, alternative postoperative pain management, and expedited rehabilitation protocols. Patients undergoing minimally invasive surgical procedures instead of open surgical techniques generally benefit from a shorter hospital stay. However, not all patients are candidates for minimally invasive PHA or THA. Commenters on

the CY 2017 OPPTS/ASC proposed rule comment solicitation on the TKA procedure have stated that benefits of outpatient PHA and THA procedures include a likelihood of fewer complications, more rapid recovery, increased patient satisfaction, recovery at home with the assistance of family members, and a likelihood of overall improved outcomes. On the contrary, unnecessary inpatient hospitalization exposes patients to the risk of hospital-acquired conditions such as infections and a host of other iatrogenic mishaps.

Like most surgical procedures, both PHA and THA need to be tailored to the individual patient's needs. Patients with a relatively low anesthesia risk and without significant comorbidities who have family members at home who can assist them may likely be good candidates for an outpatient PHA or THA procedure. These patients may be determined to also be able to tolerate outpatient rehabilitation in either an outpatient facility or at home postsurgery. On the other hand, patients with multiple medical comorbidities, aside from their osteoarthritis, would more likely require inpatient hospitalization and possibly postacute care in a skilled nursing facility or other facility. Surgeons who have discussed outpatient PHA and THA procedures in public comments in response to our CY 2017 OPPTS/ASC proposed rule comment solicitation on the TKA procedure have emphasized the importance of careful patient selection and strict protocols to optimize outpatient hip replacement outcomes. These protocols typically manage all aspects of the patient's care, including the at-home preoperative and postoperative environment, anesthesia, pain management, and rehabilitation to maximize rapid recovery, ambulation, and performance of activities of daily living.

We also note that not uncommonly we receive questions from the public about the IPO list that lead us to believe that some members of the public may misunderstand certain aspects of the IPO list. Therefore, two important principles of the IPO list must be reiterated at the outset of this discussion. First, just because a procedure is not on the IPO list does not mean that the procedure cannot be performed on an inpatient basis. IPO list procedures must be performed on an inpatient basis (regardless of the expected length of the hospital stay) in order to qualify for Medicare payment, but procedures that are not on the IPO list can be and very often are performed on individuals who are inpatients (as well as individuals who are hospital

outpatients and ASC patients). Second, the IPO list status of a procedure has no effect on the MPFS professional payment for the procedure. Whether or not a procedure is on the IPO list is not in any way a factor in the MPFS payment methodology.

2. Topics and Questions for Public Comments

We are seeking public comments on whether we should remove the procedures described by CPT codes 27125 and 27130 from the IPO list from all interested parties, including the following groups or individuals:

Medicare beneficiaries and advocate associations for Medicare beneficiaries; orthopedic surgeons and physician specialty societies that represent orthopedic surgeons who perform PHA and/or THA procedures; hospitals and hospital trade associations; and any other interested stakeholders. We are also specifically seeking public comments on the following questions:

- Are most outpatient departments equipped to provide PHA and/or THA to some Medicare beneficiaries?
- Can the simplest procedure described by CPT codes 27125 and 27130 be performed in most outpatient departments?
- Are the procedures described by CPT codes 27125 and 27130 sufficiently related to or similar to other procedures we have already removed from the IPO list?
- How often is the procedure described by CPT codes 27125 and 27130 being performed on an outpatient basis (either in an HOPD or ASC) on non-Medicare patients?
- Would it be clinically appropriate for some Medicare beneficiaries in consultation with his or her surgeon and other members of the medical team to have the option of either a PHA or THA procedure as a hospital outpatient, which may or may not include a 24-hour period of recovery in the hospital after the operation?

In addition, we are soliciting public comments on whether the PHA and THA procedures may meet the criteria to be added to the ASC Covered Procedures List. We refer readers to section XII.C.1.c. of this proposed rule for a complete discussion of the ASC Covered Procedures List.

Finally, as noted when we solicited public comment on removing the TKA procedure from the IPO list in the CY 2017 rulemaking, we solicited public comment on the effect of removing the TKA procedure from the IPO list on the Comprehensive Care for Joint Replacement (CJR) Model and the Bundled Payment for Care

Improvements (BPCI) Model. We refer readers to the CY 2017 OPPTS/ASC proposed rule for a discussion of questions we raised for public comments and again are seeking public comment on the effect of removing the PHA and THA procedures from the IPO list on these models. For a discussion of these models in the CY 2017 rulemaking, we refer readers to 81 FR 79698 through 79699.

X. Proposed Nonrecurring Policy Changes

A. Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

1. Background

Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74), enacted on November 2, 2015, 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, will not be considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPTS and will instead be paid "under the applicable payment system" under Medicare Part B if the requirements for such payment are otherwise met. 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. The implementation of section 603 of the Bipartisan Budget Act of 2015 was finalized in the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (79720 through 79729).

2. Summary of Public Comments and Our Responses Regarding Expansion of Services by Excepted Off-Campus Hospital Outpatient Departments

In the CY 2017 OPPTS/ASC final rule with comment period, we expressed interest in receiving feedback on the limitation on expansion of services of hospital outpatient departments as it related to excepted off-campus provider-based departments (PBDs) (81 FR 79707). Below we discuss certain proposals and present a summary of the public comments received and our responses to those comments.

As discussed in the CY 2017 OPPTS/ASC proposed rule and final rule with comment period (81 FR 45685 through 45686 and 81 FR 79706 through 79707), we stated that we believe section

1833(t)(21)(B)(ii) of the Act, as added by section 603 of Public Law 114–74, excepts off-campus provider based departments (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 Public Law 114–74, as guided by our regulatory definition of a department of a provider at § 413.65(a)(2). Therefore, we proposed that the excepted off-campus PBD items and services that would continue to be paid under the OPSS would be limited to the provision of items and services it was furnishing prior to the date of enactment of section 603 of Public Law 114–74. Moreover, we proposed that items and services that are not part of a clinical family of services furnished and billed by the excepted off-campus PBD prior to November 2, 2015 would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act; that is, not payable under the OPSS (81 FR 45685 through 45686).

As noted in both the CY 2017 OPSS/ASC proposed rule and final rule with comment period, we believe that the amendments to section 1833(t) of the Act by section 603 of Public Law 114–74 were intended to address items and services furnished at physicians' offices that are converted to hospital off-campus PBDs on or after November 2, 2015 from being paid at OPSS rates (81 FR 45685 through 45686 and 81 FR 79706 through 79707). One issue we contemplated is how expanded services of an excepted off-campus PBD could affect payments to a hospital in regard to newly acquired physicians' offices or new off-campus PBDs established after the date of enactment of section 603 of Public Law 114–74. Particularly, in the CY 2017 OPSS/ASC proposed rule, 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 OPSS 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 (81 FR 45685). This could result in newly purchased physician practices furnishing services that are paid at OPSS rates, which we believe these amendments to section 1833(t) of the Act were intended to address.

After reviewing the statutory authority and the concerns raised by stakeholders, we proposed for CY 2017, for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act, that

excepted status of items and services furnished in excepted off-campus PBDs would be limited to the items and services (defined as clinical families of services in Table 21 of the proposed rule (81 FR 45685 through 45686)) such a department was billing for under the OPSS and were furnished prior to November 2, 2015. We proposed that if an excepted off-campus PBD furnishes services from a clinical family of services that it did not furnish prior to November 2, 2015, and therefore did not also bill for, these new or 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. We did not propose to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish.

In addition, we considered, but did not propose, specifying a timeframe in which service lines had to be billed under the OPSS for covered OPD services furnished prior to November 2, 2015. We sought public comment through the CY 2017 OPSS/ASC proposed rule on whether we should adopt a specific timeframe for which the billing had to occur, such as CY 2013 through November 1, 2015.

Under our CY 2017 proposal, while excepted off-campus PBDs would not be eligible to receive OPSS payments for expanded clinical families of services, such excepted off-campus PBDs would continue to be eligible to receive OPSS payment for clinical families of services that were furnished and billed prior to that date.

After consideration of the public comments we received in response to the CY 2017 OPSS/ASC proposed rule, we did not finalize our proposed policy to limit service line expansion. Therefore, for CY 2017, an excepted off-campus PBD receives payments under the OPSS for all billed items and services, regardless of whether it furnished such types of items and services prior to the date of enactment of Public Law 114–74, as long as the excepted off-campus PBD remains excepted; that is, it meets the relocation and change of ownership requirements adopted in the CY 2017 OPSS/ASC final rule with comment period (81 FR 79707). Furthermore, in the CY 2017 OPSS/ASC final rule with comment period, we stated our intent to monitor service line expansion and continue to consider how a potential limitation on expansion would work. To that end, in the CY 2017 OPSS/ASC final rule with comment period, we sought public comments on how either a limitation on volume of services, as MedPAC

described in its comments, or a limitation on lines of service, as we laid out in the proposed rule, could be implemented (81 FR 79707). Specifically, we stated we were interested in what data are currently available or could be collected that would allow us to implement a limitation on service expansion. We also stated our interest in receiving suggestions for changes to the clinical families of services that we set forth in Table 21 of the proposed rule (81 FR 45685 through 45686) as we move forward.

Several of the public comments received in response to the November 2016 comment solicitation were repeated from the same stakeholders in response to the CY 2017 OPSS/ASC proposed rule. These commenters again expressed concern regarding CMS' authority to address changes in service-mix; how a limitation on service expansion or volume would stifle innovative care delivery and use of new technologies; and how the clinical families of service are not workable. Because these commenters did not provide new information, we refer readers to the CY 2017 OPSS/ASC final rule with comment period for our response to comments on statutory authority and hindrance to access to innovative technologies (81 FR 79707). A summary of and our responses to the other comments received in response to the November 2016 comment solicitation follow:

Comment: One commenter raised concern that CMS will implement policies that prohibit expansion of services at excepted off-campus PBDs. The commenter believed that excepted and nonexcepted off-campus PBDs should be allowed to expand their service offerings.

Response: We believe the commenter may have misunderstood the policy proposal to limit service line expansion as a proposal to disallow excepted off-campus PBDs from ever altering their service offerings or from treating new patients. To clarify, we proposed that the items and services furnished by an excepted off-campus PBD that would continue to be paid under the OPSS would be limited to the provision of items and services within the clinical families of services the excepted off-campus PBD was furnishing prior to November 2, 2015. In addition, we proposed that items and services that were not part of a clinical family of services furnished and billed by the excepted off-campus PBD prior to November 2, 2015 would be paid under the MPFS. We did not propose to prohibit expansion of clinical services

furnished by either excepted or nonexcepted off-campus PBDs. In the CY 2017 OPPS/ASC final rule with comment period, in response to public comments, we did not finalize our proposal to limit payment under the OPPS for expansion of services at excepted off-campus PBDs, but 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 MPFS) 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). For example, if we were to adopt a limitation on payment for expanded service lines at an excepted off-campus PBD and such PBD primarily provided infusion services prior to November 2, 2015, but added cardiology services after November 2, 2015, should payment for the cardiology services be made under the MPFS while payment for the infusion services would be made under the OPPS?

We recognize that services provided in off-campus PBDs may evolve to reflect changes in clinical practice and community health care needs. However, as stated in prior rulemaking, we believe that section 1833(t)(21)(B)(ii) of the Act excepted off-campus PBDs as they existed at the time that Public Law 114–74 was enacted, and provides the authority to define excepted off-campus PBDs, including those items and services furnished and billed by such a PBD that may be paid under the OPPS, as opposed to the authority under section 1833(t)(21)(C) of the Act.

Comment: 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 expanding its payment advantage under the OPPS into wholly new clinical areas.

Response: We appreciate the commenters' support. We are collecting data on the claims billed by off-campus PBDs with modifier "PO" (for excepted services) and modifier "PN" (for nonexcepted services). We believe that data collected using these modifiers will be a useful tool in furthering our efforts to monitor service line expansion, and address any issues as they may arise.

Comment: 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." One commenter suggested that CMS already has the necessary data to limit excepted off-campus PBDs to billing under the OPPS for only those items and services that were furnished prior to November 2, 2015. The 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.

Response: We appreciate the commenters' suggestions. While the "PO" modifier claims data are helpful to assess the billing patterns of off-campus PBDs, reporting of this modifier was voluntary for CY 2015 and did not become mandatory until CY 2016. Because of the voluntary nature of "PO" modifier reporting in CY 2015, the data may not accurately reflect all items and services furnished at excepted off-campus PBDs. We also are 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. Any future proposal on service expansion would need to be practicable and take into consideration the administrative burden on providers and the Federal Government.

Comment: A few commenters expressed concern that either a limitation on services or volume of services at an excepted off-campus PBD would result in varying beneficiary copayments at a single site, which could create confusion and inequity. Therefore, the commenters requested that CMS minimize beneficiary confusion by treating all items and services furnished at an excepted off-campus PBD as excepted under § 419.48.

Response: We appreciate these comments. We note that the cost-sharing liability under both the OPPS and the MPFS is prescribed by statute and that there is not flexibility with respect to the copayment amount that would be due for a given service.

Comment: A few commenters believed that MedPAC's proposal to cap service volume from a baseline period would still be administratively complex and unduly burdensome. In addition, the commenters disagreed with MedPAC's proposal to establish the baseline period using the 12-month period that preceded November 2, 2015 (that is, November 2, 2014 through November 1, 2015) as a baseline for volume caps. These commenters believed that such an approach would negatively affect excepted off-campus

PBDs that began operations any time during the year before the enactment of section 603 of Public Law 114–74, by possibly preventing all of the items and services furnished by that excepted off-campus PBD from being excepted from the provisions of section 603. Therefore, the commenters requested that any baseline period run no earlier than the 12-month period immediately prior to the effective date of the policy, or, for excepted off-campus PBDs that began operations within the 5-year period prior to the effective date of the policy, the 12-month period following the excepted off-campus PBD's fifth year of operations. The commenters also believed that establishment of a cap based on the modifier "PO" data is inappropriate, given that use of the modifier was not mandatory until January 1, 2016, or nearly 2 months after enactment of section 603 of Public Law 114–74. One commenter suggested that a volume cap would need to be adjusted annually to account for changes in coding and bundling of services; changes in population of community served; hospital market basket increases to OPPS payment rates; and efficiency improvements.

Response: We appreciate these comments and concerns relating to proposing a cap on service volume and the limitations of the "PO" modifier data. We will take this feedback into consideration in the development of potential future proposals to either limit service expansion or cap volume of services payable under the OPPS.

Comment: A few commenters suggested that CMS delay establishing any limitation on service expansion or volume until claims data with the "PN" modifier are available. However, the commenters believed that, even with "PO" modifier data from excepted off-campus PBDs and "PN" modifier data from nonexcepted off-campus PBDs, it would be a challenging task for CMS and providers to retroactively assess and compare which services were provided at each PBD for a 1-year period prior to November 2, 2015. As an alternative, one commenter suggested that additional questions on the CMS 855A enrollment form would be a more sensible approach to gathering information on types of services furnished at excepted off-campus PBDs, but did not provide any specific questions.

Response: We agree that evaluating data reported with the "PN" modifier by nonexcepted off-campus PBDs will be instructive as we consider options for any potential future proposal on limitation of service line expansion or volume. While we did not finalize any

policy on clinical service expansion that would establish the baseline period as a 1-year period prior to November 2, 2015, we appreciate the feedback. Regarding changes to the CMS 855A enrollment form, we are unclear on what types of questions could be added to glean a better understanding of services provided at nonexcepted off-campus PBDs; therefore, we cannot respond to this comment at this time.

We appreciate the commenters' suggestions and concerns on the issue of a limitation on clinical service line expansion or a limitation on service line volume. After consideration of the public comments we received, for CY 2018, we are not making any proposals to limit clinical service line expansion or volume increases at excepted off-campus PBDs, but will continue to monitor claims data for changes in billing patterns and utilization, and continue to invite public comments on this issue.

We refer readers to the CY 2018 MPFS proposed rule for proposed payment rates under the MPFS for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments of hospitals.

3. Implementation of Section 16002 of the 21st Century Cures Act (Treatment of Cancer Hospitals in Off Campus Outpatient Department of a Provider Policy)

In the CY 2017 OP/ASC final rule with comment period (81 FR 79699), we finalized a number of proposals to implement section 603 of the Bipartisan Budget Act of 2016 (Pub. L. 114-74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended the OP/ASC statute to require that certain items and services furnished by certain off-campus outpatient departments of a provider (off-campus PBDs) on or after January 1, 2017 will not be considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OP/ASC, and instead will be paid "under the applicable payment system" under Medicare Part B if the requirements for such payment are otherwise met. In the CY 2017 OP/ASC final rule with comment period (81 FR 79699), we established the Medicare Physician Fee Schedule as the "applicable payment system" for the majority of the nonexcepted items and services furnished by nonexcepted off-campus PBDs.

Section 16002(a) of the 21st Century Cures Act (Pub. L. 114-255) amended the Act at section 1833(t)(20)(B) and provided that with respect to applicable

items and services furnished during 2017 or a subsequent year, the term "off-campus outpatient department of a provider" excludes certain cancer hospitals. To meet this exclusion, section 16002(a) requires that such cancer hospitals (1) be described in section 1886(d)(1)(B)(v) of the Act; and (2) for hospital outpatient departments that meet the requirements for 42 CFR 413.65, after November 1, 2015 and before December 15, 2016, that the Secretary has received from the provider an attestation that the department met such requirements not later than 60 days after the date of enactment of section 16002 (December 13, 2016), or, for departments that meet the requirements after December 13, 2016, the Secretary has received from the provider an attestation that the department met the requirements not later than 60 days after the date the department first met the requirements of 42 CFR 413.65. Through operational guidance, we have provided direction to all MACs regarding this provision. We have also provided guidance on this provision to hospital providers, which can be found on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Sections-16001-16002.pdf>.

Section 16002(b) of Public Law 114-255 amended section 1833(t)(18) of the Act by adding a new subparagraph (C) that requires the Secretary, in applying 42 CFR 419.43(i) for services furnished on or after January 1, 2018, to use a target PCR that is 1 percentage point less than the target PCR that would otherwise apply. In addition to the 1 percentage point 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 in section 1833(t)(21)(C) of the Act other than for services furnished by certain cancer hospitals. Further, in making any budget neutrality adjustments under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act. We refer readers to section II.F. of this proposed rule for a discussion on the calculation of the proposed target PCR for cancer hospitals for CY 2018.

B. Medicare Site-of-Service Price Transparency (Section 4011 of the 21st Century Cures Act)

Section 4011 of the 21st Century Cures Act (Pub. L. 114-255), enacted on December 13, 2016, amended section 1834 of the Act by adding a new

subsection (t). New section 1834(t) of the Act provides that, in order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under Title XVIII, the Secretary shall, for 2018 and each year thereafter, make available to the public via a searchable Web site, with respect to an appropriate number of items and services, the estimated payment amount for the item or service under the OP/ASC payment system and the estimated beneficiary liability applicable to the item or service. We are announcing our plan to establish the searchable Web site required by section 1834(t) of the Act. Details regarding the Web site will be issued through our subregulatory process. We anticipate that the Web site will be made available in early CY 2018.

C. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93) added subsection (q) to section 1834 of the Act, which directs the Secretary to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services (the AUC program). Section 1834(q)(1)(B) of the Act defines AUC as criteria that are evidence-based (to the extent feasible) and assist professionals who order and furnish applicable imaging services to make the most appropriate treatment decisions for a specific clinical condition. The current policies for the AUC program for advanced diagnostic imaging services are codified in the regulations at 42 CFR 414.94.

There are three key components of the AUC program for advanced diagnostic imaging services program. In the CY 2016 MPFS final rule with comment period (80 FR 71102 through 71116 and 80 FR 71380 through 71382), we addressed the first component of the Medicare AUC program. The first component includes the requirements and process for the establishment and specification of the AUC. In the CY 2017 MPFS final rule with comment period (81 FR 80403 through 80428 and 81 FR 80554 through 80555), we addressed the second component of the AUC program. The second component includes the specification of qualified clinical decision support mechanisms (CDSMs). A CDSM is the electronic tool through which the ordering practitioner consults AUC. In the CY 2018 MPFS proposed rule, we are proposing to address the third component of the AUC program. The third component includes the

requirements for an ordering professional to consult with a qualified CDSM when ordering an applicable imaging service and communicate information about the AUC consultation to the furnishing professional, and for the furnishing professional to include that information on claims for the service that is furnished in an applicable setting and paid under an applicable payment system. Based on the statutory language of section 1834(q)(4)(B) of the Act, the AUC program applies to advanced imaging services for which payment is made under the following applicable payment systems: The MPFS; the OPFS; and the ASC payment system. Information on the latest proposals for requirements for the AUC program can be found in the CY 2018 MPFS proposed rule. Public comments on these proposals should be submitted in response to the CY 2018 MPFS proposed rule.

D. Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in Critical Access Hospitals (CAHs) and Certain Small Rural Hospitals

In the CY 2009 OPFS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, respectively), we clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals as well as in provider-based departments (PBDs) of hospitals, as set forth in the CY 2000 OPFS final rule with comment period (65 FR 18525). In the CY 2010 OPFS/ASC final rule with comment period (74 FR 60575 through 60591), we finalized a technical correction to the title and text of the applicable regulations at 42 CFR 410.27 to clarify that this standard applies in CAHs as well as hospitals. In response to concerns expressed by the hospital community, in particular CAHs and small rural hospitals, that they would have difficulty meeting this standard, on March 15, 2010, we instructed all Medicare administrative contractors not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs from January 1, 2010 through December 31, 2010, while the agency revisited the supervision policy during the CY 2011 OPFS/ASC rulemaking cycle.

Due to continued concerns expressed by CAHs and small rural hospitals, we extended this notice of nonenforcement ("enforcement instruction") as an interim measure for CY 2011, and expanded it to apply to small rural hospitals having 100 or fewer beds (75

FR 72007). We continued to consider the issue further in our annual OPFS notice-and-comment rulemaking, and implemented an independent review process in 2012 to obtain advice from the Hospital Outpatient Payment Panel (the Panel) on this matter (76 FR 74360 through 74371). Under this process used since CY 2012, the Panel considers and advises CMS regarding stakeholder requests for changes in the required level of supervision of individual hospital outpatient therapeutic services. In addition, we extended the enforcement instruction through CY 2012 and CY 2013. The enforcement instruction has not been in effect since December 31, 2013. Congress has taken legislative action (Pub. L. 113–198 and Pub. L. 114–112) to extend nonenforcement of the direct supervision of hospital outpatient therapeutic services in CAHs and small rural hospitals having 100 or fewer beds since December 31, 2013. The latest legislative action (Pub. L. 114–255) extended nonenforcement until December 31, 2016. The current enforcement instruction is available on the CMS Web site at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/Moratorium-on-Hospital-Supervision-Enforcement.pdf>.

Stakeholders have consistently requested that we continue the nonenforcement of the direct supervision of hospital outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds. Stakeholders stated that some small rural hospitals and CAHs have insufficient staff available to furnish direct supervision. The primary contributing factors cited were difficulty recruiting physician and nonphysician practitioners to practice in rural areas. These stakeholders noted that it is particularly difficult to furnish direct supervision for critical specialty services, such as radiation oncology services, that cannot be directly supervised by a hospital emergency department physician or nonphysician practitioner because of the volume of emergency patients or lack of specialty expertise. In addition, we are not aware of any quality of care complaints from beneficiaries or providers relating to general physician supervision as compared to direct physician supervision for outpatient hospital therapeutic services.

Therefore, we are proposing to reinstate the nonenforcement of direct supervision enforcement instruction for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for CY 2018 and 2019 to give

CAHs and small rural hospitals having 100 or fewer beds more time to comply with the supervision requirements for outpatients therapeutic services and to give all parties time to submit specific services to be evaluated by the Advisory Panel on Hospital Outpatient Payment for a recommended change in the supervision level. These hospitals will continue to be subject to conditions of participation for hospitals and other Medicare rules regarding supervision. We welcome public comments on this proposal.

E. Payment Changes for Film X-Ray Services and Proposed Payment Changes for X-Rays Taken Using Computed Radiography Technology

Section 502 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), which was enacted on December 18, 2015, contains provisions to incentivize the transition from traditional X-ray imaging to digital radiography. In particular, section 502(b) of Public Law 114–113 amended section 1833(t)(16) of the Act by adding subparagraph (F), which includes provisions that limit payment for film x-ray imaging services and computed radiography imaging services.

Section 1833(t)(16)(F)(i) of the Act specifies that, effective for services furnished during 2017 or a subsequent year, the payment under the OPFS for imaging services that are X-rays taken using film (including the X-ray component of a packaged service) that would otherwise be made under the OPFS (without application of subparagraph (F)(i) and before application of any other adjustment under section 1833(t)) shall be reduced by 20 percent. Section 1833(t)(16)(F)(iii) of the Act provides that the reductions made under section 1833(t)(16)(F) of the Act shall not be considered an adjustment under section 1833(t)(2)(E) of the Act, and shall not be implemented in a budget neutral manner.

Consistent with section 1833(t)(16)(F)(iv) of the Act, which requires the implementation of the reductions in payment set forth in subparagraph (F) through appropriate mechanisms, which may include modifiers, we implemented section 1833(t)(16)(F)(i) of the Act by establishing the modifier "FX" (X-ray taken using film), effective January 1, 2017. The payment for X-rays taken using film and furnished during 2017 or a subsequent year will be reduced by 20 percent when modifier "FX" (X-ray taken using film) is reported with the appropriate HCPCS codes. The applicable HCPCS codes describing

imaging services can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). When payment for an X-ray service taken using film is packaged into the payment for another item or service under the OPPS, no separate payment for the X-ray service is made and, therefore, there is no payment amount that can be attributed to the X-ray service. Accordingly, the amount of the payment reduction for a packaged film X-ray service is \$0 (20 percent of \$0). Further discussion of these policies and modifier “FX” can be found in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79729 through 79730).

Section 1833(t)(16)(F)(ii) of the Act provides for a phased-in reduction of payments for imaging services that are taken using computed radiography technology (as defined in section 1848(b)(9)(C) of the Act). Payments for such services (including the X-ray component of a packaged service) furnished during CY 2018, 2019, 2020, 2021, or 2022, that would otherwise be determined under section 1833(t) of the Act (without application of subparagraph (F)(ii) and before application of any other adjustment), shall be reduced by 7 percent, and if such services are furnished during CY 2023 or a subsequent year, by 10 percent. For purposes of this reduction, computed radiography technology is defined in section 1848(b)(9)(C) of the Act as cassette-based imaging which utilizes an imaging plate to create the image involved.

To implement this provision, we are establishing a new modifier “XX”, as permitted by section 1833(t)(16)(F)(iv) of the Act, that would be reported on claims to identify those HCPCS codes that describe X-rays taken using computed radiography technology. We are proposing that the payment reduction would be taken when this payment modifier is reported with the applicable HCPCS code(s) to describe imaging services that are taken using computed radiography technology. The applicable HCPCS codes describing imaging services can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). We note that modifier “XX” is a placeholder modifier whose 2-digit modifier and long descriptor will be described in the CY 2018 OPPS/ASC final rule with comment period. When payment for an X-ray service taken using computed radiography imaging is packaged into the payment for another item or service under the OPPS, no separate payment for the X-ray service is made and,

therefore, there is no payment amount that can be attributed to the X-ray. Accordingly, the amount of the payment reduction for a packaged X-ray service would be \$0 (7 percent of \$0, and 10 percent of \$0). We are inviting public comments on these proposals.

Although we adopted the payment reduction required by section 1833(t)(16)(F)(i) of the Act in the CY 2017 OPPS/ASC final rule with comment period, we did not adopt corresponding regulation text. Therefore, in this CY 2018 OPPS/ASC proposed rule, we are proposing to add new regulation text at 42 CFR 419.71 to codify our existing policies and our proposed policies for computed radiography technology services. We are proposing to add the definition of “computed radiography technology”, as it is defined in section 1848(b)(9)(C) of the Act, in paragraph (a) of proposed new § 419.71. The proposed regulation text under paragraph (b) of proposed new § 419.71 would specify the 20-percent reduction for film X-ray imaging services. We are proposing that the phased-in payment reduction for computed radiography technology imaging services would be codified at paragraph (c) of proposed new § 419.71. Paragraph (d) of proposed new § 419.71 would provide that the payment reductions taken under the section are not considered adjustments under section 1833(t)(2)(E) of the Act and are not implemented in a budget neutral manner. We are inviting public comments on this proposed regulation text.

F. Potential Revisions to the Laboratory Date of Service Policy

1. Background on the Medicare Part B Laboratory Date of Service Policy

The date of service (DOS) is a required data field on all Medicare claims for laboratory services. However, a laboratory service may take place over a period of time—the date the physician orders the laboratory test, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date the laboratory performs the test, and the date results are produced may occur on different dates. In the final rule on coverage and administrative policies for clinical diagnostic laboratory services published in the **Federal Register** on November 23, 2001 (66 FR 58791 through 58792), we adopted a policy under which the DOS for clinical diagnostic laboratory services generally is the date the specimen is collected.

A special rule was developed to apply to “archived” specimens. For laboratory

tests that use an archived specimen, we established that the DOS is the date the specimen was obtained from storage (66 FR 58792).

In 2002, we issued Program Memorandum AB-02-134 which permitted contractors discretion in making determinations regarding the length of time a specimen must be stored to be considered “archived.” In response to comments requesting that we issue a national standard to clarify when a stored specimen can be considered “archived,” in the Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services final notice, published in the **Federal Register** on February 25, 2005 (70 FR 9357), we defined an “archived” specimen as a specimen that is stored for more than 30 calendar days before testing. We established that the DOS for archived specimens is the date the specimen was obtained from storage. Specimens stored for 30 days or less continued to have a DOS of the date the specimen was collected.

2. Current Medicare DOS Policy (“14-Day Rule”)

In the final rule with comment period entitled, in relevant part, “Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B” published in the **Federal Register** on December 1, 2006 (MPFS final rule) (71 FR 69705 through 69706), we added a new § 414.510 in Title 42 of the CFR regarding the clinical laboratory DOS requirements and revised our DOS policy for stored specimens. We explained in the MPFS final rule that the DOS of a test may affect payment for the test, especially in situations in which a specimen that is collected while the patient is being treated in a hospital setting (for example, during a surgical procedure), is later used for testing after the patient has been discharged from the hospital. We noted that payment for the test is usually bundled with payment for the hospital service, even where the results of the test did not guide treatment during the hospital stay. To address concerns raised for tests related to cancer recurrence and therapeutic interventions, we finalized modifications to the DOS policy in § 414.510(b)(2)(i) for a test performed on a specimen stored less than or equal to 30 calendar days from the date it was collected (a non-archived specimen), so that the DOS is the date the test was

performed (instead of the date of collection) if the following conditions are met:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

As we stated in the MPFS final rule, we established these five criteria, which we refer to as the "14-day rule," to distinguish laboratory tests performed as part of post-hospital care from the care a beneficiary receives in the hospital. When the 14-day rule applies, laboratory tests are not bundled into the hospital stay, but are instead paid separately under Medicare Part B (as explained in more detail below).

We also revised the DOS requirements for a chemotherapy sensitivity test performed on live tissue. As discussed in the MPFS final rule (71 FR 69706), we agreed with commenters that these tests, which are primarily used to determine post-hospital chemotherapy care for patients who also require hospital treatment for tumor removal or resection, appear to be unrelated to the hospital treatment in cases where it would be medically inappropriate to collect a test specimen other than at the time of surgery, especially when the specific drugs to be tested are ordered at least 14 days following hospital discharge. As a result, we revised the DOS policy for chemotherapy sensitivity tests, based on our understanding that the results of these tests, even if they were available immediately, would not typically affect the treatment regimen at the hospital. Specifically, we modified the DOS for chemotherapy sensitivity tests performed on live tissue in § 414.510(b)(3) so that the DOS is the date the test was performed if the following conditions are met:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than

during the hospital procedure for which the patient was admitted;

- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

We explained in the MPFS final rule that, for chemotherapy sensitivity tests that meet this DOS policy, Medicare would allow separate payment under Medicare Part B, that is, separate from the payment for hospital services.

3. Billing and Payment for Laboratory Services Under the OPFS

The DOS requirements at 42 CFR 414.510 are used to determine whether a hospital bills Medicare for a clinical diagnostic laboratory test (CDLT) or whether the laboratory performing the test bills Medicare directly. This is because separate regulations at 42 CFR 410.42(a) and 411.15(m) generally provide that Medicare will not pay for a service furnished to a hospital patient during an encounter by an entity other than the hospital unless the hospital has an arrangement (as defined in 42 CFR 409.3) with that entity to furnish that particular service to its patients, with certain exceptions and exclusions. These regulations, which we will call the "under arrangements" provisions in this discussion, require that if the DOS falls during an inpatient or outpatient stay, payment for the laboratory test is usually bundled with the hospital service.

Under our current rules, if a test meets all DOS requirements in § 414.510(b)(2)(i) or § 414.510(b)(3), the DOS is the date the test was performed, and the laboratory would bill Medicare directly for the test and would be paid under the Clinical Laboratory Fee Schedule (CLFS) directly by Medicare. However, if the test does *not* meet the DOS requirements in § 414.510(b)(2)(i) or § 414.510(b)(3), the DOS is the date the specimen was collected from the patient. In that case, the *hospital* would bill Medicare for the test and then would pay the laboratory that performed the test, if the laboratory provided the test under arrangement.

In recent rulemakings, we have reviewed appropriate payment under the OPFS for certain diagnostic tests that are not commonly performed by hospitals. In CY 2014, we finalized a policy to package certain CDLTs under the OPFS (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17) and 419.22(l)). In CYs 2016 and 2017, we made some modifications to this policy (80 FR 70348 through 70350; 81 FR 79592 through 79594). Under our current

policy, certain CDLTs that are listed on the CLFS are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. Specifically, we conditionally package most CDLTs and only pay separately for a laboratory test when it is (1) the only service provided to a beneficiary on a claim; (2) considered a preventive service; (3) a molecular pathology test; or (4) an advanced diagnostic laboratory test (ADLT) that meets the criteria of section 1834A(d)(5)(A) of the Act (78 FR 74939 through 74942; 80 FR 70348 through 70350; and 81 FR 79592 through 79594). In the CY 2016 OPFS/ASC final rule with comment period, we excluded all molecular pathology laboratory tests from packaging because we believed these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.

For similar reasons, in the CY 2017 OPFS/ASC final rule with comment period, we extended the exclusion to also apply to all ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act.²³ We stated that we will assign status indicator "A" (Separate payment under the CLFS) to ADLTs once a laboratory test is designated an ADLT under the CLFS. Laboratory tests that are separately payable and are listed on the CLFS are paid at the CLFS payment rates.

4. ADLTs Under the New Private Payor Rate-Based CLFS

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), requires significant changes to how Medicare pays for CDLTs under the CLFS. Section 216(a) of PAMA also establishes a new subcategory of CDLTs known as ADLTs with separate reporting and payment requirements under section 1834A of the Act. In the CLFS final rule published in the **Federal Register** on June 23, 2016, entitled "Medicare Program; Medicare Clinical Diagnostic

²³ Under section 1834A(d)(5)(A) of the Act, an ADLT is a "CDLT that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and . . . is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result." CMS has established a regulatory definition for this type of ADLT in 42 CFR 414.502.

Laboratory Tests Payment System Final Rule” (CLFS final rule) (81 FR 41036), we implemented the requirements of section 1834A of the Act.

As defined in § 414.502, an ADLT is a CLDT covered under Medicare Part B that is offered and furnished only by a single laboratory. Additionally, an ADLT cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. And, an ADLT must meet either Criterion (A), which implements section 1834A(d)(5)(A) of the Act, or Criterion (B), which implements section 1834A(d)(5)(B) of the Act, as follows:

- *Criterion (A):* The test—is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins; when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies); provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and may include other assays.

Or:

- *Criterion (B):* The test is cleared or approved by the Food and Drug Administration (FDA).

Generally, under the revised CLFS, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, updates to ADLT payment rates occur annually instead of every 3 years. The payment methodology for ADLTs is detailed in the CLFS final rule (81 FR 41076 through 41083).

5. Potential Revisions to the Laboratory DOS Policy

In the December 1, 2006 MPFS final rule (71 FR 69706), we explained that we were very concerned that only tests that can legitimately be distinguished from the care a beneficiary receives in the hospital be subject to the 14-day rule, which changes the DOS from the date the specimen was collected to the date the test was performed and results in a separate payment for the test. We also stated that we believed it is more difficult to determine that a test ordered less than 14 days before discharge is appropriately separable from the hospital stay that preceded the test. We indicated that we wanted more information about tests that may be ordered by the patient’s physician less than 14 days following the date of the discharge that would not guide the care

during a hospital stay before taking any additional action in this area.

Recently, we have heard from certain laboratory stakeholders about operational issues the current laboratory DOS policy creates for hospitals and laboratories with regard to molecular pathology tests and laboratory tests they expect will be designated by CMS as ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. These stakeholders have expressed that although these particular tests are not packaged under the OPSS, under current DOS policy, if the tests are ordered within 14 days of a patient’s discharge from the hospital, Medicare still treats the tests as though they were ordered and furnished by the hospital itself. Under those circumstances, laboratories cannot directly seek Medicare payment for the molecular pathology test or ADLT. The hospital must bill Medicare for the test, and the laboratory must seek payment from the hospital. Specifically, stakeholders representing laboratories have expressed the following concerns:

- The current DOS policy permits hospitals to bill for tests they did not perform and that may have no relationship to or bearing on treatment received by the patient while in the hospital.

- The DOS policy may create inconsistent billing for specialty laboratories. For example, if the hospital is located in a different jurisdiction than the Medicare Administrative Contractor (MAC) used by the laboratory, a different MAC may be billed.

- Hospitals may be discouraged from utilizing ADLTs because billing for such tests that are not performed by hospitals could create administrative and financial complexities.

- The DOS policy is a potential barrier to CMS’ goal of promoting personalized medicine because the policy may disproportionately impact smaller laboratories performing innovative diagnostic tests.

- Billing complexities may affect beneficiary access to needed laboratory tests and therapies. For example, orders might be delayed until at least 14 days after discharge or even canceled to avoid the DOS policy. This may restrict patient access to tests and reduce efficacy of treatment plans due to hospitals delaying or forgoing patient testing to avoid financial risk.

- The DOS policy may limit access for Medicare beneficiaries under original Medicare fee-for-service (that is, Medicare Part A and Part B) due to the fact that Medicare Advantage Plans under Medicare Part C and private

payors allow laboratories to bill directly for tests they perform.

We recognize that the current laboratory DOS rule may impose administrative difficulties for hospitals and laboratories that furnish laboratory tests that are excluded from OPSS packaging and therefore paid separately at CLFS payment rates. Hospitals may be reluctant to bill Medicare for laboratory tests they do not perform, which as noted by stakeholders, could lead to delays in patient access to care.

In light of the concerns raised by stakeholders, we are considering potential modifications to the DOS policy that would allow laboratories to bill Medicare directly for certain laboratory tests excluded from the OPSS packaging policy. One approach under consideration would create a new exception to the DOS policy for molecular pathology tests and ADLTs that meet the criteria of section 1834A(5)(A) of the Act and have been granted ADLT status by CMS. As we stated in the CY 2017 OPSS/ASC final rule with comment period (81 FR 79592 through 79594), we believe these tests are relatively new and may have a different pattern of clinical use than more conventional laboratory tests, which may make them generally less tied to a primary service in the hospital outpatient setting than more common and routine laboratory tests that are packaged. We are seeking public comment on whether these tests, by their nature, are appropriately separable from the hospital stay that preceded the test and therefore should have a DOS that is the date of performance rather than the date of collection.

For example, we are considering modifying § 414.510(b) by adding a new paragraph (5) to establish that in the case of a molecular pathology test or an ADLT that meets the criteria of section 1834A(d)(5)(A) of the Act, the DOS must be the date the test was performed only if:

- The physician orders the test following the date of a hospital outpatient’s discharge from the hospital outpatient department;

- The specimen was collected from a hospital outpatient during an encounter (as both are defined 42 CFR 410.2);

- It would be medically inappropriate to have collected the sample from the hospital outpatient other than during the hospital outpatient encounter;

- The results of the test do not guide treatment provided during the hospital outpatient encounter; and

- The test was reasonable and medically necessary for the treatment of an illness.

We are requesting specific comments on this potential modification to the current laboratory DOS policy, which would allow laboratories to bill Medicare directly for molecular pathology tests and ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act and have been granted ADLT status by CMS, when the specimen is collected during a hospital outpatient procedure and the test is ordered after the patient is discharged from the hospital outpatient department.

(a) Limiting the DOS Rule Exception to ADLTs

We also are considering potentially revising the DOS rule to create an exception only for ADLTs that meet the criteria in section 1834A(d)(5)(A) of the Act. This exception would not cover molecular pathology tests. We are considering this approach because ADLTs approved by CMS under Criterion (A), like all ADLTs, are offered and furnished only by a single laboratory (as defined in 42 CFR 414.502). The hospital, or another laboratory, that is not the single laboratory (as defined in 42 CFR 414.502), cannot furnish the ADLT. Therefore, there may be additional beneficiary access concerns for these ADLTs that may not apply to molecular pathology tests, and that could be addressed by allowing the laboratories to bill Medicare directly for these tests. For example, a hospital may not have an arrangement with the single laboratory that furnishes a particular ADLT, which could lead the hospital to delay the order for the ADLT until 14 days after the patient's discharge to avoid financial risk and thus potentially delay medically necessary care for the beneficiary.

We believe the circumstances may be different for molecular pathology tests, which are not required to be furnished by a single laboratory. In particular, we understand there may be "kits" for certain molecular pathology tests that a hospital can purchase, allowing the hospital to perform the test. Therefore, molecular pathology tests may not present the same concerns of delayed access to medically necessary care as ADLTs, which *must* be performed by a single laboratory.

We are requesting specific comments on potentially creating an exception to the DOS policy that is limited to ADLTs that meet the criteria in section 1834A(d)(5)(A) of the Act and have been granted ADLT status by CMS. We also are requesting public comments on how the current laboratory DOS policy may affect billing for other separately payable laboratory test codes that are

not packaged under the OPPTS, such as a laboratory test that is the only service provided to a beneficiary on a claim or molecular pathology tests.

(b) Other Alternative Approaches

Finally, we are inviting public comments on alternative approaches to addressing stakeholders' concerns regarding the DOS policy, such as potentially modifying the "under arrangements" provisions in § 410.42 and § 411.15(m). Specifically, we are requesting comments on whether an exception should be added to § 410.42(b) and/or § 411.15(m)(3) for molecular pathology tests and ADLTs that are excluded from the OPPTS packaging policy under 42 CFR 419.2(b) and how such an exception should be framed.

We believe that feedback on the topics discussed in this section will help inform us regarding potential refinements to our DOS policy. We welcome comments on these topics from the public, including hospitals, laboratories, and other interested stakeholders. We are especially interested in comments regarding how the current DOS policy and "under arrangements" provisions may affect access to care for Medicare beneficiaries. We would consider finalizing the modifications described in this section.

XI. Proposed CY 2018 OPPTS Payment Status and Comment Indicators

A. Proposed CY 2018 OPPTS 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 OPPTS. They indicate whether a service represented by a HCPCS code is payable under the OPPTS or another payment system and also whether particular OPPTS policies apply to the code.

For CY 2018, we are not proposing to make any changes to the definitions of status indicators that were listed in Addendum D1 of the CY 2017 OPPTS/ASC final rule with comment period available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Regulations-and-Notices-Items/CMS-1656-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>. We believe that the existing definitions of the OPPTS status indicators would continue to be appropriate for CY 2018.

The complete list of the payment status indicators and their definitions

that we are proposing to apply for CY 2018 is displayed in Addendum D1 to this proposed rule, which is available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

The proposed CY 2018 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 Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

B. Proposed CY 2018 Comment Indicator Definitions

In this CY 2018 OPPTS/ASC proposed rule, we are proposing to use four comment indicators for the CY 2018 OPPTS. These comment indicators, "CH", "NC", "NI", and "NP", are in effect for CY 2017 and we are proposing to continue their use in CY 2018. The proposed CY 2018 OPPTS 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 are requesting 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 OPPTS comment indicators for CY 2018 are listed in Addendum D2 to this proposed rule, which is available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

We are requesting public comment on our proposed status indicators and comment indicators for CY 2018.

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, and 2017 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; and 81 FR 79732 through 79753, 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 payment 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, logically related to the categorization of services by physician experts who both establish the codes and perform the procedures, and consistent with a policy to allow ASC payment for all outpatient surgical procedures (72 FR 42477).

Recently, 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, these stakeholders stated that certain cardiac catheterization services, cardiac device programming services, and electrophysiology services should be added to the covered surgical procedures list. 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 requirement as to whether a procedure is surgical, which would give us more flexibility to include “surgery-like” procedures on the ASC Covered Procedures List (CPL). We 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. Therefore, in this CY 2018 OPPTS/ASC proposed rule, we are soliciting public comments 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 payable when furnished in the ASC

setting. In particular, we are interested in commenters’ views regarding additional criteria we might use to consider when a procedure that is surgery-like could be included on the ASC CPL. We are requesting that commenters on this issue take into consideration whether each individual procedure can be safely and appropriately performed in an ASC as required by the regulations at 42 CFR 416.166 (including that standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure), and whether the procedure requires the resources, staff, and equipment typical of an ASC. We also are interested in commenters’ views on whether and how, if we were to include such services as ASC covered surgical procedures, we would need to revise our definition ASC covered surgical procedures.

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 OPPTS/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 OPPTS/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 2018 OPPTS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2018 OPPTS/ASC final rule with comment period (and responding to those comments in the CY 2019 OPPTS/ASC final rule with comment period).

We note that we sought public comments in the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79735 through 79736) on the new and revised Level II HCPCS codes effective October 1, 2016, or January 1, 2017. These new and revised codes, with an effective date of October 1, 2016, or January 1, 2017, were flagged with comment indicator “NI” in Addenda AA and BB to the CY 2017 OPPTS/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 2017 OPPTS/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 2018 OPPTS/ASC final rule with comment period.

In Table 30 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 OPPTS.

TABLE 30—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, 2017	Level II HCPCS Codes	April 1, 2017	CY 2018 OPPTS/ASC proposed rule.	CY 2018 OPPTS/ASC final rule with comment period.

TABLE 30—COMMENT AND FINALIZATION TIMEFRAMES FOR NEW OR REVISED HCPCS CODES—Continued

ASC quarterly update CR	Type of code	Effective date	Comments sought	When finalized
July 1, 2017	Level II HCPCS Codes	July 1, 2017	CY 2018 OPPTS/ASC proposed rule.	CY 2018 OPPTS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2017	CY 2018 OPPTS/ASC proposed rule.	CY 2018 OPPTS/ASC final rule with comment period.
October 1, 2017	Level II HCPCS Codes	October 1, 2017	CY 2018 OPPTS/ASC final rule with comment period.	CY 2019 OPPTS/ASC final rule with comment period.
January 1, 2018	Level II HCPCS Codes	January 1, 2018	CY 2018 OPPTS/ASC final rule with comment period.	CY 2019 OPPTS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2018	CY 2018 OPPTS/ASC proposed rule.	CY 2018 OPPTS/ASC final rule with comment period.

Note: In the CY 2015 OPPTS/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 2018 OPPTS/ASC proposed rule for further discussion of this issue.

2. Proposed Treatment of New and Revised Level II HCPCS Codes Implemented in April 2017 for Which We Are Soliciting Public Comments in This Proposed Rule

In the April 2017 ASC quarterly update (Transmittal 3726, CR 9998,

dated March 3, 2017), we added six new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 31 below lists the new Level II HCPCS codes that were implemented April 1, 2017, along with their proposed payment indicators for

CY 2018. The proposed payment rates, where applicable, for these April codes can be found in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 31—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2017

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2018 payment indicator
C9484	Injection, eteplirsén, 10 mg	K2
C9485	Injection, olaratumab, 10 mg	K2
C9486	Injection, granisetron extended release, 0.1 mg	K2
C9487*	Ustekinumab, for intravenous injection, 1 mg	K2
C9488	Injection, conivaptan hydrochloride, 1 mg	K2
J7328	Hyaluronan or derivative, gel-syn, for intra-articular injection, 0.1 mg	K2

*HCPCS code C9487, which was effective April 1, 2017, was deleted June 30, 2017 and replaced with HCPCS code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017.

We are inviting public comments on these proposed payment indicators and the proposed payment rates for the new Level II HCPCS codes that were recognized as ASC covered ancillary services in April 2017 through the quarterly update CRs, as listed in Table 31 above. We are proposing to finalize their payment indicators and their

payment rates in the CY 2018 OPPTS/ASC final rule with comment period.

3. Proposed Treatment of New and Revised Level II HCPCS Codes Implemented in July 2017 for Which We Are Soliciting Public Comments in This Proposed Rule

In the July 2017 ASC quarterly update (Transmittal 3792, CR 10138, dated June

9, 2017), we added seven new Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 32 below lists the new Level II HCPCS codes that are effective July 1, 2017. 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 Web site).

TABLE 32—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2017

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2018 payment indicator
C9489	Injection, nusinersén, 0.1 mg	K2
C9490	Injection, bezlotoxumab, 10 mg	K2
C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube	J8
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed.	J8

TABLE 32—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2017—Continued

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2018 payment indicator
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance.	G2
Q9986	Injection, hydroxyprogesterone caproate (Makena), 10 mg	K2
Q9989*	Ustekinumab, for Intravenous Injection, 1 mg	K2

* HCPCS code C9487, which was effective April 1, 2017, was replaced with HCPCS code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017.

Through the July 2017 quarterly update CR, we also implemented ASC payment for one new Category III CPT code as an ASC covered surgical

procedure, effective July 1, 2017. This code is listed in Table 33 below, along with its proposed payment indicator. The proposed payment rate for this new

Category III CPT code can be found in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

TABLE 33—NEW CATEGORY III CPT CODE FOR COVERED SURGICAL PROCEDURE EFFECTIVE ON JULY 1, 2017

CY 2017 CPT code	CY 2017 long descriptor	Proposed CY 2018 payment indicator
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space.	J8

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 2017 through the quarterly update CRs, as listed in Tables 32 and 33 above. We are proposing to finalize their payment indicators and their payment rates in the CY 2018 OPPTS/ASC final rule with comment period.

4. Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2017 and January 1, 2018 for Which We Will Be Soliciting Public Comments in the CY 2018 OPPTS/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 OPPTS and the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS Web site, and also through the January OPPTS quarterly update CRs. In the past, we also released new and revised Level II HCPCS codes that are effective October 1 through the October OPPTS quarterly update CRs and incorporated these new codes in the final rule with comment period.

For CY 2018, consistent with our established policy, we are proposing

that the Level II HCPCS codes that will be effective October 1, 2017, and January 1, 2018, would be flagged with comment indicator “NI” in Addendum B to the CY 2018 OPPTS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPTS payment status for CY 2018. We will invite public comments in the CY 2018 OPPTS/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 2019 OPPTS/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, 2018 for Which We Will Be Soliciting Public Comments in the CY 2018 OPPTS/ASC Final Rule With Comment Period

For new and revised CPT codes effective January 1, 2018, 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 OPPTS/ASC final rule with comment period. For those new/revised CPT codes that are received too late for inclusion in this OPPTS/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 2018 ASC update, the new and revised CY 2018 Category I and III CPT codes will be effective on January 1, 2018, and can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the Internet on the CMS Web site). The new and revised CY 2018 Category I and III CPT 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 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 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 2018 CPT codes in Addendum O to this proposed rule (which is available via the Internet on the CMS Web site) so that the public can have time to adequately comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled “CY 2018 OPPTS/ASC Proposed Rule 5-Digit Placeholder Code,” to this

proposed rule. The final CPT code numbers would be included in the CY 2018 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 2018 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2018. 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 2018 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 Web site).

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 2018 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 2016 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 2016, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically “P2”, “P3”, or “R2” in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79738 through 79738).

Our review of the CY 2016 volume and utilization data resulted in our identification of two covered surgical procedures, CPT code 37241 (Vascular embolize/occlude venous) and CPT code 67227 (Destruction extensive retinopathy), 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 2018 is listed in Table 34 below.

TABLE 34—ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2018

CY 2018 CPT code	CY 2018 long descriptor	CY 2017 ASC payment indicator	Proposed CY 2018 ASC payment indicator*
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 (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles).	G2	P2/P3
67227	Destruction of extensive or progressive retinopathy (eg, diabetic retinopathy), cryotherapy, diathermy.	G2	P2/P3

* Proposed 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 0.5 percent update to the MPFS payment rates for CY 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 MPFS proposed rule.

We also reviewed CY 2016 volume and utilization data and other

information for 10 procedures designated as temporary office-based in

Tables 48 and 49 in the CY 2017 OPPS/ASC final rule with comment period (81

FR 79736 through 79738). Of these 10 procedures, there were very few claims in our data and no claims data for 8 procedures: CPT code 0402T (Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)); CPT code 10030 (Image-guided fluid collection drainage by catheter (e.g., abscess, hematoma, seroma, lymphocele, cyst), soft tissue (e.g., extremity, abdominal wall, neck), percutaneous); CPT code 36473 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated); CPT code 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); CPT code 64461

(Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed); CPT code 64463 (Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed)); CPT code 65785 (Implantation of intrastromal corneal ring segments); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (for example, retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we are proposing to maintain the temporary office-based designations for these eight codes for CY 2018. We list all of these codes for which we are proposing to maintain the temporary office-based designations for CY 2018 in Table 35 below. The procedures for which the proposed office-based designations for CY 2018 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

The volume and utilization data for one procedure that has a temporary office-based designation for CY 2017, HCPCS code G0429 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies), is sufficient to indicate that this procedure is 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" to this covered surgical procedure code in CY 2018.

HCPCS code 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound) was finalized for temporary office-based status in the CY 2017 OPPS/ASC final rule with comment period. However, this code will be deleted by the AMA effective December 31, 2017.

We are inviting public comment on our proposals.

TABLE 35—PROPOSED CY 2018 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED IN THE CY 2017 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2018 CPT code	CY 2018 long descriptor	CY 2017 ASC payment indicator *	CY 2018 proposed ASC payment indicator **
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2 *	NA
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 *	P2/P3 **
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated.	P2 *	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 *	P2/P3 **
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	P3 *	P2/P3 **
64463	Continuous infusion by catheter (includes imaging guidance, when performed).	P3 *	P2/P3 **
65785	Implantation of intrastromal corneal ring segments	R2 *	P2/P3 **
67229	Treatment of extensive or progressive retinopathy, one 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 *	P2/P3 **
G0429	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	P3 *	P2/P3 **

* If designation is temporary.

** Proposed 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 0.5 percent update to the MPFS payment rates for CY 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 MPFS proposed rule.

For CY 2018, we are proposing to designate one new CY 2018 CPT code for ASC covered surgical procedures as temporary office-based, as displayed in Table 36 below. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedure described by this new CPT code would

be predominantly performed in physicians' offices. However, because we had no utilization data for the procedure specifically described by this new CPT code, we are proposing to make the office-based designation temporary rather than permanent, and we will reevaluate the procedure when data become available. The procedure

for which the proposed office-based designation for CY 2018 is temporary is indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comments on these proposals.

TABLE 36—PROPOSED CY 2018 PAYMENT INDICATORS FOR NEW CY 2018 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED

Proposed CY 2018 OPSS/ASC proposed rule 5-Digit CMS placeholder code	CY 2018 long descriptor	Proposed CY 2018 ASC payment indicator**
382X3	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	P2/P3*

* If designation is temporary.

** Proposed 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 0.5 percent update to the MPFS payment rates for CY 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 MPFS proposed rule.

b. Proposed ASC Covered Surgical Procedures To Be Designated as Device-Intensive

(1) Background

As discussed in the CY 2017 OPSS/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. Under § 416.171(b)(2) of the regulations, we define an ASC device-intensive procedure as a procedure with a HCPCS code-level device offset of greater than 40 percent when calculated according to the standard OPSS APC ratesetting methodology.

According to this ASC payment methodology, we apply the device offset percentage based on the standard OPSS APC ratesetting methodology to the OPSS national unadjusted payment to determine the device cost included in the OPSS 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 OPSS 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 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 device credits and discontinued procedures.

In addition, in the CY 2017 OPSS/ASC final rule with comment period, 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 (81 FR 79739 through 79740). This default device offset amount of 41 percent would not be calculated from claims data; instead it would be 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 may 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 will be 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 2018

For CY 2018, we are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, reflecting the proposed individual HCPCS code device offset percentages based on CY 2016 OPSS claims and cost report data available for the 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 2018, are assigned payment indicator “J8” and are included in Addendum AA to this proposed rule (which is available on the CMS Web site). The CPT code, the CPT code short descriptor, the proposed CY 2018 ASC payment indicator, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy would apply also are included in Addendum AA to this proposed rule.

We are inviting public comments on the proposed list of ASC device-intensive procedures.

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 OPSS policy that was in effect until CY 2014. Specifically, the OPSS policy that was in effect through CY 2013 provided a reduction in OPSS 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 OPSS to which this policy applies. We refer readers to the CY 2009 OPSS/ASC final rule with comment period for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices (73 FR 68742 through 68744).

As discussed in section IV.B. of the CY 2014 OPSS/ASC final rule with comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing OPSS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPSS, our policy was to reduce OPSS 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 OPSS 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 OPSS, 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 OPSS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual amount 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.

We are proposing to update the list of ASC covered device-intensive procedures, which would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2018. Specifically, when a device-intensive procedure is subject to the no cost/full credit or partial credit device adjustment policy and 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 implantation procedures that are subject to the no cost/full credit or partial credit device adjustment policy 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 a device-intensive surgical procedure that is subject to the no cost/full credit or partial credit device adjustment policy, 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 OPSS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost/full credit or partial credit, we apply our FB/FC policy to all device-intensive procedures.

We are inviting public comments on our proposals to adjust ASC payments for no cost/full credit and partial credit devices.

d. Proposed Additions to the List of ASC Covered Surgical Procedures

We conducted a review of HCPCS codes that currently are paid under the OPSS, but not included on the ASC list of covered surgical procedures, 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 three procedures to the list for CY 2018. We determined that these three procedures are separately paid under the OPSS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. Therefore, we are proposing to include these three procedures on the list of ASC covered surgical procedures for CY 2018.

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 2018 payment indicators, are displayed in Table 37 below.

TABLE 37—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2018

CY 2018 CPT code	CY 2018 long descriptor	Proposed CY 2018 ASC payment indicator
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical.	J8
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection); second level, cervical (list separately in addition to code for primary procedure).	N1
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250g	G2

We are inviting public comments on our proposals.

e. Comment Solicitation on Adding Additional Procedures to the ASC Covered Procedures List

As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68724), we adopted a policy to include, in our annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS inpatient only list for possible inclusion on the ASC list of covered surgical procedures. We are proposing to remove the following two procedures described by CPT codes from the OPPS inpatient only list for CY 2018: CPT codes 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)) and 58666 (Laparoscopy, surgical prostatectomy, retroperitoneal radical, including nerve sparing, includes robotic assistance, when performed). We evaluated each of the two procedures we are proposing to remove from the OPPS IPO list for CY 2018 according to the criteria for inclusion on the list of ASC covered surgical procedures, and considered whether they should be added to the list of ASC covered surgical procedures for CY 2018. Because our understanding is that these procedures typically require more than 24 hours of active medical care following the procedure, we believe they should continue to be excluded from the list of ASC covered surgical procedures.

In the CY 2017 OPPS/ASC proposed rule (81 FR 45679 through 45681), we solicited comments regarding whether the TKA procedure described by CPT code 27447 should be removed from the OPPS inpatient only list. During the comment period, some stakeholders requested that CMS also add the TKA procedure to the list of surgical procedures covered in an ASC setting. In the CY 2017 proposed rule, we only

solicited public comments on removing the TKA procedure from the OPPS inpatient only list for CY 2017. However, in this CY 2018 proposed rule, we are proposing to remove the TKA procedure from the OPPS inpatient only list for CY 2018, as discussed in section IX. of this proposed rule. In light of the public comments we received on the CY 2017 proposed rule (81 FR 79697 through 79699) and our proposal to remove the TKA procedure from the OPPS IPO list for CY 2018, in this proposed rule, we are soliciting public comments on whether the TKA procedure should also be added to the ASC list of covered surgical procedures. We also are inviting public comments on our proposed continued exclusion of CPT code 58666 from the list of ASC covered surgical procedures.

In considering whether or not the TKA procedure should be added to the ASC list of covered surgical procedures, we are requesting that commenters take into consideration the regulations at 42 CFR 416.2 and 416.166. For example, commenters should assess whether this procedure would be expected to pose a significant risk to beneficiary safety when performed in an ASC, whether standard medical practice dictates that the beneficiary would typically be expected to require active medical monitoring and care at midnight following the procedure (“overnight stay”), and whether this procedure would fall under our general exclusions for covered surgical procedures at 42 CFR 416.166(c) (for example, would it generally result in extensive blood loss, require major or prolonged invasion of body cavities, directly involve major blood vessels, among others).

In addition, in this CY 2018 proposed rule, we are soliciting comment on whether CPT codes 27125 (Hemiarthroplasty, hip, partial (e.g., femoral stem prosthesis, bipolar arthroplasty)) and 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft

or allograft) meet the criteria to be removed from the OPPS IPO list, as discussed in section IX. of this proposed rule. As noted in that section, we also are soliciting comment on whether these two procedures meet the criteria to be added to the ASC covered surgical procedure list.

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 2018 OPPS. 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 2018. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2017, but is proposed for packaged status under the CY 2018 OPPS, to maintain consistency with the OPPS, we would also propose to package the ancillary service under the ASC payment system for CY 2018. 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 Web site) 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 2018.

All ASC covered ancillary services and their proposed payment indicators for CY 2018 are included in Addendum BB to this proposed rule. We are inviting public comments on this proposal.

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 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 rule) or the amount calculated using the ASC standard ratesetting 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 ratesetting 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 2018

We are proposing to update ASC payment rates for CY 2018 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 ratesetting methodology and the payment amount for the device portion based on the proposed CY 2018 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 2018 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 2017, for CY 2018, 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.

We are inviting public comments on these proposals.

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 indicator “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 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 (nondevice) 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 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 reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2018

For CY 2018 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 2018 OPPS and ASC payment rates and subsequent year payment rates. We also are proposing to continue to set the CY 2018 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 2018 and subsequent year payment rates.

Covered ancillary services and their proposed payment indicators for CY 2018 are listed in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site). For those 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 effective January 1, 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 MPFS proposed rule that is available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

E. New Technology Intraocular Lenses (NTIOLs)

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 Web site 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 OPSS 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 OPSS 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 2018

We did not receive any requests for review to establish a new NTIOL class for CY 2018 by March 1, 2017, the due date published in the CY 2017 OPSS/ASC final rule with comment period (81 FR 79748).

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 2018.

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 OPSS/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, OPSS 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 OPSS/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 OPSS/ASC final rule with comment period (74 FR 60622). In the CY 2017 OPSS/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

OPSS/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 Web site) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year; 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 OPSS/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 2018, 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 2017 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2018 compared to the CY 2017 descriptors that are included in ASC Addenda AA and BB to this proposed rule are labeled with proposed new comment indicator “NP” to indicate that these CPT and Level II HCPCS codes are open for comment as part of this proposed rule. Proposed new 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; 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 2018 OPSS/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 Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2018 update.

G. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates

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 cost 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 2018.

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 on the Web site 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.

For CY 2018, the proposed CY 2018 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 2018 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 2018 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 2016, we are proposing to compare the total payment using the CY 2017 ASC relative payment weights with the total payment using the CY 2018 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2017 and CY 2018. We are proposing to use the ratio of CY 2017 to CY 2018 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2018. The proposed CY 2018 ASC weight scalar is 0.8995 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 have available 98 percent of CY 2016 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 2016 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2016 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 the proposed rule, is posted on the CMS Web site 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 2018, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2016 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2018 ASC wage indexes. Specifically, holding CY 2016 ASC utilization and service-mix and the proposed CY 2018 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2017 ASC wage indexes (which would fully reflect the new OMB delineations) and the total adjusted payment using the proposed CY 2018 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 2017 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2018 ASC wage indexes and applied the resulting ratio of 1.0004 (the proposed CY 2018 ASC wage index budget neutrality adjustment) to the CY 2017 ASC conversion factor to calculate the proposed CY 2018 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. Therefore, 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. Therefore, the annual update to the ASC payment system is the CPI-U (referred to as the CPI-U update factor).

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 OPSS/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 OPSS/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 currently is the CPI-U, 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 accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the "percentage increase" in the CPI-U, which we interpret cannot be a negative percentage. Thus, in the instance where the percentage change in the CPI-U for a year is negative, we would hold the CPI-U 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 rules 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 OPSS/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, based on IHS Global Insight's (IGI's) 2017 first quarter forecast with historical data through the fourth quarter of 2016, for the 12-month period ending with the midpoint of CY 2018, the CPI-U update was projected to be 2.3 percent. Also, based on IGI's 2017 first quarter forecast, the MFP adjustment for the period ending with the midpoint of CY 2018 was projected to be 0.4 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 OPSS/ASC final rule with comment period (80 FR 70500 through 70501).

For CY 2018, we are proposing to reduce the CPI-U update of 2.3 percent by the MFP adjustment of 0.4 percentage point, resulting in an MFP-adjusted CPI-U update factor of 1.9 percent for ASCs meeting the quality reporting requirements. Therefore, we are proposing to apply a 1.9 percent MFP-adjusted CPI-U update factor to the CY 2017 ASC conversion factor for ASCs meeting the quality reporting requirements. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the CPI-U for ASCs that fail to meet the ASCQR Program requirements. We are proposing to reduce the CPI-U update of 2.3 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then apply the 0.4 percentage point MFP adjustment. Therefore, we are proposing to apply a -0.1 percent MFP-adjusted CPI-U update factor to the CY 2017 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 CY 2018 CPI-U update and MFP adjustment), we would use such data, if appropriate, to determine the CY 2018 ASC update for the final rule with comment period.

For CY 2018, we are proposing to adjust the CY 2017 ASC conversion factor (\$45.003) by the proposed wage index budget neutrality factor of 1.0004 in addition to the MFP-adjusted CPI-U update factor of 1.9 percent discussed above, which results in a proposed CY 2018 ASC conversion factor of \$45.876 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are proposing to adjust the CY 2017 ASC conversion factor (\$45.003) by the proposed wage index budget neutrality factor of 1.0004 in addition to the quality reporting/MFP-adjusted CPI-U update factor of -0.1 percent discussed above, which results in a proposed CY 2018 ASC conversion factor of \$44.976.

We are inviting public comments on these proposals.

4. Comment Solicitation on ASC Payment Reform

a. Historical Perspective

In 1982, Medicare implemented the ASC benefit to provide payment to ASCs to perform certain covered surgical procedures.²⁴ ASCs were recognized by Medicare as a less costly

²⁴ Omnibus Reconciliation Act of 1980 (ORA), Pub. L. 96-499, 934(b), 94 Stat. 2599, 2637 (codified, as amended, at 42 U.S.C. 1395(i)).

alternative to hospital inpatient care given differences in patient acuity and specialization of services which promotes efficient and cost-effective delivery of care. Medicare's initial payment rates to ASCs were based on ASC historical cost and charge data from 1979 and 1980 collected from approximately 40 ASCs and used to establish four facility payment rate groups (55 FR 4527).

The ASC facility payment rate was set as a standard overhead amount based on CMS' (known then as the Health Care Financing Administration (HCFA)) estimate of a fair fee, taking into account the costs incurred by ASCs generally in providing facility services in connection with the performance of a specific procedure. The Report of the Conference Committee accompanying section 934 of the Omnibus Budget Reconciliation Act of 1980 (P.L. 96-499), which enacted the ASC benefit in December 1980, states, "This overhead factor is expected to be calculated on a prospective basis * * * utilizing sample survey and similar techniques to establish reasonable estimated overhead allowances for each of the listed procedures which take account of volume (within reasonable limits)" (H.R. Rep. No 7479, 96th Cong., 2nd Sess. 134 (1980)).

In 1987, we updated the ASC facility payment rates for the first time since 1982. The updated rates were based on the projected increase in the CPI-U from September 1982 to January 1988. CMS (then, HCFA) rebased payments to ASCs in 1990, relying on a survey of 1986 ASC cost, charge, and utilization data. The ASC payments were updated annually based on the 1986 cost data until implementation of the revised ASC payment system in 2008.

Congress directed the GAO to conduct a study comparing the relative costs of procedures furnished in ASCs to those furnished in HOPDs paid under the OPSS, including examining the accuracy of the APC codes with respect to surgical procedures furnished in ASCs. On November 30, 2006, the GAO published the statutorily mandated report entitled, "Medicare: Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient Payment System" (GAO-07-86).²⁵ As directed by section 626(d) of Pub. L. 108-173, the report included recommendations on the following issues:

1. Appropriateness of using groups of covered services and relative weights established for the OPSS as the basis of payment for ASCs.

2. If the OPSS relative weights are appropriate for this purpose, whether the ASC payments should be based on a uniform percentage of the payment rates or weights under the OPSS, or should vary, or the weights should be revised based on specific procedures or types of services.

3. Whether a geographic adjustment should be used for ASC payment and, if so, the labor and nonlabor shares of such payment.

We refer readers to the CY 2008 OPSS/ASC final rule with comment period (71 FR 42474) for a detailed summary of the GAO's methodology, results, and recommendations. Notably, based on the findings from the study, the GAO recommended that CMS implement a payment system for procedures performed in ASCs based on the OPSS, taking into account the lower relative costs of procedures performed in ASCs compared to HOPDs in determining ASC payment rates.

We considered the report's methodology, findings, and recommendations implementing the current ASC payment system, effective in 2008 (71 FR 42474). Consistent with statutory requirements and the GAO's recommendations, we finalized policies to implement a revised ASC payment system based on the OPSS resource costs and relativity of service offerings.

The payment system for ASC facility services was designed as a prospective payment system to pay all procedures included in an APC a standard rate. Under a prospective payment system, payment is set to reflect the average cost to furnish a service. That is, some cases may be more costly than the average while others may be less costly. This type of payment system inherently provides incentives for each facility to be more efficient.

MedPAC conducts an annual review of the ASC payment system and submits its findings and recommendations in a report to Congress. As part of this review, MedPAC examines indicators such as beneficiaries' access to care, capacity and supply of providers, and volume of services, in part to assess the adequacy of Medicare payments to ASCs. Based on its analysis of indicators of payment adequacy, in its March 2017 Report to Congress, MedPAC found that the number of Medicare-certified ASCs had increased, beneficiaries' use of ASCs had increased, and access to capital has been adequate. As a result, for CY 2018, MedPAC stated that payments to ASCs are adequate and recommended that no payment update should be given for 2018 (that is, the update factor would be 0 percent). In addition, MedPAC recommended that

Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers, which would help inform decisions about the ASC update. Also, while MedPAC is concerned that the CPI-U may not reflect ASCs' cost structure, until cost information is available from ASCs, MedPAC cannot determine whether an alternative update factor would be more appropriate.²⁶

b. Solicitation of Comments

We are broadly interested in feedback, including recommendations and ideas for ASC payment system reform. We recognize that ASCs provide a critically important access point to beneficiaries who may be too ill or have the need for too complicated a procedure to be treated in the physician office setting, but for whom hospital care is either not medically necessary or undesirable. The current ASC payment system was implemented in 2008 and major revisions have not been made since that time. Average ASC payment rates have declined relative to OPSS payments rates over the past 10 years, from 65 percent of average OPSS rates in CY 2008 to 56 percent (as proposed) of average OPSS rates in CY 2018. However, in the absence of ASC-specific cost data, it is difficult, if not impossible, to determine whether ASC facility payment rates are in line with ASC facility resource costs and the impact on beneficiary access to care.

With respect to the update factor that is applied to ASC payments, section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated the payment 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. Therefore, the statute does not mandate the adoption of any particular update mechanism, except in the absence of any update, when it requires the payment amounts to be increased by the increase in the CPI-U.

CMS adopted a 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.

²⁶ MedPAC. March 2017 Report to Congress. Chapter 5 "Ambulatory Surgical Center Services". http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch5.pdf?sfvrsn=0.

²⁵ <http://www.gao.gov/assets/260/253992.pdf>.

Therefore, the annual update to the ASC payment system is the CPI-U (referred to as the CPI-U update factor). This update factor is adjusted by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1833(i)(2)(D)(v) of the Act. In this proposed rule, we are soliciting comment on the ASC payment system update factor and are interested in data from ASCs that would help determine whether the ASC payment system should continue to be updated by the CPI-U, or by an alternative update factor, such as the hospital market basket, the Medicare Economic Index, a blend of update factors or other mechanism. The hospital market basket update is typically higher than the CPI-U, while the Medicare Economic Index is typically lower. Because the rate update is not applied in a budget neutral manner, applying a higher update factor would be a cost to the Medicare program while applying a lower update factor would result in savings to the Medicare program. As mentioned above, in the absence of an alternative update, the Act requires payments to ASCs to be increased in an amount equal to the percentage increase in the CPI-U.

With respect to the ASC update, in its March 2017 Report to Congress, MedPAC stated that ASCs have a much higher share of expenses for supplies and drugs than do hospitals or physician offices, a much smaller share of employee compensation costs than hospitals, and a smaller share of all other costs (such as rent) than physician offices. We are seeking public comment on information related to ASC costs for items such as supplies, drugs, employee compensation, rent and other inputs as compared to those of hospitals or physician offices, including qualitative and quantitative data from ASCs. Information on the cost structure of ASCs will help to identify an appropriate alternative update factor.

In addition, we are seeking public comment on whether the Secretary should collect cost data from ASCs to use in determining ASC payment rates. To the extent commenters recommend that ASC cost data should be used in the determination of ASC payment rates, we are seeking comment on what specific method of cost collection commenters recommend (such as cost reports or a survey). We recognize that the submission of costs may be an administrative burden to ASCs, and we are interested in comments that detail how we could mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC

costs. We note that the ability to calculate ASC-specific costs may obviate the need for tying the ASC payment system to that of the OPSS. In addition, collecting cost data from ASCs could inform whether an alternative input price index would be an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed.

With respect to the ability to adopt payment policies that exist under the OPSS into the ASC payment system, as discussed in prior rulemaking, due to differences in the systems used to process claims for hospitals and ASCs, we were not able to implement certain OPSS payment policies in the ASC payment system, such as comprehensive APCs, conditional packaging, and the "FD" value modifier for device credits (79 FR 66923). ASC facilities report services on a professional claim (or CMS-1500) rather than an institutional claim (or UB-04) used by hospitals. The ASC claim form is processed in the Medicare Claims System (MCS), the same system used to process claims submitted by physicians and other clinicians, while hospital claims are processed through the Fiscal Intermediary Shared System (FISS). In part because of differences in the claim form and the claims processing systems, it is not always possible to adopt OPSS payment policies into the ASC payment system. The resulting divergence in payment policies between the two systems may contribute to unintended disparities in payment rates for the same services. We are interested in stakeholder comments on whether billing on an institutional claim form rather than a professional claim form would address some of the issues affecting ASC payment reform.

As noted earlier in this section, we are broadly interested in feedback from stakeholders and other interested parties on potential reforms to the current ASC payment system, including, but not limited to (1) the rate update factor applied to ASC payments, (2) whether and how ASCs should submit costs, (3) whether ASCs should bill on the institutional claim form rather than the professional claim form, and (4) other ideas to improve payment accuracy for ASCs.

5. Display of CY 2018 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS Web site) display the proposed updated ASC payment rates for CY 2018 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 final 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, 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 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 2018 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 OPSS/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 2018 Payment Weight" are the proposed relative payment weights for each of the listed services for CY 2018. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPSS 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 2018 payment rate displayed in the “Proposed CY 2018 Payment Rate” column, each ASC payment weight in the “Proposed CY 2018 Payment Weight” column was multiplied by the proposed CY 2018 conversion factor of \$45.876. 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 2018 Payment Weight” column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The “Proposed CY 2018 Payment” column displays the proposed CY 2018 national unadjusted ASC payment rates for all items and services. The proposed CY 2018 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 2017.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2018. We are inviting public comments on these proposals.

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 for other care settings that provide financial incentives for the reporting of quality data to CMS. These additional programs include reporting for care furnished by:

- Physicians and other eligible professionals, under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI)). We note that 2018 is the last year of the PQRS payment adjustment. Beginning in 2019, eligible clinicians may be subject to upward or downward payment adjustments under the Merit-based Incentive Payment System (MIPS) or be able to earn a positive payment incentives through participation in certain advanced alternative payment models (APMs) under the Quality Payment Program (QPP) (81 FR 77008);
- Inpatient rehabilitation facilities, under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals, under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP);
- PPS-exempt cancer hospitals, under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers, under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities, under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program;
- Home health agencies, under the Home Health Quality Reporting Program (HH QRP); and
- Hospices, under the Hospice Quality Reporting Program (HQRP).

In addition, CMS has implemented several value-based purchasing programs that link payment to performance, including the Hospital Value-Based Purchasing (VBP) Program; the Hospital-Acquired Condition (HAC) Reduction Program; and the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP); and the Quality Payment Program (QPP).

In implementing the Hospital OQR Program and other quality reporting programs, we have focused on measures that have high impact and support national priorities for improved quality and efficiency of care for Medicare beneficiaries as reflected in the National Quality Strategy (NQS) and the CMS

Quality Strategy for conditions with reported wide cost and treatment variations despite established clinical treatment guidelines. To the extent possible under various authorizing statutes, our ultimate goal is to align the clinical quality measure requirements of the various quality reporting programs. As appropriate, we will consider the adoption of measures with electronic specifications to enable the collection of this information for our quality programs.

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68467 through 68469) for a discussion on the principles underlying consideration for future measures that we intend to use in implementing this and other quality reporting programs. In this proposed rule, we are not proposing any changes to these policies.

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 2017 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). We have also codified certain requirements under the Hospital OQR Program at 42 CFR 419.46. In this proposed rule, we are proposing editorial changes to 42 CFR 419.46, replacing the terms “Web” and “Web site” with the terms “web” and “Web site,” respectively.

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. In this proposed rule, we are not proposing any changes to our measure selection policy.

2. Accounting for Social Risk Factors in the Hospital OQR Program

We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE)²⁷ and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.²⁸ The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.²⁹

²⁷ Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs>.

²⁸ Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs>.

²⁹ National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

As noted in the FY 2017 IPPS/LTCH PPS final rule, the NQF has undertaken a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures, and we will closely review its findings.

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, we are seeking public comment on whether we should account for social risk factors in the Hospital OQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include:

Confidential reporting to providers of measure rates stratified by social risk factors; public reporting of stratified measure rates; and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, we are seeking public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We are seeking comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the Hospital OQR Program.

We look forward to working with stakeholders as we consider the issue of

accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we also welcome comment on operational considerations. CMS is committed to ensuring that its beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

3. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously adopted a policy to retain measures from the previous year's Hospital OQR Program measure set for subsequent years' measure sets in the CY 2013 OPPI/ASC final rule with comment period (77 FR 68471). 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 rule for more information. In this proposed rule, we are not proposing any changes to our retention policy for previously adopted measures.

4. Removal of Quality Measures From the Hospital OQR Program Measure Set

a. Considerations in Removing Quality Measures From the Hospital OQR Program

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43863), for the Hospital IQR Program, we finalized a process for immediate retirement, which we later termed "removal," of Hospital IQR Program measures based on evidence that the continued use of the measure as specified raised patient safety concerns. We adopted the same immediate measure retirement policy for the Hospital OQR Program in the CY 2010 OPPI/ASC final rule with comment period (74 FR 60634 through 60635). We refer readers to the CY 2013 OPPI/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. In this proposed rule, we are not proposing any changes to our policy to immediately remove measures as a result of patient safety concerns.

In the CY 2013 OPPI/ASC final rule with comment period, we finalized a set of criteria for determining whether to

remove measures from the Hospital OQR Program. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our policy on removal of quality measures from the Hospital OQR Program. The benefits of removing a measure from the Hospital OQR Program will be 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 criterion. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for our list of factors considered in removing measures from the Hospital OQR Program. In this proposed rule, we are not proposing any changes to our measure removal policy.

b. Criteria for Removal of “Topped-Out” Measures

We refer readers to the CY 2015 OPPS/ASC final rule with comment period where we finalized our proposal to refine the criteria for determining when a measure is “topped-out” (79 FR 66942). In this proposed rule, we are not proposing any changes to our “topped-out” criteria policy.

c. Measures Proposed for Removal From the Hospital OQR Program

In this proposed rule, we are proposing to remove a total of six measures. Specifically, beginning with the CY 2020 payment determination, we are proposing to remove: (1) OP–21: Median Time to Pain Management for Long Bone Fracture; and (2) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures. In addition, beginning with the CY 2021 payment determination, we are proposing to remove: (1) OP–1: Median Time to Fibrinolysis; (2) OP–4: Aspirin at Arrival; (3) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional; and (4) OP–25: Safe Surgery Checklist. By removing these six measures, our intent is to alleviate the maintenance costs and administrative burden to hospitals associated with retaining them. These proposals are discussed in detail below.

(1) Proposed Removal of OP–21: Median Time to Pain Management for Long Bone Fracture Beginning With the CY 2020 Payment Determination

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72088), where we adopted the OP–21: Median Time to Pain Management for Long Bone Fracture measure. This process of care measure assesses the median time from

emergency department arrival to time of initial oral, nasal, or parenteral pain medication (opioid and non-opioid) administration for emergency department patients with a principal diagnosis of long bone fracture (LBF).

We have previously finalized a policy to note that the benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis (79 FR 66941 through 66942). Accordingly, although it does not exactly meet one of the specific measure removal criteria finalized for the Hospital OQR Program (77 FR 68472 through 68473), it has the potential to lead to negative unintended consequences (removal factor #7). Therefore, we are proposing to remove OP–21: Median Time to Pain Management for Long Bone Fracture for the CY 2020 payment determination and subsequent years due to the concerns described in more detail below.

Given the growing body of evidence on the risks of opioid misuse, CMS has developed a strategy to impact the national opioid misuse epidemic by combating non-medical use of prescription opioids, opioid use disorder, and overdose through the promotion of safe and appropriate opioid utilization, improved access to treatment for opioid use disorders, and evidence-based practices for acute and chronic pain management.³⁰

Due to the potential for a misinterpretation of the intent of the measure, we are concerned that OP–21: Median Time to Pain Management for Long Bone Fracture may create undue pressure for hospital staff to prescribe more opioids. We note that the measure only assesses the time to initial, acute administration of pain medication in a specific acute clinical situation, and does not promote long-term pain medication prescriptions. In fact, this measure assesses an element of appropriate pain management, specifically the time to pain medication administration in the case of long bone fracture. In addition, the measure assesses the use of both opioid and non-opioid pain medications. While we acknowledge that pain control is an important issue for patients and clinical care, and the measure does not call for increased opioid prescriptions, many factors outside the control of CMS quality program requirements may contribute to the perception of a link between the measure and opioid prescribing practices. Although we are

³⁰ CMS Opioid Misuse Strategy 2016. Retrieved from: <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Prescription-Drug-Information-for-Partners-Items/CMS-Opioid-Misuse-Strategy-2016.html>.

not aware of any scientific studies that support an association between this measure and opioid prescribing practices, out of an abundance of caution, we are proposing to remove the measure in order to remove any potential ambiguity and to avoid misinterpretation of the intent of the measure. We also note that in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79856), we removed the Pain Management dimension of the HCAHPS Survey in the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain beginning with the FY 2018 program year for the Hospital VBP Program for similar reasons. In addition, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20035 through 20039), we proposed new pain management questions to replace the current ones in the HCAHPS Survey measure for the Hospital IQR Program.

We are inviting public comment on our proposal to remove the OP–21: Median Time to Pain Management for Long Bone Fracture measure for the CY 2020 payment determination and subsequent years as discussed above.

(2) Proposed Removal of OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures Beginning With the CY 2020 Payment Determination

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74468), where we adopted OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures beginning with the CY 2014 payment determination. This measure, which is submitted via a web-based tool, collects surgical procedure volume data on eight categories of procedures frequently performed in the outpatient hospital setting.

We believe there is a lack of evidence to support this measure’s link to improved clinical quality. The measure requires hospitals to report on the volumes of surgical procedures performed at the facility.³¹ This information, number of surgical procedures, does not offer insight into the facilities’ overall performance or quality improvement in regards to surgical procedures. Accordingly, this measure meets the following measure removal criterion: performance or improvement on a measure does not result in better patient outcomes (79 FR 66941). We believe the burden of this

³¹ OP–26 Measure Information Form. Retrieved from: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPPage%2FSpecsManualTemplate&cid=1228775748170>.

measure, which is submitted via a web-based tool, outweighs the value, and therefore, we are proposing to remove OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures for the CY 2020 payment determination and subsequent years. We also refer readers to section XIV.B.3.b.(3) of this proposed rule, where the ASCQR Program is proposing to remove a similar measure.

We are inviting public comment on our proposal to remove the OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures measure for the CY 2020 payment determination and subsequent years as discussed above.

(3) Proposed Removal of OP–1: Median Time to Fibrinolysis Beginning With the CY 2021 Payment Determination

We refer readers to the CY 2008 OPPS/ASC final rule with comment period (referred to as “ED–AMI–2—Median Time to Fibrinolysis” in 72 FR 66862 through 66865) where we adopted OP–1: Median Time to Fibrinolysis beginning with services furnished in CY 2009. This chart-abstracted measure assesses the median time from ED arrival to administration of fibrinolytic therapy in ED patients with ST-segment elevation on the ECG performed closest to ED arrival and prior to transfer.

We believe that this measure meets the following measure removal criterion—the availability of a measure that is more strongly associated with desired patient outcomes for the

particular topic (79 FR 66941). We note that the currently adopted OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (72 FR 66862 through 66865) has been designed with a threshold that is based on a clinical standard, allows us to measure this topic area, and provides meaningful and clinically relevant data on the receipt of fibrinolytic therapy. National guidelines recommend that fibrinolytic therapy be given within 30 minutes of hospital arrival in patients with ST-segment elevation myocardial infarction.³² As a result, because OP–1 measures only the median time from door to needle and does not note whether or not that value exceeds the clinical best practice of 30 minutes, we do not believe that reporting of OP–1 improves quality of care or patient outcomes. In addition, we believe that continuing to collect OP–1 would be redundant with OP–2. As a result, we are proposing to remove OP–1: Median Time to Fibrinolysis for the CY 2021 payment determination and subsequent years. We note that although OP–1: Median Time to Fibrinolysis is a chart-abstracted measure, we do not expect removing this measure would reduce burden, as the data collected for this measure is required to calculate another program measure in the AMI measure set (OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and will therefore continue to be collected even if the proposal to remove OP–1 is finalized as proposed.

We are inviting public comment on our proposal to remove OP–1: Median

Time to Fibrinolysis for the CY 2021 payment determination and subsequent years as discussed above.

(4) Proposed Removal of OP–4: Aspirin at Arrival Beginning With the CY 2021 Payment Determination

We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66862 through 66865) where we adopted OP–4: Aspirin at Arrival beginning with services furnished in CY 2009. This chart-abstracted measure assesses the rate of patients with chest pain or possible heart attack who received aspirin within 24 hours of arrival or before transferring from the emergency department.

We previously 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 (COV) is less than or equal to 0.10 (79 FR 66942). Based on our analysis of Hospital OQR Program measure data, we have determined that performance on this measure is so high and unvarying that meaningful distinctions in improvement cannot be made; specifically, our analyses show that there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance for this measure. These analyses are captured in the table below.

OP–4 TOPPED OUT ANALYSIS

Encounters	Number of hospitals	75th percentile	90th percentile	Truncated COV
CY 2014	1,706	100.00	100.00	0.030
CY 2015	1,749	100.00	100.00	0.035
CY 2016	1,803	100.00	100.00	0.042

As displayed in the table above, there is no distinguishable difference in hospital performance between the 75th and 90th percentiles under the OP–4 measure, and the truncated coefficient of variation has been below 0.10 since 2014. Therefore, this OP–4 measure meets both “topped out” measure criteria for the ASCQR Program.

Thus, we believe the burden of reporting this chart-abstracted measure is not justified by the value of retaining it in the program and are proposing to

remove OP–4: Aspirin at Arrival from the program for the CY 2021 payment determination and subsequent years.

We are inviting public comment on our proposal to remove the OP–4: Aspirin at Arrival measure for the CY 2021 payment determination and subsequent years as discussed above.

(5) Proposed Removal of OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional Beginning With the CY 2021 Payment Determination

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72087–72088) where we adopted OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional for the CY 2013 payment determination. This chart-abstracted measure assesses the time from ED

³² Antman EM, Hand M, Armstrong PW, Bates ER, Green LA, Halasyamani LK, et al. 2007 focused update of the ACC/AHA 2004 Guidelines for the Management of Patients With ST-Elevation

Myocardial Infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Group to Review New Evidence and Update the ACC/AHA

2004 Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction). J Am Coll Cardiol. 2008; 51:210–47.

arrival to provider contact for Emergency Department patients.

During regular measure maintenance, specific concerns about OP–20 were raised by a Technical Expert Panel (TEP), which was made up of experts representing a variety of stakeholders and was convened by a CMS contractor. These concerns include: (1) Limited evidence linking the measure to improved patient outcomes; (2) validity concerns related to wait times and the accuracy of door-to-door time stamps; and (3) potential for skewed measure performance due to disease severity and institution-specific confounders. After our own analysis, we agree with the TEP’s analysis and believe that this measure meets the following measure removal criterion: Performance or improvement on a measure does not result in better patient outcomes. As a result, we believe the burden of continuing to include this chart-abstracted measure in the program

outweighs the benefits; and thus, we are proposing to remove OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional for the CY 2021 payment determination and subsequent years.

We are inviting public comment on our proposal to remove OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional for the CY 2021 payment determination and subsequent years as discussed above.

(6) Proposed Removal of OP–25: Safe Surgery Checklist Use Beginning With the CY 2021 Payment Determination

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74464–74466), where we adopted OP–25: Safe Surgery Checklist Use beginning with the CY 2014 payment determination. This structural measure of hospital process assesses whether a hospital employed a safe surgery checklist that covered each of

the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data collection period. Based on our review of reported data under the measure, this measure meets our first criterion for measure removal that measure performance 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 66942). Our estimations indicate that performance on this measure is trending towards topped out status. This analysis is captured in the table below.

OP–25 PERFORMANCE ANALYSIS

Encounters	Number of hospitals	Rate	75th percentile	90th percentile	Truncated COV
CY 2012	3,227	0.910	100.000	100.000	0.314
CY 2013	3,184	0.949	100.000	100.000	0.232
CY 2014	3,177	0.963	100.000	100.000	0.196
CY 2015	3,166	0.970	100.000	100.000	0.176

Based on the analysis above, the national rate of “Yes” response for the OP–25 measure is nearly 1.0, or 100 percent, nationwide, and has remained at this level for the last two years. In addition, the truncated coefficient of variation has decreased such that it is trending towards 0.10 and there is no distinguishable difference in hospital performance between the 75th and 90th percentiles. We have previously stated the benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis (79 FR 66941 through 66942). We believe that removal of this measure from the Hospital OQR Program measure set is appropriate, as there is little room for improvement. We believe that the safe surgical checklist is widely used and that hospitals will continue its use. In addition, removal of this measure would alleviate the administrative burden to hospitals associated with reporting on this measure. As such, we believe the reporting burden of this measure outweigh the benefits of keeping the measure in the Hospital OQR Program.

Therefore, we are proposing to remove OP–25: Safe Surgery Checklist Use for the CY 2021 payment determination and subsequent years. We

refer readers to section XIV.B.3.b.(2) of this proposed rule, where the ASCQR Program is also proposing to remove a similar measure.

We are inviting public comment on our proposal to remove the OP–25: Safe Surgery Checklist Use measure for the CY 2021 payment determination and subsequent years as discussed above.

5. Proposal to Delay OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With the CY 2020 Payment Determination

We refer readers to the CY 2017 OPPS/ASC final rule with comment period where we adopted OP–37a–e (81 FR 79771–79784), and finalized data collection and data submission timelines (81 FR 79792 through 79794). These measures assess patients’ experience with care following a procedure or surgery in a hospital outpatient department by rating patient experience as a means for empowering patients and improving the quality of their care.

In this proposed rule, we are proposing to delay implementation of the Outpatient and Ambulatory Surgery

Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Based Measures OP–37a–e beginning with the CY 2020 payment determination (2018 data collection) and subsequent years. Since our adoption of these measures, we have come to believe that we lack important operational and implementation data. Specifically, we want to ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; reaffirm the reliability of national OAS CAHPS survey data; and appropriately account for the burden associated with administering the survey in the outpatient setting of care. We note that commenters expressed concern over the burden associated with the survey in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79777). We believe that the national implementation of the survey, which began in January 2016 and will conclude in December 2017, would provide valuable information moving forward. We plan to conduct analyses of the national implementation data to undertake any necessary modifications to the survey tool and/or CMS systems. We believe it is important to allow time

for any modifications before requiring the survey under the Hospital OQR Program. However, we continue to believe that these measures address an area of care that is not adequately addressed in our current measure set and will be useful to assess aspects of care where the patient is the best or only source of information. Further, we continue to believe these measures will enable objective and meaningful comparisons between hospital outpatient departments. Therefore, we

are proposing to delay implementation of OP-37a-e beginning with the CY 2020 payment determination (2018 data collection) until further action in future rulemaking. We also refer readers to section XIV.B.4. of this proposed rule where we are making a similar proposal in the ASCQR Program.

We are inviting public comment on our proposal to delay the OAS CAHPS survey measures beginning with the CY 2020 payment determination (2018 data collection) as discussed above.

6. Previously Adopted Hospital OQR Program Measure Set 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 79784) for the previously finalized measure set for the Hospital OQR Program CY 2020 payment determination and subsequent years. These measures also are listed below.

PREVIOUSLY FINALIZED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
0287	OP-1: Median Time to Fibrinolysis.†
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.
0286	OP-4: Aspirin at Arrival.†
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.
None	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP-21: Median Time to Pain Management for Long Bone Fracture.
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.
None	OP-25: Safe Surgery Checklist Use.
None	OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel.
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).

**** Proposed to delay measure reporting beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of this proposed rule.

7. Summary of the Hospital OQR Program Measure Set Proposed for the CY 2020 and CY 2021 Payment Determinations and Subsequent Years

In this proposed rule, we are not proposing any new measures for the Hospital OQR Program. However, we are proposing to remove a number of

measures for both the CY 2020 and 2021 payment determinations in section XIII.B.4.c. of this proposed rule, above, and we are proposing to delay OP-37a-e beginning with the CY 2020 payment determination (2018 data collection) in section XIII.B.5. of this proposed rule. The tables below outline the Hospital OQR Program measure set we are

proposing in this proposed rule for the CY 2020 and CY 2021 payment determination and subsequent years, respectively. Both of these charts reflect the measure set as if our proposals to remove measures and to delay reporting of OP-37a-e beginning with CY 2018 reporting and for subsequent years are finalized as proposed.

HOSPITAL OQR PROGRAM MEASURE SET PROPOSED FOR THE CY 2020 PAYMENT DETERMINATION

NQF No.	Measure name
0287	OP-1: Median Time to Fibrinolysis.†
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.
0286	OP-4: Aspirin at Arrival.†
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.
None	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
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.
None	OP-25: Safe Surgery Checklist Use.
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel.
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 OPPI/ASC final rule with comment period (79 FR 66946 through 66947).

*** Proposed to delay measure reporting beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of this proposed rule.

In addition, the table below outlines for the CY 2021 payment determination the Hospital OQR Program measure set and subsequent years we are proposing in this proposed rule

HOSPITAL OQR PROGRAM MEASURE SET PROPOSED 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.
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.
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel.
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.*

HOSPITAL OQR PROGRAM MEASURE SET PROPOSED FOR THE CY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF No.	Measure name
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 OPPTS/ASC final rule with comment period (79 FR 66946 through 66947).

*** Proposed to delay measure reporting beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of this proposed rule.

8. Hospital OQR Program Measures and Topics for Future Consideration

In this proposed rule, we are seeking public comment on: (1) Future measure topics; and (2) future development of OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival as an electronic clinical quality measure (eCQM). These are discussed in detail below.

a. Future Measure Topics

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.

We are moving towards the use of outcome measures and away from the 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 specifically request comment on any outcome measures that

would be useful to add to the Hospital OQR Program as well as any clinical process measures that should be eliminated from the Hospital OQR Program.

b. Possible Future Adoption of the Electronic Version of OP-2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival

We have previously stated that automated electronic extraction and reporting of clinical quality data, including measure results calculated automatically by appropriately certified health IT, could significantly reduce the administrative burden on hospitals under the Hospital OQR Program (81 FR 79785). In the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79786), some commenters supported CMS' goal to incorporate electronic clinical quality measures (eCQMs) in the Hospital OQR Program.

OP-2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival was finalized in the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66865), where it was designated as ED-AMI-3. In the CY 2009 OPPTS/ASC final rule with comment period (73 FR 68761), the measure was re-labeled as OP-2 for the CY 2010 payment determination and subsequent years. OP-2 measures the number of AMI patients receiving fibrinolytic therapy during the ED visit with a time from hospital arrival to fibrinolysis of 30 minutes or less.

We are considering developing OP-2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival³³ as an eCQM and proposing the

eCQM in future rulemaking. We note that since OP-2 is not yet developed as an eCQM, electronic measure specifications are not available at this time. We are considering OP-2 in particular because we believe it is the most feasible out of all the existing Hospital OQR Program measures.

We are inviting public comment on the possible future development and future adoption of an eCQM version of OP-2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival.

9. 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 Web site at: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244>.

For a history of our policies regarding maintenance of technical specifications for quality measures, we refer readers to the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60631), the CY 2011 OPPTS/ASC final rule with comment period (75 FR 72069), and the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68469 through 68470). In this proposed rule, we are not proposing any changes to our technical specifications policies.

³³ eCQI Resource Center: [https://ecqi.healthit.gov/eh/ecqms-2016-reporting-period/fibrinolytic-](https://ecqi.healthit.gov/eh/ecqms-2016-reporting-period/fibrinolytic-therapy-received-within-30-minutes-hospital-arrival)

[therapy-received-within-30-minutes-hospital-arrival](https://ecqi.healthit.gov/eh/ecqms-2016-reporting-period/fibrinolytic-therapy-received-within-30-minutes-hospital-arrival).

10. Public Display of Quality Measures

a. Background

We refer readers to the CY 2014 and CY 2017 OPPTS/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 proposing to update public reporting for the OP-18 measure.

b. Public Reporting of OP-18c: Median Time From Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients

OP-18 was finalized for reporting for the CY 2013 payment determination and subsequent years in the CY 2011 OPPTS/ASC final rule with comment period (75 FR 72086). This measure addresses ED efficiency in the form of the median time from ED arrival to time of departure from the ED for patients discharged from the ED (also known as ED throughput). Reducing the time patients spend in the ED can improve the quality of care. As discussed in the measure specifications and Measure Information Form (MIF),^{34,35} OP-18 measure data is stratified into four separate calculations: (1) OP-18a is defined as the overall rate; (2) OP-18b is defined as the reporting measure; (3) OP-18c is defined as assessing Psychiatric/Mental Health Patients; and (4) OP-18d is defined as assessing Transfer Patients.

Section 1833(t)(17)(E) of the Act, requires that the Secretary establish procedures to make data collected under the Hospital OQR Program available to the public and that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public, with respect to the hospital prior to such data being made public. Currently, and as detailed in the OP-18 MIF, the OP-18 measure publicly reports data only for the calculations designated as OP-18b: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Reporting Measure, which excludes

psychiatric/mental health patients and transfer patients.³⁶

The ICD-10 diagnostic codes for OP-18c include numerous substance abuse codes for inclusion in this subset, along with numerous non-substance abuse codes. We believe it is important to publicly report data for OP-18c (Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients) to address a behavioral health gap in the publicly reported Hospital OQR Program measure set. Therefore, in this proposed rule, we are proposing to also publicly report OP-18c and begin public reporting as early as July of 2018 using data from patient encounters during the third quarter of 2017. In addition, we would make corresponding updates to our MIF to reflect these proposals,³⁷ such as: (1) Renaming OP-18b from “Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Reporting Measure” to “OP-18b: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Excluding Psychiatric/Mental Health Patients and Transfer Patients;” and (2) modifying the form to reflect that OP-18c would also be publicly reported. Administrative changes made to the MIF would not affect hospital reporting requirements or burden. The data required for public reporting are already collected and submitted by participating outpatient hospital departments and that our proposal to publicly report OP-18c does not create additional burden. We note that hospitals would be able to preview this data in accordance with our previously established 30-day preview period procedures (81 FR 79791).

In developing this proposal, we also considered proposing to publicly report around July 2019 (not 2018 as proposed) using data from patient encounters occurring during the first quarter of 2018. However, we decided against this timeline, because under this reporting option, we would not be able to publicly report behavioral health data until as

early as July of 2019, creating a delay in our efforts to address the behavioral health data gap in the publicly reported measure set.

We are inviting public comment on our proposal to publicly report OP-18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients beginning with third quarter 2017 data as discussed above.

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 OPPTS/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).

2. Requirements Regarding Participation Status

a. Background

We refer readers to the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75108 through 75109) and the CY 2016 OPPTS/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). In this proposed rule, we are proposing changes to the NOP submission deadline, as described below.

b. Proposed Changes to the NOP Submission Deadline

We finalized in the CY 2014 OPPTS/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 Web site before beginning to report data; (2) identify and register a QualityNet security administrator; and (3) complete and submit an online participation form available at the *QualityNet.org* Web site 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 OPPTS/ASC final rule with comment period (78 FR 75108 through 75109) we finalized the requirement that hospitals must submit the NOP according to the following deadlines:

³⁴ A Measure Information Form provides detail on the rationale for a measure as well as the relevant numerator statements, denominator statements and measure calculations.

³⁵ Hospital OQR Program ED Throughput Measures Information Form: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228775748170>.

³⁶ Hospital OQR Program ED Throughput Measures Information Form: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228775748170>.

³⁷ Hospital OQR Program ED Throughput Measures Information Form: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228775748170>.

- 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 Program 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.

These requirements are also codified at 42 CFR 419.46(a).

In this proposed rule, beginning with the CY 2020 payment determination, we are proposing to: (1) Revise the NOP submission deadline described above, and (2) make corresponding revisions at 42 CFR 419.46(a). Specifically, we are proposing to change the NOP submission deadlines such that hospitals are required to submit the NOP any time prior to registering on the QualityNet Web site, rather than by the deadlines specified above. For example, under this proposal, and in accordance with the data submission deadlines described in section XIII.D.1. of this proposed rule, below and finalized in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70519 through 70520), a hospital submitting data for Q1 2019 encounters would be required to submit the NOP only prior to registering on the QualityNet Web site, which must be done prior to the data submission deadline of August 1, 2019 (80 FR 70519 through 70520).

We believe this proposed timeline is appropriate, because registration with the QualityNet Web site is necessary to submit data. We believe that extending the NOP submission deadline will better enable hospitals to meet the Hospital OQR Program participation requirements.

As discussed above, we also are proposing to make conforming revisions at 42 CFR 419.46(a).

We are inviting public comment on our proposals as discussed above.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Payment Determinations

In the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75110 through 75111) and the CY 2016 OPPTS/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 OPPTS/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 tables 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 this proposed rule, for the CY 2020 payment determination and subsequent years, we are proposing to revise the data submission requirements for hospitals that did not participate in the previous year’s Hospital OQR Program. Specifically, we are proposing to revise the first quarter for which newly participating hospitals are required to submit data (see details below). We are not proposing changes to the previously finalized data submission deadlines for each quarter.

In the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68482), we finalized the following data submission requirements for hospitals that did not participate in the previous year’s Hospital OQR Program:

- If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must submit data beginning with encounters occurring during the first calendar quarter of the 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 data for encounters beginning with the first full quarter following submission of the completed Hospital OQR Program Notice of Participation Form; and

- Hospitals with a Medicare acceptance date before or after January 1 of the year prior to an affected annual payment update must follow data

submission deadlines as posted on the QualityNet Web site.

These policies are also codified at 42 CFR 419.46(c)(3). In this proposed rule, we are proposing to: (1) Align the timeline specifying the initial quarter for which hospitals must submit data for all hospitals that did not participate in the previous year’s Hospital OQR Program, rather than specifying different timelines for hospitals with Medicare acceptance dates before versus after January 1 of the year prior to an affected annual payment update; and (2) make conforming revisions at 42 CFR 419.46(c)(3). Specifically, we are proposing that any hospital that did not participate in the previous year’s Hospital OQR Program must submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update. We note that hospitals must still follow data submission deadlines corresponding to the quarter for which they are reporting data as posted on the QualityNet Web site.

We are inviting public comment on our proposals to align the initial data submission timeline for all hospitals that did not participate in the previous year’s Hospital OQR Program and to make conforming revisions at 42 CFR 419.46(c)(3).

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPTS/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.

In this proposed rule, 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.c. of this proposed rule, we are proposing to remove OP–21: Median Time to Pain Management for Long Bone Fracture for the CY 2020 payment determination and subsequent years and OP–1: Median Time to Fibrinolysis, OP–4: Aspirin at Arrival, and OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional for the CY 2021 payment determination and subsequent years. Therefore, if these proposals are finalized as proposed, 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-5: Median Time to ECG (NQF #0289);
- OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496);
- OP-23: Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival (NQF #0661).

3. Claims-Based Measure Data Requirements for the CY 2020 Payment Determination and Subsequent Years

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. In this proposed rule, we are not proposing any changes to our claims-based measures submission policies for the CY 2020 payment determination and subsequent years.

There are a total of nine claims-based measures for the CY 2020 payment determination and subsequent years:

- OP-8: MRI Lumbar Spine for Low Back Pain (NQF #0514);
- OP-9: Mammography Follow-Up Rates;
- OP-10: Abdomen CT—Use of Contrast Material;
- OP-11: Thorax CT—Use of Contrast Material (NQF #0513);
- OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery (NQF #0669);
- OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT);
- 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).

4. Data Submission Requirements for the OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 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. However, we refer readers to section XIII.B.5. of this proposed rule, where we are proposing to delay implementation of the OP-37a-e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 data collection) until further action in future rulemaking.

As noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79815) some commenters suggested shortening sections of the survey, such as the “About You” section. We continue to evaluate the utility of individual questions as we collect new data from the survey’s voluntary national implementation, and will consider different options for shortening the OAS CAHPS Survey without the loss of important data in the future. Specifically, we continue to consider the removal of two demographic questions—the “gender” and “age” questions—from the OAS CAHPS Survey in a future update.

5. 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 Web site (<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 Web site 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 (specifically, the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431)) submitted via the Centers for Disease Control and

Prevention (CDC) NHSN Web site. In this proposed rule, 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.c. of this proposed rule, we are proposing to remove OP-25: Safe Surgery Checklist Use (beginning with CY 2021), and OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (beginning with CY 2020). Therefore, if these proposals are finalized as proposed, the following web-based quality measures previously finalized and retained in the Hospital OQR Program will require data to be submitted via a web-based tool (CMS’ QualityNet Web site or CDC’s NHSN Web site) for the CY 2021 payment determination and subsequent years:

- 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 Web site);
- OP-17: Tracking Clinical Results between Visits (NQF #0491) (via CMS’ QualityNet Web site);
- OP-22: Left Without Being Seen (NQF #0499) (via CMS’ QualityNet Web site);
- OP-27: Influenza Vaccination Coverage among Healthcare Personnel (via the CDC NHSN Web site) (NQF #0431);
- OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) (via CMS’ QualityNet Web site);
- OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659) (via CMS’ QualityNet Web site);
- OP-31: Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (NQF #1536) (via CMS’ QualityNet Web site); and
- OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) (via CMS’ QualityNet Web site).

6. 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.

7. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data 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 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 our validation requirements. We also refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487) for a discussion of finalized policies regarding our medical record validation procedure requirements. We codified these policies at 42 CFR 419.46(e). For the CY 2018 payment determination and subsequent years, validation is based on four quarters of data (validation quarter 1 (January 1–March 31), validation quarter 2 (April 1–June 30), validation quarter 3 (July 1–September 30), and validation quarter 4 (October 1–December 31)) (80 FR 70524).

In this proposed rule, we are: (1) Clarifying the hospital selection process previously finalized for validation; (2) proposing to codify the procedures for targeting hospitals at 42 CFR 419.46(e); and (3) proposing to formalize and update our educational review process. These are discussed in more detail below.

a. Clarification

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), we finalized a validation selection process in which we select a random sample of 450 hospitals for validation purposes, and select an additional 50 hospitals based on the following specific criteria:

- Hospital fails the validation requirement that applies to the previous year's payment determination; or
- Hospital has an outlier value for a measure based on the data it submits. We defined an "outlier value" for purposes of this targeting as a measure value that appears to deviate markedly from the measure values for other hospitals. Specifically, we would select hospitals for validation if their measure value for a measure is greater than 5 standard deviations from the mean, placing the expected occurrence of such a value outside of this range at 1 in 1,744,278.

We note that the criteria for targeting 50 outlier hospitals, described above, does not specify whether high or low performing hospitals will be targeted. Therefore, in this proposed rule, we are clarifying that hospitals with outlier

values indicating specifically poor scores on a measure (for example, a long median time to fibrinolysis) will be targeted for validation. In other words, an "outlier value" is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score.

b. Proposed Codification

We note that the previously finalized procedures for targeting hospitals for validation, described in section XIII.D.7.a., above, and finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), are not yet codified at 42 CFR 419.46. In this proposed rule, we are proposing to codify the previously finalized procedures for targeting hospitals and well as the procedures regarding outlier hospitals as discussed and clarified above at 42 CFR 419.46(e)(3).

We are inviting public comment on our proposal to codify our validation targeting criteria as discussed above.

c. Proposed Formalization and Modifications to the Educational Review Process for Chart-Abstracted Measures Validation

(1) Background

We have described our processes for educational review on the QualityNet Web site.³⁸ We note that historically this process functioned as an outreach and education opportunity we provided to hospitals, but based on our experience, stakeholder feedback, and more robust validation requirements, we believe that it would be beneficial to hospitals to propose formalizing and updating this process.

Under the current informal process, if results of an educational review indicate that CDAC or CMS has incorrectly scored a hospital after validation, those results are not changed, but are taken into consideration if the hospital submits a reconsideration request. Stakeholder feedback, provided via email, has indicated that while the educational review process is helpful to participating hospitals, it is limited in its impact, given that a hospital's validation result is not corrected even after an educational review determines that CMS reached an incorrect conclusion regarding a hospital's validation score for a given quarter. Based on this feedback, we are proposing to formalize and update the Hospital OQR Program's chart-

abstracted measure validation educational review process. Our goal is to reduce the number of reconsideration requests by identifying and correcting errors before the final yearly validation score is derived. By identifying and correcting any mistakes early on, this process could help decrease the burden during the annual reconsideration process, both for hospitals and CMS.

Therefore, in an effort to streamline this process, in this proposed rule, we are proposing to: (1) Formalize this process; and (2) specify that if the results of an educational review indicate that we incorrectly scored a hospital's medical records selected for validation, the corrected quarterly validation score would be used to compute the hospital's final validation score at the end of the calendar year. These proposals are discussed in more detail below.

(2) Proposed Educational Review Process for the CY 2020 Payment Determination and Subsequent Years

(a) Formalizing the Educational Review Process

As stated above, our informal processes for educational review have been described on the QualityNet Web site.³⁹ Under the informal process, hospitals that were selected and received a score for validation may request an educational review in order to better understand the results. Many times, hospitals request an educational review to examine any data element discrepancies, if they believe the score is incorrect, or when they have general questions about their score. Currently, hospitals receive validation results on a quarterly basis⁴⁰ and can request informal educational reviews for each quarter. Under this informal process, a hospital has 30 calendar days from the date the validation results are posted on the QualityNet Secure Portal Web site to contact the CMS designated contractor, currently known as the Validation Support Contractor (VSC), to request an educational review.⁴¹ In response to a request, the VSC obtains and reviews medical records directly from the Clinical Data Abstraction Center (CDAC) and provides feedback. CMS, or its contractor, generally provides

³⁹ Data Validation—Educational Reviews: Hospitals-Outpatient. <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic/Page/QnetTier3&cid=1228764927987>.

⁴⁰ QualityNet: Data Validation Overview. Retrieved from: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228758729356>.

⁴¹ The educational review request form can be found at: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228764927987>.

³⁸ Data Validation—Educational Reviews: Hospitals-Outpatient. <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic/Page/QnetTier3&cid=1228764927987>.

educational review results and responses via a secure file transfer to the hospital.⁴²

In this proposed rule, we are proposing to formalize this educational review process, as described above, for the CY 2020 payment determination and subsequent years—in other words, starting for validations of CY 2018 data affecting the CY 2020 payment determination and subsequent years.

We are inviting public comment on our proposal to formalize the chart-abstracted measures validation educational review process for the CY 2020 payment determination and subsequent years as described above.

(b) Validation Score Review and Correction

We previously finalized, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105 to 72106), that we calculate validation scores under the Hospital OQR Program using the upper bound of a one-tailed confidence interval (CI) with a 75 percent threshold level with a binomial approach. Using that approach, at the end of each calendar year, CMS computes a CI using the results of all four quarters to determine the final validation score.⁴³ If the upper bound of this confidence interval is 75 percent or higher, the hospital will pass the Hospital OQR Program validation requirement.⁴⁴ In this proposed rule, we are proposing that if the results of a validation educational review determine that the original quarterly validation score was incorrect, the corrected score would be used to compute the final validation score and CI at the end of each calendar year.

In order to determine whether a quarterly validation score was correct, we are proposing to use a similar process as one previously finalized for reconsideration requests. Specifically, we are proposing that during an educational review request, evaluating a validation score would consist of and be limited to reviewing data elements that were labeled as mismatched (between the originally calculated measure score and the measure score calculated in validation) in the original validation

results. We would also take into consideration written justifications provided by hospitals in the Educational Review request. For more information about the previously finalized reconsideration request procedures, 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), and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795).

For the CY 2020 payment determination and subsequent years, we are further proposing that if an educational review requested for any of the first 3 quarters of validation yields incorrect CMS validation results for chart-abstracted measures, according to the review process described and proposed above, we would use the corrected quarterly score, as recalculated during the educational review process, to compute the final CI at the end of the calendar year.⁴⁵ We note that for the last quarter of validation, because of the need to calculate the confidence interval in a timely manner and the insufficient time available to conduct educational reviews prior to the annual payment update, the validation score review and correction would not be available. Instead, the existing reconsideration process would be used to dispute any unsatisfactory validation result. We refer readers to section XIII.D.9. of this proposed rule for a discussion about our reconsideration and appeals process.

The corrected scores would be applicable to the corresponding quarter, for the first 3 quarters of validation, for which a request was submitted. Under this proposal, after evaluating the validation score during the educational review process, if results show that there was indeed an error in the originally calculated score, we would take steps to correct it. However, so as not to dissuade participation in the educational review process, corrected scores identified through the educational review would only be used to recalculate the CI if they indicate that the hospital performed more favorably than previously determined. If the hospital performed less favorably, their score would not be updated to reflect the less favorable score.

⁴⁵ Validation pass-fail status is determined by the confidence interval report. Detail at: <http://www.qualityreportingcenter.com/wp-content/uploads/2017/01/OQR-CY18-Validation-Webinar.508.2.pdf>.

We note that under this proposal, the quarterly validation reports issued to hospitals would not be updated to reflect the corrected score due to the burden associated with reissuing corrected reports. However, the corrected score would be communicated to the hospital via secure file format as discussed above.

We are inviting public comment on our proposal, as discussed above for the CY 2020 payment determination and subsequent years, to use corrected quarterly scores, as recalculated during the educational review process described and proposed in section XIII.D.7.c.(2)(a) of this proposed rule above, to compute the final confidence interval for the first 3 quarters of validation.

8. Extraordinary Circumstances Exception 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), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances extension or exception process under the Hospital OQR Program.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), we finalized an update to our extraordinary circumstances exemption (ECE) policy to extend the ECE request deadline for both chart-abstracted and web-based measures from 45 days following an event causing hardship to 90 days following an event causing hardship, effective with ECEs requested on or after January 1, 2017.

We note that many of our quality reporting and value-based purchasing programs share a common process for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control. The Hospital IQR, Hospital OQR, IPFQR, ASCQR, and PCHQR Programs, as well as the Hospital Acquired Condition Reduction Program and the Hospital Readmissions Reduction Program, share similar processes for ECE requests. We refer readers to policies for the Hospital IQR Program (76 FR 51651 through 51652, 78 FR 50836 through 50837, 79 FR 50277, 81 FR 57181 through 57182, and 42 CFR 412.140(c)(2)), the IPFQR Program (77 FR 53659 through 53660 and 79 FR 45978), the ASCQR Program

⁴² Hospital OQR Validation Educational Review Process: Retrieved from: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228764927987>.

⁴³ QualityNet Data Validation Overview. Retrieved from: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228758729356>.

⁴⁴ QualityNet Data Validation Overview. Retrieved from: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228758729356>.

(77 FR 53642 through 53643 and 78 FR 75140 through 75141), the PCHQR Program (78 FR 50848), the HAC Reduction Program (80 FR 49579 through 49581), and the Hospital Readmissions Reduction Program (80 FR 49542 through 49543) for program specific information about extraordinary circumstances exceptions requests.

In reviewing the policies for these programs, we recognized that there are five areas in which these programs have variances regarding ECE requests. These are: (1) Allowing the facilities or hospitals to submit a form signed by the facility's or hospital's CEO versus CEO or designated personnel; (2) requiring the form be submitted within 30 days following the date that the extraordinary circumstance occurred versus within 90 days following the date the extraordinary circumstance occurred; (3) inconsistency regarding specification of a timeline for us to provide our formal response notifying the facility or hospital of our decision; (4) inconsistency regarding specification of our authority to grant ECEs due to CMS data system issues; and (5) referring to the program as "extraordinary extensions/exemptions" versus as "extraordinary circumstances exceptions." We believe addressing these five areas, as appropriate, can improve administrative efficiencies for affected facilities or hospitals.

We note that, in the FY 2018 IPPS/LTCH PPS proposed rule, we examined our policies in these areas for the Hospital Readmissions Reduction Program, the HAC Reduction Program, the Hospital IQR Program, the PCHQR Program and the IPFQR Program (82 FR 19967, 19990, 20075, 20085 and 20128) and proposed to address differences in these areas for those programs. In section XIV.D.6. of this proposed rule, we are also proposing revisions to our policies for the ASCQR Program.

With the exception of the specification of a timeline for us to provide our formal response and the terminology used to describe these processes (items 3 and 5 above), the Hospital OQR Program is aligned with the existing and proposed policies for the other quality reporting programs discussed above. As a result, in this proposed rule, we are proposing to rename the process as the extraordinary circumstances exceptions (ECE) policy and make conforming changes to 42 CFR 419.46(d).

a. ECE Policy Nomenclature

We have observed that while all quality programs listed above have developed similar policies to provide exceptions from program requirements

to facilities that have experienced extraordinary circumstances, such as natural disasters, these programs refer to these policies using inconsistent terminology. Some programs refer to these policies as "extraordinary circumstances extensions/exemptions" while others refer to the set of policies as "extraordinary circumstances exceptions." Several programs (specifically, the Hospital VBP Program, HAC Reduction Program, and the Hospital Readmissions Reduction Program) are not able to grant extensions to required data reporting timelines due to their reliance on data external to their program, and thus the term, "extraordinary circumstances extensions/exemptions" is not applicable to all programs. However, all of the described programs are able to offer exceptions from their reporting requirements.

As stated above, in order to align this policy across CMS quality programs, we are therefore proposing to: (1) Change the name of this policy from "extraordinary circumstances extensions or exemptions" to "extraordinary circumstances exceptions" for the Hospital OQR Program, beginning January 1, 2018; and (2) revise 42 CFR 419.46(d) of our regulations to reflect this change. We note that changing the name of this policy does not change the availability for a hospital to request an extension under the Hospital OQR Program.

We are inviting public comment on these proposals as discussed above.

b. Timeline for CMS Response to ECE Requests

We also note that we believe it is important for facilities to receive timely feedback regarding the status of ECE requests. We strive to complete our review of each ECE request as quickly as possible. However, we recognize that the number of requests we receive, and the complexity of the information provided impacts the actual timeframe to make ECE determinations. To improve transparency of our process, we believe it is appropriate to specify that we will strive to complete our review of each request within 90 days of receipt.

9. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPSS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPSS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPSS/ASC final rule with comment period (80 FR

70524), and the CY 2017 OPSS/ASC final rule with comment period (81 FR 79795) for a discussion of our reconsideration and appeals procedures. We codified the process by which participating hospitals may submit requests for reconsideration at 42 CFR 419.46(f). We also codified language at § 419.46(f)(3) regarding appeals with the Provider Reimbursement Review Board.

We are not proposing any changes to our reconsideration and appeals procedures.

E. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2018 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 OPSS 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 OPSS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPSS equal the product of the OPSS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPSS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPSS 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 Web site): “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 2018

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 2018 annual payment update factor. For the CY 2018 OPPS, the proposed reporting

ratio is 0.980, calculated by dividing the proposed reduced conversion factor of 74.953 by the proposed full conversion factor of 76.483. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2018 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”). As noted above, 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. 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 also are 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.

We are inviting public comments on these proposals.

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.

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 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, we implemented the ASCQR Program. We refer readers to section XV.A.3. of the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75122), section XIV. of the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66966 through 66987), section XIV. of the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70526 through 70538) and section XIV. of the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79797 through 79826) for an overview of the regulatory history of the ASCQR Program.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPTS/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 this policy.

2. Accounting for Social Risk Factors in the ASCQR Program

We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant

Secretary for Planning and Evaluation (ASPE)⁴⁶ and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.⁴⁷ The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine, the body provided various potential methods for accounting for social risk factors, including stratified public reporting.⁴⁸

As noted in the FY 2017 IPPS/LTCH PPS final rule, the NQF has undertaken a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures, and we will closely review its findings.

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF trial on risk adjustment for quality

⁴⁶ Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. 21 Dec. 2016. Available at: <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

⁴⁷ Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

⁴⁸ National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, we are seeking public comment on whether we should account for social risk factors in the ASCQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: confidential reporting to providers of measure rates stratified by social risk factors; public reporting of stratified measure rates; and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, we are seeking public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We are seeking comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the ASCQR Program. We note that any such changes would be proposed through future notice and comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we also welcome comment on operational considerations. CMS is committed to ensuring that its beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

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). We are not proposing any changes to this policy.

b. Proposed Measure Removal

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. We are not proposing any changes to this process.

In this proposed rule, we are proposing to remove a total of three measures for the CY 2019 payment determination and subsequent years: (1) ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing; (2) ASC-6: Safe Surgery Checklist Use; and (3) ASC-7: ASC Facility Volume Data on Selected Procedures. These proposals are discussed in more detail below.

(1) Proposed Removal of ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing Beginning with the CY 2019 Payment Determination

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74499 through 74501) where we adopted ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing measure (formerly NQF #0264) beginning with the CY 2014 payment determination and finalized the measure's data collection and data submission timelines (76 FR 74515

through 74516). This measure assesses whether intravenous antibiotics given for prevention of surgical site infection were administered on time.

Based on our analysis of ASCQR Program measure data for CY 2014 through 2016 encounters, ASC performance on this measure is so high and unvarying that meaningful distinctions in improvement cannot be made; as a result, we believe this measure meets removal criterion number one under the ASCQR Program's finalized measure removal criteria. 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 (COV) is less than or equal to 0.10 (79 FR 66968 through 66969). These analyses are captured in the table below.

ASC-5 TOPPED OUT ANALYSIS

Encounters	Number of ASCs	75th percentile	90th percentile	Truncated COV
CY 2014	2,206	100.000	100.000	0.02633
CY 2015	2,196	100.000	100.000	0.03289
CY 2016	2,158	100.000	100.000	0.02619

As displayed in the table above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles under the ASC-5 measure, and the truncated coefficient of variation has been below 0.10 since 2014. Therefore, this ASC-5 measure meets both "topped out" measure criteria for the ASCQR Program.

Furthermore, we note that the NQF endorsement was removed on February 13, 2015; in its discussion of whether to continue endorsement for ASC-5, the Surgery Standing Committee also noted that ASC performance on this measure was very high, with 99 percent of facilities meeting the timely antibiotic administration threshold in CY 2013.⁴⁹ We believe that removal of this measure from the ASCQR Program measure set is appropriate, as there is little room for improvement and removal would alleviate maintenance costs and administrative burden to ASCs. As such, we believe the burdens outweigh the benefits of keeping the measure in the ASCQR Program. Therefore, we are

proposing to remove the ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing measure for the CY 2019 payment determination and subsequent years. Furthermore, we note that a similar measure was removed from the Hospital OQR Program in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66942 through 66944) due to topped-out status.

We are inviting public comment on our proposal to remove the ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing measure for the CY 2019 payment determination and subsequent years as discussed above.

(2) Proposed Removal of ASC-6: Safe Surgery Checklist Use Beginning With the CY 2019 Payment Determination

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74505 through 74507 and 74509), where we adopted ASC-6: Safe Surgery Checklist Use beginning with the CY 2015 payment determination. This structural measure of facility

process assesses whether an ASC employed a safe surgery checklist that covered each of the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data collection period.

Based on our analysis of ASCQR Program measure data for CYs 2014 to 2016 encounters, the ASC-6 measure meets our first criterion for measure removal that measure performance 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). These analyses are captured in the table below.

⁴⁹ NQF. "NQF-Endorsed Measures for Surgical Procedures". Technical Report. Available at: http://www.qualityforum.org/Publications/2015/02/NQF-Endorsed_Measures_for_Surgical_Procedures.aspx.

ASC-6 PERFORMANCE ANALYSIS

Encounters	Number of ASCs	Rate	75th percentile	90th percentile	Truncated COV
CY 2012	4,356	0.989	100.000	100.000	0.106
CY 2013 ⁵⁰	(*)	(*)	(*)	(*)	(*)
CY 2014	4,328	0.997	100.000	100.000	0.050
CY 2015	4,305	0.998	100.000	100.000	0.043

Based on the analysis above the national rate of “Yes” response for the ASC-6 measure is nearly 1.0, or 100 percent, nationwide, and has remained at this level for the last 2 years. In addition, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles under measure, and the truncated coefficient of variation has been below 0.10 since 2014. We believe that removal of this measure from the ASCQR Program measure set is appropriate, as there is little room for improvement. In addition, removal of this measure would alleviate the maintenance costs and administrative burden to ASCs associated with retaining the measure. As such, we believe the burdens of this measure outweigh the benefits of keeping the measure in the Program.

Therefore, we are proposing to remove ASC-6 from the ASCQR Program measure set beginning with the CY 2019 payment determination. We also refer readers to section XIII.B.4.c.(6) of this proposed rule, where the Hospital OQR Program is also proposing to remove a similar measure.

We are inviting public comment on our proposal to remove the ASC-6: Safe Surgery Checklist Use measure for the CY 2019 payment determination and subsequent years as discussed above.

(3) Proposed Removal of ASC-7: ASC Facility Volume Data on Selected Procedures Beginning With the CY 2019 Payment Determination

We refer readers to the CY 2012 OPPI/ASC final rule with comment period (76 FR 74507 through 74509), where we adopted ASC-7: ASC Facility Volume Data on Selected Procedures beginning with the CY 2015 payment determination. This structural measure of facility capacity collects surgical procedure volume data on six categories

⁵⁰ We note that no performance data was collected for CY 2013 events for the web-based measures; therefore, we lack performance data for the ASC-6 measure for this year of the ASCQR Program. https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890196351&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DASC_wbnr_prsntn_121813_1ppg.pdf&blobcol=urldata&blobtable=MungoBlobs.

of procedures frequently performed in the ASC setting (76 FR 74507).

We adopted the ASC-7 measure based on evidence that volume of surgical procedures, particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased medical errors and mortality (76 FR 74507). We further stated our belief that publicly reporting volume data would provide patients with beneficial performance information to use in selecting a care provider. However, over time, we have adopted, and are proposing and intend to continue to adopt, more measures assessing ASCs' performance on specific procedure types. For example, in the CY 2017 OPPI/ASC final rule with comment period (81 FR 79801 through 79803), we adopted ASC-14: Unplanned Anterior Vitrectomy, a measure assessing patient outcomes following ophthalmologic procedures, and are proposing to adopt a second ophthalmology-specific measure, ASC-16: Toxic Anterior Segment Syndrome, in section XIV.B.6.a. of this proposed rule. We believe these procedure-type-specific measures will provide patients with more valuable ASC performance data than the ASC-7 measure in selecting an ASC for their care. For this reason, we believe the ASC-7 measure meets our second criterion for removal from the program; specifically, that there are other measures available that are more strongly associated with desired patient outcomes for the particular topic. In addition, removal of this measure would alleviate the maintenance costs and administrative burden to ASCs associated with retaining the measure. As such, we believe the burdens of this measure outweigh the benefits of keeping the measure in the ASCQR Program. Therefore, we are proposing to remove ASC-7: ASC Facility Volume Data on Selected Procedures from the ASCQR Program beginning with the CY 2019 payment determination. We refer readers to section XIII.B.4.c.(2) of this proposed rule where we are proposing to remove a similar measure from the Hospital OQR Program.

We are inviting public comment on our proposal to remove the ASC-7: ASC Facility Volume Data on Selected

Procedures measure for the CY 2019 payment determination and subsequent years as discussed above.

4. Proposal to Delay ASC-15a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With the CY 2020 Payment Determination

We refer readers to the CY 2017 OPPI/ASC final rule with comment period where we adopted ASC-15a-e (81 FR 79803 through 79817), and finalized data collection and data submission timelines (81 FR 79822 through 79824). These measures assess patients' experience with care following a procedure or surgery in an ASC by rating patient experience as a means for empowering patients and improving the quality of their care.

In this proposed rule, we are proposing to delay implementation of the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based Measures (ASC-15a-e) beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking. Since our adoption of these measures, we have come to believe that we lack important operational and implementation data. Specifically, we want to ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; reaffirm the reliability of national OAS CAHPS Survey data; and appropriately account for the burden associated with administering the survey in the outpatient setting of care. We note that commenters expressed concern over the burden associated with the survey in the CY 2017 OPPI/ASC final rule with comment period (81 FR 79810). We believe that the national implementation of the survey, which began in January 2016 and will conclude in December 2017, would provide valuable information moving forward. We plan to conduct analyses of the national implementation data to undertake any necessary modifications to the survey tool and/or CMS systems. We believe it is important to allow time

for any modifications before requiring the survey under the ASCQR Program. However, we continue to believe that these measures address an area of care that is not adequately addressed in our current measure set and will be useful to assess aspects of care where the patient is the best or only source of information.

Further, we continue to believe these measures will enable objective and meaningful comparisons between ASCs. Therefore, we are proposing to delay

implementation of ASC-15a-e beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking. We also refer readers to section XIII.B.5. of this proposed rule where we are making a similar proposal in the Hospital OQR Program.

We are inviting public comment on our proposal to delay the OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination as discussed above.

5. ASCQR Program Quality Measures Adopted in Previous Rulemaking

For the CY 2020 payment determination and subsequent years, we have previously finalized the following measure set. We note that this chart includes the ASC-5, ASC-6, and ASC-7 measures, which are being proposed for removal as discussed above, as well as the ASC-15a-e. measures, which are being proposed for delay beginning with the CY 2020 payment determination and until further action as discussed above:

ASCQR PROGRAM MEASURE SET PREVIOUSLY FINALIZED 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-5	0264 †	Prophylactic Intravenous (IV) Antibiotic Timing.*
ASC-6	None	Safe Surgery Checklist Use.*
ASC-7	None	ASC Facility Volume Data on Selected Procedures.*
ASC-8	0431	Influenza Vaccination Coverage Among Healthcare Personnel.
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.***

† We note that NQF endorsement for this measure was removed.

* Measure proposed for removal beginning with the CY 2019 payment determination, as discussed in section XIV.B.3.b. of this proposed rule.

** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPSS/ASC final rule with comment period (79 FR 66984 through 66985).

*** Measure proposed 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 this proposed rule.

6. Proposed New ASCQR Program Quality Measures for the CY 2021 and CY 2022 Payment Determinations and Subsequent Years

We refer readers to the CY 2014 OPSS/ASC final rule with comment period (78 FR 75124) for a detailed discussion of our approach to measure selection for the ASCQR Program. In this proposed rule, we are proposing to adopt a total of three new measures for the ASCQR Program: One measure collected via a CMS web-based tool for the CY 2021 payment determination and subsequent years (ASC-16: Toxic Anterior Segment Syndrome), and two measures collected via claims for the CY 2022 payment determination and subsequent years (ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and ASC-18: Hospital Visits after Urology

Ambulatory Surgical Center Procedures). These measures are discussed in detail below.

a. Proposed Adoption of ASC-16: Toxic Anterior Segment Syndrome Beginning With the CY 2021 Payment Determination

(1) Background

Toxic Anterior Segment Syndrome (TASS), an acute, noninfectious inflammation of the anterior segment of the eye, is a complication of anterior segment eye surgery that typically develops within 24 hours after surgery.⁵¹ The TASS measure assesses the number of ophthalmic anterior

segment surgery patients diagnosed with TASS within two days of surgery. Although most cases of TASS can be treated, the inflammatory response associated with TASS can cause serious damage to intraocular tissues, resulting in vision loss.⁵² Prevention requires careful attention to solutions, medications, and ophthalmic devices and to cleaning and sterilization of surgical equipment because of the numerous potential etiologies.⁵³ Despite

⁵² Breebaart AC, Nuyts RM, Pels E, Edelhauser HF, Verbraak FD. Toxic Endothelial Cell Destruction of the Cornea after Routine Extracapsular Cataract Surgery. Arch Ophthalmol 1990; 108:1121-1125.

⁵³ Hellinger WC, Bacalis LP, Erdhauser HF, Mamalis N, Milstein B, Masket S. ASCRS Ad Hoc Task Force on Cleaning and Sterilization of Intraocular Instruments: Recommended Practices for Cleaning and Sterilizing Intraocular Surgical

⁵¹ Centers for Disease Control and Prevention. Toxic Anterior Segment Syndrome after Cataract Surgery—Maine, 2006. MMWR Morb Mortal Wkly Rep. 2007 Jun 29;56(25):629-630.

a recent focus on prevention, cases of TASS continue to occur, sometimes in clusters.⁵⁴ With millions of anterior segment surgeries being performed in the United States each year, measurement and public reporting have the potential to serve as an additional tool to drive further preventive efforts.

TASS is of interest to the ASCQR Program because cataract surgery is an anterior segment surgery commonly performed at ASCs. In addition, the TASS measure addresses the MAP-identified priority measure area of procedure complications for the ASCQR Program.⁵⁵

(2) Overview of Measure

We believe it is important to monitor the rate of TASS in the ASC setting because ophthalmologic procedures such as anterior segment surgery are commonly performed in this setting of care. Therefore, we are proposing to adopt the ASC-16: Toxic Anterior Segment Syndrome measure, which is based on aggregate measure data collected by the ASC and submitted via a CMS online data submission tool (QualityNet), in the ASCQR Program for the CY 2021 payment determination and subsequent years. We expect the measure would promote improvement in patient care over time, because measurement coupled with transparency in publicly reporting of measure information would make patient outcomes following anterior segment procedures more visible to ASCs and patients and incentivize ASCs to incorporate quality improvement activities to reduce the incidence of TASS where necessary.

Section 1890A of the Act requires the Secretary to establish a prerulemaking process with respect to the selection of certain categories of quality and efficiency measures. Under section 1890A(a)(2) of the Act, the Secretary must make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering for the Medicare program. The proposed ASC-16 measure was included on the 2015 MUC list⁵⁶ and reviewed by the MAP.

Instruments. J Cataract Refract Surg. 2007 Jun;33(6):1095-1100.

⁵⁴ Moyle W, Yee RD, Burns JK, Biggins T. Two Consecutive Clusters of Toxic Anterior Segment Syndrome. *Optom Vis Sci.* 2013 Jan;90(1):e11-23.

⁵⁵ National Quality Forum. "MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals." Report. 2017. Available at: <http://www.qualityforum.org/map/under/Hospitals-Final-Report>.

⁵⁶ National Quality Forum. *2015 Measures Under Consideration List*. National Quality Forum, Dec. 2016. Available at: <http://www.qualityforum.org/>

The MAP reviewed the measure (MUC15-1047) and conditionally supported it for the ASCQR Program pending NQF review and endorsement.⁵⁷ The MAP noted the high value and urgency of this measure, given many new entrants to the ambulatory surgical center space, as well as the clustering outbreaks of TASS. The MAP also cautioned that the measure be reviewed and endorsed by NQF before adoption into the ASCQR Program, so that a specialized standing committee can evaluate the measure for scientific acceptability.⁵⁸ A summary of the MAP recommendations can be found at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

Sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, when read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care furnished by ASCs that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. However, we note that section 1833(i)(7)(B) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, under section 1833(i)(7)(B) of the Act, section 1833(t)(17)(C)(i) of the Act applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment. We believe this proposed measure meets these statutory requirements.

The proposed ASC-16 measure is not NQF-endorsed. However, this measure is maintained by the ASC Quality

2015 Measures Under Consideration.aspx, under "2015 Measures Under Consideration List (PDF)."

⁵⁷ National Quality Forum. *2016 Spreadsheet of Final Recommendations to HHS and CMS*. Available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

⁵⁸ National Quality Forum. *2016 Spreadsheet of Final Recommendations to HHS and CMS*. Available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

Collaboration,⁵⁹ an entity recognized within the community as an expert in measure development for the ASC setting. We believe that this measure is appropriate for the measurement of quality care furnished by ASCs because ophthalmologic procedures are commonly performed in ASCs and, as discussed above, the inflammatory response associated with TASS can cause serious damage to patients' vision, but TASS is also preventable through careful attention to solutions, medications, ophthalmic devices, and to cleaning and sterilization of surgical equipment. While the Toxic Anterior Segment Syndrome measure is not NQF-endorsed, we believe this measure reflects consensus among affected parties, because the MAP, which represents stakeholder groups, reviewed and conditionally supported the measure⁶⁰ for use in the ASCQR Program. The MAP agreed that this measure is high-value and urgent in the current healthcare marketplace and the number of new entrants to the surgical center place, as well as the clustering outbreaks of TASS.⁶¹ Furthermore, we believe that this measure is scientifically acceptable, because the measure steward has completed reliability testing and validity assessment of the measure.⁶² Specifically, a retrospective chart audit of the ASCs participating in measurement testing found no differences between the originally submitted and re-abstracted TASS rates, providing strong evidence the measure is reliable. The measure steward also conducted a formal consensus review to assess the measure's validity; the results of this assessment showed participants believe the measure appears to measure what it is intended to, and is defined in a way that will allow for consistent interpretation of the inclusion and exclusion criteria from ASC to ASC.

⁵⁹ ASC Quality Collaboration. "ASC Quality Collaboration." Available at: <http://www.ascquality.org/>.

⁶⁰ National Quality Forum. *2016 Spreadsheet of Final Recommendations to HHS and CMS*. Available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

⁶¹ National Quality Forum. *2016 Spreadsheet of Final Recommendations to HHS and CMS*. Available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

⁶² AHRQ Measure Summary. Retrieved from: <https://www.qualitymeasures.ahrq.gov/summaries/summary/49582/ambulatory-surgery-percentage-of-ophthalmic-anterior-segment-surgery-patients-diagnosed-with-toxic-anterior-segment-syndrome-tass-within-2-days-of-surgery>.

(3) Data Sources

This measure is based on aggregate measure data collected via chart-abstraction by the ASC and submitted via a CMS online data submission tool (that is, QualityNet).

We are proposing that the data collection period for the proposed ASC-16 measure would be the calendar year two years prior to the applicable payment determination year. For example, for the CY 2021 payment determination, the data collection period would be CY 2019. We also are proposing that ASCs submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 2021 payment determination, the submission period would be January 1, 2020 to May 15, 2020. We refer readers to section XIV.D.3.b. of this proposed rule for a more detailed discussion of the

requirements for data submitted via a CMS online data submission tool.

(4) Measure Calculation

The outcome measured in the proposed ASC-16 measure is the number of ophthalmic anterior segment surgery patients diagnosed with TASS within 2 days of surgery. The numerator for this measure is all anterior segment surgery patients diagnosed with TASS within 2 days of surgery. The denominator for this measure is all anterior segment surgery patients. The specifications for this measure for the ASC setting can be found at: <http://ascquality.org/documents/ASC%20QC%20Implementation%20Guide%203.2%20October%202015.pdf>.

(5) Cohort

The measure includes all patients, regardless of age, undergoing anterior segment surgery at an ASC. Additional methodology and measure development

details are available at: <http://www.ascquality.org/qualitymeasures.cfm> under “ASC Quality Collaboration Measures Implementation Guide.”

(6) Risk Adjustment

The proposed ASC-16 measure is not risk-adjusted; risk adjustment for patient characteristics is not appropriate for this measure.

We are inviting public comment on our proposal to adopt the ASC-16: Toxic Anterior Segment Syndrome measure for the CY 2021 payment determination and subsequent years as discussed above. If the proposals in section XIV.B.3.b., XIB.b.4. and XIV.B.6.a. of this proposed rule are finalized, the measure set for the ASCQR Program CY 2021 payment determination and subsequent years would be as listed below. We note that the measures being proposed for removal in this proposed rule are not included in this chart.

ASCQR PROGRAM MEASURE SET PREVIOUSLY FINALIZED AND PROPOSED FOR THE CY 2021 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-8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
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.**
ASC-16	None	Toxic Anterior Segment Syndrome.***

† We note that NQF endorsement for this measure 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 OPFS/ASC final rule with comment period (79 FR 66984 through 66985).

** Measure proposed for delay in reporting beginning with the CY 2020 payment determination (CY 2018 data collection) and until further action in future rulemaking, as discussed in section XIV.B.4. of this proposed rule.

*** New measure proposed for the CY 2021 payment determination and subsequent years.

b. Proposed Adoption of ASC-17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures Beginning With the CY 2022 Payment Determination

(1) Background

Reporting the quality of care provided at ASCs is a key priority in the context of growth in the number of ASCs and the number of procedures performed in

this setting. More than 60 percent of all medical or surgical procedures performed in 2006 were performed at ASCs; this represents a three-fold increase from the late 1990s.⁶³ In 2015, more than 3.4 million fee-for-service Medicare beneficiaries were treated at 5,475 Medicare-certified ASCs, and

⁶³ Cullen KA, Hall MJ, Golosinskiy A, Statistics NFcH. Ambulatory Surgery in the United States, 2006. *Nat Health Stat Rept*; 2009.

spending on ASC services by Medicare and its beneficiaries amounted to 4.1 billion dollars.⁶⁴ The patient population served at ASCs has increased not only in volume, but also in age and complexity, which can be partially

⁶⁴ Medicare Payment Advisory Commission (MedPAC). Report to Congress: Medicare Payment Policy. March 2017; available at: http://www.medpac.gov/docs/default-source/reports/mar17_entirereport.pdf?sfvrsn=0.

attributed to improvements in anesthetic care and innovations in minimally invasive surgical techniques.⁶⁵ ⁶⁶ As such, ASCs have become the preferred setting for the provision of low-risk surgical and medical procedures in the United States, as many patients experience shorter wait times, prefer to avoid hospitalization, and are able to return to work more quickly.⁶⁷ As the number of orthopedic procedures performed in ASCs increases, it is increasingly important to report the quality of care for patients undergoing these procedures. According to Medicare claims data, approximately seven percent of surgeries performed in ASCs in 2007 were orthopedic in nature, which reflects a 77-percent increase in orthopedic procedures performed at ASCs from 2000 to 2007.⁶⁸

We believe measuring and reporting seven-day unplanned hospital visits following orthopedic ASC procedures will incentivize ASCs to improve care and care transitions. Patients that have hospital visits that occur at or after discharge from the ASC and may not be readily visible to clinicians because such patients often present to alternative facilities, such as emergency departments where patient information is not linked back to the ASC. Furthermore, many of the reasons for hospital visits following surgery at an ASC are preventable; patients often present to the hospital for complications of medical care, including infection, post-operative bleeding, urinary retention, nausea and vomiting, and pain. One study found that of 10,032 patients who underwent orthopedic surgery in an ASC between 1993 and 2012, 121 (1.2 percent) needed attention in the emergency department in the first 24 hours after discharge due to pain or bleeding, while others were admitted later for issues related to pain and swelling.⁶⁹ Therefore, we believe tracking and reporting these events would facilitate efforts to lower the rate of preventable adverse events and to

improve the quality of care following orthopedic surgeries performed at an ASC.

(2) Overview of Measure

Based on the increasing prevalence of orthopedic surgery in the ASC setting, we believe it is important to minimize adverse patient outcomes associated with these orthopedic ASC surgeries. Therefore, we are proposing to adopt the ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures measure in the ASCQR Program for the CY 2022 payment determination and subsequent years. We expect the measure would promote improvement in patient care over time, because measurement coupled with transparency in publicly reporting measure information would make the rate of unplanned hospital visits (emergency department visits, observation stays, and unplanned inpatient admissions) following orthopedic surgery at ASCs more visible to both ASCs and patients and would incentivize ASCs to incorporate quality improvement activities to reduce these unplanned hospital visits. The measure also addresses the CMS National Quality Strategy domains of making care safer by reducing harm caused in the delivery of care and promoting effective communication and coordination of care.

Section 1890A of the Act requires the Secretary to establish a prerulemaking process with respect to the selection of certain categories of quality and efficiency measures. Under section 1890A(a)(2) of the Act, the Secretary must make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering for the Medicare program. The ASC-17 measure we are proposing was included on a publicly available document entitled "List of Measures under Consideration for December 1, 2016."⁷⁰ The MAP reviewed this measure (MUC16-152) and recommended this measure be refined and resubmitted prior to adoption, stating that testing results should demonstrate reliability and validity at the facility level in the ambulatory surgical setting.⁷¹ MAP also recommended that this measure be submitted to NQF for review and

endorsement.⁷² At the time of the MAP's review, this measure was still undergoing field testing.

Since the MAP's review and recommendation of 'Refine and Resubmit' in 2016, we have completed testing for this measure and continued to refine this proposed measure in response to the MAP's recommendations. Results of continued development activities, including stakeholder feedback from the public comment period and pilot test findings will be presented to the MAP during the MAP feedback loop meeting in fall 2017. The proposed measure is consistent with the information submitted to the MAP, and the original MAP submission and our continued refinements support its scientific acceptability for use in quality reporting programs. Facility-level testing showed variation in unplanned hospital visits among ASCs after adjusting for case-mix differences, which suggests variation in quality of care and opportunities for quality improvement; and reliability testing showed fair measure score reliability.⁷³ As expected, the reliability increased for ASCs with more patients; ASCs with at least 250 cases showed moderate reliability, consistent with other publicly reported Medicare claims-based, risk-adjusted outcome measures.⁷⁴ The validity testing results demonstrated that the measure scores are valid and useful measures of ASC orthopedic surgical quality of care and will provide ASCs with information that can be used to improve their quality of care. Detailed testing results are available in the technical report for this measure, located at: <https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

Sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, when read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care

⁶⁵ Bettelli G. High Risk Patients in Day Surgery. *Minerva Anestesiologica*. 2009;75(5):259-268. See also Fuchs K. Minimally Invasive Surgery. *Endoscopy*. 2002;34(2):154-159.

⁶⁶ Fuchs K. Minimally invasive surgery. *Endoscopy*. 2002;34(2):154-159.

⁶⁷ Cullen KA, Hall MJ, Golosinskiy A, Statistics NfCh. Ambulatory Surgery in the United States, 2006. *Nat Health Stat Rept*; 2009.

⁶⁸ Goyal KS, Jain S, Buterbaugh GA, et al. The Safety of Hang and Upper-Extremity Surgical Procedures at a Freestanding Ambulatory Surgical Center. *The Journal of Bone and Joint Surgery*. 2016;90:600-604.

⁶⁹ Martín-Ferrero MA, Faour-Martín O. Ambulatory surgery in orthopedics: experience of over 10,000 patients. *Journal of Orthopaedic Surgery*. 2014;19:332-338.

⁷⁰ National Quality Forum. *List of Measures under Consideration for December 1, 2016*. National Quality Forum, Dec. 2016. Available at: <http://www.qualityforum.org/map/>.

⁷¹ National Quality Forum. *2016-2017 Spreadsheet of Final Recommendations to HHS and CMS*. Available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

⁷² National Quality Forum. *2016-2017 Spreadsheet of Final Recommendations to HHS and CMS*. Available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

⁷³ Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. 1977;33(1):159-174.

⁷⁴ Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE) Measure Technical Report: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10-Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf.

furnished by ASCs that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. However, we note that section 1833(i)(7)(B) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, under section 1833(i)(7)(B) of the Act, section 1833(t)(17)(C)(i) of the Act applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-NQF-endorsed measures. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment. We believe this proposed measure meets these statutory requirements.

The proposed ASC-17 measure is not currently NQF-endorsed. However, we intend to submit this measure for review and endorsement by NQF once an appropriate NQF project has a call for measures. We believe that this measure is appropriate for the measurement of quality care furnished by ASCs, because surgeries are becoming increasingly common in ASCs and, as discussed above, can signify unanticipated admissions after care provided in ASCs. Such visits are an unexpected and potentially preventable outcome for patients with a low anticipated perioperative risk. We also believe this proposed measure reflects consensus among affected parties, because it was developed with stakeholder input from a Technical Expert Panel convened by a CMS contractor as well as from the measure development public comment period.⁷⁵ During the MAP and measure development processes, public commenters supported the measure's focus on assessing patient outcomes after orthopedic surgery performed in ASC setting of care, and agreed that the measure would be meaningful and improve quality of care. In addition, the ASC-17 measure addresses the MAP-identified priority measure area of surgical complications for the ASCQR

Program.⁷⁶ Therefore, we believe it is appropriate to incorporate this measure into the ASCQR Program measure set because collecting and publicly reporting these data will improve transparency, inform patients and providers, and foster quality improvement efforts.

(3) Data Sources

This measure is claims-based and uses Part A and Part B Medicare administrative claims and Medicare enrollment data to calculate the measure.

We are proposing that the data collection period for the proposed ASC-17 measure would be the two calendar years ending two years prior to the applicable payment determination year. For example, for the CY 2022 payment determination, the data collection period would be CY 2019 to 2020. Because the measure data are collected via claims, ASCs will not need to submit any additional data directly to CMS. We refer readers to section XIV.D.4. of this proposed rule for a more detailed discussion of the requirements for data submitted via claims.

(4) Measure Calculation

The measure outcome is all-cause, unplanned hospital visits within seven days of an orthopedic procedure performed at an ASC. For the purposes of this measure, "hospital visits" include emergency department visits, observation stays, and unplanned inpatient admissions. When there are two or more qualifying surgical procedures within a 7-day period, the measure considers all procedures as index procedures; however, the timeframe for outcome assessment is defined as the interval between procedures (including the day of the next procedure) and then 7 days after the last procedure.

The facility-level score is a risk-standardized hospital visit rate, calculated by multiplying the ratio of the predicted to the expected number of post-surgical hospital visits among the given ASC's patients by the national observed hospital visit rate for all ASCs. For each ASC, the numerator of the ratio is the number of hospital visits predicted for the ASC's patients accounting for its observed rate, the number of the orthopedic surgeries performed at the ASC, the case-mix, and the surgical complexity mix. The denominator of the ratio is the expected

number of hospital visits given the ASC's case-mix and surgical complexity mix. A ratio of less than one indicates the ASC facility's patients were estimated as having fewer post-surgical visits than expected compared to ASCs with similar surgical complexity and patients; and a ratio of greater than one indicates the ASC facility's patients were estimated as having more visits than expected. The national observed hospital visit rate is the national unadjusted proportion of patients who had a hospital visit following an orthopedic ASC surgery. For more information on measure calculations, we refer readers to: <https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

(5) Cohort

The patient cohort for the proposed ASC-17 measure includes all Medicare beneficiaries ages 65 and older undergoing outpatient orthopedic surgery at an ASC who have 12 prior months of Medicare fee-for-service Parts A and B enrollment. The target group of procedures includes those that: (1) Are routinely performed at ASCs; (2) involve some increased risk of post-surgery hospital visits; and (3) are routinely performed by orthopedists.

Procedures included in the measure cohort are on Medicare's list of covered ambulatory surgical center (ASC) procedures.⁷⁷ Medicare developed this list to identify surgeries that have a low to moderate risk profile. Surgeries on the ASC list of covered procedures do not involve or require major or prolonged invasion of body cavities, extensive blood loss, major blood vessels, or care that is either emergent or life threatening. Medicare annually reviews and updates this list, and includes a transparent public comment submission and review process for addition and/or removal of procedure codes.⁷⁸ The current list is accessible in the Downloads section at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html.

In addition, to focus the measure only on the subset of surgeries on Medicare's list of covered ASC procedures that impose a meaningful risk of post-

⁷⁵ National Quality Forum. "MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals." Report. 2017. Available at: <http://www.qualityforum.org/map/under/Hospitals-Final-Report>.

⁷⁶ National Quality Forum. "MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals." Report. 2017. Available at: <http://www.qualityforum.org/map/under/Hospitals-Final-Report>.

⁷⁷ Centers for Medicare and Medicaid Services. "Ambulatory Surgical Center (ASC) Payment: Addenda Updates". Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html.

⁷⁸ Centers for Medicare and Medicaid Services. "Ambulatory Surgical Center (ASC) Payment: Addenda Updates". Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html.

orthopedic ASC surgery hospital visits, the measure includes only “major” and “minor” procedures, as indicated by the Medicare Physician Fee Schedule global surgery indicator (GSI) values of 090 and 010, respectively. This list of GSI values is publicly available at: <https://www.cms.gov/Medicare/Medicare-fee-for-service-payment/physicianfeesched/pfs-federal-regulation-notice-items/cms-1590-fc.html> (download Addendum B). Moreover, to identify the subset of ASC procedures typically performed by orthopedists, we used the Clinical Classifications Software (CCS) developed by the Agency for Healthcare Research and Quality (AHRQ) and include in this measure procedures from AHRQ’s “operations on the musculoskeletal system” group of procedures.⁷⁹ For more cohort details, we refer readers to the measure technical report located at: <https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

The measure excludes patients who survived at least 7 days following orthopedic surgery at an ASC, but were not continuously enrolled in Medicare fee-for-service Parts A and B in the 7 days after surgery. These patients are excluded to ensure all patients captured under this measure have full data available for outcome assessment. There are no additional inclusion or exclusion criteria for the proposed ASC–17 measure. Additional methodology and measure development details are available at: <https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

(6) Risk Adjustment

The statistical risk-adjustment model includes 29 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within seven days following ASC orthopedic surgery. The measure risk adjusts for age, 27 comorbidities, and a variable for work Relative Value Units (RVUs) to adjust for surgical complexity.⁸⁰ Additional risk adjustment details are available in the technical report at: <https://www.cms.gov/medicare/Quality->

⁷⁹ Healthcare Cost and Utilization Project. *Clinical Classifications Software for Services and Procedures*. Available at: https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcsproc.jsp.

⁸⁰ S. Coberly. *The Basics; Relative Value Units (RVUs)*. National Health Policy Forum. January 12, 2015. Available at: http://www.nhpj.org/library/the-basics/Basics_RVUs_01-12-15.pdf.

Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

(7) Public Reporting

As stated above, facility-level testing showed variation in unplanned hospital visits among ASCs after adjusting for case-mix differences, which suggests variation in quality of care and opportunities for quality improvement.⁸¹ Reliability testing showed fair measure score reliability.⁸² As expected, the reliability increased for ASCs with more patients; ASCs with at least 250 cases showed moderate reliability, consistent with other publicly reported Medicare claims-based, risk-adjusted outcome measures. If this measure is adopted, we are proposing to publicly report results only for facilities with sufficient case numbers to meet moderate reliability standards.⁸³ CMS will determine the case size cutoff for meeting moderate reliability standards using the interclass correlation (ICC) during the measure dry run (discussed below) by testing the reliability of the scores at different case sizes in the dry run data. However, we would also provide confidential performance data directly to smaller facilities, which do not meet the criteria for sufficient case numbers for reliability considerations, that would benefit from seeing their measure results and individual patient-level outcomes. These data are currently largely unknown to ASCs and providers. The validity testing results demonstrated that the measure scores are valid and useful measures of ASC orthopedic surgical quality of care and will provide ASCs with information that can be used to improve their quality of care. Detailed testing results are available in the technical report for this measure, located at: <https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

⁸¹ Yale New Haven Health Services Corporation. *Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0)*. May 2017. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf.

⁸² Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. 1977;33(1):159–174.

⁸³ Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. 1977;33(1):159–174.

(8) Provision of Facility-Specific Information Prior to Public Reporting

If this proposed measure is finalized as proposed, we intend to conduct a dry run before the official data collection period or any public reporting. A dry run is a period of confidential reporting and feedback during which ASCs may review their dry-run measure results, and in addition, further familiarize themselves with the measure methodology and ask questions. For the dry-run, we intend to use the most current 2-year set of complete claims (usually 12 months prior to the start date) available at the time of dry run. For example, if the dry run began in June 2018, the most current 2-year set of data available would likely be July 2015 to June 2017. Because we use paid, final action Medicare claims, ASCs would not need to submit any additional data for the dry run. The dry run would generate confidential feedback reports for ASCs, including patient-level data indicating whether the patient had a hospital visit and, if so, the type of visit (emergency department visit, observation stay, or unplanned inpatient admission), the admitting facility, and the principal discharge diagnosis. Further, the dry run would enable ASCs to see their risk-standardized hospital visit rate prior to the measure being implemented. General information about the dry run as well as confidential facility-specific reports would be made available for ASCs to review on their accounts at: <http://www.qualitynet.org>. We plan to continue to generate these reports for ASCs after we implement the measure so ASCs can use the information to identify performance gaps and develop quality improvement strategies.

These confidential dry run results are not publicly reported and do not affect payment. We expect the dry run to take approximately one month to conduct, during which facilities would be provided the confidential report and the opportunity to review their performance and provide feedback to us. However, after the dry run, measure results would have a payment impact and be publicly reported beginning with the CY 2022 payment determination and for subsequent years as proposed.

We are inviting public comment on our proposal to adopt the ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures measure beginning with the CY 2022 payment determination as discussed above.

c. Proposed Adoption of ASC-18: Hospital Visits After Urology Ambulatory Surgical Center Procedures Beginning With the CY 2022 Payment Determination

(1) Background

As the number of urology procedures performed in ASCs increases, it is of increasing importance to report the quality of care provided to patients undergoing these procedures. One study found that urology procedures accounted for 4.8 percent of unanticipated admissions, and that urology surgery patients were almost twice as likely as orthopedics, plastic surgery, or neurosurgery to be admitted following surgery.⁸⁴ Similarly, a recent study found outpatient urology surgery has an overall 3.7 percent readmission rate.⁸⁵ A third study using a 5-percent national sample of Medicare beneficiaries ages 65 and older who underwent one of 22 common outpatient urologic procedures at ASCs from 1998 to 2006 found a 7.9 percent 30-day risk-adjusted rate of inpatient admission following surgery, with more frequent same-day admissions following outpatient surgery at ASCs than at hospitals.⁸⁶

Because urology surgery performed at an ASC is a significant predictive factor for unanticipated admissions compared to other procedures,⁸⁷ we believe measuring and reporting 7-day unplanned hospital visits following urology procedures will incentivize ASCs to improve care and care transitions. Many of the reasons for hospital visits following surgery at an ASC are preventable; patients often present to the hospital following urology surgery for complications of medical care, including urinary tract infection, calculus of the ureter, urinary retention, hematuria, and septicemia.⁸⁸ However, increased patient and staff education present opportunities to improve the success rate of urology

surgeries in ASCs.⁸⁹ Therefore, we believe tracking and reporting these events would facilitate efforts to lower the rate of preventable adverse events and to improve the quality of care following urology procedures performed at an ASC.

(2) Overview of Measure

We believe it is important to minimize adverse patient outcomes associated with urology ASC surgeries. Therefore, we are proposing to adopt the ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures measure in the ASCQR Program for the CY 2022 payment determination and subsequent years. We expect the measure would promote improvement in patient care over time, because measurement coupled with transparency in publicly reporting measure information would make the rate of unplanned hospital visits (emergency department visits, observation stays, and unplanned inpatient admissions) following urology procedures at ASCs more visible to both ASCs and patients, and would incentivize ASCs to incorporate quality improvement activities to reduce these unplanned hospital visits. The measure also addresses the CMS National Quality Strategy domains of making care safer by reducing harm caused in the delivery of care and promoting effective communication and coordination of care.

Section 1890A of the Act requires the Secretary to establish a prerulemaking process with respect to the selection of certain categories of quality and efficiency measures. Under section 1890A(a)(2) of the Act, the Secretary must make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering for the Medicare program. The ASC-18 measure we are proposing was included on a publicly available document entitled "List of Measures under Consideration for December 1, 2016."⁹⁰ The MAP reviewed this measure (MUC16-153) and recommended that this measure be refined and resubmitted prior to adoption by the ASCQR Program because, at the time of the MAP's review, this measure was still undergoing field testing. The Workgroup stated testing results should demonstrate reliability and validity at

the facility level in the ambulatory surgical setting, and recommended this measure be submitted to NQF for review and endorsement.⁹¹

Since the MAP's review and recommendation of 'Refine and Resubmit' in 2016, we have completed testing for this measure and continued to refine this proposed measure in response to the MAP's recommendations. Results of continued development activities, including stakeholder feedback from the public comment period and pilot test findings will be presented to the MAP during the MAP feedback loop meeting in fall 2017. The proposed measure is consistent with the information submitted to the MAP, and the original MAP submission and our continued refinements support its scientific acceptability for use in quality reporting programs. Facility-level testing showed significant variation in unplanned hospital visits among ASCs after adjusting for case-mix differences, which suggests variation in quality of care. Our testing found moderate measure score reliability⁹² for this measure, which is consistent with existing measures of patient outcomes in the ASC setting, such as ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (described in the CY 2015 OPPS/ASC final rule with comment period at 79 FR 66973). Validity testing demonstrated that the measure scores identify differences in quality across facilities. Detailed testing results are available in the technical report for this measure, located at: <https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

Sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, when read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care furnished by ASCs that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. However, we note that section 1833(i)(7)(B) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a

⁸⁴ Fortier J. Unanticipated Admission after Ambulatory Surgery—A Prospective Study. *Can J Anaesth.* 1998;45(7):612-619.

⁸⁵ Rambachan A. Predictors of Readmission Following Outpatient Urological Surgery. *Annals of the Royal College of Surgeons of England. Journal of Urology.* 2014;192(1):183-188.

⁸⁶ Hollingsworth JM. Surgical Quality Among Medicare Beneficiaries Undergoing Outpatient Urological Surgery. *The Journal of Urology.* 2012;188(4):1274-1278.

⁸⁷ Fortier J. Unanticipated Admission after Ambulatory Surgery—A Prospective Study. *Can J Anaesth.* 1998;45(7):612-619.

⁸⁸ Paez, A. Adverse Events and Readmissions after Day-Care Urological Surgery. *International Braz J Urol.* 2007;33(3):330-338.

⁸⁹ Paez, A. Adverse Events and Readmissions after Day-Care Urological Surgery. *International Braz J Urol.* 2007;33(3):330-338.

⁹⁰ National Quality Forum. *List of Measures under Consideration for December 1, 2016.* National Quality Forum, Dec. 2016. Available at: <http://www.qualityforum.org/map/>.

⁹¹ National Quality Forum. 2016-2017 Spreadsheet of Final Recommendations to HHS and CMS, available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=81593>.

⁹² Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159-174.

national consensus building entity, or by the NQF specifically. Further, under section 1833(i)(7)(B) of the Act, section 1833(t)(17)(C)(i) of the Act applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment. We believe this proposed measure meets these statutory requirements.

The proposed ASC-18 measure is not currently NQF-endorsed. However, we intend to submit this measure for review and endorsement by the NQF once an appropriate measure endorsement project has a call for measures. We believe that this measure is appropriate for the measurement of quality care furnished by ASCs because urology procedures are becoming increasingly common in ASCs and, as discussed above, can signify unanticipated admissions after care provided in ASCs. Such visits are an unexpected and potentially preventable outcome for patients with a low anticipated perioperative risk. We also believe this measure depicts consensus among affected parties, as it was developed with stakeholder input from both a Technical Expert Panel convened by a contractor as well as the measure development public comment period.⁹³ During the MAP and measure development processes, public commenters supported the measure's focus on assessing patient outcomes after urology ASC and agreed that the measure would be meaningful and improve quality of care. In addition, the ASC-18 measure addresses the MAP-identified priority measure area of surgical complications for the ASCQR Program.⁹⁴ Therefore, we believe it is appropriate to incorporate this measure

⁹³ Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE). Public Comment Summary Report: Development of Facility-Level Quality Measures of Unplanned Hospital Visits after Selected Ambulatory Surgical Center Procedures. Fall 2016. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html>.

⁹⁴ National Quality Forum. "MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals." Report. 2017. Available at: <http://www.qualityforum.org/map/under/Hospitals—Final-Report>.

into the ASCQR Program measure set because collecting and publicly reporting this data will improve transparency, inform patients and providers, and foster quality improvement efforts.

(3) Data Sources

This measure is claims-based and uses Part A and Part B Medicare administrative claims and Medicare enrollment data to calculate the measure.

We are proposing that the data collection period for the proposed ASC-18 measure would be the 2 calendar years ending 2 years prior to the applicable payment determination year. For example, for the CY 2022 payment determination, the data collection period would be CY 2019 to 2020. Because these measure data are collected via claims, ASCs will not need to submit any additional data directly to CMS. We refer readers to section XIV.D.4. of this proposed rule for a more detailed discussion of the requirements for data submitted via claims.

(4) Measure Calculations

The measure outcome is all-cause, unplanned hospital visit occurring within seven days of the urology procedure performed at an ASC. For the purpose of this measure, "hospital visits" include emergency department visits, observation stays, and unplanned inpatient admissions. When there are two or more qualifying surgical procedures within a 7-day period, the measure considers all procedures as index procedures. However, the timeframe for outcome assessment is defined as the interval between procedures (including the day of the next procedure) and then 7 days after the last procedure.

The facility-level score is a risk-standardized hospital visit rate, calculated by multiplying the ratio of the predicted to the expected number of postsurgical hospital visits among the given ASC's patients by the national observed hospital visit rate for all ASCs. For each ASC, the numerator of the ratio is the number of hospital visits predicted for the ASC's patients accounting for its observed rate, the number of the urology procedures performed at the ASCs, the case-mix, and the surgical complexity mix. The denominator of the ratio is the expected number of hospital visits given the ASC's case-mix and surgical complexity mix. A ratio of less than one indicates the ASC facility's patients were estimated as having fewer post-surgical visits than expected compared to ASCs with similar surgical complexity and

patients; and a ratio of greater than one indicates the ASC facility's patients were estimated as having more visits than expected. The national observed hospital visit rate is the national unadjusted proportion of patients who had a hospital visit following a urology ASC surgery. For more information on measure calculations, we refer readers to: <https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

(5) Cohort

The patient cohort for the proposed ASC-18 measure includes all Medicare beneficiaries ages 65 and older undergoing outpatient urology procedures at an ASC who have 12 prior months of Medicare fee-for-service Parts A and B enrollment. The target group of procedures are those that: (1) Are routinely performed at ASCs; (2) involve increased risk of post-surgery hospital visits; and (3) are routinely performed by urologists.

Procedures included in the measure cohort are on Medicare's list of covered ambulatory surgical center (ASC) procedures.⁹⁵ Medicare developed this list to identify surgeries have a low to moderate risk profile. Surgeries on the ASC list of covered procedures do not involve or require major or prolonged invasion of body cavities, extensive blood loss, major blood vessels, or care that is either emergent or life threatening.⁹⁶ Medicare annually reviews and updates this list, and includes a transparent public comment submission and review process for addition and/or removal of procedure codes.⁹⁷ The current list is accessible in the Downloads section at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html. In addition, to focus the measure only on the subset of surgeries on Medicare's list of covered ASC procedures that impose a meaningful risk of post-urology ASC surgery hospital visits, the measure includes only "major" and "minor" procedures, as indicated by the MPFS

⁹⁵ Centers for Medicare and Medicaid Services. "Ambulatory Surgical Center (ASC) Payment: Addenda Updates". Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html.

⁹⁶ Centers for Medicare and Medicaid Services. "Ambulatory Surgical Center (ASC) Payment: Addenda Updates". Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html.

⁹⁷ Centers for Medicare and Medicaid Services. "Ambulatory Surgical Center (ASC) Payment: Addenda Updates". Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html.

global surgery indicator (GSI) values of 090 and 010, respectively, and therapeutic cystoscopy procedures. This list of GSI values is publicly available at: <https://www.cms.gov/Medicare/Medicare-fee-for-service-payment/physicianfeesched/pfs-federal-regulation-notice-items/cms-1590-fc.html> (download Addendum B). Moreover, to identify the subset of ASC procedures typically performed by urologists, we used the Clinical Classifications Software (CCS) developed by the Agency for Healthcare Research and Quality (AHRQ) and include in this measure procedures from two of AHRQ's categories, "operations on the urinary system" and "operations on the male genital organs."⁹⁸ For more cohort details, we refer readers to the measure technical report located at: <https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

The measure excludes patients who survived at least 7 days following a urology procedure at an ASC, but were not continuously enrolled in Medicare fee-for-service Parts A and B in the 7 days after surgery. These patients are excluded to ensure all patients captured under this measure have full data available for outcome assessment. There are no additional inclusion or exclusion criteria for the proposed ASC-18 measure. Additional methodology and measure development details are available at: <https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

(6) Risk Adjustment

The statistical risk-adjustment model includes nine clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within seven days following ASC urology surgery. The measure risk adjusts for age, six comorbidities, number of qualifying procedures, and work Relative Value Units (RVUs) to adjust for surgical complexity.⁹⁹ Additional risk adjustment details are available in the technical report at: <https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

⁹⁸ Healthcare Cost and Utilization Project. *Clinical Classifications Software for Services and Procedures*. Available at: https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccsvproc.jsp.

⁹⁹ S. Coberly. The Basics; Relative Value Units (RVUs). National Health Policy Forum. January 12, 2015. Available at: http://www.nhpforum.org/library/the-basics/Basics_RVUs_01-12-15.pdf.

Instruments/HospitalQualityInits/Measure-Methodology.html.

(7) Public Reporting

As stated above, facility-level testing showed variation in unplanned hospital visits among ASCs after adjusting for case-mix differences, which suggests variation in quality of care and opportunities for quality improvement.¹⁰⁰ Reliability testing showed fair measure score reliability.¹⁰¹ As expected, the reliability increased for ASCs with more patients; ASCs with at least 250 cases showed moderate reliability, consistent with other publicly reported Medicare claims-based, risk-adjusted outcome measures. If this measure is adopted, we are proposing to publicly report results only for facilities with sufficient case numbers to meet moderate reliability standards.¹⁰² CMS will determine the case size cutoff for meeting moderate reliability standards using the interclass correlation (ICC) during the measure dry run (discussed below) by testing the reliability of the scores at different case sizes in the dry run data. However, we would also provide confidential performance data directly to smaller facilities which do not meet the criteria for sufficient case numbers for reliability considerations that would benefit from seeing their measure results and individual patient-level outcomes, as these data are currently largely unknown to ASCs and providers. The validity testing results demonstrated that the measure scores are valid and useful measures of ASC urology surgical quality of care and will provide ASCs with information that can be used to improve their quality of care. Detailed testing results are available in the technical report for this measure, located at: <https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

(8) Provision of Facility-Specific Information Prior to Public Reporting

If this proposed measure is finalized, but before the official data collection

¹⁰⁰ Yale New Haven Health Services Corporation. *Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0)*. May 2017. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf.

¹⁰¹ Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. 1977;33(1):159-174.

¹⁰² Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. 1977;33(1):159-174.

period or public reporting for the proposed ASC-18 measure, we intend to conduct a dry run. A dry run is a period of confidential feedback during which ASCs may review their dry-run measure results, and in addition, further familiarize themselves with the measure methodology, and ask questions. For the dry-run, we intend to use the most current 2-year set of complete claims (usually 12 months prior to the start date) available at the time of dry run. For example, if the dry run began in June 2018, the most current 2-year set of data available would likely be July 2015 to June 2017. Because we use paid, final action Medicare claims, ASCs would not need to submit any additional data for the dry run. The dry run would generate confidential feedback reports for ASCs, including patient-level data indicating whether the patient had a hospital visit and, if so, the type of visit (emergency department visit, observation stay, or unplanned inpatient admission), the admitting facility, and the principal discharge diagnosis. Further, the dry run would enable ASCs to see their risk-standardized hospital visit rate prior to the measure being implemented. General information about the dry run as well as confidential facility-specific reports would be made available for ASCs to review on their accounts at: <http://www.qualitynet.org>. We intend to continue to generate these reports for ASCs after we implement the measure so ASCs can use the information to identify performance gaps and develop quality improvement strategies.

Confidential dry run results are not publicly reported and do not affect payment. We expect the dry run to take approximately 1 month to conduct, during which facilities would be provided the confidential report and the opportunity to review their performance and provide feedback to us. However, the measure would affect payment and would be publicly reported beginning with the CY 2022 payment determination and subsequent years as proposed.

We are inviting public comment on our proposal to adopt the ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures measure beginning with the CY 2022 payment determination as discussed above.

d. Summary of Previously Adopted Measures and Newly Proposed ASCQR Program Measures for the CY 2022 Payment Determination and Subsequent Years

If the proposals in sections XIV.B.3.b., XIV.B.4. and XIV.B.6.a. through c. of

this proposed rule are finalized, the measure set for the ASCQR Program CY 2022 payment determination and subsequent years would be as listed below.

ASCQR PROGRAM MEASURE SET WITH PREVIOUSLY FINALIZED AND NEWLY PROPOSED MEASURES FOR THE CY 2022 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-8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
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.**
ASC-16	None	Toxic Anterior Segment Syndrome.***
ASC-17	None	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures.***
ASC-18	None	Hospital Visits after Urology Ambulatory Surgical Center Procedures.****

† We note that NQF endorsement for this measure 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 OPPI/ASC final rule with comment period (79 FR 66984 through 66985).

** Measure proposed for delay beginning with CY 2018 reporting until further action in future rulemaking as discussed in section XIV.B.4. of this proposed rule.

*** New measure proposed for the CY 2021 payment determination and subsequent years.

**** New measure proposed for the CY 2022 payment determination and subsequent years.

7. ASCQR Program Measures and Topics for Future Consideration

In the CY 2013 OPPI/ASC final rule with comment period (77 FR 68493 through 68494), we set forth our considerations in the selection of ASCQR Program quality measures. We seek to develop a comprehensive set of quality measures to be available for widespread use for making informed decisions and quality improvement in the ASC setting (77 FR 68496). We also seek to align these quality measures with the National Quality Strategy (NQS), the CMS Strategic Plan (which includes the CMS Quality Strategy), and our other quality reporting and value-based purchasing (VBP) programs, as appropriate. Accordingly, as we stated in the CY 2015 OPPI/ASC final rule with comment period (79 FR 66979), in considering future ASCQR Program measures, we are focusing on the following NQS and CMS Quality Strategy measure domains: Make care safer by reducing harm caused in the delivery of care; strengthen person and family engagement as partners in their care; promote effective communication and coordination of care; promote effective prevention and treatment of chronic disease; work with communities

to promote best practices of healthy living; and make care affordable.

In this proposed rule, we are inviting public comment on one measure developed by the CDC for potential inclusion in the ASCQR Program in future rulemaking, the Ambulatory Breast Procedure Surgical Site Infection Outcome measure (NQF #3025), and are seeking public comment on accounting for social risk factors in the ASCQR Program. This potential measure is discussed in more detail below.

Healthcare-associated infections (HAIs) are a major cause of morbidity and mortality in healthcare settings in the United States, with the most recent prevalence surveys of HAIs estimating that approximately four percent of inpatients in acute care settings have developed at least one HAI, translating to 721,800 infections in 648,000 patients in 2011.¹⁰³ Surgical site infection (SSI) is one of the most common HAIs, comprising approximately 22 percent of all HAIs, and contribute greatly to the mortality and cost burden of HAIs.¹⁰⁴

¹⁰³ Magill S.S., Edwards J.R., Bamberg W., Beldavs Z.G., Dumyati G., Kainer M.A. Multistate Point-Prevalence Survey of Health Care-Associated Infections. *N Engl J Med.* 2014;370:1198–1208.

¹⁰⁴ Magill S.S., Edwards J.R., Bamberg W., Beldavs Z.G., Dumyati G., Kainer M.A. Multistate

Breast SSIs represent a substantial proportion of SSIs overall in inpatient settings, and have one of the highest infection risks of any procedure type in outpatient settings.¹⁰⁵ While SSI rates following breast procedures vary from one percent to over 30 percent depending on procedure type,¹⁰⁶ the trend in surgery transitioning to outpatient and ambulatory surgery

Point-Prevalence Survey of Health Care-Associated Infections. *N Engl J Med.* 2014;370:1198–1208.

¹⁰⁵ This statement is based on an analysis of data reported to the National Healthcare Safety Network (NHSN). Out of 67,150 ASC procedures report to NHSN from 2010 to 2013, 30,787 (45.9 percent) were breast procedures. Out of the 142 surgical site infections reported from ASCs during the same time period, 78 (54.9 percent) were related to breast procedures, indicating an SSI risk of 0.25 percent. This was the highest volume and SSI risk out of all outpatient ASC procedures reported in the timeframe.

¹⁰⁶ Vilar-Compte D, Jacquemin B., Robles-Vidal C., and Volkow P. Surgical Site Infections in Breast Surgery: Case-Control Study. *World Journal of Surgery.* 2004;28(3):242–246; Mannin J., Wille J.C., Snoeren R.L. van den Hof S. Impact of Postdischarge Surveillance on Surgical Site Infection Rates for Several Surgical Procedures: Results from the Nosocomial Surveillance Network in the Netherlands. *Infect Control Hosp Epidemiol.* 2006;27:809–816; Vilar-Compte D., Rosales S., Hernandez-Mello N., Maafs E. and Volkow P. Surveillance, Control, and Prevention of Surgical Site Infections in Breast Cancer Surgery: a 5-year Experience. *American Journal of Infection Control.* 2009;37(8):674–679.

settings due to advances in surgical techniques and economic incentives for ambulatory surgery make these events an outcome of interest for the ASCQR Program.

Numerous individual studies and systematic reviews provide strong evidence that measurement and feedback of surgical site infections leads to lower SSI rates in the long term.¹⁰⁷ Although standardized metrics have been developed to measure SSI rates for inpatient surgeries in the hospital setting,¹⁰⁸ these have not yet been developed for outpatient surgeries in ASCs, which comprise a fast-growing proportion of all surgeries performed in the United States.¹⁰⁹ We believe this measure, if adopted in the future, could serve as a quantitative guide for ASCs, enabling them to benchmark SSI rates in their facilities against nationally aggregated data and set targets for improvement.

This issue is of interest to the ASCQR Program because breast procedures are becoming increasingly common at ASCs.¹¹⁰ In addition, the Ambulatory Breast Procedure Surgical Site Infection Outcome measure addresses the MAP-identified measure gap area of surgical quality measures, including surgical site infection measures, for the ASCQR Program.¹¹¹

The Ambulatory Breast Procedure Surgical Site Infection Outcome measure was included on the 2016 MUC list¹¹² and reviewed by the MAP. The MAP conditionally supported the measure (MUC16–155), noting the rapid shift of care to the ambulatory surgery

setting and the need to ensure transparency about the safety of ambulatory surgery centers.¹¹³ The MAP further noted that this measure should be submitted for NQF review and endorsement.¹¹⁴ A summary of the MAP recommendations can be found at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>. We note that this measure received NQF endorsement in January 2017, and therefore satisfies the MAP's condition for support.¹¹⁵

The Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome measure is used to assess the risk-adjusted Standardized Infection Ratio (SIR) for all SSIs following breast procedures conducted at ASCs among adult patients and reported to the CDC's National Healthcare Safety Network. The measure compares the reported number of SSIs observed at an ASC with a predicted value based on nationally aggregated data. The numerator for this measure is all SSIs during the 30-day and 90-day postoperative periods following breast procedures in ASCs. The term SSI as used in this measure is defined in accordance with the CDC NHSN's surveillance protocol as an infection, following a breast procedure, of either the skin, subcutaneous tissue and breast parenchyma at the incision site (superficial incisional SSI), deep soft tissues of the incision site (deep incisional SSI), or any part of the body deeper than the fascial/muscle layers that is opened or manipulated during the operative procedure (organ/space SSI).¹¹⁶ The denominator for this measure is all adult patients (defined as patients ages 18 to 108 years) undergoing breast procedures, as specified by the operative codes that comprise the breast procedure category of the NHSN Patient Safety Component Protocol, at an ASC. This measure cohort excludes hospital inpatient and outpatient departments, pediatric patients (patients younger than 18 years) and very elderly patients (older than 108 years), and brain-dead patients whose organs are being removed for

donor purposes. The specifications for this measure for the ASC setting can be found at: <http://www.qualityforum.org/QPS/> after searching "Ambulatory Breast Procedure Surgical Site Infection Outcome Measure."

We are inviting public comment on the possible inclusion of this measure in the ASCQR Program measure set in the future.

8. 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 making updates to the 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 with comment period (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 Web site, but stated that we will continue to display the technical specifications for the ASCQR Program on the QualityNet Web site. In addition, our policies regarding the maintenance of technical specifications for the ASCQR Program are codified at 42 CFR 416.325. We are not proposing any changes to our policies regarding the maintenance of technical specifications for the ASCQR Program.

9. 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 Web site 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

¹⁰⁷ Anderson D.J., Podgorny K., Berríos-Torres S. et al. Strategies to Prevent Surgical Site Infections in Acute Care Hospitals: 2014 Update. *Infection Control & Hospital Epidemiology*. 2014;35:605–627; Mangram A.J, Horan T.C., Pearson M.L., Silver L.C., Jarvis W.R. Guideline for Prevention of Surgical Site Infection. *Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol*. 1999;720:250–278; Gaynes R., Richards C., Edwards J.R., et al Feeding Back Surveillance Data to Prevent Hospital-Acquired Infections. *Emerg Infect Dis*. 2001;7:295–298.

¹⁰⁸ Mu Y., et al. Improving Risk-Adjusted Measures of Surgical Site Infection for the National Healthcare Safety Network. *Infect Control Hosp Epidemiol*. 2011;32(10):970–986.

¹⁰⁹ Mu Y., et al. Improving Risk-Adjusted Measures of Surgical Site Infection for the National Healthcare Safety Network. *Infect Control Hosp Epidemiol*. 2011;32(10):970–986.

¹¹⁰ Cullen KA, Hall MJ, Golosinskiy A, Statistics NFCh. Ambulatory Surgery in the United States, 2006. *Nat Health Stat Rept*; 2009.

¹¹¹ National Quality Forum. "MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals." Report. 2017. Available at: <http://www.qualityforum.org/map/under/Hospitals—Final Report>.

¹¹² http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx, under "2016 Measures Under Consideration List (PDF)."

¹¹³ National Quality Forum. 2016–2017 Spreadsheet of Final Recommendations to HHS and CMS, available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

¹¹⁴ National Quality Forum. 2016–2017 Spreadsheet of Final Recommendations to HHS and CMS, available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

¹¹⁵ National Quality Forum. Endorsed measure specification available at: <http://www.qualityforum.org/QPS/3025>.

¹¹⁶ Centers for Disease Control and Prevention. "Surgical Site Infection (SSI) Event. Available at: <https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscasicurrent.pdf>.

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, 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* Web site, or other CMS Web site 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 Web site and/or on our applicable listservs (81 FR 79819 through 79820). We are not proposing any changes to these policies. However, we note that in section XIV.B.6.b. and c. of this proposed rule we are proposing two new measures: ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, and ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures, beginning with the CY 2022 payment determination, and specific public reporting policies associated with these proposed measures.

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 section XIV.D.3. of this proposed rule, we are proposing to expand submission via the CMS online tool to also allow for batch data submission and make corresponding changes to the 42 CFR 416.310(c)(1)(i).

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. 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). We are not proposing any changes to these requirements.

We note that, in section XIV.B.3.b.(1) of this proposed rule, we are proposing to remove one claims-based measure using QDCs, ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing, beginning with the CY 2019 payment determination. If this proposal is finalized as proposed, the following previously finalized claims-based measures using QDCs will be collected for the CY 2020 payment determination and subsequent years:

- 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.

2. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135 through 75137), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534 through 70535) as well as 42 CFR 416.310(a)(3) and 42 CFR 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. We 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 2012 OPPS/ASC final rule with comment period (76 FR 74505 through 74509); CY 2014 OPPS/ASC final rule with comment period (78 FR 75137 through 75140); CY 2015 OPPS/ASC final rule with comment period (79 FR 66983 through 66986); CY 2016 OPPS/ASC final rule with comment period (80 FR 70535 through 70536); CY 2017 OPPS/ASC final rule with comment period (81 FR 79820 through 79822); 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>. We note that we are proposing to remove two measures submitted via a CMS online data submission tool in section XIV.B.3.b.(2) and XIV.B.3.b.(3) of this proposed rule and to adopt one measure submitted via a CMS online data submission tool in section XIV.B.6.a. of this proposed rule.

a. Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140) and 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 (CDC NHSN Web site). 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 are not proposing any changes to the reporting requirements for this measure.

b. Proposals Regarding Requirements for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75137 through 75139), CY 2016 OPPS/ASC final rule with comment period (80 FR 70535 through 70536), CY 2017 OPPS/ASC final rule with comment period (81 FR 79821 through 79822), 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 Web site as our CMS online data submission tool: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetHomepage&cid=1120143435383>. In this proposed rule, we are making one proposal to the method of data submission via a CMS online data submission tool.

(1) Batch Submission

We are not proposing any changes to our policies regarding data submitted via a CMS online data submission tool when data is entered for individual facilities. Currently, for individual facility data entry, users must have a QualityNet account and use one Hospital Quality Reporting (HQR) External File per facility that is uploaded into the QualityNet secure portal. However, using one HQR External File that only allows data entry for one facility can be burdensome for entities responsible for submitting such data for multiple facilities, such as multi-facility ASCs. Therefore, in an effort to streamline the process, we are proposing to expand the CMS online tool to also allow for batch submission beginning with data submitted during CY 2018 for the CY 2020 payment determination and subsequent years.

Batch submission is submission of data for multiple facilities simultaneously using a single, electronic file containing data from multiple facilities submitted via one agent QualityNet account. Under the batch submission process, ASC agents (for example, a corporate representative for a corporate entity consisting of multiple ASC facilities with separate NPIs) would be assigned a vendor ID and an ASC's representative would submit the Security Administrator (SA) form with the assigned vendor ID for the agent to establish their own QualityNet account. Once approved, the agent may submit data for any ASC associated with that ID, individually or in a batch, and access data reports for the same ASCs. Agents would only have access to data reports for facilities that have authorized them to have access. For batch submission, agents would be provided the HQR external file layout with which to upload their associated ASCs' data under the agents' QualityNet account. In order to submit batch data, agents would need to meet all QualityNet account requirements, such as establishing a QualityNet account and maintaining a QualityNet security administrator. Additional details

regarding logistics of batch data submission would be included in future guidance in the Specifications Manual.

In addition, we are proposing to make corresponding changes to 42 CFR 416.310(c)(1)(i) to reflect this proposal and replace the term "ASCs" with the phrase "ASCs, and any agents submitting data on an ASC's behalf."

We are inviting public comment on our proposals, as discussed above, to: (1) Expand the CMS online tool to also allow for batch submission of measure data beginning with data submitted during CY 2018, and (2) make corresponding changes to modify 42 CFR 416.310(c)(1)(i) to reflect the aforementioned proposal.

(2) Measures Using the CMS Online Data Submission Tool for the CY 2020 Payment Determination And Subsequent Years

In sections XIV.B.3.b.(2) and XIV.B.3.b.(3) of this proposed rule, respectively, we are proposing to remove two measures collected via a CMS online data submission tool—ASC-6: Safe Survey Checklist Use and ASC-7: ASC Facility Volume Data on Selected Surgical Procedures—beginning with the CY 2019 payment determination. If these proposals are finalized as proposed, the following previously finalized measures will require data to be submitted via a CMS online data submission tool for the CY 2020 payment determination and subsequent years:

- 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.¹¹⁷

Furthermore, in section XIV.B.6.a. of this proposed rule, we are proposing to adopt one new measure collected via a CMS online data submission tool, ASC-16: Toxic Anterior Segment Syndrome, beginning with the CY 2021 payment determination.

4. Requirements for Claims-Based Measure Data

We refer readers to the CY 2015 OPPS/ASC final rule with comment

¹¹⁷ 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).

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 collection 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 requirements.

We note that one previously finalized measure, ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, will be collected via claims for the CY 2020 payment determination and subsequent years (79 FR 66970 through 66978). In addition, in sections XIV.B.6.b. and c., respectively, of this proposed rule, we are proposing to adopt two new claims-based measures—ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, and ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures—beginning with the CY 2022 payment determination.

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 section XIV.B.4. of this proposed rule, we are proposing to delay 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 refer readers to that section for more details.

As noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79815), some commenters suggested shortening sections of the survey, such as the "About You" section. We continue to evaluate the utility of individual questions as we collect new data from the survey's voluntary national implementation, and will consider different options for shortening the OAS CAHPS Survey without the loss of important data in the future. Specifically, we continue to consider the removal of two demographic questions—the "gender" and "age"

questions—from the OAS CAHPS Survey in a future update.

6. Extraordinary Circumstances Extensions or Exemptions for the CY 2019 Payment Determination and Subsequent Years

a. Background

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643), the CY 2014 OPSS/ASC final rule with comment period (78 FR 75140 through 75141), the CY 2017 OPSS/ASC final rule with comment period (81 FR 79824 through 79825), and 42 CFR 416.310(d) for the ASCQR Program's policies for extraordinary circumstance extensions or exemptions (ECE) requests.¹¹⁸

Many of our quality reporting and value-based purchasing programs share a common process for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control. We refer readers to the Hospital IQR Program (76 FR 51615 through 51652, 78 FR 50836 through 50837, 79 FR 50277, 81 FR 57181 through 57182, and 42 CFR 412.140(c)(2)), the Hospital OQR Program (77 FR 68489, 78 FR 75119 through 75120, 79 FR 66966, and 80 FR 70524), the IPFQR Program (77 FR 53659 through 53660 and 79 FR 45978), and the PCHQR Program (78 FR 50848), as well as the HAC Reduction Program (80 FR 49542 through 49543) and the Hospital Readmissions Reduction Program (80 FR 49542 through 49543), for program-specific information about extraordinary circumstances exemption requests.

In reviewing the policies for these programs, we recognized that there are five areas in which these programs have variances regarding ECE requests. These are: (1) Allowing the facilities or hospitals to submit a form signed by the facility's or hospital's CEO versus CEO or designated personnel; (2) requiring the form be submitted within 30 days following the date that the extraordinary circumstance occurred versus within 90 days following the date the extraordinary circumstance occurred; (3) inconsistency regarding specification of a timeline for us to provide our formal response notifying the facility or hospital of our decision; (4) inconsistency regarding specification of our authority to grant ECEs due to CMS data system issues; and (5) referring to

the program as “extraordinary extensions/exemptions” versus as “extraordinary circumstances exceptions.” We believe addressing these five areas, as appropriate, can improve administrative efficiencies for affected facilities or hospitals. We note that, in the FY 2018 IPPS/LTCH PPS proposed rule, we examined our policies in these areas for the Hospital Readmissions Reduction Program, the HAC Reduction Program, the Hospital IQR Program, the PCHQR Program and the IPFQR Program (82 FR 19967, 19990, 20074 through 20075, 20085 through 20086 and 20128 through 20130, respectively) and proposed to address differences in these areas for those programs. In section XIII.D.8. of this proposed rule, we are also proposing revisions to our ECE policies for the Hospital OQR Program.

With the exception of the terminology used to describe these processes (item 5 above), the ASCQR Program is aligned with other quality reporting programs. As a result, in this proposed rule, we are proposing to rename the process as the extraordinary circumstances exceptions (ECE) policy and make conforming changes to 42 CFR 416.310(d).

b. ECE Policy Nomenclature

We have observed that while all quality programs listed above have developed similar policies to provide exceptions from program requirements to facilities that have experienced extraordinary circumstances, such as natural disasters, these programs refer to these policies using inconsistent terminology. Some programs refer to these policies as “extraordinary circumstances extensions/exemptions” while others refer to the set of policies as “extraordinary circumstances exceptions.” Several programs (specifically, the Hospital VBP Program, the HAC Reduction Program, and the Hospital Readmissions Reduction Program) are not able to grant extensions to required data reporting timelines due to their reliance on data external to their program, and thus the term, “extraordinary circumstances extensions/exemptions” is not applicable to all programs. However, all of the described programs are able to offer exceptions from their reporting requirements. Therefore, in an effort to align across CMS quality programs, we are proposing to change the name of this policy from “extraordinary circumstances extensions or exemption” to “extraordinary circumstances exceptions” for the ASCQR Program, beginning January 1, 2018, and to revise § 416.310(d) of our regulations to reflect this change.

We are inviting public comment on this proposal as discussed above.

c. Timeline for CMS Response to ECE Requests

We also note that we believe it is important for facilities to receive timely feedback regarding the status of ECE requests. We strive to complete our review of each ECE request as quickly as possible. However, we recognize that the number of requests we receive, and the complexity of the information provided impacts the actual timeframe to make ECE determinations. To improve transparency of our process, we believe it is appropriate to clarify that we will strive to complete our review of each request within 90 days of receipt.

7. ASCQR Program Reconsideration Procedures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644), the CY 2014 OPSS/ASC final rule with comment period (78 FR 75141), the CY 2016 OPSS/ASC final rule with comment period (80 FR 70537), and 42 CFR 416.330 for the ASCQR Program's reconsideration policy. 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 OPSS/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. 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. Currently, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the multifactor productivity (MFP)-adjusted CPI-U update factor, which is the adjustment set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted CPI-U update factor is the Consumer Price Index for all urban consumers (CPI-U), which currently is the annual update for the ASC payment system, minus the MFP adjustment. As discussed in the CY 2011 MPFS final rule with comment period (75 FR

¹¹⁸In the CY 2015 OPSS/ASC final rule with comment period (79 FR 66987), we stated that we will refer to the process as the “Extraordinary Circumstances Extensions or Exemptions” process rather than the “Extraordinary Circumstances Extensions or Waivers” process.

73397), if the CPI-U is a negative number, the CPI-U would be held to zero. Under the ASCQR Program in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPI/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, we refer readers to section XII.G. of this proposed rule.

In the CY 2013 OPPI/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 Web site): “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 OPPI payment rates, and certain office-based

procedures, certain radiology services and diagnostic tests where payment is based on the MPFS 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 MPFS 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 OPPI/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 OPPI and when they are integral to covered ASC surgical procedures) will be at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology. In the CY 2013 OPPI/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 OPPI/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 and CY 2017 OPPI/ASC final rules with comment period (79 FR 66981 through 66982; 80 FR 70537 through 70538; and 81 FR 79825 through 79826, respectively), we did not make any other changes to these policies.

We are not proposing any changes to these policies for CY 2018.

XV. Request for Information and Public Comments

A. Request for Information on CMS Flexibilities and Efficiencies

CMS is committed to transforming the health care delivery system—and the Medicare program—by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. We seek to reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. These are the reasons we are including this Request for Information in this proposed rule.

As we work to maintain flexibility and efficiency throughout the Medicare program, we would like to start a national conversation about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. We aim to increase quality of care, lower costs, improve program integrity, and make the health care

system more effective, simple, and accessible.

We would like to take this opportunity to invite the public to submit their ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those of Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences. Responses to this Request for Information could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers. Where practicable, data and specific examples would be helpful. If the proposals involve novel legal questions, analysis regarding CMS' authority is welcome for CMS' consideration. We are particularly interested in ideas for incentivizing organizations and the full range of relevant professionals and paraprofessionals to provide screening, assessment, and evidence-based treatment for individuals with opioid use disorder and other substance use disorders, including payment methodologies, care coordination, systems and services integration, use of paraprofessionals such as community paramedics, and other strategies. We are requesting commenters to provide clear and concise proposals that include data and specific examples that could be implemented within the law.

We note that this is a Request for Information only. Respondents are encouraged to provide complete but concise responses. This Request for Information is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This Request for Information does 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 this Request for Information 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 this Request for Information; all costs associated with responding to this Request for

Information will be solely at the interested party's expense. We note that not responding to this Request for Information does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this Request for Information announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this Request for Information. CMS will not respond to comment submissions in response to this Request for Information in the CY 2018 OPPTS/ASC final rule with comment period. Rather, CMS will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. CMS may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this Request for Information. Responses to this Request for Information 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 this Request for Information may be used by the U.S. Government for program planning on a nonattribution basis. Respondents should not include any information that might be considered proprietary or confidential. This Request for Information 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 post on a Web site for public use the public comments received, or a summary of those public comments, in response to this Request for Information.

B. Eliminating Inappropriate Medicare Payment Differentials for Similar Services in the Inpatient and Outpatient Settings

In the past, CMS has requested public comment on potential payment policy options to address the issue of payment differentials between hospital services provided in the inpatient and outpatient settings. CMS has recognized that, even when particular hospital inpatient services and hospital outpatient services are similar, Medicare payment differentials may exist because different statutory provisions and different payment methodologies apply. CMS is committed to eliminating inappropriate Medicare payment differentials for similar services in the inpatient and

outpatient settings in order to execute our responsibility to taxpayers to prudently pay for high quality care. As MedPAC has previously noted, "The high profitability of one-day stays under the inpatient prospective payment system (IPPS) and the generally lower payment rates for similar care under the outpatient prospective payment system (OPPS) have heightened concern about the appropriateness of inpatient one-day stays" (Medicare and the Health Care Delivery System Report to Congress, June 2015). Furthermore, we are concerned that, to the extent Medicare payment differentials exist (and may be inappropriate), there is a corresponding effect on financial liability of patients.

Our most recent solicitation for public comments on these issues occurred in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70549). Since that time, both hospitals and CMS have had the opportunity to gain experience under the various policy changes that have occurred with respect to short inpatient hospital stays. In this context, we believe it is an appropriate time to seek public comment again on transparent ways to identify and eliminate inappropriate payment differentials for similar services provided in the inpatient and outpatient settings.

C. Request for Information Regarding Physician-Owned Hospitals

We are seeking public comments on the appropriate role of physician-owned hospitals in the delivery system. We would like to explore whether physician-owned hospitals could play a more prominent role in the delivery system. In addition, we are seeking public comments on the impact of the current requirements of the physician self-referral law regarding physician-owned hospitals. In particular, we are interested in comments on the impact on Medicare beneficiaries.

XVI. Files Available to the Public via the Internet

The Addenda to the OPPTS/ASC proposed rules and the final rules with comment period are published and available only via the Internet on the CMS Web site. To view the Addenda to this proposed rule pertaining to proposed CY 2018 payments under the OPPTS, we refer readers to the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>; select "1678-P" from the list of regulations. All OPPTS Addenda to this proposed rule are contained in the zipped folder entitled "2018 OPPTS

1678–P Addenda” at the bottom of the page. To view the Addenda to this proposed rule pertaining to the proposed CY 2018 payments under the ASC payment system, we refer readers to the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html>; select “1678–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.”

XVII. 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 (82 FR 20031 through 20075). We refer readers to the CY 2011 through CY 2017 OP/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; and 81 FR 79862 through 79863, 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.

In section XIII.B.4.c. of this proposed rule, we are proposing to remove six measures: (1) OP–21: Median Time to Pain Management for Long Bone Fracture beginning with the CY 2020 payment determination; (2) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures beginning with the CY 2020 payment determination; (3) OP–1: Median Time to Fibrinolysis beginning with the CY 2021 payment determination; (4) OP–4: Aspirin at Arrival beginning with the CY 2021 payment determination; (5) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional beginning with the CY 2021 payment determination; and (6) OP–25: Safe Surgery Checklist beginning with the CY 2021 payment determination. We expect these proposals would reduce the burden of reporting for the Hospital OQR Program, as discussed below. We note that we discuss only the changes in burden resulting from the provisions in this proposed rule.

In this proposed rule, we are proposing to publicly report OP–18c using data beginning with patient encounters during the third quarter of 2017. We are also proposing to delay the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection period) until further notice in future rulemaking. In addition, in this proposed rule, beginning with the CY 2020 payment determination, we are proposing: (1) To codify at § 419.46(e) our previously finalized process for targeting hospitals for validation of chart-abstracted measures; (2) to formalize the educational review process and use it to correct incorrect validation results for chart-abstracted measures; (3) to change the NOP submission deadlines such that hospitals are required to submit the NOP any time prior to registering on the QualityNet Web site and to make conforming revisions at 42 CFR 419.46(a); (4) to align the first quarter for which hospitals must submit data for all hospitals that did not participate in the previous year’s Hospital OQR Program, and make corresponding revisions at 42 CFR 419.46(c)(3); and (5) to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy and make conforming changes to the CFR. We do not believe that these proposed changes would affect our

burden estimates, as further discussed below.

2. Proposed Change in Hourly Labor Cost for Burden Calculation for the Hospital OQR Program

In previous rules (80 FR 70581), we estimated that a hospital pays an individual approximately \$30 per hour to abstract and submit clinical data. In this proposed rule, we are proposing to estimate that reporting data for the Hospital OQR Program can be accomplished by staff with a median hourly wage of \$18.29 per hour.¹¹⁹ This labor rate is based on the Bureau of Labor Statistics (BLS) median hourly wage for a Medical Records and Health Information Technician. The BLS is the principal Federal agency responsible for measuring labor market activity, working conditions, and price changes in the economy.¹²⁰ Acting as an independent agency, the BLS provides objective information for not only the government, but also for the public.¹²¹ The BLS describes Medical Records and Health Information Technicians as those responsible for processing and maintaining health information data.¹²² Therefore, we believe is reasonable to assume that these individuals would be tasked with abstracting clinical data for the Hospital OQR Program measures.

We also are proposing to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage rate ($\$18.29 \times 2 = \36.58) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of \$36.58 throughout the discussion below for the Hospital OQR Program.

We are inviting public comment on these proposals.

¹¹⁹ BLS Occupational Employment Statistics; May 2016. Retrieved from: <https://www.bls.gov/oes/current/oes292071.htm>.

¹²⁰ <http://www.bls.gov/bls/infhome.htm>.

¹²¹ <http://www.bls.gov/bls/infhome.htm>.

¹²² BLS Occupational Employment Statistics; May 2016. Retrieved from: <https://www.bls.gov/oes/current/oes292071.htm>.

3. Estimated Burden Due to Proposal To Delay OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With the CY 2020 Payment Determination

As described in section XIII.B.5. of this proposed rule, we are proposing to delay OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection period). We recognize that delaying mandatory implementation of the survey-based measures will reduce the number of HOPDs administering the OAS CAHPS Survey in CY 2018 and future years. Implementation of the survey-based measures would have made survey administration mandatory for all eligible HOPDs participating in the program. Delaying implementation of the survey-based measures also delays the requirement that HOPDs must administer the survey to eligible patients and we therefore expect fewer HOPDs to administer the survey. Given the proposed delay in mandatory implementation of the OAS CAHPS Survey, there is a corresponding reduction in burden for HOPDs. As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79863), the information collection requirements associated with the five OAS CAHPS Survey-based measures (OP–37a, OP–37b, OP–37c, OP–37d, and OP–37e) are currently approved under OMB Control Number 0938–1240. This PRA package assumes 4,006 HOPDs would administer the OAS CAHPS Survey. The estimated average burden per HOPD as captured in this PRA package is \$6,070 annually and includes patient/respondent burden, time for preparing patient records to send to a survey vendor, and contracting with a survey vendor. Consistent with the voluntary national implementation of the OAS CAHPS Survey that began in 2016, however, we anticipate that not all HOPDs will voluntarily administer the survey.¹²³ For this reason, we

¹²³ Currently, 1,124 HOPDs have selected a vendor to conduct the survey on their behalf as part of a national voluntary implementation of the OAS CAHPS Survey, for a total estimated burden of voluntary survey administration of \$6,822,680 (1,124 HOPDs × \$6,070 per HOPD). If the survey were to become part of the Hospital OQR Program as mandatory, we estimate approximately 3,228 HOPDs that meet eligibility requirements for the Hospital OQR Program would begin administering the survey and reporting data to CMS under OMB Control Number 0938–1240. We assume HOPDs voluntarily administering the survey will continue to do so even if implementation of the survey-based

anticipate that each HOPD participating in the Hospital OQR Program that chooses not to voluntarily administer the OAS CAHPS Survey under the voluntary national implementation in CY 2018 and future years would experience an anticipated burden reduction of approximately \$6,070 as a result of this proposal. However, as noted above, this burden reduction is included under OMB Control Number 0938–1240 and is not included in our burden estimates for the Hospital OQR Program.

4. Estimated Burden Due to Proposal to Publicly Report OP–18c: Median Time From Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients- Psychiatric/Mental Health Patients

In section XIII.B.10.b. of this proposed rule we are proposing to publicly report 18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients- Psychiatric/Mental Health Patients beginning with patient encounters from the third quarter of 2017. As noted in that section, the data required for public reporting of OP–18c is already collected as part of the existing Hospital OQR Program requirements. Accordingly, we do not expect this proposal to affect burden.

5. Estimated Burden Due to Proposals for the CY 2020 Payment Determination and Subsequent Years

a. Burden Due to Proposed Measure Removals

In section XIII.B.4.c.(1) and (2) of this proposed rule, we are proposing, beginning with the CY 2020 payment determination, to remove one chart-abstracted measure (OP–21: Median Time to Pain Management for Long Bone Fracture) and one web-based measure (OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures). In total, we expect these proposals would reduce burden by 152,680 hours and \$5.6 million for the

measures is delayed for the Hospital OQR Program; therefore, we anticipate that approximately 2,104 HOPDs (3,228 eligible HOPDs–1,124 HOPDs voluntarily reporting under the voluntary national implementation) that would have administered the survey as a mandatory requirement of the Hospital OQR Program will not do so for CY 2018 and future years if the survey-based measures are delayed. This results in an estimated aggregate burden reduction of \$12,771,280 (2,104 HOPDs × \$6,070 per HOPD) across all HOPDs meeting eligibility requirements for the Hospital OQR Program. As noted above, this burden reduction is included under OMB Control Number 0938–1240 and is not included in our burden estimates for the Hospital OQR Program.

CY 2020 payment determination. These estimates are described in detail below.

We calculated the burden reduction associated with the proposed removal of OP–21: Median Time to Pain Management for Long Bone Fracture by considering the time per case to report chart-abstracted measures, which are submitted using a web-based tool, as well as the number of cases per hospital and the number of participating hospitals. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582), we estimated the burden to collect chart-abstracted data for a single web-based measure, including OP–21, to be 2.92 minutes. In this proposed rule, we estimate that 3,300 Hospital Outpatient Departments (HOPDs) report data under the Hospital OQR Program. Based on the most recent data from CY 2015 reporting, we also estimate that 947 cases are reported per hospital for each chart-abstracted measure. Accordingly, we estimate a total burden reduction of 46.1 hours per HOPD due to the removal of one chart-abstracted measure (2.92 minutes per measure/60 minutes per hour × 1 measure × 947 cases per hospital). In total, across 3,300 HOPDs, we estimate a burden reduction of 152,130 hours (46.1 hours per hospital × 3,300 hospitals) and \$5,564,915 (152,130 total hours × \$36.58 per hour) for the CY 2020 payment determination due to the proposed removal of OP–21: Median Time to Pain Management for Long Bone Fracture.

We calculated the burden reduction associated with the proposed removal of OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures by considering the time per measure to report web-based measures as well as the number of participating hospitals. As previously stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582), we estimate that hospitals spend approximately 10 minutes per measure to report web-based measures and that 3,300 HOPDs report data under the Hospital OQR Program. Accordingly, for the CY 2020 payment determination, we estimate a total burden reduction of 550 hours across 3,300 HOPDs due to the removal of one web-based measure (10 minutes per measure/60 minutes per hour × 1 measure × 3,300 hospitals). We further estimate a cost reduction of \$20,119 due to this proposal (550 total hours × \$36.58 per hour).

In total, we expect these proposals would reduce burden by 152,680 hours (152,130 + 550) and \$5,585,034 (\$5,564,915 + \$20,119) for the CY 2020 payment determination.

b. Burden Due to Updates to Previously Finalized Chart-Abstracted Measure Validation Procedures and the Educational Review Process

We previously estimated the burden associated with validation of chart-abstracted measures in the CY 2013 and CY 2014 OPPS/ASC final rules with comment period (77 FR 68531 and 78 FR 75172, respectively). In section XIII.D.7.a. of this proposed rule, we are providing clarification on our procedures for validation of chart-abstracted measures to note that the 50 poorest performing outlier hospitals will be targeted for validation. We do not expect this clarification to influence burden because it does not alter the number of hospitals selected for validation or the requirements for those hospitals that are selected.

In addition, in section XIII.D.7.c. of this proposed rule, we are proposing to formalize the process of allowing hospitals to use an educational review process to correct incorrect validation results for the first three quarters of validation for chart-abstracted measures. We are also proposing to update the process to specify that if the results of an educational review indicate that we incorrectly scored a hospital's medical records selected for validation, the corrected quarterly validation score would be used to compute the hospital's final validation score at the end of the calendar year. Under this proposal, the educational review request process remains the same for the CY 2020 payment determination and subsequent years, except that revised scores identified through an educational review would be used to correct a hospital's validation score. As stated in the CY 2014 OPPS/ASC final rule (78 FR 75171), we believe there is a burden associated with successful participation in the Hospital OQR Program, where successful participation results in a full annual payment update (APU) for a particular payment determination. This burden would include, but would not be limited to, maintaining familiarity with the Hospital OQR Program requirements, which includes checking feedback reports to indicate a facility's current status or performance. The overall administrative burden, which we believe includes the educational review process, is estimated at 42 hours per hospital and has previously been calculated (78 FR 75171). This burden would not be changed by the proposal to use revised scores identified through an educational review to correct a hospital's validation score.

c. Burden Due to Proposed Update to NOP Submission Deadline

We previously estimated the burden associated with Hospital OQR Program participation and requirements in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171). In section XIII.C.2. of this proposed rule, we are proposing to revise the NOP submission deadlines such that hospitals are required to submit the NOP any time prior to registering on the QualityNet Web site. While we expect this proposal to make it generally easier for hospitals to comply with the Hospital OQR Program requirements by extending the NOP deadline, we anticipate a negligible effect on the time and cost of completing the participation requirements. As a result, the proposal to revise the NOP submission deadline would not impact our burden estimates.

d. Burden Due to Proposal To Align the First Quarter for Which Hospitals Must Submit Data for All Hospitals That Did Not Participate in the Previous Year's Hospital OQR Program

In section XIII.D.1 of this proposed rule, we are proposing to align the timeline specifying the initial quarter for which hospitals must submit data for all hospitals that did not participate in the previous year's Hospital OQR Program, rather than specifying different timelines for hospitals with Medicare acceptance dates before versus after January 1 of the year prior to an affected annual payment update. Although this proposal alters the timeline for hospitals to begin submitting data for the Hospital OQR Program, it does not alter program requirements. As a result, we do not anticipate that this proposal will influence burden.

e. Burden Due to Proposed Updates to the Previously Finalized ECE Policy

We previously estimated the burden associated with general and administrative Hospital OQR Program requirements in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171). In section XIII.D.8. of this proposed rule, we discuss our intent to align the naming of this exception policy and to update 42 CFR 419.46(d) to reflect our current ECE policies. We are also clarifying the timing of our response to ECE requests. Because we are not seeking any new or additional information in our ECE proposals, we believe the updates would have no effect on burden for hospitals.

6. Estimated Burden Due to Proposals for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.c.(3) through (6) of this proposed rule, we are proposing to remove four measures beginning with the CY 2021 payment determination: three chart-abstracted measures (OP-1: Median Time to Fibrinolysis, OP-4: Aspirin at Arrival, and OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional); and one web-based measure (OP-25: Safe Surgery Checklist Use). In total, we expect the removal of these measures would reduce burden by 304,810 hours and \$11.1 million for the CY 2021 payment determination, as described below.

We calculated the burden reduction associated with the removal of chart-abstracted measures by considering the time per case to report chart-abstracted measures, as well as the number of cases per hospital and the number of participating hospitals. As previously stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582), we estimate that hospitals spend approximately 2.92 minutes per case per chart-abstracted measure and that 3,300 HOPDs report data under the Hospital OQR program. In addition, based on the most recently available data from CY 2015 reporting, we estimate that 947 cases are reported per hospital for each chart-abstracted measure. We note that although OP-1: Median Time to Fibrinolysis is a chart-abstracted measure, we do not expect removing this measure would reduce burden, as the data collected for this measure is required to calculate another program measure in the AMI measure set (OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and will, therefore, continue to be collected as an underlying part of OP-2 even if the proposal to remove OP-1 is finalized as proposed. Accordingly, there is no change in burden associated with the proposed removal of this measure included in our calculations below.

We estimate a total burden reduction of 92.2 hours per HOPD due to the removal of OP-4: Aspirin at Arrival and OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional (2.92 minutes per measure/60 minutes per hour \times 2 measures \times 947 cases per hospital). In total, across 3,300 HOPDs we estimate a burden reduction of 304,260 hours (92.2 hours per hospital \times 3,300 hospitals) and \$11,129,831 (304,260 total hours \times \$36.58 per hour) for the CY 2021 payment determination due to the proposed removal of OP-4: Aspirin at Arrival and OP-20: Door to

Diagnostic Evaluation by a Qualified Medical Professional.

We calculated the burden reduction associated with the removal of OP–25: Safe Surgery Checklist Use by considering the time per measure to report web-based measures as well as the number of participating hospitals. As previously stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582), we estimate that hospitals spend approximately 10 minutes per measure to report web-based measures and that 3,300 HOPDs report data under the Hospital OQR program. Accordingly, for the CY 2021 payment determination, we estimate a total burden reduction of 550 hours across 3,300 HOPDs due to the removal of one web-based measure (10 minutes per measure/60 minutes per hour × 1 measure × 3,300 hospitals). We further estimate a cost reduction of \$20,119 due to this proposal (550 total hours × \$36.58 per hour).

In total, we expect these proposals would reduce burden by 304,810 hours (304,260 + 550) and \$11,149,950 (\$11,129,831 + \$20,119) for the CY 2021 payment determination for the Hospital OQR Program.

We are inviting public comment on the burden associated with these information collection requirements.

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, and CY 2017 OPPS/ASC final rules with comment periods (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; and 81 FR 79863 through 79865, 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 provisions in this proposed rule.

In section XIV.B.3.b. of this proposed rule, we are proposing, beginning with the CY 2019 payment determination, to remove three measures (ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing, ASC–6: Safe Surgery Checklist Use, and ASC–7: Ambulatory Surgical Center Facility Volume Data on Selected Ambulatory Surgical Center Surgical

Procedures) from the ASCQR Program measure set. In section XIV.B.6.a. of this proposed rule, we are proposing, beginning with the CY 2021 payment determination, to adopt one new measure, ASC–16: Toxic Anterior Segment Syndrome. In section XIV.B.6.b. and c. of this proposed rule, we are proposing, beginning with the CY 2022 payment determination, to adopt two new measures collected via claims (ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures and ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures). We expect these proposals would reduce the overall burden of reporting data for the ASCQR Program, as discussed below.

In this proposed rule, we are also proposing: (1) To delay ASC–15a–e: OAS CAHPS survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection); (2) to expand the CMS online tool to also allow for batch submission beginning with data submitted during CY 2018 and to make corresponding revisions to the CFR; and, (3) to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy beginning with CY 2018 and to make conforming changes to the CFR. As discussed below, we do not expect these proposals to influence our burden estimates.

2. Proposed Change in Hourly Labor Cost for Burden Calculation for the ASCQR Program

To better align this program with our other quality reporting and value-based purchasing programs, we are proposing to update our burden calculation methodology to standardize elements within our burden calculation. Specifically, we are proposing to utilize an updated standard hourly labor cost for data reporting activities.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79863 through 79864), we finalized our proposal to use the hourly labor cost of \$32.84 (hourly wage plus fringe and overhead, discussed in more detail below) in estimating the labor costs associated with abstracting clinical data. This labor rate was based on the Bureau of Labor Statistics (BLS) median hourly wage for a Medical Records and Health Information Technician of \$16.42 per hour.¹²⁴ The BLS is the principal Federal agency responsible for measuring labor market activity, working conditions, and price changes

¹²⁴ <http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.

in the economy.¹²⁵ Acting as an independent agency, the BLS provides objective information for not only the government, but also for the public.¹²⁶ The BLS describes Medical Records and Health Information Technicians as those responsible for processing and maintaining health information data.¹²⁷ Therefore, we believe it is reasonable to assume that these individuals would be tasked with abstracting clinical data for ASCQR Program measures.

The BLS recently released updated wage estimates for Medical Records and Health Information Technicians. These updates increased the median hourly wage from \$16.42 per hour to \$18.29 per hour.¹²⁸ Applying the same 100 percent overhead cost estimate finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79863 through 79864) to estimate the elements assigned as “indirect” or “overhead” costs, we estimate an updated total hourly labor cost of \$36.58. Therefore, we are proposing to apply an updated hourly labor cost of \$36.58 (\$18.29 base salary + \$18.29 fringe and overhead) to our burden calculations for chart abstraction.

We are inviting public comment on this proposal.

3. Estimated Burden of ASCQR Program Proposals Beginning With CY 2018

In section XIV.B.4. of this proposed rule we are proposing to delay ASC–15a–e: OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection) until further notice in future rulemaking. We recognize that delaying mandatory implementation of the survey-based measures will reduce the number of ASCs administering the OAS CAHPS Survey in CY 2018 and future years. Implementation of the survey-based measures would have made survey administration mandatory for all eligible ASCs participating in the program. Delaying implementation of the survey-based measures also delays the requirement that ASCs must administer the survey to eligible patients and we therefore expect fewer ASCs to administer the survey. Given the proposed delay in mandatory implementation of the OAS CAHPS Survey, there is a corresponding reduction in burden for ASCs. As described in the CY 2017 OPPS/ASC final rule with comment period (81 FR

¹²⁵ <http://www.bls.gov/bls/infohome.htm>.

¹²⁶ <http://www.bls.gov/bls/infohome.htm>.

¹²⁷ BLS Occupational Employment Statistics; May 2016. Retrieved from: <https://www.bls.gov/oes/current/oes292071.htm>.

¹²⁸ <https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.

79864), the information collection requirements associated with the five OAS CAHPS Survey based measures (ASC–15a, ASC–15b, ASC–15c, ASC–15d, and ASC–15e) are currently approved under OMB Control Number 0938–1240. This PRA package assumes 5,357 ASCs, or roughly all ASCs paid under the ASC payment system, would administer the OAS CAHPS Survey. The estimated average burden per ASC as captured in this PRA package is \$6,070 annually and includes patient/respondent burden, time for preparing patient records to send to a survey vendor, and contracting with a survey vendor. Consistent with the voluntary national implementation of the OAS CAHPS Survey that began in 2016, however, we anticipate that not all ASCs will voluntarily administer the survey.¹²⁹ For this reason, we anticipate that each ASC participating in the ASCQR Program that chooses not to voluntarily administer the OAS CAHPS Survey under the voluntary national implementation in CY 2018 and future years would experience an anticipated burden reduction of approximately \$6,070 as a result of this proposal. However, as noted above, this burden reduction is included under OMB Control Number 0938–1240 and is not included in our burden estimates for the ASCQR Program.

In section XIV.D.3. of this proposed rule, we are proposing to expand the CMS online tool to also allow for batch submission beginning with data submitted during the CY 2018 reporting period and to make corresponding revisions to the CFR. We expect this proposal to increase the efficiency of data submission via the CMS online

¹²⁹ Currently, 719 ASCs have selected a vendor to conduct the survey on their behalf as part of a national voluntary implementation of the OAS CAHPS Survey, for a total estimated burden of voluntary survey administration of \$4,364,330 (719 ASCs × \$6,070 per ASC). If the survey were to become part of the ASCQR Program as mandatory, we estimate approximately 3,937 ASCs that meet eligibility requirements for the ASCQR Program would begin administering the survey and reporting data to CMS under OMB Control Number 0938–1240. We assume ASCs voluntarily administering the survey will continue to do so even if implementation of the survey-based measures is delayed for the ASCQR Program; therefore, we anticipate that approximately 3,218 ASCs (3,937 eligible ASCs—719 ASCs voluntarily reporting under the voluntary national implementation) that would have administered the survey as a mandatory requirement of the ASCQR Program will not do so for CY 2018 and future years if the survey-based measures are delayed. This results in an estimated aggregate burden reduction of \$19,533,260 (3,218 ASCs × \$6,070 per ASC) across all ASCs meeting eligibility requirements for the ASCQR Program. As noted above, this burden reduction is included under OMB Control Number 0938–1240 and is not included in our burden estimates for the ASCQR Program.

tool. However, the proposal does not change our data reporting requirements, and therefore, we do not expect a change in the burden experienced by ASCs.

In section XIV.D.6. of this proposed rule, we are proposing to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy beginning with CY 2018 and to make conforming changes to the CFR. We are also clarifying the timing of our response to ECE requests. Because we are not seeking any new or additional information in our ECE proposals, we believe the updates would have no effect on burden for hospitals.

4. Estimated Burden of ASCQR Program Proposals for the CY 2019 Payment Determination

In section XIV.B.3.b. of this proposed rule, we are proposing, beginning with the CY 2019 payment determination, to remove three measures from the ASCQR Program. These measures include one claims-based measure (ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing) and two collected via a CMS online data submission tool (ASC–6: Safe Surgery Checklist Use and ASC–7: Ambulatory Surgical Center Facility Volume Data on Selected Ambulatory Surgical Center Surgical Procedures).

Data for ASC–5 is submitted via CMS claims using Quality Data Codes, which impose only a nominal burden on providers because these claims are already submitted for the purposes of payment. Therefore, we estimate a nominal reduction in burden associated with our proposal to remove the ASC–5 measure from the ASCQR Program measure set beginning with the CY 2019 payment determination.

We believe 3,937 ASCs would experience a reduction in burden associated with our proposals to remove ASC–6 and ASC–7 from the ASCQR Program measure set. In the CY 2014 OPPI/ASC final rule with comment period (78 FR 75173), we finalized our estimates that each participating ASC would spend 10 minutes per measure per year to collect and submit the required data for the ASC–6 and ASC–7 measures, making the total estimated annual burden associated with each of these measures 657 hours (3,937 ASCs × 0.167 hours per ASC) and \$24,033 (657 hours × \$36.58 per hour). Therefore, we estimate a total reduction in burden of 1,314 (657 hours × 2 measures) hours and \$48,066 (1,314 hours × \$36.58 per hour) for all ASCs as a result of our proposals to remove ASC–6 and ASC–7 from the ASCQR Program measure set. The reduction in burden associated with these

requirements is available for review and comment under OMB Control Number 0938–1270.

5. Estimated Burden of ASCQR Program Proposals for the CY 2021 Payment Determination

In section XIV.B.6.a. of this proposed rule, we are proposing, beginning with the CY 2021 payment determination, to adopt one new measure collected via a CMS online data submission tool, ASC–16: Toxic Anterior Segment Syndrome.

We believe 3,937 ASCs would incur a burden associated with abstracting numerators, denominators, and exclusions for the proposed ASC–16 measure collected and reported via a CMS online data submission tool. In addition, we estimate that each ASC reporting data for this measure would report data on approximately one case per year, and would spend 15 minutes (0.25 hours) per case to collect and submit this data. Therefore, we estimate a total burden for all reporting ASCs with a single case per ASC of 984 hours (3,937 ASCs × 1 case per ASC × 0.25 hours per case) and \$36,004 (984 hours × \$36.58 per hour). The additional burden associated with these requirements is available for review and comment under OMB Control Number 0938–1270.

6. Estimated Burden of ASCQR Program Proposals for the CY 2022 Payment Determination

In section XIV.B.6.b. and c. of this this proposed rule, we are proposing, beginning with the CY 2022 payment determination, to adopt two measures collected via claims: (1) ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and (2) ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures. Data used to calculate scores for these measures is collected via Part A and Part B Medicare administrative claims and Medicare enrollment data, and therefore does not require ASCs 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 additional burden associated with these proposals.

We are inviting public comment on the burden associated with these information collection requirements.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention: CMS Desk Officer*, CMS-1678-P, *Fax: (202) 395-6974*; or, *Email: OIRA_submission@omb.eop.gov*.

XVIII. 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 proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XIX. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

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 Contract with America Advancement Act of 1996 (Pub. L. 104-121) (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). This section of the proposed rule contains the impact and other economic analyses for the provisions that we are proposing for CY 2018.

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 Contract with America Advancement Act of 1996 (Pub. L. 104-121). 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.

2. Statement of Need

This proposed rule is necessary to make updates to the Medicare hospital OPSS rates. It is necessary to make proposed changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2018. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPSS 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, 2016, through and including December 31, 2016, and processed through December 31, 2016, and updated cost report information.

This proposed rule also is necessary to make updates to the ASC payment rates for CY 2018, 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 2018. Because ASC payment rates are based on the OPSS relative payment weights for the majority of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPSS 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.

3. Overall Impacts for the Proposed OPSS and ASC Payment Provisions

We estimate that the total increase in Federal government expenditures under the OPSS for CY 2018, compared to CY 2017 due to the changes in this proposed rule, will be approximately \$897 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the OPSS expenditures for CY 2018 will be approximately \$5.7 billion

higher relative to expenditures in CY 2017. Because this proposed rule 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 38 displays the distributional impact of the proposed CY 2018 changes in OPSS payment to various groups of hospitals and for CMHCs.

We estimate that the proposed update to the conversion factor and other proposed adjustments (not including the effects of proposed outlier payments, the proposed pass-through estimates, and the proposed application of the frontier State wage adjustment for CY 2017) would increase total OPSS payments by 1.8 percent in CY 2018. 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 OPSS payments because these changes to the OPSS are budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system. We estimate that the proposed total change in payments between CY 2017 and CY 2018, considering all payments, proposed changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, would increase total estimated OPSS payments by 1.9 percent.

We estimate the proposed 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 under the ASC payment system for CY 2018 compared to CY 2017 to be approximately \$67 million. Because the provisions for the ASC payment system are part of a proposed rule that is economically significant as measured by the \$100 million threshold, we have prepared a regulatory impact analysis of the 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. Table 39 and 40 of this proposed rule display the redistributive impact of the proposed CY 2018 changes regarding ASC payments, grouped by

specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. 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 reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we 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. We are seeking public comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$105.16 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/2016/may/naics4_621100.htm). Assuming an average reading speed, we estimate that it would take approximately 6.4 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is \$673 (6.4 hours x \$105.16). Therefore, we estimate that the total cost of reviewing this regulation is \$1,708,074 (\$673 x 2,538 reviewers).

5. Detailed Economic Analyses

a. Estimated Effects of OPSS Changes in This Proposed Rule

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2018 policy changes on various hospital groups. We post on the CMS Web site our hospital-specific estimated payments for CY 2018 with the other supporting documentation for

this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. At the Web site, select "regulations and notices" from the left side of the page and then select "CMS-1678-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 38 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 policy changes. In addition, we have not made adjustments for future changes in variables such as service volume, service-mix, or number of encounters.

We are soliciting public comment and information about the anticipated effects of the proposed changes included in this proposed rule on providers and our methodology for estimating them. Any public comments that we receive will be addressed in the applicable sections of the final rule with comment period that discuss the specific policies.

(2) Estimated Effects of Proposed OPSS Changes to Part B Drug Payment on 340B Eligible Hospitals Paid Under the OPSS

In section V.B.7. of this proposed rule, we discuss our proposal to reduce the payment for nonpass-through, separately payable drugs purchased by 340B-participating hospitals through the 340B drug pricing program. Specifically, we are proposing to pay for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through status and vaccines, at the average sales price (ASP) minus 22.5 percent instead of ASP+6 percent.

We recognize that it is difficult to determine precisely what the impact on Medicare spending would be because OPSS claims data do not currently indicate if the drug being provided was purchased with a 340B discount. Furthermore, a list of outpatient drugs

covered under the 340B program is not publicly available. Accordingly, for purposes of estimating the impact, we assumed that all applicable drugs purchased by hospitals eligible to participate in the 340B drug pricing program were purchased at a discounted price under the 340B program. We assumed that all governmental-owned, cancer, and children's hospitals, as well as those hospitals with a DSH percentage greater than 11.75 percent, sole community hospitals with a DSH percentage greater than 8 percent, and rural referral centers with a DSH percentage greater than 8 percent, all participated in the 340B program. We did not assume changes in the quantity of 340B purchased drugs provided (thereby affecting unit volume) or changes in the number of hospitals participating in the 340B program that may occur due to the proposed payment reduction.

While we acknowledge that there are some limitations in Medicare's ability to prospectively calculate a precise estimate for purposes of this proposed rule, we note that each hospital has the ability to calculate how this proposal would change its Medicare payments for separately payable drugs in CY 2018. Specifically, each hospital that is not participating in the 340B program would know that its Medicare payments for drugs would be unaffected by this proposal; whereas each hospital participating in the 340B program has access to 340B ceiling prices (and subceiling prices if it participates in the Prime Vendor Program), knows the volume of 340B drugs that it has historically billed to Medicare, and can generally project the specific covered 340B drugs (and volume thereof) for which it expects to bill Medicare in CY 2018. Accordingly, an affected hospital is able to estimate the difference in payment that it would receive if Medicare were to pay ASP minus 22.5 percent instead of ASP+6 percent for 340B drugs.

Using CY 2016 claims data for the applicable separately payable drugs and biologicals, excluding those on pass-through status and vaccines, billed by hospitals eligible to participate in the 340B program, we estimate that OPSS payments for separately payable drugs, including beneficiary copayment, could decrease by as much as \$900 million under this proposal. Because we are proposing to implement this payment reduction in a budget neutral manner within the OPSS, the reduced payments for separately payable drugs purchased through the 340B drug pricing program would increase payment rates (and by extension, beneficiary coinsurance

liabilities) for other items and services paid under the OPPS by an offsetting aggregate amount.

Because data on drugs that are purchased with a 340B discount are not publicly available, it is not possible to more accurately estimate the amount of the aggregate payment reduction and the offsetting amount of the adjustment that is necessary to ensure budget neutrality through higher payment rates for other services. Furthermore, there are potential offsetting factors, including possible changes in provider behavior and overall market changes that would likely lower the impact of the payment reduction. As a result, if we finalize this proposal in the CY 2018 OPPS/ASC final rule with comment period, we may need to make an adjustment in future years to revise the conversion factor once we have received more accurate data on drugs purchased with a 340B discount within the OPPS, similar to the adjustment we made for clinical diagnostic laboratory test packaging policy in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592).

We project that reducing payment for 340B drugs to ASP minus 22.5 percent would increase non-drug OPPS payment rates by approximately 1.4 percent in CY 2018. We note that the proposed payment rates and estimated impacts included in this proposed rule do not reflect the effects of this proposal. We remind commenters that this estimate could change in the final rule based on a number of factors, including other policies that are adopted in the final rule and the availability of updated data and/or method of assessing the impact in the final rule. We are seeking public comment on our estimate and are especially interested in whether commenters believe there are other publicly available data sources or proxies that can be used for determining which drugs billed by hospitals paid under the OPPS were acquired under the 340B program.

In addition, we are soliciting public comment on whether we should apply all or part of the savings generated by this payment reduction to increase payments for specific services paid under the OPPS, or under Part B generally, in CY 2018, rather than simply increasing the conversion factor. In particular, we are seeking public comment on whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured. Finally, we are seeking public comment on whether the redistribution of savings associated with this proposal would result in

unnecessary increases in the volume of covered services paid under the OPPS that should be adjusted in accordance with section 1833(t)(2)(F) of the Act.

(3) Estimated Effects of Proposed OPPS Changes on Hospitals

Table 38 below shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 38, 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 2018, 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 proposed 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 2018 is 2.9 percent (82 FR 19931). Section 1833(t)(3)(F)(i) of the Act reduces that 2.9 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.4 percentage point for FY 2018 (which is also the proposed MFP adjustment for FY 2018 in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19931 through 19932)), 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 1.75 percent. We are using the proposed OPD fee schedule increase factor of 1.75 percent in the calculation of the CY 2018 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 2018 estimates in Table 38.

To illustrate the impact of the proposed CY 2018 changes, our analysis begins with a baseline simulation model that uses the CY 2017 relative payment weights, the FY 2017 final IPPS wage indexes that include reclassifications, and the final CY 2017 conversion factor. Table 38 shows the estimated redistribution of the proposed increase or decrease in payments for CY 2018 over CY 2017 payments to hospitals and CMHCs as a result of the following factors: the impact of the proposed APC reconfiguration and recalibration changes between CY 2017 and CY 2018 (Column 2); the proposed 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 1.75 percent OPD fee schedule increase factor update to the conversion factor; and the estimated impact taking into account all proposed payments for CY 2018 relative to all payments for CY 2017, including the impact of proposed changes in estimated outlier payments, the frontier State wage adjustment, and proposed changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are proposing to maintain the current adjustment percentage for CY 2018. 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 proposed projected pass-through payment for CY 2018 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would change), and the impact of the proposed wage index changes on the hospital. However, proposed 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 2017 and CY 2018 by various groups of hospitals, which CMS cannot forecast.

In CY 2016, we excluded all molecular pathology laboratory tests from our packaging policy, and in CY 2017, we expanded the laboratory packaging exception to apply to all advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act. For CY 2018, we are seeking public comments on whether laboratories (instead of hospitals) should be permitted to bill Medicare directly for molecular pathology tests and ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act (and are granted ADLT status by CMS), that are ordered less than 14 days following the date of a hospital outpatient's discharge from the hospital outpatient department.

The laboratory date of service issue is discussed in section X.F. of this proposed rule. Because there are currently no laboratory tests designated as ADLTs and because the payment rate for laboratory tests excluded from our packaging policy billed by a hospital would have been the applicable rate for the laboratory test under the CLFS, if any aspect of this discussion would be finalized, it would not result in a net costs or savings to the program. Accordingly, section X.F. of this proposed rule is not included in the impact table in the regulatory impact analysis.

Overall, we estimate that the proposed rates for CY 2018 would increase Medicare OPPS payments by an estimated 1.9 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in a proposed estimated 2.0 percent increase in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 38 shows the total number of facilities (3,828), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2016 hospital outpatient and CMHC claims data to model CY 2017 and proposed CY 2018 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 2017 or proposed

CY 2018 payment and entities that are not paid under the OPSS. 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 disproportionate share hospital (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 OPSS hospitals (3,714), 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 48 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 0.2 percent to a decrease of 0.1 percent, depending on the number of beds. Rural hospitals would experience no change, with the impact ranging from an increase of 0.1 percent to a decrease of 0.1 percent, depending on the number of beds. Major teaching hospitals would experience a decrease of 0.1 percent overall.

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 2018 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 2017 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 proposed budget neutrality for the proposed 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 5. We did not model a budget neutrality adjustment for the proposed rural adjustment for SCHs because we are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2018, as described in section II.E. of this proposed rule.

We modeled the independent effect of proposing to update 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 2018 scaled weights and a CY 2017 conversion factor that included a budget neutrality adjustment for the effect of the proposed changes to the wage indexes between CY 2017 and CY 2018. The proposed FY 2018 wage policy results in modest redistributions.

There is a slight increase of less than 0.1 in Column 3 for the proposed CY 2018 cancer hospital payment adjustment budget neutrality calculation because we are using a payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2018 of 0.89, compared to the CY 2017 OPSS/ASC final rule with comment period (81 FR 79869) payment-to-cost ratio target of 0.91. We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we are proposing to apply in section II.F. of this proposed rule.

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 1.75 percent. Overall, these proposed changes would increase payments to

urban hospitals by 1.8 percent and to rural hospitals by 1.8 percent. Most classes of hospitals would receive an increase in line with the proposed 1.8 percent overall increase after the proposed update is applied to the proposed budget neutrality adjustments.

Column 5: All Proposed Changes for CY 2018

Column 5 depicts the full impact of the proposed CY 2018 policies on each hospital group by including the effect of all of the proposed changes for CY 2018 and comparing them to all estimated payments in CY 2017. Column 5 shows the combined budget neutral effects of Columns 2 and 3; the proposed OPD fee schedule increase; the impact of the proposed frontier State wage index adjustment; the impact of estimated proposed 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 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 2017 update (and assumed, for modeling purposes, to be the same number for CY 2018), we included 30 hospitals in our model because they had both CY 2016 claims data and recent cost report data. We estimate that the cumulative effect of all of the proposed changes for CY

2018 would increase payments to all facilities by 1.9 percent for CY 2018. We modeled the independent effect of all of the proposed changes in Column 5 using the final relative payment weights for CY 2017 and the proposed relative payment weights for CY 2018. We used the final conversion factor for CY 2017 of \$75.001 and the proposed CY 2018 conversion factor of \$76.483 discussed in section II.B. of this proposed rule.

Column 5 contains simulated outlier payments for each year. We used the proposed 1-year charge inflation factor used in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20173) of 5.1 percent (1.05074) to increase individual costs on the CY 2016 claims, and we used the most recent overall CCR in the April 2017 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2017. Using the CY 2016 claims and a proposed 5.1 percent charge inflation factor, we currently estimate that outlier payments for CY 2017, using a multiple threshold of 1.75 and a fixed-dollar threshold of \$3,825 would be approximately 1.04 percent of total payments. The estimated current outlier payments of 1.04 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 10.4 percent (1.104055) and the CCRs in the April 2017 OPSF, with an adjustment of 0.979187, to reflect relative changes in cost and charge inflation between CY 2016 and CY 2018, to model the proposed CY 2018 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of \$4,325. The charge inflation and CCR

inflation factors are discussed in detail in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20173).

Overall, we estimate that facilities would experience an increase of 1.9 percent under this proposed rule in CY 2018 relative to total spending in CY 2017. This projected increase (shown in Column 5) of Table 38 reflects the proposed 1.75 percent OPD fee schedule increase factor, plus 0.22 percent for the proposed change in the pass-through estimate between CY 2017 and CY 2018, minus a decrease of 0.04 percent for the difference in estimated outlier payments between CY 2017 (1.04 percent) and CY 2018 (proposed 1.0 percent). We estimate that the combined effect of all of the proposed changes for CY 2018 would increase payments to urban hospitals by 2.0 percent. Overall, we estimate that rural hospitals would experience a 2.0 percent increase as a result of the combined effects of all of the proposed changes for CY 2018.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects of all changes would include an increase of 1.7 percent for major teaching hospitals and an increase of 2.1 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 2.0 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 1.9 percent, proprietary hospitals would experience an increase of 2.3 percent, and governmental hospitals would experience an increase of 1.9 percent.

TABLE 38—ESTIMATED IMPACT OF THE PROPOSED CY 2018 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	APC recalibration (all proposed changes)	Proposed new wage index and provider adjustments	All proposed budget neutral changes (combined cols 2,3) with market basket update	All proposed changes
	(1)	(2)	(3)	(4)	(5)
ALL FACILITIES*	3,828	0.0	0.0	1.8	1.9
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,714	0.0	0.0	1.8	2.0
URBAN HOSPITALS	2,902	0.0	0.0	1.8	2.0
LARGE URBAN (GT 1 MILL.)	1,577	0.1	-0.1	1.8	1.9
OTHER URBAN (LE 1 MILL.)	1,325	0.0	0.1	1.9	2.0
RURAL HOSPITALS	812	0.0	0.0	1.8	2.0
SOLE COMMUNITY	371	0.0	0.2	1.9	2.1
OTHER RURAL	441	0.0	-0.2	1.6	1.8
BEDS (URBAN)					
0-99 BEDS	988	0.2	0.0	1.9	2.1
100-199 BEDS	841	0.2	0.0	1.9	2.1
200-299 BEDS	465	0.1	0.0	1.8	2.0
300-499 BEDS	395	0.0	0.0	1.8	2.0

TABLE 38—ESTIMATED IMPACT OF THE PROPOSED CY 2018 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	APC recalibration (all proposed changes)	Proposed new wage index and provider adjustments	All proposed budget neutral changes (combined cols 2,3) with market basket update	All proposed changes
	(1)	(2)	(3)	(4)	(5)
500 + BEDS	213	-0.1	0.1	1.7	1.8
BEDS (RURAL)					
0-49 BEDS	337	0.0	-0.2	1.5	1.7
50-100 BEDS	289	0.1	-0.2	1.6	1.9
101-149 BEDS	101	0.0	0.1	1.9	2.1
150-199 BEDS	46	0.0	0.1	1.9	2.1
200 + BEDS	39	-0.1	0.3	2.0	2.1
REGION (URBAN)					
NEW ENGLAND	144	0.2	0.1	2.1	2.2
MIDDLE ATLANTIC	343	0.1	-0.3	1.5	1.7
SOUTH ATLANTIC	461	0.1	0.2	2.0	2.2
EAST NORTH CENT.	464	0.0	0.1	1.8	1.9
EAST SOUTH CENT.	172	-0.2	-0.1	1.5	1.7
WEST NORTH CENT.	185	-0.2	0.5	2.0	2.2
WEST SOUTH CENT.	501	0.1	0.2	2.0	2.2
MOUNTAIN	202	0.2	-0.9	1.0	1.3
PACIFIC	382	0.1	0.0	1.8	2.0
PUERTO RICO	48	-0.3	0.3	1.7	1.9
REGION (RURAL)					
NEW ENGLAND	21	0.0	1.6	3.4	3.5
MIDDLE ATLANTIC	53	0.1	-0.1	1.8	2.0
SOUTH ATLANTIC	123	0.0	-0.7	1.0	1.2
EAST NORTH CENT.	121	0.0	-0.1	1.7	1.9
EAST SOUTH CENT.	155	-0.1	-0.1	1.5	1.7
WEST NORTH CENT.	96	0.0	0.2	2.0	2.3
WEST SOUTH CENT.	162	0.1	0.3	2.1	2.3
MOUNTAIN	57	0.0	-0.3	1.5	1.9
PACIFIC	24	0.1	0.1	1.9	2.1
TEACHING STATUS					
NON-TEACHING	2,624	0.1	0.1	2.0	2.1
MINOR	746	0.0	0.0	1.8	2.0
MAJOR	344	-0.1	-0.1	1.6	1.7
DSH PATIENT PERCENT					
0	11	0.0	-0.1	1.7	1.8
GT 0-0.10	277	0.2	0.0	2.0	2.1
0.10-0.16	269	0.2	-0.1	1.8	2.0
0.16-0.23	577	0.1	0.2	2.1	2.2
0.23-0.35	1,121	0.0	0.0	1.8	1.9
GE 0.35	920	0.0	-0.1	1.7	1.8
DSH NOT AVAILABLE**	539	-1.5	0.1	0.3	0.5
URBAN TEACHING/DSH					
TEACHING & DSH	982	0.0	-0.1	1.7	1.8
NO TEACHING/DSH	1,394	0.2	0.2	2.1	2.2
NO TEACHING/NO DSH	11	0.0	-0.1	1.7	1.8
DSH NOT AVAILABLE**	515	-1.5	0.1	0.4	0.5
TYPE OF OWNERSHIP					
VOLUNTARY	1,970	0.0	0.0	1.8	1.9
PROPRIETARY	1,253	0.2	0.1	2.1	2.3
GOVERNMENT	491	-0.1	0.1	1.8	1.9
CMHCs	48	-0.1	0.2	1.9	2.1

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2018 OPPS policies and compares those to the CY 2017 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2018 hospital inpatient wage index, including all hold harmless policies and transitional wages. The proposed rural adjustment continues 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 1.0003 because the target payment-to-cost ratio changes from 0.91 in CY 2017 to 0.90 in CY 2018 and is further reduced by one percentage point to 0.89 in accordance with the 21st Century Cures Act; however this reduction does not affect the budget neutrality adjustment consistent with statute.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 1.75 percent OPD fee schedule update factor (2.9 percent reduced by 0.4 percentage points for the proposed productivity adjustment and further reduced by 0.75 percentage point as required by law).

Column (5) shows the additional adjustments to the conversion factor resulting from the frontier adjustment, a change in the pass-through estimate, and adding estimated outlier payments.

* These 3,828 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.

(4) Estimated Effects of Proposed OPPS Changes on CMHCs

The last line of Table 38 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2017, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming that CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2016 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 2.1 percent increase in payments from CY 2017 (shown in Column 5). 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 2018 wage index values would result in a small increase of 0.2 percent to CMHCs. Column 4 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2018 and the proposed FY 2018 wage index updates, would result in an estimated increase of 1.9 percent. Column 5 shows that adding the proposed changes in outlier and pass-through payments would result in a total 2.1 percent increase in payment for CMHCs. This reflects all proposed changes to CMHCs for CY 2018.

(5) 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 will increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For further discussion 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 2018. The estimated aggregate beneficiary coinsurance reflects general system

adjustments, including the CY 2018 comprehensive APC payment policy discussed in section II.A.2.e. of this proposed rule.

(6) 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.

(7) 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 \$897 million in program payments for OPPS services furnished in CY 2018. 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 refer readers to our discussion of the impact on beneficiaries in section XIX.A.4.a.(4) of this proposed rule.

(8) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing and the reasons for our selected alternatives are discussed throughout this proposed rule.

- Alternatives considered for the enforcement instruction for the supervision of outpatient therapeutic services in critical access hospitals (CAHs) and certain small rural hospitals.

We considered whether to address enforcement of the direct supervision requirement for outpatient therapeutic services in CAHs and small, rural hospitals with fewer than 100 beds by extending the notice of nonenforcement while we further develop our policies. There are grounds for applying the same supervision requirements to CAHs as to all other hospitals. One of these grounds is that hospital outpatient services are furnished "incident to" physicians' services, and we believe that the incident to rules apply equally to critical access and other types of hospitals. We also believe that Medicare should purchase the same basic level of quality and safe outpatient care for all beneficiaries, whether from a CAH, a small rural hospital, or other hospitals. At the same time, we acknowledge that in order to ensure the same level of outpatient care is furnished in CAHs and small rural hospitals as other hospitals, we need to continue the

national discussion about what constitutes the appropriate supervision for a given service. We also need to acknowledge the challenges CAHs and small, rural hospitals have in recruiting and retaining physicians and qualified nonphysician practitioners.

Therefore, we are proposing to extend the notice of nonenforcement for CAHs and small rural hospitals with fewer than 100 beds for CY 2018 and CY 2019, to give all parties time to submit specific services to be considered for a reduced minimum supervision standard. We believe that the policies in this proposed rule will address industry concerns while maintaining an adequate level of safety and quality of care in the hospital outpatient services that Medicare purchases.

- 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 2017 to the high cost group in CY 2018, 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 2018 MUC or PDC threshold. We would continue to assign products that exceed either the overall CY 2018 MUC or PDC threshold to the high cost group. We also considered, but did not propose, retaining 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 2018 MUC or PDC threshold based on calculations done for either the proposed rule or final rule with comment period.

b. Estimated Effects of Proposed CY 2018 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 2018 ASC relative payment weights by scaling the proposed CY 2018 OPPS relative payment weights by the ASC scalar of 0.9002. 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 39 and 40 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which currently is the CPI-U) 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 2018 payment determinations will be based on the application of a 2.0 percentage points reduction to the annual update factor, which currently is the CPI-U. We calculated the proposed CY 2018 ASC conversion factor by adjusting the CY 2017 ASC conversion factor by 1.0004 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2017 and CY 2018 and by applying the proposed CY 2018 MFP-adjusted CPI-U update factor of 1.9 percent (projected CPI-U update of 2.3 percent minus a proposed projected productivity adjustment of 0.4 percentage point). The proposed CY 2018 ASC conversion factor is \$45.876.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2018 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2016 and CY 2018 with precision. We believe that the net effect on Medicare expenditures resulting from the proposed CY 2018 changes will be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs will experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) 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 2018 payments will depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the proposed CY 2018 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2016 claims data. Table 39 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2017 payments to estimated CY 2018 payments, and Table 40 shows a comparison of estimated CY 2017 payments to estimated CY 2018 payments for procedures that we estimate will receive the most Medicare payment in CY 2017.

Table 39 shows the estimated effects on aggregate Medicare payments under the ASC payment system by surgical specialty or ancillary items and services group. 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 39.

- 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 2017 ASC Payments were calculated using CY 2016 ASC utilization (the most recent full year of ASC utilization) and CY 2017 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2017 ASC payments.

- Column 3—Estimated Proposed CY 2018 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 2018 compared to CY 2017.

As seen in Table 39, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the update to ASC payment rates for CY 2017 will result in a 2-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 3-percent increase in aggregate payment amounts for digestive system procedures, 2-percent increase in aggregate payment amounts for nervous system procedures, a 4-percent increase in aggregate payment amounts for musculoskeletal system procedures, a 1-percent increase in aggregate payment amounts for genitourinary system procedures, and a 5-percent increase in aggregate payment amounts for integumentary system procedures.

Also displayed in Table 39 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 decrease by 43 percent for CY 2018.

TABLE 39.—ESTIMATED IMPACT OF THE PROPOSED CY 2018 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2018 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2017 ASC payments (in millions) (2)	Estimated Proposed CY 2018 percent change (3)
Total	\$4,460	2%
Eye and ocular adnexa	1,688	2
Digestive system	852	3
Nervous system	849	2
Musculoskeletal system	530	3
Genitourinary system	186	1
Integumentary system	141	5
Ancillary items and services	55	-43

Table 40 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 2018. The table displays 30 of the procedures receiving the greatest estimated CY 2017 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in

descending order by estimated CY 2017 program payment.
 • Column 1—CPT/HCPCS code.
 • Column 2—Short Descriptor of the HCPCS code.
 • Column 3—Estimated CY 2017 ASC Payments were calculated using CY 2016.
 ASC utilization (the most recent full year of ASC utilization) and the CY

2017 ASC payment rates. The estimated CY 2017 payments are expressed in millions of dollars.
 • Column 4—Estimated CY 2018 Percent Change reflects the percent differences between the estimated ASC payment for CY 2017 and the estimated proposed payment for CY 2018 based on the proposed update.

TABLE 40—ESTIMATED IMPACT OF THE PROPOSED CY 2018 UPDATE TO THE ADC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code (1)	Short descriptor (2)	Estimated CY 2017 ASC payment (in millions) (3)	Estimated CY 2018 percent change (4)
66984	Cataract surg w/iol 1 stage	\$1,172	%2
45380	Colonoscopy and biopsy	216	3
43239	Egd biopsy single/multiple	178	3
63685	Insrt/redo spine n generator	151	-4
45385	Colonoscopy w/lesion removal	146	3
63650	Implant neuroelectrodes	118	3
64483	Inj foramen epidural l/s	99	3
66982	Cataract surgery complex	94	2
0191T	Insert ant segment drain int	86	1
66821	After cataract laser surgery	69	1
64635	Destroy lumb/sac facet jnt	68	2
29827	Arthroscop rotator cuff repr	61	3
64493	Inj paravert f jnt l/s 1 lev	60	3
64590	Insrt/redo pn/gastr stimul	50	-1
G0105	Colorectal scrn; hi risk ind	45	3
62323	Njx interlaminar lmr/sc	45	4
45378	Diagnostic colonoscopy	44	3
G0121	Colon ca scrn not hi rsk ind	42	3
64721	Carpal tunnel surgery	34	2
15823	Revision of upper eyelid	32	6
29881	Knee arthroscopy/surgery	30	3
29880	Knee arthroscopy/surgery	26	3
67042	Vit for macular hole	25	2
28285	Repair of hammertoe	24	3
52000	Cystoscopy	23	-1
26055	Incise finger tendon sheath	23	2
43235	Egd diagnostic brush wash	23	2
64561	Implant neuroelectrodes	22	6
50590	Fragmenting of kidney stone	21	2
67904	Repair eyelid defect	20	1

(3) Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2018 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures that we are proposing to add to the ASC list of covered surgical procedures and for those that we are proposing to designate as office-based for CY 2018. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPSS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services). Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPSS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPSS 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 OPSS 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. However, for those additional procedures that we are proposing to designate as office-based in CY 2018, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the MPFS 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).

(4) Alternative ASC Payment Policies Considered

Alternatives to the ASC changes we are proposing and the reasons for our selected alternatives are discussed throughout this proposed rule.

c. Accounting Statements and Tables

As required by OMB Circular A-4 (available on the Office of Management and Budget Web site at: [https://](https://www.whitehouse.gov/omb/circulars_a004_a-4#a)

www.whitehouse.gov/omb/circulars_a004_a-4#a), we have prepared two accounting statements to illustrate the impacts of this proposed rule. The first accounting statement, Table 41 below, illustrates the classification of expenditures for the proposed CY 2018 estimated hospital OPSS incurred benefit impacts associated with the proposed CY 2018 OPD fee schedule increase, based on the 2017 Trustee's Report. The second accounting statement, Table 42 below, illustrates the classification of expenditures associated with the proposed 1.9 percent CY 2018 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the 2017 Trustee's Report. Lastly, the tables classify most estimated impacts as transfers.

TABLE 41—ACCOUNTING STATEMENT: PROPOSED CY 2018 ESTIMATED HOSPITAL OPSS TRANSFERS FROM CY 2017 TO CY 2018 ASSOCIATED WITH THE PROPOSED CY 2018 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers.	\$897 million.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPSS.
Total	\$897 million.

TABLE 42—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2017 TO CY 2018 AS A RESULT OF THE PROPOSED CY 2018 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers.	\$67 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Total	\$67 million.

d. Effects of Requirements for the Hospital OQR Program

(1) Background

We refer readers to the CY 2017 OPSS/ASC final rule with comment period (81 FR 79874), 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 3,228 hospitals that met eligibility requirements for the CY 2017 payment determination, we determined that 87 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. Most of these hospitals (66 of the 87), chose not to participate in the Hospital OQR Program for the CY 2017 payment determination. We estimate that approximately 100 hospitals will not receive the full OPD fee schedule increase factor for the CY 2018 payment determination and subsequent years.

In section XIII.B.4.c.(1) and (2) of this proposed rule, we are proposing to remove: (1) OP-21: Median Time to Pain Management for Long Bone Fracture; and (2) OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures beginning with the CY 2020 payment determination and for subsequent years. In section XIII.B.4.c.(3) through (6) of this proposed rule, we are proposing to remove: (1) OP-1: Median Time to Fibrinolysis; (2) OP-4: Aspirin at Arrival; (3) OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional; and (4) OP-25: Safe Surgery Checklist beginning with the CY 2021 payment determination and for subsequent years. We expect these proposals to reduce the burden of reporting for the Hospital OQR Program, as discussed below.

In this proposed rule, we are proposing to publicly report OP-18c using data from patient encounters beginning with the third quarter of 2017. We are also proposing to delay OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection) and until further notice in future rulemaking. In addition, in this proposed rule, beginning with the CY 2020 payment determination, we are proposing: (1) To codify at § 419.46(e) our previously finalized process for targeting hospitals for validation of chart-abstracted measures; (2) to formalize the educational review process and use it to correct incorrect validation results for chart-abstracted measures; (3) to change the NOP submission deadlines such that hospitals are required to submit the NOP any time prior to registering on the QualityNet Web site and to make conforming revisions at 42 CFR 419.46(a); (4) to align the first quarter for which hospitals must submit data for all hospitals that did not participate in the

previous year's Hospital OQR Program, and make corresponding revisions at 42 CFR 419.46(c)(3); and (5) to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy and make conforming changes to the CFR. We do not believe that these proposed changes would affect our burden estimates, as further discussed below.

(2) Estimated Burden Due to Proposal to Delay OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning with the CY 2020 Payment Determination

As described in section XIII.B.5. of this proposed rule, we are proposing to delay OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection). As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79863), the information collection requirements associated with the five OAS CAHPS Survey-based measures (OP-37a, OP-37b, OP-37c, OP-37d, and OP-37e) are currently approved under OMB Control Number 0938-1240. For this reason, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79863), we did not provide an independent estimate of the burden associated with OAS CAHPS Survey based measures for the Hospital OQR Program. Similarly, our proposal to delay reporting for these measures does not influence our current burden estimates.

(3) Estimated Burden Due to Proposal to Publicly Report OP-18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients

In section XIII.B.10.b. of this proposed rule, we are proposing to publicly report 18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients beginning with patient encounters from the third quarter of 2017. As noted in that section, the data required for public reporting of OP-18c is already collected as part of the existing Hospital OQR Program requirements. Accordingly, we do not expect this proposal to affect burden.

(4) Estimated Impact of Proposals for the CY 2020 Payment Determination and Subsequent Years

(a) Impact of Proposed Measure Removals

In section XIII.B.4.c.(1) and (2) of this proposed rule, we are proposing to remove one chart-abstracted measure (OP-21: Median Time to Pain Management for Long Bone Fracture) and one web-based measure (OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures) for the CY 2020 payment determination and subsequent years. As described in detail in section XVII.B. of this proposed rule, we expect these proposals to reduce burden by 152,680 hours and \$5.6 million for the CY 2020 payment determination for the Hospital OQR Program.

(b) Impact of Updates to Previously Finalized Validation Procedures and the Educational Review Process

In section XIII.D.7.a. of this proposed rule, we provide clarification on our procedures for validation of chart-abstracted measures to note that the 50 poorest performing outlier hospitals will be targeted for validation. We do not expect this clarification to influence burden, as it does not alter the number of hospitals selected for validation or the requirements for those hospitals that are selected.

In addition, in section XIII.D.7.c. of this proposed rule, we are proposing to formalize the process of allowing hospitals to use an educational review process to correct incorrect validation results for the first three quarters of validation for chart-abstracted measures. Additionally, we are proposing to update the process to specify that if the results of an educational review indicate that we incorrectly scored a hospital, the corrected score would be used to compute the hospital's final validation score whether or not the hospital submits a reconsideration request. Under this proposal, the educational review request process remains the same for the CY 2020 payment determination and subsequent years, except that revised scores identified through an educational review would be used to correct a hospital's validation score. As stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we believe there is a burden associated with successful participation in the Hospital OQR Program, where successful participation results in a full annual payment update (APU) for a particular payment determination. This burden would include, but would not be limited to, maintaining familiarity with

the Hospital OQR Program requirements, which includes checking feedback reports to indicate a facility's current status or performance. The overall administrative burden, which we believe includes the educational review process, is estimated at 42 hours per hospital (78 FR 75171) and would not be changed by the proposal to use revised scores identified through an educational review to correct a hospital's validation score.

(c) Impact of Proposed Updates to NOP Submission Deadlines

In section XIII.C.2. of this proposed rule, we are proposing to revise the NOP submission deadlines such that hospitals are required to submit the NOP any time prior to registering on the QualityNet Web site. While we expect this proposal to make it generally easier for hospitals to comply with the Hospital OQR Program requirements by extending the NOP deadline, we anticipate a negligible effect on the time and cost of completing the participation requirements. As a result, the proposal to revise the NOP submission deadlines does not impact our burden estimates.

(d) Burden Due to Proposal To Align the First Quarter for Which Hospitals Must Submit Data for All Hospitals That Did Not Participate in the Previous Year's Hospital OQR Program

In section XIII.D.1. of this proposed rule, we are proposing to align the timeline specifying the initial quarter for which hospitals must submit data for all hospitals that did not participate in the previous year's Hospital OQR Program, rather than specifying different timelines for hospitals with Medicare acceptance dates before versus after January 1 of the year prior to an affected annual payment update. Although this proposal alters the timeline for hospitals to begin submitting data for the Hospital OQR Program, it does not alter program requirements. As a result, we do not anticipate that this proposal will influence burden.

(e) Impact of Proposed Updates to the Previously Finalized ECE Policy

In section XIII.D.8. of this proposed rule, we discuss our intent to align the naming of this exception policy and update 42 CFR 419.46(d) to reflect our current ECE policies. We are also clarifying the timing of CMS' response to ECE requests. Because we are not seeking any new or additional information in our ECE proposals, we believe the updates will have no effect on burden for hospitals.

(5) Estimated Impact of Proposals for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.c. of this proposed rule, we are proposing to remove three chart-abstracted measures (OP-1: Median Time to Fibrinolysis, OP-4: Aspirin at Arrival, and OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional) and one web-based measure (OP-25: Safe Surgery Checklist Use) for the CY 2021 payment determination and subsequent years. As described in detail in section XVII.B. of this proposed rule, we expect the removal of one web-based measure and three chart-abstracted measures to reduce burden by \$11.1 million and 304,810 hours for the CY 2021 payment determination.

We refer readers to section XVII.B. of this proposed rule (information collection requirements) for a detailed discussion of the burden of the requirements for submitting data to the Hospital OQR Program.

e. Effects of Proposed Requirements for the ASCQR Program

1. Background

In section XIV. of this proposed rule, we discuss our proposals to adopt policies affecting the ASCQR Program. For the CY 2017 payment determination, of the 3,937 ASCs that met eligibility requirements for the ASCQR Program, 209 ASCs did not meet the requirements to receive the full annual payment update. We note that, in the CY 2017 OPSS/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 2018 due to failure to meet the ASCQR Program requirements (CY 2017 and CY 2018 payment determination information were not yet available).

In this proposed rule, we are also proposing: (1) To delay ASC-15a-e: OAS CAHPS survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection); (2) to expand the CMS online tool to also allow for batch submission beginning with data submitted during CY 2018 and to make corresponding revisions to the CFR; and, (3) to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy beginning with CY 2018 and to make conforming changes to the CFR. As discussed below, we do not expect these proposals to influence our burden estimates.

2. Estimated Burden of ASCQR Program Proposals Beginning With CY 2018

As described in section XIV.B.4. of this proposed rule, we are proposing to delay ASC-15a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection). As described in the CY 2017 OPSS/ASC final rule with comment period (81 FR 79864), the information collection requirements associated with the five OAS CAHPS Survey based measures (ASC-15a, ASC-15b, ASC-15c, ASC-15d, and ASC-15e) are currently approved under OMB Control Number 0938-1240. For this reason, we did not provide an independent estimate of the burden associated with OAS CAHPS Survey administration for the ASCQR Program in the CY 2017 OPSS/ASC final rule with comment period (81 FR 79864). Similarly, our proposal to delay reporting on these measures does not affect our current burden estimates.

For CY 2018, we are making two additional proposals. First, in section XIV.D.3.b. of this proposed rule, we are proposing to expand the CMS online tool to also allow for batch submission beginning with data submitted during CY 2018 and to make corresponding revisions to the CFR. Second, in section XIV.D.6. of this proposed rule, we discuss our intent to align the naming of this exception policy and update 42 CFR 416.310(d) to reflect our current ECE policies. We are also clarifying the timing of CMS' response to ECE requests. Because neither of these proposals changes the reporting requirements of the ASCQR Program nor require ASCs to submit any new or additional information, we believe the updates will have no effect on burden for ASCs.

3. Estimated Burden of ASCQR Program Proposals for the CY 2019 Payment Determination

In section XIV.B.3.b. of this proposed rule, we are proposing to remove one claims-based measure (ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing¹³⁰) and two measures collected via a CMS online data submission tool

¹³⁰ As discussed in section XVII.C.4. of this proposed rule, data for ASC-5 is submitted via CMS claims using Quality Data Codes, which impose only a nominal burden on providers because these claims are already submitted for the purposes of payment. We therefore estimate a nominal reduction in burden associated with our proposal to remove the ASC-5 measure from the ASCQR Program measure set beginning with the CY 2019 payment determination.

(ASC-6: Safe Surgery Checklist Use and ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures) from the ASCQR Program measure set beginning with the CY 2019 payment determination. As discussed in section XVII.C.4. of this proposed rule, we estimate the proposals to remove ASC-6 and ASC-7 from the ASCQR Program measure set would reduce ASCs' data collection and submission burden by approximately 657 hours (3,937 ASCs × 0.167 hours per ASC) and \$24,033 (657 hours × \$36.58 per hour) per measure, or a total burden reduction of 1,314 (657 hours × 2 measures) and \$48,066 (1,314 hours × \$36.58 per hour) across all ASCs.

We are not proposing to add any quality measures to the ASCQR measure set for the CY 2020 payment determination, 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. (We refer readers to section XIV.B.5. of this proposed rule for a list of these measures.) 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.

4. Estimated Burden of ASCQR Program Proposals for the CY 2021 Payment Determination

For the CY 2021 payment determination and subsequent years, we are making one new proposal. In section XIV.B.6.a. of this proposed rule, we are proposing to adopt one measure collected via a CMS online data submission tool, ASC-16: Toxic Anterior Segment Syndrome. As discussed in section XXI.C.5. of this proposed rule, we estimate a data collection and submission burden of approximately 0.25 hours per ASC for reporting data for the proposed ASC-16 measure. This results in a total estimated burden of 984 hours (3,937 ASCs × 1 case per ASC × 0.25 hours per case) and \$36,004 (984 hours × \$36.58 per hour) for the proposed ASC-16 measure across all ASCs.

5. Estimated Burden of ASCQR Program Proposals for the CY 2022 Payment Determination

In sections XIV.B.6.b. and c. of this proposed rule, we are proposing to add two new measures collected via claims to the ASCQR program measure set for the CY 2022 payment determination: (1) ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and (2) ASC-18: Hospital Visits after Urology Ambulatory

Surgical Center Procedures. As discussed in sections XIV.B.6.b. and c. of this proposed rule, data used to assess performance under these measures is collected via Part A and Part B Medicare administrative claims and Medicare enrollment data and therefore does not require facilities to report any additional data. Because these measures do not require facilities to submit any additional data, we do not believe there is any additional burden associated with these proposals.

We refer readers to the information collection requirements in section XVII.C. of this proposed rule for a detailed discussion of the financial and hourly burden of the ASCQR Program's current and proposed requirements.

We are inviting public comment on the burden associated with these proposals.

B. 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule would increase payments to small rural hospitals by less than 2 percent; therefore, it should not have a significant impact on approximately 626 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

C. 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 \$148 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. 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 is a transfer rule that does not impose more than *de minimis* costs as described above and thus is not a regulatory action for the purposes of Executive Order 13771.

E. Conclusion

The changes we are proposing to make in this proposed rule would affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2018. Table 38 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 1.9 percent increase in payments for all services paid under the OPPS in CY 2018, 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, proposed estimated payment for outliers, 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 2018.

The proposed updates to the ASC payment system for CY 2018 would affect each of the approximately 5,500 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will depend on its mix of patients, the proportion of the 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 39 demonstrates the estimated distributional impact among ASC surgical specialties of the proposed MFP-adjusted CPI-U update factor of 1.9 percent for CY 2018.

XX. 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 38 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 1.9 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 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 416.310 is amended by revising paragraphs (c)(1)(i) and (d) to read as follows:

§ 416.310 Data collection and submission requirements under the ASCQR Program.

* * * * *

(c) * * *

(1) * * *

(i) *QualityNet account for web-based measures.* ASCs, and any agents submitting data on an ASC's behalf, must maintain a QualityNet account in order to submit quality measure data to the QualityNet Web site for all web-based measures submitted via a CMS online data submission tool. A QualityNet security administrator is necessary to set up such an account for the purpose of submitting this information.

* * * * *

(d) *Extraordinary circumstances exceptions.* CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or if CMS determines that a systemic problem with one of its data collection systems directly affected the ability of the hospitals to submit data. CMS may grant an exception as follows:

(1) *Upon request of the ASC.* Specific requirements for submission of a request for an exception are available on the QualityNet Web site; or

(2) *At the discretion of CMS.* CMS may grant exceptions to ASCs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

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PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 3. 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, 1395(t), and 1395hh).

■ 4. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(9) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(9) For calendar year 2018, a multiproductivity adjustment (as determined by CMS) and 0.75 percentage point.

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■ 5. Section 419.46 is amended by—

■ a. Amending paragraph (a)(1) by removing the phrase “Web site” and adding in its place the term “website”;

■ b. Revising paragraph (a)(3);

■ c. Amending paragraphs (b) and (c)(2) by removing the phrase “Web site” and adding in its place the term “website”;

■ d. Revising paragraphs (c)(3)(i) and (ii) and (d);

■ e. Adding paragraph (e)(3); and

■ f. Amending paragraphs (f)(1) and (g)(2) by removing the phrase “Web site” and adding in its place the term “website” wherever it appears.

The revisions and additions read as follow:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) * * *

(3) Complete and submit an online participation form available at the *QualityNet.org* Web site 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). For Hospital OQR Program purposes, hospitals that share the same CCN are required to complete a single online participation form. Once a hospital has submitted a participation form, it is considered to be an active Hospital OQR Program participant until such time as it submits a withdrawal form to CMS or no longer has an effective Medicare provider agreement. Hospitals must submit the online participation form at any time prior to registering on the QualityNet Web site.

* * * * *

(c) * * *

(3) * * *

(i) Hospitals that did not participate in the previous year's Hospital OQR Program must initially submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update.

(ii) Hospitals that did not participate in the previous year's Hospital OQR Program must follow data submission

deadlines as specified in paragraph (c)(2) of this section.

* * * * *

(d) *Exception.* CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) *Upon request by the hospital.* Specific requirements for submission of a request for an exception are available on the QualityNet Web site.

(2) *At the discretion of CMS.* CMS may grant exceptions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

(e) * * *

(3) CMS will select a random sample of 450 hospitals for validation purposes, and will select an additional 50 hospitals for validation purposes based on the following criteria:

(i) The hospital fails the validation requirement that applies to the previous year's payment determination; or

(ii) The hospital has an outlier value for a measure based on the data it submits. An “outlier value” is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score.

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■ 6. Section 419.71 is added to read as follows:

§ 419.71 Payment reduction for certain X-ray imaging services.

(a) *Definition.* For purposes of this section, the term “computed radiography technology” means cassette-based imaging which utilizes an imaging plate to create the image involved.

(b) *Payment reduction for film X-ray imaging services.* For an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) is reduced by 20 percent.

(c) *Payment reduction for computed radiography imaging services.* The payment amount for an imaging service that is an X-ray taken using computed radiography technology (including the X-ray component of a packaged service) is reduced by—

(1) 7 percent, for such services furnished in CY 2018, 2019, 2020, 2021, or 2022.

(2) 10 percent, for such services furnished in CY 2023 or a subsequent calendar year.

(d) *Application without regard to budget neutrality.* The reductions taken under this section are not considered

adjustments under section 1833(t)(2)(E) of the Act and are not implemented in a budget neutral manner.

Dated: June 28, 2017.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: June 30, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

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